

The Use of Functional Electrical Stimulation to Improve the Daily Life of a Stroke Survivor

Submitted by

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Statement of Authorisation

This thesis includes work by the author that has been published or accepted for publication as described in the text. Except where reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma. No other person's work has been used without due acknowledgement in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

Contribution of Others to Work in this Thesis

Associate Professor Carol McKinstry was the co-supervisor for the student researcher between 2012 and 2015 and was the primary supervisor from 2015 to 2020. Carols primary contributions to study one and two are outlined in the below section (author contributions to publications). For study three, Carol provided fundamental guidance and input for the study design, data collection/analysis, data interpretation, and reviewing chapter content. Carol provided editorial advice regarding content, structure and copyediting of all chapters in the thesis.

Professor Natasha Lannin was the primary supervisor for the student researcher from 2012 to 2015 and was the co-supervisor between 2015 and 2020. Natasha's contributions to study one and two are outlined in the below section (author contributions to publications). For study three, Natasha provided guidance and input with study design, interpretation of data, and reviewing chapter content. Natasha also provided editorial advice regarding content, structure and copyediting of all chapters in the thesis.

Professor Louise Ada provided guidance and input with study one. The contributions are described in the below section (author contributions to publications).

Author Contributions to Publications

- Howlett, O., Lannin, N., Ada, L., & McKinstry, C. (2015). Functional electrical stimulation improves activity after stroke: A systematic review with meta-analysis. *Archives of Physical Medicine and Rehabilitation*, 96(5), 934-943.
doi:10.1016/j.apmr.2015.01.013

OH: Study design, completing the search, abstract/title reviewer, full-text reviewer, data extraction, data analysis/interpretation, manuscript drafting/editing and submission.

NL: Study design, full-text reviewer, data interpretation, manuscript review and primary supervision of candidate.

LA: Study design, data interpretation, manuscript review.

CM: Manuscript review and co-supervision of the candidate.

- Howlett, O., McKinstry, C., & Lannin, N. (2018a). Using the cognitive interviewing process to improve survey design by allied health: a qualitative study. *Australian Journal of Occupational Therapy*. 65(2), 126-134. doi 10.1111/1440-1630.12445.

OH: Study design, ethics application, survey design, recruitment, interviews, coding, data analysis/interpretation and drafting/editing/submitting manuscript.

CM: Study design, data interpretation, manuscript review and primary supervision of candidate.

NL: Study design, survey design, reviewing manuscript and co-supervision of the candidate.

- Howlett, O., McKinstry, C., & Lannin, N. (2018b). The use of functional electrical stimulation by occupational therapists and physiotherapists: A quantitative survey. *Australian Occupational Therapy Journal*, 65(4). doi:10.1111/1440-1630.12482

OH: Study and survey design, ethics application, recruitment, data analysis/interpretation and drafting/editing/submission of the manuscript.

CM: Study design, manuscript review and primary supervision of candidate.

NL: Study design, manuscript review and co-supervision of the candidate.

Ethical Research Conduct

The three research studies reported in this thesis were conducted following Australian ethical conduct regulations. Study one did not require formal ethical approval as the research method was a systematic review of the published literature. Study two and three received ethical approvals. The College of Science, Health and Education Ethics Committee of La Trobe University provided ethical approval for study two phase one, study two phase two and study three. Bendigo Health provided ethical approval for research conducted in study two phase one and study three. Proof of authorisation is located in Appendix B1, B2, B8, C1 and C2.

Assistance Received

As allowed by the La Trobe University Graduate Research Examinations Procedure, this thesis has been copyedited by Lauren Canfield. Copyediting activities included reviewing clarity, grammar, spelling, punctuation and for format/layout consistency.

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Research Dissemination

The following three publications form part of the thesis.

- Howlett, O., Lannin, N., Ada, L., & McKinstry, C. (2015). Functional electrical stimulation improves activity after stroke: A systematic review with meta-analysis. *Archives of Physical Medicine and Rehabilitation*, 96(5), 934-943.
doi:10.1016/j.apmr.2015.01.013
- Howlett, O., McKinstry, C., & Lannin, N. (2018a). Using the cognitive interviewing process to improve survey design by allied health: a qualitative study. *Australian Journal of Occupational Therapy*. 65(2), 126-134. doi 10.1111/1440-1630.12445.
- Howlett, O., McKinstry, C., & Lannin, N. (2018b). The use of functional electrical stimulation by occupational therapists and physiotherapists: A quantitative survey. *Australian Occupational Therapy Journal*, 65(4). doi:10.1111/1440-1630.12482

The following oral presentations at scientific meetings have occurred to present findings.

- Howlett, O. A., Lannin, N. A., Ada, L., & McKinstry, C. (2013). Protocol for a systematic review of functional electrical stimulation to improve activity and participation after stroke. *Australian Occupational Therapy Journal* 60, 76
- Howlett, O. A., Lannin, N. A., Ada, L., & McKinstry, C. (2015). What Is The Evidence For Using Functional Electrical Stimulation To Improve Upper Limb Activity Engagement After Stroke? *Australian Occupational Therapy Journal* 62, 138

The following poster presentations at scientific meetings have occurred to present findings.

- Howlett, O., McKinstry, C., & Lannin, N. (2016). Improving survey design using cognitive interviewing. *Occupational Therapy Australia Victorian Tasmania Regional Conference*, 2nd – 3rd September, Melbourne, Australia

- Howlett, O., McKinstry, C., & Lannin, N (2017). Using cognitive interviewing to improve survey development. *Australian Occupational Therapy 27th National Conference and Exhibition*, 18th – 20th July 2017, Perth, Australia
- Howlett, O., McKinstry, C., & Lannin, N. (2017). *Australian Occupational Therapy 27th National Conference and Exhibition*, 18th – 20th July 2017, Perth, Australia
- Howlett, O., McKinstry, C., & Lannin, N. (2017). Identifying Barriers and Enablers to Translating the Intervention of Functional Electrical Stimulation into Clinical Practice. *Bendigo Health Research Symposium*, 28th November 2017, Bendigo, Australia

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Abbreviations

C	control
CT	controlled trial
CCT	crossover controlled trial
CPD	continuing professional development
CVA	cerebrovascular accident
ES	electrical stimulation
EMG	electromyographic
Exp	experimental
F	female
FES	functional electrical stimulation
Hz	hertz
KH	Kim Howlett
KTA	knowledge to action
LL	lower limb
M	male
mA	mill amperes
MeSH	Medical Subject Headings
MD	mean difference
m/s	metres per second
N	number
NA	not applicable
NL	Natasha Lannin
NMES	neuromuscular electrical stimulation
OH	Owen Howlett
OTseeker	Occupational Therapy Systematic Evaluation of Effectiveness
PEDro	Physiotherapy Evidence Database
RCT	randomised control trial
SMD	standardised mean difference
TENS	transcutaneous stimulation
µs	micro-second
UL	upper limb

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Thesis Abstract

Introduction

A functional electrical stimulation (FES) stimulated motor training program is an evidence-based intervention to improve motor recovery after stroke. The aim was to identify how clinicians use FES to improve the daily life of a stroke survivor.

Methods

Multiple research methods were used to address this aim. A systematic review with meta-analysis evaluated the evidence for using a FES stimulated motor training program for stroke rehabilitation. A purposively designed survey collected quantitative data on the use of FES by Victorian rehabilitation clinicians. Lastly, a qualitative inductive inquiry using focus group data sought to understand the barriers encountered by clinicians in a local context when using FES. Findings from all studies were synthesised qualitatively using the Knowledge to Action Framework.

Results

A meta-analysis demonstrated that the use of FES improved activity outcomes in comparison to training alone (SMD 0.56, 95% CI 0.29 to 0.92), as well as compared to a placebo or no intervention group (SMD 0.40, 95% CI 0.09 to 0.72). An evidence to practice gap was then identified, with only 52% of 98 respondents using FES in their motor training programs. Barriers to using FES in a regional health service were lack of confidence/expertise, scope of practice, interdisciplinary collaboration, organisational factors, perception of being time poor, consumer factors, and professional development. The behaviour change strategies of education, training, modelling and environmental restructure are recommended strategies to improve FES use in a regional health care setting.

Conclusion

Contextual practice barriers and knowledge gaps in the evidence may be influencing clinicians' use of a FES stimulated motor training program to improve the daily life of a stroke survivor. The evidence to practice gap for using a FES stimulated motor training program is proposed to be lessened by addressing contextual practice barriers.

Chapter 1. Introduction

The use of a functional electrical stimulation (FES) stimulated motor retraining program has the potential to assist stroke survivors recover the use of their weak arm or leg in daily life as demonstrated in clinical trials (Barker, Hayward, Carson, Lloyd & Brauer, 2017; Bogataj, Gros, Kljajic, Acimovic, & Malezic, 1995; Hwang, Lee, Lee, & Lee, 2015; Mann, Burridge, Malone, & Strike, 2005; Mathieson, Parsons, Kaplan, & Parsons, 2018; Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2004; Sabut, Sikdar, Mondal, Kumar, & Mahadevappa, 2010; Thrasher, Zivanovic, McIlroy, & Popovic, 2008). While the benefits of FES have been demonstrated, less is known about its use within the stroke rehabilitation setting, or about how clinicians embed FES in their clinical practice. To demonstrate that a FES stimulated motor training program can be designed to support the motor recovery of a stroke survivor, this introductory chapter of the thesis will describe a FES stimulated motor training program's proposed mechanism for improving limb movement. Additionally, the chapter will describe the factors which could limit the outcomes achieved from FES. The thesis rationale, research question, objectives, and hypothesis are then outlined.

1.1 Stroke

A stroke occurs because of an artery blockage or bleed, which can lead to neuronal cell death (Sacco et al., 2013). An estimated 56,000 people have a new stroke each year in Australia (Stroke Foundation, 2017b), 795,000 people in the United States of America (Mozaffarian et al., 2016), 1.1 million people in Europe (Béjot, Bailly, Durier, & Giroud, 2016) and in Africa, there are an estimated 483,000 new strokes every year in people aged older than 15 years (Adeloye, 2014). The significant prevalence and increasing rate of stroke is, therefore, a global health issue.

After a stroke, cell death leads to brain damage which disrupts body functions, including motor control (Gray, Rice, & Garland, 2012). Up to 80% of people who have a stroke will experience muscle weakness (Cauraugh & Kim, 2003; Langhorne, Coupar, & Pollock, 2009), which is often in the upper limb (Raghavan, 2015). This muscle weakness, commonly viewed as the inability to move the hand or arm after stroke, is linked with a person's inability to participate in daily activities and engage in meaningful occupations (Deloitte Access Economics, 2013; Franceschini, La Porta, Agosti, & Massucci, 2010). A stroke can thus have devastating effects on a person's ability to return to their everyday life.

1.2 The Impact of Stroke on Daily Life

The International Classification of Functioning (World Health Organization, 2001), will be used throughout the thesis to describe the impact of stroke and also the outcomes achieved from FES stimulated motor training programs (Hoyle, Gustafsson, Meredith, & Ownsworth, 2012). The International Classification of Functioning is a classification framework which describes the relationship between function and health within a context of personal and environmental factors (World Health Organization, 2001). According to the International Classification of Functioning, three domains of function exist: body functions and structures, activities, and participation (World Health Organization, 2001). Body function and structures are descriptors of the physiological structures or processes such as the neurological and musculoskeletal systems containing muscles, bones and nerves (Salter, Jutai, Teasell, Foley, & Bitensky, 2005a). Impairments are due to disruptions to these structures or systems (Salter et al., 2005a), for example muscle weakness. The domain of activity describes tasks and actions carried out by an individual (Salter et al., 2005b), for example walking or moving objects. Disruption in the ability to perform activities is known as activity limitations (Salter et al., 2005b). Finally, the participation domain describes how activities are performed in real life contexts (Salter et al., 2005c), such as being able to shop at the local supermarket. A disruption in participation is known as participation restriction

(Salter et al., 2005c). The International Classification of Functioning describes the relationship between a health condition (such as stroke), the resulting body impairments (such as hemiplegia) and the ability of the person to engage in activities in real-life contexts (such as showering). Refer to Figure 1.1 for the framework diagram. Throughout the thesis, the daily life of a stroke survivor will be characterised by referring to the International Classification of Functioning domains of activity and participation; as the way of exploring the impact that a FES stimulated motor training program may have on daily life.

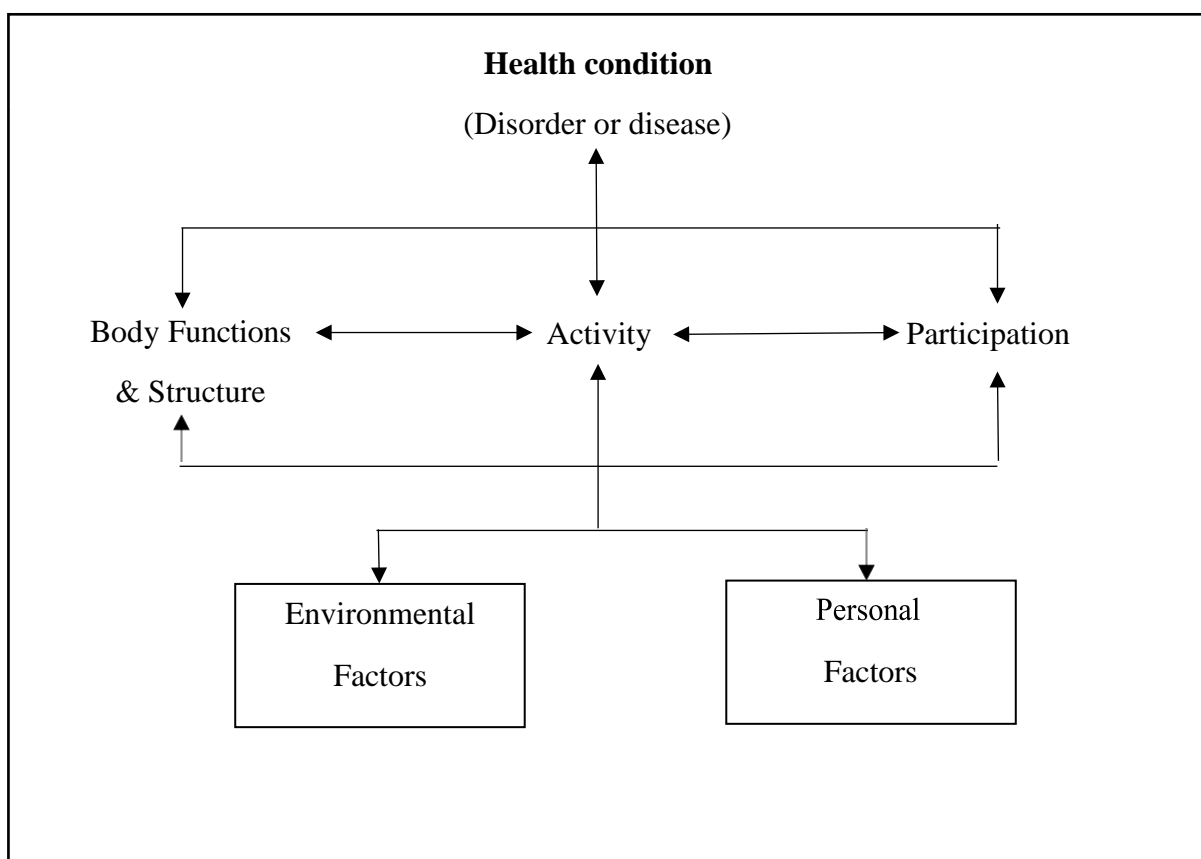


Figure 1.1. International Classification of Functioning (World Health Organization, 2001, p18).

Difficulties with daily life can be caused by the changes in body functions and structure after stroke, in particular, muscle weakness (Cohen et al., 2018; Franceschini et al., 2010; Morris, van Wijck, Joice, & Donaghy, 2013; Rosa, Marques, Demain, & Metcalf, 2015). Muscle weakness in the lower limbs correlates with limitations in mobility activities,

and upper-limb muscle weakness correlates with limitations in usual and self-care activity performance (Franceschini et al., 2010). The amount of motor impairment experienced in the arm after stroke predicts a stroke survivor's quality of life six months after stroke (Morris et al., 2013). Similarly, when motor impairment in the lower limb reduces walking speed, both community walking capacity (Rosa et al., 2015) and quality of life (Cohen et al., 2018) are also significantly restricted. The impact of muscle weakness (impairment) and the resultant difficulties with using the arm or leg during tasks (activity performance), can be devastating to a person's daily life. Interventions that reduce daily activity limitations and participation restrictions are therefore needed for people presenting with muscle weakness caused by stroke.

1.3 Knowledge Translation

The use of a FES stimulated motor retraining program by clinicians, to improve the daily life of a stroke survivor, will be understood and reported using a knowledge translation systems approach (Luke & Stamatakis, 2012). Knowledge translation describes the processes of how research knowledge is understood and implemented to deliver health care (Pablos-Mendez et al., 2005). A knowledge translation systems approach aims to understand the complexities and processes of delivering health care based on research knowledge (Northridge & Metcalf, 2016; Von Bertalanffy, 1968). For example, to translate research knowledge into practice there might be multiple components that can involve non-hierarchical processes, and multiple stakeholders including researchers, translators and knowledge users (Bauer, Damschroder, Hagedorn, Smith, & Kilbourne, 2015; Parent, Roy, & St-Jacques, 2007; Striffler et al., 2018). An example of a knowledge translation approach is the Knowledge to Action Framework (Graham et al., 2006).

The Knowledge to Action Framework (Graham et al., 2006) is a theoretical framework describing how findings from research studies can be embedded into clinical practice (Sudsawad, 2007). First described by Graham et al. (2006) in response to a lack of

clarity relating to implementation terminology, he sought to guide clinicians on *how* to transfer research knowledge into clinical practice. Refer to Figure 1.2 for a pictorial representation of the Knowledge to Action Framework. The framework has two distinct features, knowledge creation in the centre, and the action cycle around the outer circle (Field, Booth, Ilott, & Gerrish, 2014). Knowledge creation provides a structure for understanding the current research evidence, whereas the action cycle provides a framework for understanding how that research evidence is implemented into healthcare practices (Straus, Tetroe & Graham, 2011b).

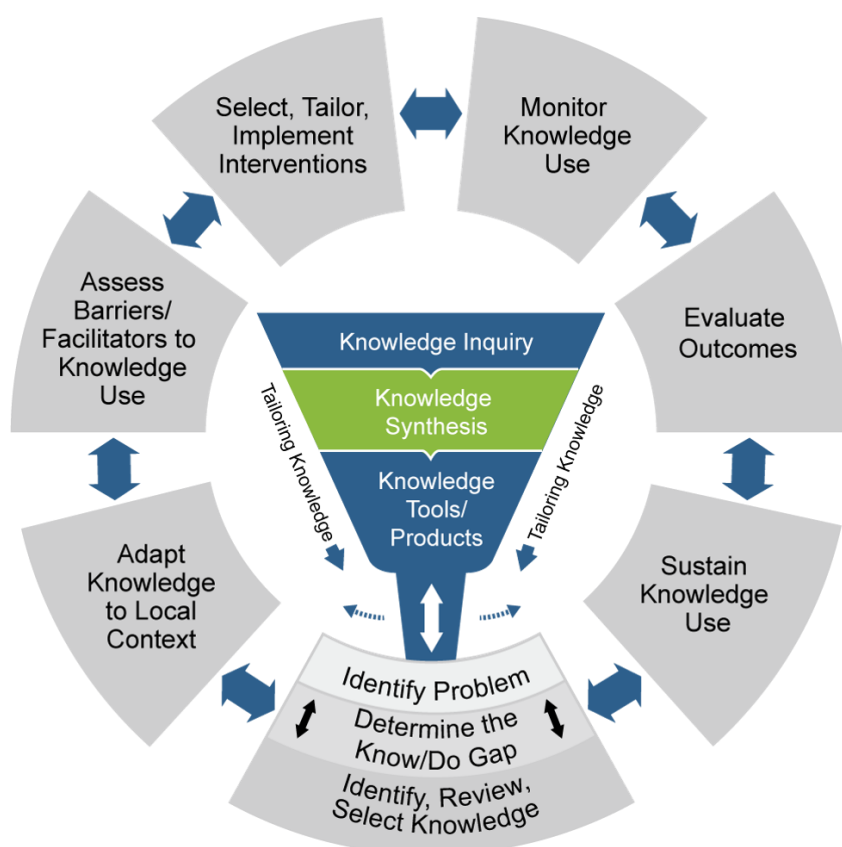


Figure 1.2. Knowledge to Action Cycle (Reprinted from *Knowledge translation in health care: moving from evidence to practice*. 2nd ed [p.10] by S.E Straus, J. Tetroe, & J. Graham, 2013, Oxford: BMJ Books. Copyright 2013 BMJ Books Wiley. Reprinted with permission).

The use of the Knowledge to Action Framework has previously been described in studies investigating the knowledge translation practices of occupational therapists and physiotherapists. A systematic review (Field et al., 2014) using citation analysis, identified ten studies which have used the Knowledge to Action Framework to guide the implementation of interventions into practice. In the review, studies included the disciplines of physiotherapy (Russell et al., 2010) and occupational therapy (Petzold, Korner-Bitensky, & Menon, 2010), while another two of the included studies targeted interventions which were used with stroke survivors (Molfenter, Ammoury, Yeates, & Steele, 2009; Petzold et al., 2010). The Knowledge to Action Framework has been used previously by allied health professionals to guide the implementation of an evidence-based intervention, demonstrating that it is an appropriate and feasible framework to understand how clinicians use FES with stroke survivors (Petzold et al., 2010; Russell et al., 2010).

The Knowledge to Action Framework has informed all stages of this current research program. In the literature review chapter (Chapter Two), the student researcher describes the relevant research evidence as categorised by the Knowledge to Action Framework levels of knowledge creation: (a) knowledge inquiry, (b) knowledge synthesis, and (c) product tools. In the method chapter (Chapter Three), the Knowledge to Action Framework is revisited to describe the theoretical framework for this research program. In the discussion chapter (Chapter Seven), the Knowledge to Action Framework is used to guide the synthesis of findings from the three studies conducted in this research program investigating the use of a FES stimulated motor training program by stroke rehabilitation clinicians.

1.4 The Use of Functional Electrical Stimulation for Stroke Rehabilitation

1.4.1 Background to functional electrical stimulation.

The development of FES commenced in the 1960s after a portable device was used to electrically stimulate a weak tibialis anterior muscle with seven stroke survivors during the activity of walking (Liberson and Holmquest, 1961). Without stimulation from the device,

walking was difficult. After eight weeks, improvements (albeit unquantified) were maintained even when the device had been switched off and the electrodes removed, highlighting the therapeutic opportunity to restore functional ability in a weak limb by using FES (Liberson & Holmquest, 1961). Similar improvements were demonstrated using a FES device designed to facilitate the use of a hand in tasks such as moving an object from one location to another (Merletti, Acimovic, Grobelsnik, & Cvilak, 1975). These studies conducted in the 1960s and 1970s initiated the use of FES as a therapeutic intervention for use in stroke rehabilitation, moving it from being novel to becoming part of usual rehabilitation care today.

Since the conceptualisation of a FES stimulated motor training program (Liberson & Holmquest, 1961; Merletti et al., 1975), FES has been used for therapeutic and orthotic purposes (Dimitrijevic, 2008). The use of a FES device as an orthosis provides stimulation during activity to immediately improve the performance of that activity (Burridge et al., 2008). There is no expectation that the use of FES will result in improvements in activity performance once the FES device is withdrawn (Kottink et al., 2004). An example of using FES as an orthosis is the use of FES to improve the quality of gait during walking (Wilkinson et al., 2012). In contrast, therapeutic FES is used to assist a person to perform activities, with expected improvements to continue when the FES device is switched off (Chae & Yu, 2002). The research program reported in this thesis investigates the therapeutic use of a FES stimulated motor training program in stroke rehabilitation; therefore, further description of how FES has been used for orthotic purposes is not required.

The rehabilitation technique of FES is defined as the use of an external electrical stimulation device to facilitate the use of a weak arm or leg during motor retraining (Peckham & Knutson, 2005). An example of a FES stimulated motor training program for lower limb training includes the placement of electrodes onto a peroneal nerve to assist ankle dorsiflexion in facilitating walking on a 100-metre walkway for 30-60 minutes a day for 3

weeks (Bogataj et al., 1995). An example of a FES stimulated motor training program for upper limb training includes the placement of electrodes onto the flexor and extensor muscle groups of a forearm to facilitate the grasp and release of blocks, sponges and cups for 20 minutes a day, for four weeks (Mohamed Faisal, Priyabanani Neha Om, & Ajith, 2012). To provide a consistent definition of FES throughout the thesis, the characteristics of FES are: (a) electrical stimulation provided to the muscles by a portable device with the electrodes placed onto the skin, and (b) the stimulation facilitates motor training while the device is activated.

Multiple interchangeable terms have been used to describe a therapeutic FES stimulated motor training program, including neuro-muscular electrical stimulation (NMES), neuro-prosthesis, therapeutic electrical stimulation, functional electrical therapy (FET), transcutaneous electrical stimulation (TENS), electrical stimulation (ES), therapeutic electrical stimulation (TES) and therapeutic functional electrical stimulation (Campbell & Meadows, 1992; Pomeroy, King, Pollock, Baily- Hallam, & Langhorne, 2006). The use of inconsistent terms and different definitions for FES may have led to confusion for new users regarding when to use FES. For example, Koyuncu and colleagues (2010) described FES as the use of a portable device with electrodes to cause repetitive muscle contraction of shoulder muscles, to prevent shoulder subluxation.

Koyuncu's et al. intervention, however, would not be classified as FES using the Peckham and Knutson's (2005) definition, because no motor retraining activities were used during the stimulation. Such inconsistency in terminology impacts the ability to discuss and compare FES. The consistent use of Peckham and Knutson's definition of FES will be used throughout this thesis.

1.4.2 FES device.

During a FES stimulated motor training program, an electrical impulse is generated by a portable device commonly powered by a 9-volt battery (Snyder-Mackler, Delitto, Stralka, &

Bailey, 1994). The impulse is delivered into the body traditionally via cabling connected to electrodes placed externally onto the skin (Alon, 2018; Dimitrijevic, 2008). The impulse stimulates muscle motor units via the motor fibres located in the muscle belly or via motor neurons (Peckham & Knutson, 2005). The electrically mediated muscle contraction influences the peripheral (including joints, neuromuscular, and vascular structures) and the central nervous system (including the sensory cortex) (Alon, 2013). Depending on electrode placement, the electrical impulse will facilitate a muscle contraction which can be used in motor retraining during activities such as walking (Ng et al., 2008), grasp and release of objects (Thrasher et al., 2008) or during reaching (Barker, Brauer, & Carson, 2008).

The electrical impulse created by the FES device needs to be initiated by either a device's internal parameters, a physiological trigger, or an external mechanical switch (Burridge & Ladouceur, 2001). A variety of triggering mechanisms have been reported in the literature such as a heel or foot-activated switch (Embrey, Holtz, Alon, Brandsma, & McCoy, 2010), a therapist or stroke survivor-controlled button (Alon et al., 2008), stimulation synchronised with the movement of a mechanical device (Cheng, Yang, Cheng, Lin, & Wang, 2010), sensor driven accelerometer (Kojovic, Djuric-Jovicic, Dosen, Popovic & Popovic et al., 2009), or triggered by the client's own electromyography signal (Barker et al., 2008). When the FES device has no triggering mechanism, it will be referred to as cyclic FES because the stroke survivor must coordinate any active/functional movements with the device settings, allowing the device to initiate the electrical stimulus (Daly et al., 2005; Lin & Yan, 2011; Mangold, Schuster, Keller, Zimmermann-Schlatter, & Ettlin, 2009; Mann et al., 2005; Mohamed Faisal et al., 2012; Peurala, Tarkka, Pitkanen, & Sivenius, 2005).

1.4.3 Electrically stimulated versus a neurally mediated muscle contraction.

A neural mediated muscle contraction is a muscle contraction that is triggered by the motor cortex in the brain, i.e., normal skeletal muscle contraction (Doucet, Lam, & Griffin, 2012). Skeletal muscle fibres can be categorised into two types: slow-twitch (Type I) and

fast-twitch (Type II) contractile fibres (Schmalbruch, 2012). Type I fibres provide prolonged muscle activity, while Type II fibres respond quickly, with a fast contraction velocity and fatigue more rapidly (Kent, 2017). A neural mediated muscle contraction requires synaptic input from motor neurons to produce muscle contraction, and occurs sequentially (in that motor units recruit Type I fibres initially, followed by the activation of Type II fibres) (Barss et al., 2018; Peri, Guanziroli, Ferrante, Pedrocchi & Molteni, 2018,). The sequential recruitment order of fibre types produces a muscle contraction which has efficient energy use and torque production, and can be used effectively during daily activities (Barss et al., 2018). A neurally mediated muscle contraction is not the same as a contraction stimulated by a FES device since the FES device cannot mimic this sequential and efficient recruitment of motor units.

A FES device will cause random recruitment of motor units (Bergquist et al., 2011). The recruitment of motor units has been called an “all-or-nothing” response in the electrically-stimulated muscle contraction, meaning that when the threshold for enough electrical activity has occurred, the muscle fibres will be activated, but with no ability to control fibre type or number recruited (Feiereisen, Duchateau & Hainaut, 1997). A FES stimulated contraction tends to activate higher numbers of Type II fibres, causing muscle fatigue and an inability to truly replicate a natural pattern of motor recruitment during motor training (Barss et al., 2018). A clinician has some capacity to minimise muscle fatigue and the non-adaptive motor response (caused by the electrical mediated stimulus) by selecting specific parameters on the FES device (Binder-Macleod & Snyder-Mackler, 1993; Doucet et al., 2012). Even though researchers are investigating how natural motor recruitment patterns can be mimicked (Barss et al., 2018) the natural pattern of motor recruitment can not be replicated by a FES device.

1.4.4 Parameters.

The electrical impulse generated by a FES device has a shape (waveform), size

(amplitude), duration, and frequency (Laufer, Ries, Leininger, & Alon, 2001). There are potentially negative outcomes when the most appropriate device parameters are not used in clinical sessions (Kesar, Chou, & Binder-Macleod, 2008); these include: (a) not producing a muscle contraction which can be used in activity-based motor training, (b) muscular fatigue, which limits the number of minutes of FES training, or (c) fewer activity repetitions than the stroke survivor is capable of performing. Each parameter will now be discussed to demonstrate the importance of setting up the FES device to achieve movement which can be incorporated into a therapeutic motor retraining program.

A FES electrical impulse can be monophasic, biphasic, symmetrical, or voltage in its waveform (Alon, 1994). The waveform of the pulse is thought to determine how it moves through the neural network (Peckham & Knutson, 2005). In the quadricep muscles, monophasic and biphasic waveforms have been shown to generate higher muscle torque with less fatigue compared to polyphasic waveforms from a FES device (Laufer et al., 2001). Therefore, past research has most commonly used either biphasic or monophasic waveforms when testing the effectiveness of FES stimulated motor training programs (Alon & Ring, 2003; Mann et al., 2005). Further, biphasic waveforms are preferred over monophasic because it minimises ion build-up “at the electrode-tissue interface” (Peri et al., 2018, pp.297), reducing discomfort during the stimulation. The remainder of this thesis chapter will, subsequently, discuss the use of biphasic waveforms. The parameters of the biphasic waveform can be adjusted to change the quality of muscle contraction during FES, with the parameters adjusted being frequency, duration and amplitude (Glaviano & Saliba, 2016).

The frequency of a waveform is the number of electrical impulses delivered to a muscle per second, and is expressed in units of Hertz (Hz), e.g. 30 Hz = 30 pulses per second (Robertson, Ward and Reed, 2006). Frequencies between 30 - 50 Hz are the most common in FES clinical trials (Johnson, Burridge, Strike, Wood, & Swain, 2004; Peurala et al., 2005),

and though lower frequencies of 20-25 Hz are reported, they are less common (Mangold et al., 2009; Peurala et al., 2005). Frequencies less than 30 Hz, and as low as 10Hz may create a muscle contraction which may not result in enough muscle torque to translate into a usable movement for a functional task (Doucet et al., 2012). While higher frequencies lead to increased torque production as compared to lower frequencies (Glaviano & Saliba, 2016), they are not without problems. Frequencies of above 60 Hz have been reported to increase muscle fatigue (Bergquist et al., 2011; Gondin, Guette, Ballay, Martin, 2005), and as a result, settings of 20 - 40 Hz are often recommended to attain a muscle contraction (tetany) while minimising the side effect of muscle fatigue (Bergquist et al., 2011; Glaviano & Saliba, 2016). Thus the clinical selection of the frequency of the waveform is essential to produce a muscle contraction sufficient enough to use the limb in motor training and engage in activity.

Pulse duration is the time span of a single electrical pulse within a waveform. Reported in microseconds (ms or μ s), the pulse duration determines the amount of electrical charge required to cause an action potential to trigger a muscle contraction (Robertson et al., 2006). When durations of under 100 μ s are administered, higher adjustments in amplitude are required to achieve a visible muscle contraction, while for durations between 100 and 1000 μ s only small increments of amplitude will be required to increase contraction intensity (Robertson et al., 2006). Since each electrical impulse is able to stimulate both sensory and motor neurones, with higher pulse durations stimulating pain neurones (Maffiuletti et al., 2018), increasing pulse duration in an effort to achieve a visible muscle contraction may also cause discomfort or pain (Robertson et al., 2006).

Pulse durations between 200-400 μ s are commonly reported in studies using electro-stimulation (Doucet et al., 2012). However, pulse widths of greater than 600 μ s have been combined with high frequencies (greater than 60Hz) to better understand whether the combination of these parameters have the potential to create an efficient and effective muscle contraction (Bergquist et al., 2016). When training the arm using a FES stimulated motor

training program, trials often use a pulse duration setting of between 200-300 μs (Barker et al., 2008; Daly et al., 2005; Lin & Yan, 2011; Mangold et al., 2009; Thrasher et al., 2008). The pulse duration of a FES impulse during the training of the lower limb is often reported to be 300-400 μs (Johnson et al., 2004; Kojovic et al., 2009; Ng, Tong, & Li, 2008; Peurala et al., 2005; Sabut et al., 2010). Pulse duration determines the level of muscular comfort and interacts with frequency and amplitude to achieve a motor response which can be used in motor training.

Amplitude determines the intensity of an electrical impulse and is expressed as microamperes (mA or μA) (Doucet et al., 2012). An increase in amplitude of a FES device will increase the number of recruited motor units causing a muscle contraction to create movement (Lee, Lee & Kim, 2013). Adjustments of amplitude have been reported to increase the torque production of muscles when amplitudes are set high (Gondin et al., 2011), or alternatively, the recruitment of the central nervous system occurs when the amplitude is set low (Doucet et al., 2012). Amplitude settings can be adjusted during a session to reduce the impact of muscular fatigue while maintaining movement (Barss et al., 2018). In studies investigating the efficacy of FES, the amplitude setting has often been set to achieve comfort or the desired movement to assist the stroke survivor to walk or pick up an object (Daly et al., 2005; Mann et al., 2005). The balance of selecting the amplitude while considering the effect brought about by the selection of settings for each of the other parameters, requires high level clinical reasoning by the physiotherapist or occupational therapist to develop an effective, painless but efficient FES stimulated motor training program.

Duty cycle describes the amount of time an electrical stimulus is being delivered to muscle fibres (Robertson et al., 2006) and is expressed as a ratio or a percentage (Doucet et al., 2012). For example, a ratio of 1:3 will mean that an electrical stimulus of two seconds (known as 'on-time') will be followed by six seconds of no stimulus (known as 'rest' or 'off-time'). Duty cycle is used to ensure the electrical stimulus creates an active prolonged

muscle contraction for use in motor training while minimising muscular fatigue (Packman-Braun, 1988; Taylor, Fornusek, & Ruys, 2018a; Taylor, Fornusek, & Ruys, 2018b). Further to minimising fatigue, higher work:rest duty cycles have been used with higher frequencies to strengthen muscles (Lieber & Kelly, 1993), increasing capacity of the stroke survivor to participate in motor training. The most common duty cycle reported in studies of the effectiveness of FES is 1:1 (Alon & Ring, 2003; Daly et al., 2005; Lin & Yan, 2011; Mann et al., 2005; Mohamed Faisal et al., 2012; Page, Levin, Hermann, Dunning, & Levine, 2012; Sabut et al., 2010), therefore for a one-second contraction, a one-second rest occurred. Duty cycles of 1:2 (Lee et al., 2018; Barker et al., 2018) have also been reported. The duty cycle will determine the duration of the impulses being delivered into a muscle, while the position of an electrode will determine where the impulses will be delivered (Alon, 2013). In this way, all the parameters are linked, but so too is the placement of the electrodes on the skin surface.

1.4.5 Electrode placement.

Electrode placement determines which paretic muscle is stimulated, which is used to engage a stroke survivor in task-based training (Botter et al., 2011). When placing electrodes of any size, the two conventional methods reported are over the muscle belly, or over the muscle motor point (Doucet et al., 2012). A muscle belly is the bulkiest part of a muscle, while a motor point is “where the motor branch of a nerve enters the muscle belly” (Gobbo, Maffiuletti, Orizio & Minetto, 2014, p.2). Both the muscle belly and motor point can be stimulated by placing an electrode on the skin which is over these areas. In addition to the placement of the electrode on the skin surface, the size of the electrode also influences the movement. An increase in the size of an electrode will disperse the current over a wider surface area, activating more motor units; while the use of smaller electrodes will direct the current into a focal point, minimising activation of adjacent muscles (Doucet et al., 2012). Further to considering the size of the electrode, the skin under the electrodes can become

uncomfortable or itchy due to changes in the skin's balance of acidity and alkalinity (Robertson et al., 2006). The selection of electrode size is determined by which muscles are to be stimulated while avoiding side effects caused by electrode sizing.

Electrode placement over the muscle belly will activate motor fibres directly under the electrode leading to a muscle contraction (Bergquist et al., 2016), whereas placement over a motor point will lead to activation of superficial motor units connected to the motor point (Botter et al., 2012). Gobbo, Gaffurini, Bissolotti, Esposito and Orizio. (2011) compared the two methods of electrode placement while stimulating the tibialis anterior muscle. When placed over the motor point, the muscle's physiological response improved (muscle contraction, torque, blood flow and oxygenation) as compared to the placement of the electrode over the muscle belly (Gobbo et al., 2011). It is still not known which method elicits less fatigue while still delivering desired clinical outcomes (Doucet et al., 2012). Studies of FES have described varying methods of electrode placement to improve contractions while minimising fatigue. Some studies placed electrodes over the muscle belly (Mann et al., 2005), while others were placed over a motor point (Barker et al., 2008), and others did not describe their method of placement (Daly et al., 2005). Despite this variability, it is widely acknowledged clinically that placement of electrodes plays a large role in the success of an electrically stimulated motor training program, so this should be a factor considered during the clinical prescription of electrical stimulation.

1.5 Motor Training during Functional Electrical Stimulation

While electrical stimulation can be provided in isolation, a FES stimulated motor training program is guided by a task-oriented motor learning framework. Firstly, a task-oriented approach is when a stroke survivor practises activity to regain the use of available and emerging movements (French et al., 2016). For example, the practising of walking to improve the performance of walking. Secondly, motor learning is the process of gaining motor skills through practise (Kitago & Krakauer, 2013; Krakauer, 2006; Krakauer &

Carmichael, 2017). For example, a person with a weak upper limb after stroke will need to relearn how to use existing and emerging movements to skilfully hold objects which he or she would like to transport from one bench to another. In the context of stroke rehabilitation, motor learning is when a person relearns how to use existing and emerging motor abilities into skilful movement (Shumway-Cook & Woollacott, 2007). The use of a FES stimulated motor training program facilitates engagement in task-oriented therapy.

The use of a motor learning paradigm is aimed at not only creating an improved performance of the trained activity during the therapy session but also at facilitating the generalisation of skill acquisition away from the clinical setting (Shumway-Cook & Woollacott, 2007). A motor learning approach to therapy is believed to enhance functional restoration through the promotion of neurological recovery within the brain (Arya, Pandian, Verma, & Garg, 2011; Bowden, Woodbury, & Duncan, 2013; Mangold et al., 2009; Takeuchi & Izumi, 2013). A systematic review of 13 intervention trials which did not use electrical stimulation but were modelled on motor learning principles, demonstrated that improvements of function were achieved (SMD 0.84, 95% CI 0.76 to 0.93) (Richards, Stewart, Woodbury, Senesac, & Cauraugh, 2008). This review provides some support that interventions built on motor learning principles may be effective in improving upper limb motor recovery.

Multiple critical motor learning retraining principles have been identified in the literature. Levac and colleagues identified that it must involve active repetitive task practise, include whole training rather than part-training, use variable training rather than constant task practise, and maintain sufficient task challenge (Levac, Missiuna, Wishart, DeMatteo & Wright, 2011). While Shumway-Cook and colleagues highlighted that there needs to be consideration of practise conditions plus the provision of feedback during and after movement practise (Shumway-Cook & Woollacott, 2007). In their Cochrane review, French and colleagues included all studies where motor training was task-based and repetitive (French et al., 2016); while Bowden and colleagues also involved concepts of intensive and

progressive practise (Bowden, Woodbury, & Duncan, 2013). For the purpose of the thesis, four commonly reported principles of a task-oriented motor retraining program will be discussed to demonstrate how a FES stimulated motor training program can be structured to deliver a task-oriented motor retraining program. These principles are: (a) repetitive task practise, (b) progressive task practise, (c) intensive task practise, and (d) provision of feedback during task practise.

1.5.1 Repetitive task practise.

Repetitive task practise occurs when a task is performed repetitively to enable the learning of how to perform that task (Schaefer, Patterson, & Lang, 2013). To successfully engage in task practise, the stroke survivor will be required to use both cognitive skills (for example memory, planning and problem solving) and motor skills (strength, movement, and coordination) (Bowden, Woodbury, & Duncan, 2013). A FES stimulated motor training program can enable the weak limb to perform repetitive task practise when otherwise, participation would be difficult or even impossible (Page et al., 2012). Repetitive task practise can be facilitated by FES, including tasks such as arm or leg cycling (Ambrosini, Ferrante, Pedrocchi, Ferrigno, & Molteni, 2011), walking (Burrage, Taylor, Hagan, Wood, & Swain, 1997), manipulation, grasp and release of single objects (Popovic et al., 2004), and reaching (Barker et al., 2017).

Systematic reviews have reported that repetitive task interventions have improved activity outcomes (Corbetta, Sirtori, Castellini, Moja, & Gatti, 2015; English & Hillier, 2010; French et al., 2016), providing support for the common use of repetitive task interventions in stroke rehabilitation in Australia. A review of six randomised controlled trials which include 292 participants, reported an increase in walking speed after task-based circuit training (MD 0.12, 95% CI 0.00 to 0.24, $p = 0.04$) (English & Hillier, 2010). A review of 33 randomised controlled and quasi-randomised controlled trials with 1,853 participants demonstrated small improvements with arm function (SMD 0.25, 95% CI 0.01 to 0.49), hand function (SMD

0.25, 95% CI 0.00 to 0.51), lower limb functional measures (SMD 0.29, 95% CI 0.10 to 0.48), walking distance (MD 34.80, 95% CI 18.19 to 51.41) and functional ambulation (SMD 0.35, 95% CI 0.04 to 0.66) (French et al. 2016). Improvements were maintained at six months and were not altered by the type or dosage of intervention; nor by time since stroke onset. A review of 42 randomised controlled and quasi-randomised controlled trials with 1,453 participants demonstrated that repetitive task practise using constraint-induced movement therapy (CIMT), improved arm motor function (SMD 0.34, 95% CI 0.12 to 0.55) (Corbetta et al., 2015). Together, these three systematic reviews demonstrate that repetitive task practise can improve stroke survivors' active use of their upper or lower limb. It is not evident if facilitating repetitive task practise using FES further improves limb use, or allows people who cannot currently move to take part in repetitive task practise for the first time.

The use of FES has been undertaken to facilitate repetitive task practise in upper limb rehabilitation (Mann et al., 2005; Page et al., 2012), and lower limb rehabilitation (Ng, Tong, & Li, 2008; Sabut et al., 2010), or both together (Embrey et al., 2010). Randomised controlled trials have compared the outcomes from FES stimulated motor training programs to control groups receiving no intervention (Cheng et al., 2010b; Mohamed Faisal et al., 2012), or to an active control intervention which included the same motor training but without the combined electrical stimulation (Kojovic et al., 2009; Peurala et al., 2005). While individual trials have investigated the use of FES for both upper and lower limb training to enable repetitive task practise, these findings had not been synthesised in a systematic review at the time of reviewing the literature for the thesis.

1.5.2 Progressive task practise.

Progressive task practise occurs when the clinician varies and increases the challenge of repetitive task movements throughout and between sessions, rather than repeating the same activity over and over (Bowden et al., 2013). Preclinical research (animal experiments) has demonstrated that cortical structures are developed when animals performed activities which were novel and when the activity progressed in difficulty (Kleim, Barbay, & Nudo, 1998; Hosp & Luft, 2011); these studies formed the basis for progressive task practise in humans. Progressive task practise will support the engagement in activities throughout a therapy session while considering the grading of the complexity of the activity (Shumway-Cook & Woollacott, 2007). Progressive task practise is a key characteristic of a FES stimulated motor training program.

The research evidence demonstrates that a FES stimulated motor training program can be designed to vary task practise, introduce new task demands or increase the level of difficulty as recovery occurs. Once the desired reaching activity has been achieved (for example, touching the mouth), a new activity can be introduced which incorporates the previously learnt skill (such as picking up a cup) (Thrasher et al., 2008). Alternatively, multiple actions could be used in one session to vary movement and activity demands. For example, where stroke survivors can commence with an achievable goal of reaching for and grasping a cup this can then progress to reach for and picking up objects such as a telephone, pen or toothbrush (Popovic, Popovic & Sinkjaer, 2002b). Stroke survivors could also be asked to identify participation goals, then practise components of the activity multiple times of the day (Page et al., 2012). Even though a FES stimulated motor training program can be delivered to vary task practise, some FES trials do not report if activity demands were progressed (Burridge et al., 1997; Ng et al., 2008). Task progression is an important consideration in delivering a FES stimulated motor training program.

1.5.3 Intensity of task practise.

The intensity of task practice influences the outcomes from a motor training program. Intensity of task practice can be recorded by the effort exerted during task practice (Bowden et al., 2020) or the number of repetitions per session (Birkenmeier, Prager, & Lang, 2010). Intensity is often expressed as the length of time scheduled for therapy (Veerbeek et al., 2014), however, the dose response relationship between the amount of movement practise and outcomes has been largely unknown. (Lang, Lohse & Birkenmeier, 2015). Findings from a meta-analysis of 30 randomised trials (of studies not using a FES stimulated motor training program) which included 1,750 participants, demonstrated that when a stroke survivor participated in an increased amount of motor retraining therapy, outcomes were more significant as compared to training in a less amount of time (Hedge's $g = 0.35$, 95% CI 0.26 to 0.45) (Lohse, Lang & Boyd et al., 2014). These findings were supported by a later meta-analysis of 14 randomised or quasi-randomised clinical trials, which included 954 stroke survivors, which selected trials that provided a consistent type of motor training to all; varying only the dose of training (Schneider, Lannin, Ada, & Schmidt, 2016). The authors reported that activity outcomes were enhanced after extra rehabilitation was provided (SMD 0.39, 95% CI 0.07 to 0.71, $I^2 = 66\%$) (Schneider et al., 2016). Furthermore, Schneider's et al. findings reported that the effect was greater when a substantial increase in training time was provided as compared to the control group (SMD 0.59, 95% CI 0.23 to 0.94, $I^2 = 44\%$). The Australian Stroke Foundation Clinical Guidelines (Stroke Foundation, 2017) cited these systematic reviews, thus recommending stroke survivors participate in two hours of task practise a day to improve motor activity. A significant amount of repetitive task practise is required to achieve an improvement in motor control. Achieving the required amount of practise for stroke survivors who are unable to move is not possible without interventions such as FES, therefore the intensity of task practise from a FES stimulated motor training program is important to consider.

The intensity of practice from a FES stimulated motor training program has predominantly been reported by modifying session length, to facilitate an increase in the dose of task repetitions. Positive trial results have been reported from FES session lengths ranging from 20-minute (Ng et al., 2008; Popovic et al., 2004), 45 to 60 minutes (Barker et al., 2008; Mann et al., 2005; Sabut et al., 2010) and up to 120 minutes (Page et al., 2012). The impact of increasing the intensity of task practise on activity outcomes was reported in a randomised controlled trial which compared the outcomes of three groups, each receiving a different amount of active FES stimulated motor training (30, 60 or 120 minutes) (Page et al., 2012). While not a dose- response study, the findings did show that 120 minutes of FES led to significantly greater improvements on activity outcomes compared to 30 or 60 minutes, suggesting that increasing the amount of time spent in training is beneficial. Considering all aspects, this research suggests that the duration of a FES stimulated motor training program session needs to be sufficient to support a high number of task repetitions, likely for >2 hours every day, while opportunity is also given for the stroke survivor to receive feedback.

1.5.4 Provision of feedback during practise.

Feedback is a method to facilitate a person to learn to reacquire lost or diminished skills (Kuitago & Krakauer, 2013). When a person learns a new skill, they need to interpret the visual information they experience, understand the sensory-motor experiences of the body and comprehend the skill demand of the activity (Shumway-Cook & Woollacott, 2007). Feedback is influenced by its frequency, delivery method and content (Stanton, Ada, Dean & Preston, 2015). Feedback includes receiving information about movement and skill errors but also about movement-related information which can be used to focus the motor learning (Schmidt & Lee, 2014). In this way, feedback can assist the stroke survivor to understand and address the new skill's demands caused by the impairments resulting from a stroke (Bowden et al., 2013) and to make corrections to motor performance during the relearning of activities (Magil & Anderson, 2014). Feedback may be either intrinsic or augmented. Intrinsic

feedback describes the intuitive awareness of movement and body demands from completing the required skill (Shumway-Cook & Woollacott, 2007), and is often impaired in people who have had a stroke (van Villett & Wulf, 2006). A person may automatically improve their motor performance during an activity by receiving and acting upon intrinsic feedback relating to motor performance (Takeuchi & Izumi, 2013). When walking, a person may be aware of how their legs, hips, and body move in response to going up an incline, including characteristics such as force generation, variations of joint angles and speed of limb involvement (Molier, Van Asseldonk, Hermie & Jannink, 2010). Intrinsic feedback is the natural awareness that the person has about body position (physiologically as well as cognitively) to learn how to adjust and correct movements during skill acquisition (Schmidt & Lee, 2014).

Alternatively, augmented feedback is when information is provided by an external means to provide knowledge of results or knowledge of performance which can be used to guide the learning process (Schmidt & Lee, 2014). A number of techniques have been established to provide augmented feedback to the stroke survivor, including observing the non-impaired limb during an activity (Ertelt & Binkofski, 2012; Franceschini et al., 2012), technology providing movement feedback via digital displays or auditory signals (Jonsdottir et al., 2010; Levac et al., 2011) and knowledge of results/performance given by a clinician (Shumway-Cook & Woollacott, 2007). Feedback is an integral part of neurological recovery and can be incorporated into a FES stimulated motor training program (Kitago & Krakauer, 2013).

A variety of methods of feedback have been reported in trials using FES to improve recovery outcomes after stroke (In-Chul & Byoung-Hee, 2012; Cheng et al., 2012; Mangold et al., 2009; Popovic et al., 2003). Intrinsic feedback was reported to occur through the body's proprioceptive and sensory systems which are activated due to the delivery of an electrical impulse during task-oriented therapy (Popovic et al. 2002b). Where as augmented

feedback was reported in numerous trials comparing a FES stimulated motor training program to a control group. For example, the use of a digital display provided visual feedback to the stroke survivor about how their walking performance compared to the desired walking pattern (In-Chul & Byoung-Hee, 2012) or the provision of verbal feedback from the therapists regarding the stroke survivors activity performance (Mangold et al., 2009; Popovic, Popovic, Sinkjaer, Stefanovic & Schwirtlich et al., 2003). In contrast to the studies reporting an active feedback mechanism, the authors of two FES trials did not report the use of feedback during sessions (Mohamed et al., 2012; Tarkka, Pitkanen, Popovic, Vanninen, & Kononen, 2011). A FES stimulated motor training program can be designed to actively use both augmented and intrinsic feedback mechanisms to enable motor relearning at various time points after stroke onset.

1.6 Confounding Factors Impacting the Outcome of FES for Stroke Rehabilitation

1.6.1 Time after stroke onset.

A predominant viewpoint in the rehabilitation literature is that improvements in the performance of activities are expected to occur in the first six months after stroke onset (Kwakkel & Kollen, 2013). The expected improvement originated from a prospective design study of 1,197 participants which reported that stroke survivors achieved maximal functional recovery by three months after stroke onset (Jørgensen, Nakayama, Raaschou, & Olsen, 1995; Jørgensen et al., 1995). The maximum walking ability was achieved by 95% of stroke survivors at 11-weeks after stroke onset (Jørgensen, Nakayama, Raaschou, & Olsen, 1995). Also, the maximum arm function was achieved by 95% of stroke survivors at nine weeks after stroke onset (Jørgensen et al., 1995). Further, trials examining outcomes six months after stroke onset have demonstrated that 5 to 10% of participants will improve in activities, and 15 to 25% will decline in capability (Kwakkel & Kollen, 2013; van de Port, Kwakkel, van Wijk, & Lindeman, 2006). As time is a determinant of recovery of activity after a stroke, it was necessary to identify if the use of FES occurs at different time points after stroke.

The use of FES has been categorised according to whether the stroke survivors participating in the FES stimulated motor training program had a stroke onset less than or greater than six months. Outcomes examining the effectiveness of FES on activity outcomes in the six months following stroke onset have been investigated (Alon & Ring, 2003; Bogataj et al., 1995; Kojovic et al., 2009; Macdonell et al., 1994; Mangold et al., 2009; Ng et al., 2008; Popovic et al., 2004; Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2002b; Popovic et al., 2003; Ring & Rosenthal, 2005; Shindo et al., 2011; Thrasher, Zivanovic et al., 2008; Tong, Ng, & Li, 2006). A considerable number of studies involving FES have investigated activity outcomes, six months after stroke onset (Barker et al., 2008; BurrIDGE et al., 1997; Daly et al., 2005; Embrey et al., 2010; Hara, Ogawa, & Muraoka, 2008; Johnson et al., 2004; Lin & Yan, 2011; Lo, Hsu, Hsueh, & Yeh, 2012; Mann et al., 2005; Page et al., 2012; Peurala et al., 2005; Tarkka et al., 2011.). The expectation of a change in activity performance after the six-month time frame has been previously reported to be low (Jørgensen, Nakayama, Raaschou, & Olsen, 1995; Jørgensen et al., 1995; Kwakkel & Kollen, 2013). As a FES stimulated motor training program has been used in the two predominate time-frames after stroke onset (less than six months and greater than six months), it was also essential to understand the evidence on whether stroke severity influences the use of FES in clinical practice.

1.6.2 Stroke severity.

Greater severity of stroke has been associated with stroke survivors having more extended lengths of hospitalisation, being discharged to institutional care, lower functional gains, poorer health outcomes and higher levels of disability (Burton et al., 2018; Kwakkel & Kollen, 2013). In studies of stroke survivors with motor weakness, the severity of a stroke influences the outcomes achieved from rehabilitation interventions (Coupar, Pollock, Rowe, Weir, & Langhorne, 2012; Hendricks, van Limbeek, Geurts, & Zwarts, 2002). A systematic review with narrative analysis of 13 prognostic cohort studies and one randomised controlled trial which included 3,491 participants, concluded that greater severity of motor paresis

predicted more reduced motor recovery (Hendricks et al., 202). The authors of another systematic review of 58 cohort studies which investigated prognostic variables for stroke survivors with upper limb impairments, reported that the greater severity of activity restrictions, the less likelihood of motor recovery (odds ratio 14.84, 95% CI 9.08 to 24.25) or activity performance recovery (odds ratio 38.62, 95% CI 8.40 to 177.53) (Coupar et al., 2012). The severity of muscle weakness is thus considered to be a strong predictor of activity outcomes after stroke rehabilitation interventions.

The stroke severity of participants in FES clinical trials have been reported in various formats: the amount of active range of motion (Alon & Ring, 2003; Popovic et al., 2004; Popovic et al., 2002b, 2003), the level of ability as described by a measure of activity (Mangold et al., 2009; Ng et al., 2008; Page et al., 2012; Peurala et al., 2005; Thrasher, Zivanovic et al., 2008; Tong et al., 2006), and paresis as measured by the United Kingdom Medical Research Council Muscle Strength Grading System (Barker et al., 2008). Clinical trials involving FES have investigated the effectiveness of treatment as related to the severity of muscle weakness by randomising participants to the experimental and control groups dependent on initial stroke severity (Popovic et al., 2002b, 2003). Favourable clinical and statistical trends were reported in activity outcomes for participants having less muscle weakness (Popovic et al., 2002b; 2003). The thesis considered if the reported FES trial outcomes varied depending on the severity of impairments of the stroke survivor.

1.7 Rationale for Research: The Translation of Evidence about Functional Electrical Stimulation into Clinical Practice

The studies reported in this thesis have investigated the clinical use of FES (whilst drawing on the literature on motor training and electrical stimulation) and how knowledge about FES is translated into clinical care. The process of knowledge translation is known by interchangeable terms such as implementation research, research adoption, improvement science, dissemination, quality improvement and improvement science (Newhouse et al., 2013; McKibbin, Wilczynski, & Haynes, 2010), but it is essentially the process of developing, synthesising and applying research knowledge into practice (Canadian Institutes of Health Research, 2008; Morris, Wooding, & Grant, 2011). There is an expectation that clinicians will engage with the knowledge translation process by reading journal articles reporting research trials or systematic reviews, or clinical practice guidelines, which will then be the impetus to practice change (MacDermid & Graham, 2009). In more recent years, health services have acknowledged that active engagement in knowledge translation at a service level has the potential of enabling the implementation of effective health care interventions and ceasing the implementation of ineffectual interventions (Sudswad, 2007; Wathen & MacMillan, 2018).

Health care interventions used by clinicians have not always demonstrated research evidence (Flores-Mateo & Argimon, 2007; Hanney et al., 2015). It has been reported by authors investigating the effectiveness of implementing research evidence in clinical care, that between 10 and 40% of people did not receive an intervention that was supported by evidence indicating high levels of effectiveness, while 20% of people received interventions that were either harmful or ineffectual (Grol & Grimshaw, 2003). The evidence supporting the use of FES has increased over recent years; however, there is uncertainty as to how and if the evidence-based intervention of FES has translated into clinical practice in Australia.

At the commencement of my doctoral research, I was an occupational therapist

working as a clinician in stroke rehabilitation. I was increasingly becoming aware of my limited ability to assist stroke survivors improve the use of their hand and arm in daily life. While I had a broad understanding of the research evidence supporting the rehabilitation of the upper limb, I was uncertain and confused as to how to implement this research evidence into my practice. At the same time, I had started to use a FES stimulated motor training program to assist stroke survivors in recovering the use of their hand. These experiences increased my curiosity, which guided the creation of the thesis' primary research question and research hypothesis.

1.8 Research Objective and Hypothesis for Thesis

When considering the translation of FES research knowledge into stroke rehabilitation, three issues were identified. Firstly, it was not known if the accumulative evidence of FES for stroke rehabilitation demonstrates effectiveness in improving the daily life of a stroke survivor. Secondly, the use of FES by either physiotherapists or occupational therapists in routine practice was mostly unknown. Finally, the barriers and enablers for using FES in practice are not well understood. The thesis aim was to identify how clinicians were using FES in clinical practice and determine if practice reflected research evidence. At the commencement of the research program, the research hypothesis was that some occupational therapists and physiotherapists were using FES in stroke rehabilitation; however, contextual practice barriers existed which limited the use of FES in clinical practice.

1.9 Overview of Thesis

The thesis contains eight chapters. Chapter One has described the intervention of FES, highlighting the potential benefits and considerations of using a FES stimulated motor training program in practice. Chapter Two summarises the evidence as related to the research gaps and the need for the current research program. Chapter Three justifies the research methods used to answer the research questions. Chapter Four describes and discusses the first study, demonstrating the overall effectiveness of FES. Chapter Five describes and discusses the second study, determining if FES is being used in the state of Victoria by occupational therapists and physiotherapists. Chapter Six describes and discusses the third study, identifying possible barriers to using FES by clinicians in a regional health service. Chapters Four and Five include published findings for study one (Howlett, Lannin, Ada, & McKinstry 2015) and study two (Howlett, McKinstry, & Lannin, 2018a, 2018b). In Chapter Seven, a response is provided regarding how the three standalone studies support the acceptance or rejection of the research hypothesis while also describing how research findings compare to current research evidence. Finally, Chapter Eight describes the implication of research findings for the stroke survivor, clinicians, educators and health care organisations; and provides recommendations for future research. Appendices contain copies of published manuscripts, copies of conference presentations, copies of ethics committees correspondence for study two and three, data collection forms from study one and two, and copies of recruitment methods for study two and three. Appendices also contain permissions for reprint of published studies and included reproduction of diagrams. A complete reference list is provided at the completion of Chapter Eight.

Chapter 2. Literature Review

2.1 Introduction

The literature review chapter will describe and evaluate the evidence for using FES to improve a stroke survivor's participation in everyday life. In this thesis, the Knowledge to Action Framework (Graham et al., 2006) is used to classify the types of evidence investigating a FES stimulated motor training program. The literature review is structured into three sections, outlining the state of the evidence at the commencement of the research program.

1. Is there research support for the use of FES to improve the daily life of stroke survivors who have motor weakness of the upper and/or lower limbs? To understand if an intervention should be put into practice, it must be determined if the research evidence supports the use of that evidence. Question one will be answered by discussing the recommendations and findings originating from knowledge tools, knowledge synthesis studies, and knowledge inquiry studies (Graham et al., 2006).

2. Is FES used in the clinical practice of occupational therapists and physiotherapists? Question two will be answered by presenting results from knowledge inquiry studies (Graham et al., 2006) investigating the use of FES by clinicians in stroke rehabilitation.

3. What are the known barriers to using FES in practice for occupational therapists and physiotherapists? Question three will be answered by reviewing the findings of knowledge inquiry studies (Graham et al., 2006) investigating the barriers to using a FES stimulated motor training program.

To demonstrate the need for the proposed research program (which is described in Chapter Three), the strengths and limitations of previous FES research will be firstly described in this chapter. In doing so, the gaps in the literature will then be identified.

2.2 Is There Research Support for the Use of FES to Improve the Daily Life of Stroke Survivors who have Motor Weakness of the Upper and/or Lower Limbs?

2.2.1 Knowledge tools.

The Knowledge to Action Framework recommends that clinicians seek direction from clinical guidelines as a first step to identify if an intervention should be used in practice (Booth, 2017; Graham et al., 2006; MacDermid & Graham, 2009), because clinical guideline authors have pre-appraised and synthesised the research evidence into a format which can often be more easily used by clinicians (Farquhar, Kofa, & Slutsky, 2002; Greenfield et al., 2011). To identify the recommendations made as related to a FES stimulated motor training program, the student researcher retrieved major stroke rehabilitation clinical guidelines developed prior to 2014 (Intercollegiate Stroke Working Party, 2012; Lindsay et al., 2012; Miller et al., 2010; National Institute for Health and Care Excellence, 2013; Stroke Foundation, 2010; Scottish Intercollegiate Guidelines Network, 2010). It was then determined if the guidelines included recommendations for the use of FES for either upper or lower limb retraining, as well as if FES was recommended for orthotic or therapeutic purposes. Lastly, the student researcher classified the guidelines' recommendations using the International Classification Framework (World Health Organization, 2001), into outcomes of either body function, activity or participation. By understanding if FES was recommended in known clinical practice guidelines, a decision could be made if an extended examination of the literature, such as a systematic review, was justified.

Reference to the use of a FES stimulated motor training program was made in six clinical practice guidelines (Intercollegiate Stroke Working Party, 2012; Lindsay et al., 2012; Miller et al., 2010; National Institute for Health and Care Excellence, 2013; Scottish Intercollegiate Guidelines Network, 2010; Stroke Foundation, 2010), and these recommendations have been summarised in Table 2.1. The National Institute for Health and Care Excellence (2013) supported the use of FES to reduce the impairment of muscle

weakness of the upper limb, while the Scottish Intercollegiate Guidelines Network (2010) stated that there was insufficient evidence to support or refute the use of FES for upper limb retraining. The guidelines by Lindsay et al. (2012), the Stroke Foundation (2010) and Miller et al. (2010) all reported the use of FES for lower limb training to improve performance in activities. In contrast to Lindsay et al., Stroke Foundation and Miller et al., the guidelines by Intercollegiate Stroke Working Party, the National Institute for Health and Care Excellence and the Scottish Intercollegiate Guidelines Network all stated that there was a lack of evidence to support or refute the use of FES and electrical stimulation to improve daily life. The National Institute for Health and Care Excellence report was the only guideline which based their recommendations solely on studies investigating FES. It was evident that FES was inconsistently recommended as an intervention to improve outcomes for upper and lower limb motor performance.

Table 2.1

Recommendations from clinical practice guidelines regarding the use of functional electrical stimulation (FES)

Title	Intervention	Evidence level supporting recommendation*	Upper limb recommendations	Lower limb recommendations
Intercollegiate Stroke Working Party (2012)	FES orthotic	Level I	NA	For use in the correction of foot drop
	ES/FES	Expert opinion	Not to be used in clinical practice unless within the context of a clinical trial	Not to be used in clinical practice unless within the context of a clinical trial
Lindsay et al. (2012)	ES/FES	Level II	FES to wrist and forearm muscles will improve arm function	For use to improve activity/reduce impairment
Miller et al. (2010)	ES/FES	Level II	Support for use. Outcomes not clear	For use to improve activity and reduce impairment
National Institute for Health and Care Excellence (2013)	FES	Not stated	For use to reduce impairment	
	FES orthotic	Level I	NA	Consider using to correct for foot drop.
Stroke Foundation (2010)	ES/FES	Level II	For use to improve activity and reduce impairment	NA
Scottish Intercollegiate Guidelines Network (2010)	FES orthotic	Level I	NA	Consider using to correct for foot drop
	ES/FES	Level II	Insufficient evidence to support or refute use	NA

Note. NA = not applicable; ES = electrical stimulation; FES = functional electrical stimulation. ; * = levels of evidence determined by the National Health Medical Research Council levels of evidence (National Health and Medical Research Council, 2009)

The inconsistencies in recommendations between clinical guidelines may be due to variations in the evidence included to inform their recommendations. Many clinical guidelines based their recommendations on Level II studies (National Health and Medical Research Council, 2009) such as randomised controlled trials investigating the use of electrical stimulation (de Kroon, van der Lee, & Lankhorst, 2002) or FES (Peckham & Knutson, 2005). Interventions using electrical stimulation predominately strengthen the muscles by repetitive movements, while FES improves the performance of the limb during activities by using a motor learning approach to rehabilitation (Nascimento et al., 2014). It would be plausible that depending on which guideline a clinician chose to apply in clinical practice, a stroke survivor may receive quite different rehabilitation in different settings. The Knowledge to Action Framework recommends that if clinical guidelines do not provide strong direction, the next level of evidence of the knowledge creation domain should be investigated to identify if the evidence has the strength to warrant implementation (Graham et al., 2006). Therefore, there was a need to identify if there were available knowledge synthesis studies investigating treatment effectiveness such as systematic reviews of Level II studies.

2.2.2 Knowledge synthesis.

A knowledge synthesis combines the findings from individual studies to inform decisions regarding whether an intervention is effective (Graham et al., 2006) and includes a meta-analysis of statistical findings and an appraisal of risk of bias (Higgins & Green, 2011; Moher et al., 2015; National Health and Medical Research Council, 2009; Smith, Devane, Begley, & Clarke, 2011). An example of a knowledge synthesis study is a systematic review of randomised controlled trials (National Health and Medical Research Council, 2009). A systematic review reporting on the effectiveness of a FES stimulated motor training program could provide guidance to whether FES should be used in stroke rehabilitation (Bennett, Hannes & O'Connor, 2017).

Multiple systematic reviews claimed to investigate a FES stimulated motor training program for stroke rehabilitation (Glanz, Klawansky, Stason, Berkey, & Chalmers, 1996; Glinsky, Harvey, & Van Es, 2007; Handy, Salinas, Blanchard, & Aitken, 2004; Hayward, Barker, & Brauer, 2010; Pereira, Mehta, McIntyre, Lobo & Teasell, 2012; Pomeroy et al., 2006; Robbins, Houghton, Woodbury, & Brown, 2006; Roche, Laighin, & Coote, 2009). Two of the eight systematic reviews reported the inclusion of FES trials; however, none of their included source studies could be categorised as FES because they did not include a motor retraining activity while the electrical device was activated (Glanz et al., 1996; Handy et al., 2004). A further three systematic reviews included less than 15% of studies which investigated FES (Glinsky, Harvey, & Van Es, 2007; Hayward et al., 2010; Pomeroy et al., 2006). The remaining three systematic reviews investigated the use of a FES stimulated motor training program for the lower limb demonstrating changes in the outcome of activity (Pereira et al., 2012; Robbins et al., 2006; Roche et al., 2009).

The treatment effectiveness of FES was reported in three systematic reviews (Pereira et al., 2012; Robbins et al., 2006; Roche et al., 2009), including two with meta-analysis (Pereira et al., 2012; Robbins et al., 2006). A systematic review of seven randomised controlled trials involving 231 subjects identified a significant but small positive treatment effect on walking speed (0.379 SMD +/- 0.152, 95% CI 0.08 to 0.68 $p = 0.013$) (Pereira et al., 2012). The review by Robbins et al. (2006) also contained meta-analysed data, including eight controlled trials involving 161 participants. This review identified a positive treatment effect on walking speed (0.18 MD, 95% CI 0.08 to 0.28) (Robbins et al., 2006). In contrast to the two meta- analyses, the narrative approach to synthesising trial findings used by Roche et al. (2009) has a potential bias due to lack of statistical analysis (Higgins & Green, 2011), therefore this study will not be further discussed in this thesis. The two systematic reviews with meta- analysis of findings from Level II studies (Pereira et al., 2012; Robbins et al.,

2006) identified beneficial effects on activity outcomes after the use of FES for lower limb training after stroke onset, however did not include upper limb training studies, leaving a gap in the understanding of potential clinical benefit.

It is crucial to understand if the findings from the systematic reviews reported a change which is significant for stroke survivors (Jakobsen, Wetterslev, Winkel, Lange, & Gluud, 2014). Clinical significance identifies if a participant experiences notable improvement after receiving the experimental or control intervention (Guyatt, Osoba, Wu, Wyrwich, & Norman, 2002). Interpreting a meta-analysis' clinical significance depends on the type of statistical analysis used. For continuous data, the use of a standardised mean difference (SMD) statistic provides an estimated treatment effect that requires statistical interpretation, whereas the mean difference (MD) statistic provides an expected treatment effect in a clinically measurable outcome (Higgins & Green, 2011; Johnston et al., 2010). Pereira et al. (2012) reported the findings as an SMD, whereas Robbins et al. (2006) reported the analysed data as an MD. Pereira et al. results provide a statistical estimated treatment effect of a small to moderate size, while Robbins' et al. use of the MD statistic provides insight into what outcomes may be seen clinically. The MD treatment effect of 0.18 reported by Robbins et al. indicates an expected improvement of walking speed of 0.18 m/s after receiving FES and is expected to create change which is important for the participant because the walking speed was greater than 0.1 m/s (Chui, Ethan Hood, & Klima, 2012). In summary, two systematic reviews supported the use of FES for lower limb training (Pereira et al., 2012; Robbins et al., 2006), with one review describing a clinically significant outcome in walking speed (Robbins et al., 2006).

Participants described in the two located systematic reviews were predominantly representative of those stroke survivors in the chronic stage of recovery (greater than six months post-stroke onset) (Pereira et al., 2012; Robbins et al., 2006). Pereira et al. (2012) only included trials with participants who had a stroke onset greater than six months, while the review by

Robbins et al. (2006) included all trials, irrespective of time post-stroke in the meta-analysis however only included one trial with participants having a stroke onset less than six months. Future examination of the literature using a systematic review methodology was thus justified to determine the treatment effect of FES at all time frames following stroke onset.

The methodological quality of a systematic review determines the value, and the applicability of a review (Moher, Liberati, Tetzlaff, & Altman, 2009). The validated Assessment of Multiple Systematic Reviews (Shea et al., 2009) was used to investigate the potential biases of the reviews investigating FES (Pereira et al., 2012; Robbins et al., 2006). It was identified that both reviews used pre-planned search and data extraction methods, demonstrating that the procedures of Pereira's et al., (2012) and Robbins's et al., (2006) supported the intention to only include relevant studies (Higgins & Green, 2011). In contrast, potential biases were identified relating to the reporting of the methodological quality of included trials (Pereira et al., 2012; Robbins et al., 2006), and the heterogeneity of results (Pereira et al., 2012). These two sources of bias will now be discussed.

The methodological quality of the included trials was stated by Pereira's et al. (2012) and Robbins' et al. (2006). Neither review stated how the quality of the included trials impacted the meta-analysis findings. It was not reported if a sub group analysis was conducted to determine if the treatment effect varied depending on the inclusion or exclusion of studies with various quality. Findings from systematic reviews may be inflated due to the methodological biases of the included trials (Higgins & Green, 2011). It is therefore not known if the estimated treatment effect of FES as reported by Pereira et al. and Robbins et al., is an accurate representation of an effect or is inflated due to the methodological quality of trials included into the meta-analyses. Systematic reviews should ensure that trial quality is

considered as one component of analysis or inclusion in meta-analyses to overcome this limitation.

The treatment effect of FES as reported by Level I trials may be influenced by heterogeneity, where statistical findings can occur not due to chance but due to identified or non-identified variables (Higgins & Thompson, 2002). Both Robbins et al. (2006) and Pereira et al. (2012) pre-stated their threshold for identifying heterogeneity using the I^2 statistic. Robbins et al. reported no heterogeneity between trials in their systematic review because the I^2 statistic was 0% (Higgins & Green, 2011). Pereira et al. stated that heterogeneity would be present if the I^2 statistic was greater than 50% and that they would investigate the heterogeneity by sub group analysis if the threshold was exceeded. Even when the I^2 statistic is between 30 – 50 %, the analysis may contain heterogeneity and still requires exploration by sub group or a random-effects meta-analysis (Higgins & Green, 2011). It is not known if Pereira's et al. results were homogenous because the percentage of I^2 statistic was not stated. While the reviewers took steps to examine heterogeneity, it remains unknown whether the small treatment effect reported by Pereira et al. (2012) is an accurate representation of the actual treatment effect for FES for lower limb training.

In summary, there was limited evidence from two systematic reviews, each having a meta-analysis, demonstrating that FES for lower limb training improved walking speed for stroke survivors with a stroke onset of greater than six months (Pereira et al., 2012; Robbins et al., 2006). It was not known if FES was effective for upper limb training; therefore it was necessary to identify if there were controlled trials (Level II and III study designs) investigating the use of a FES stimulated motor training program for the upper limb. It was also necessary to identify if further randomised controlled trials for lower limb FES had been conducted since those reported in Pereira et al. (2012) and Robbins et al. (2006). A review of the existing knowledge inquiry studies was conducted.

2.2.3 Knowledge inquiry studies.

Knowledge inquiry studies are the individual research studies which investigate the effectiveness, feasibility or the practicality of health care practices (Graham et al., 2006). The research evidence to support the implementation of an intervention from an individual study should be either a Level II (randomised controlled trials) or Level III (pseudorandomised trials or comparative trial designs with no random allocation) (National Health and Medical Research Council, 2009). Both Level II and III study designs have a control group which allows a comparison of an intervention to either an alternative, placebo or no intervention. Level II trials are the highest level of evidence from a single trial (National Health and Medical Research Council, 2009), while Level III trials have an increased risk of reporting bias due to lack of random allocation (Del Mar, Hoffmann & Glasziou, 2017).

There were 29 Level II studies located, all of which reported the efficacy of a FES stimulated motor training program after randomising participants to either an experimental or control group. Lower limb FES training was tested in 14 randomised controlled trials (Burridge et al., 1997; Bogataj et al., 1995; Cheng et al., 2010; Embrey et al., 2010; Johnson et al., 2002; Johnson et al. 2004; Kojovic et al., 2009; Lo et al., 2012; Lin & Yan, 2011; Macdonell et al., 1994; Ng et al., 2008; Peurala et al., 2005; Tanovic, 2009; Tong et al., 2006) with mixed results. Upper limb FES training was tested in 15 randomised controlled trials (Alon, Levitt, & McCarthy, 2007; Alon & Ring, 2008; Barker et al., 2008; Daly et al., 2005; Hara et al., 2008; Mangold et al., 2009; Mann et al., 2005; Mohamed Faisal et al., 2012; Page et al., 2012; Popovic et al., 2004; Popovic, Popovic, Sinkjaer, Stefanovic, & Schwirtlich, 2002; Popovic et al., 2003; Shindo et al., 2011; Tarkka et al., 2011; Thrasher, Zivanovic et al., 2008), again with variable results. At the time of the literature review, the effectiveness of FES has thus been reported in 29 published manuscripts.

Beyond these 29 individual knowledge inquiry studies, there were three FES stimulated motor training studies (Alon & Ring, 2003; Ring & Rosenthal, 2005; Sabut et al., 2010) that did not randomise subjects to the comparison group (Level III studies). All Level III studies reported favourable results for the group receiving FES, although these trials may have overestimated the intervention treatment effect due to the lack of randomisation (Deeks et al., 2003). Due to methodological bias, conclusions from Level III trials need to be considered with caution when translating the findings into practice. Together, these Level II and III studies report variable outcomes, suggesting that there are sufficient individual quantitative research studies investigating the effectiveness of FES for both upper and lower limb motor training, however without synthesis using meta-analysis, understanding the true effect of a FES stimulated motor training program is difficult.

The methodological quality of Level II and III trials were examined using the validated PEDro Scale (de Morton, 2009) which has an interval scale to investigate the validity and clinical generalisability of a clinical trial (The George Institute for Global Health, 2014). The methodological characteristics investigated were random allocation; concealed allocation; baseline comparability, subject blinding; therapist blinding, assessor blinding; greater than 85% follow-up, intention to treat analysis, between-group statistical comparison and, reporting of point estimates and variability (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). The individual PEDro Scale domains were used to identify potential biases of clinical trials investigating the use of FES and will now be discussed in relation to Level II and III trials investigating the effectiveness of FES.

Non-concealment of subject randomisation in Level II and III studies may influence the internal validity of the clinical trial's findings (Del Mar et al., 2017). Concealment of randomisation was reported in 11 Level II and III trials examining the effectiveness of FES (Barker et al., 2008; Bogataj et al., 1995; BurrIDGE et al., 1997; Cheng et al., 2010; Johnson et

al., 2004; Johnson et al., 2002; Mann et al., 2005; Page et al., 2012; Peurala et al., 2012; Tarkka et al., 2011; Thrasher, Zivanovic et al., 2008). An overestimation of treatment effect can occur due to the non-concealment of randomisation (Schulz et al., 1995). As a result, 21 of the identified trials investigating FES effectiveness may have provided an over or underestimation of treatment effect.

The use of blinded assessors in some FES clinical trials may have decreased the level of observer bias. Blinding of assessors occurred in 14 Level II and III FES trials (Barker et al., 2008; Cheng et al., 2010; Daly et al., 2005; Hara et al., 2006; Hara et al., 2008; C. Johnson et al., 2004; Macdonell et al., 1994; Page et al., 2012; Popovic et al., 2004; Popovic et al., 2003; Ring & Rosenthal, 2005; Sabut et al., 2010; Thrasher, Zivanovic et al., 2008; Tong et al., 2006). Overestimation of results has been demonstrated when assessors are not blinded (Hróbjartsson et al., 2012). The majority of trials (17 of the 32 trials) did not report blinding of assessors, therefore, some exaggeration of results may have occurred.

Bias may exist for Level II and III FES trials due to a lack of intention to treat analysis which considers all subjects to be treated as allocated and provides an estimation of treatment effect based on intended allocation (Lachin, 2000). If an intention to treat analysis is not completed, an incorrect estimation of treatment effect may occur (Hollis & Campbell, 1999). Intention to treat analysis was conducted in five Level II and III trials (Alon & Ring, 2003; Barker et al., 2008; Mangold et al., 2009; Ng et al., 2008; Tong, Ng, Li, & So, 2006) and accordingly, most of the Level II and III FES trials may have reported a favourable result due to a lack of intention to treat analysis.

The findings of a controlled clinical trial can be interpreted by examining the reported statistical analysis and baseline comparability (Maher et al., 2003). Of the 32 clinical trials reported, 30 studies have available point measures and measures of variability demonstrating the treatment effect of FES. While favourable results were reported, Johnson et al. (2002)

and Ring and Rosenthal (2005) did not report the statistical findings of their clinical trials. Findings from Johnson et al. (2002) are reported in a later publication involving the same cohort of subjects (Johnson et al. 2004). The availability of 30 clinical trials with point estimates indicated that a systematic review with meta-analysis investigating the treatment effect of FES for upper and lower limb training, and an assessment of the included trials' risk of bias, was feasible.

In summary, at the commencement of this research program, the literature review identified 30 clinical trials demonstrating varied treatment effect after an upper or lower limb FES stimulated motor training program. As the clinical trials were reported over an 18-year time frame (Macdonell et al., 1994; Page et al., 2012), it is plausible that clinicians may have translated the findings from these clinical trials into practice. From the reviewed literature, it was not yet known if the research evidence describing the use of a FES stimulated motor training program had been incorporated into clinical practice by occupational therapists and physiotherapists.

2.3 Is FES Used in the Clinical Practice of Occupational Therapists and Physiotherapists?

The Knowledge to Action Framework describes that an evidence to practice gap exists when the provision of a specific health care intervention does not match the intervention as described in the research evidence (Graham et al., 2006). It was necessary to determine if a FES stimulated motor training program had been implemented in health care services, particularly in Australia, by physiotherapists and occupational therapists. Evidence regarding the use of FES with stroke survivors by allied health professionals can be drawn from four studies which have surveyed occupational therapists, physiotherapists and orthotists (Auchstaetter et al., 2016; Gustafsson & Yates, 2009; Scottish Stroke Allied Health Professionals Forum, 2014; Turner & Whitfield, 1999). These four studies provide some

insights into the use of FES by clinicians to improve the daily life of a stroke survivor, however, they vary in the country of origin, inclusion criteria, and the sample size, which ultimately leads to differences in clinical context so not all studies may be relevant to clinicians in Australia.

The evidence reporting the use of a FES stimulated motor training program by Australian occupational therapists is limited to one electrostimulation study (Gustafsson & Yates, 2009) involving a survey of 55 Australian occupational therapists. The findings indicate that 39% of the 55 respondents used electrostimulation in their practice. The study did not identify subtypes of electrostimulation; therefore, it is not known if motor training based on motor learning principles were incorporated with the electrostimulation. The sample was drawn from an Internet listserv originating from Australia, with a reported membership of 250 occupational therapists (Gustafsson & Yates, 2009). The limited response rate of 22% may have favoured a viewpoint or self-interest in FES, which may have resulted in sample source bias (Everaert et al., 2013). The survey provided some indication that electrostimulation is being used by Australian occupational therapists, but provides no evidence that clinicians have translated the research evidence of FES into clinical practice.

Studies of physiotherapists using purposively designed surveys have also been conducted (Auchstaetter et al., 2016; Turner & Whitfield, 1999). A survey of 560 English and Australian physiotherapists identified that 49% of respondents used electrostimulation for conditions with an orthopedic, musculoskeletal or neurological origin (Turner & Whitfield, 1999). Similar to the study by Gustafsson and Yates (2009), the use of FES for stroke rehabilitation was not investigated, therefore findings are of limited value in determining whether FES is being used in stroke rehabilitation. The other survey of physiotherapists (Auchstaetter et al., 2016), involved 298 Canadian physiotherapists and used a definition of FES which is consistent with the definition used in this current thesis (Peckham and Knutson,

2005), however, is limited to the Canadian context. Auchstaetter et al. (2016) is the only identified study which has investigated the use of a FES stimulated motor training program by clinicians, consistent with the definitions used in this thesis, therefore further understanding of Auchstaetter et al. is described.

In the study investigating the use of FES stimulated motor training programs in stroke rehabilitation, Canadian physiotherapists expected that walking speed, arm function and muscle strength would improve, however, the majority of these physiotherapists had rarely or had never used FES in clinical practice (Auchstaetter et al., 2016). The authors reported that they validated the content and the test-retest capability of the survey to ensure that the survey was measuring what was intended. The study did not provide a power analysis (Cohen, 1992), therefore uncertainty exists as to whether the findings are a valid representation of Canadian physiotherapists (Suresh & Chandrashekara, 2012). The recruitment method was reported to be comprehensive because “it ensured that the study information reached all practicing physiotherapists in Canada” (Auchstaetter et al., 2016, p. 999), however, no information was provided regarding the response rate, other than that responses were received from most provinces and territories, making this difficult to confirm. Overall, the quantitative component of the survey demonstrated methodological strategies to ensure valid data was collected (Kelley, Clark, Brown, & Sitzia, 2003), however, some concerns regarding sampling frame and biases remain. The applicability of Canadian therapists’ views to an Australian population is also unknown.

The findings of a survey of Scottish occupational therapists, physiotherapists, and orthotists was reported in a non-peer reviewed consensus statement on the use of electrostimulation interventions in Scottish stroke rehabilitation settings (Scottish Stroke Allied Health Professionals Forum, 2014). Of the 137 clinicians responding, 28% used an intervention involving electrostimulation which may or may not have included motor

retraining activities (Scottish Stroke Allied Health Professionals Forum, 2014). When the respondents reportedly used FES, they expected FES to assist in reducing foot drop or improving upper and lower limb muscle recovery; however it was not stated if FES was being used for orthotic or therapeutic purposes, or to improve the daily life of a stroke survivor. Biases and reporting limitations in the Scottish survey limits its applicability to answer the current thesis questions in relation to an Australian clinical context.

Studies using surveys have investigated FES as an orthotic device from the perspectives of the clinician (Wilkinson et al., 2012) and the stroke survivor (Bulley, Shiels, Wilkie, & Salisbury, 2011; BurrIDGE et al., 2008; McAdam, Kenney, Nester, Bowen, & Taylor, 2006; Taylor et al., 1999; Wilkie, Shiels, Bulley, & Salisbury, 2012; Wilkinson et al., 2012). The clinical applicability from studies using surveys investigating orthotic FES has limited value for understanding therapeutic FES. The experiences of those administering or receiving therapeutic FES may be different to those associated with FES used for orthotic purposes due to factors including the wearing regimen, activities used during training, therapist input, and the different mechanism of benefit. Evidence is available regarding the user experiences of orthotic FES; however, these results have limited applicability to understanding the use of therapeutic FES to improve the daily life of a stroke survivor, and are not within the scope of this investigation.

In summary, there is evidence that FES is rarely used in clinical practice by physiotherapists in Canada (Auchstaetter et al., 2016). When used, FES was expected to improve walking and the use of the arm in activities. No information was available regarding whether occupational therapists have translated the evidence relating to the use of FES into clinical practice, and no investigation has occurred within the context of the Australian healthcare system.

2.4 What are the Barriers to Using FES in Practice for Occupational Therapists and Physiotherapists?

Barriers can reduce the uptake of evidence-based interventions (Handley, Gorukanti, & Cattamanchi, 2016), however their impact can be lessened through behaviour change strategies (Glasziou, 2005; Graham et al., 2006; Metzler & Metz, 2010; Michie, van Stralen, & West, 2011). To understand the extent, and how FES is being used in practice, it was necessary first to identify if there were contextual practice barriers that had been previously reported in the literature. By understanding the barriers experienced by clinicians who intend to use FES in clinical practice, strategies to improve the use of FES may be identified and implemented (Baker et al., 2010; 2015).

2.4.1 Method to identify qualitative studies.

A narrative synthesis of qualitative studies (Barnett-Page & Thomas, 2009; Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005) was conducted to identify, select and organise relevant studies reporting the barriers to using a FES stimulated motor training program. The use of qualitative data was appropriate because it provided insights into the user's experience of using or planning to use FES as an intervention (Schutt, 2012). Due to the variety of methods of conducting and reporting qualitative studies (Barroso et al., 2003; Pope, Ziebland, & Mays, 2000), a comprehensive search strategy was conducted by the student researcher to locate relevant studies.

Predetermined search terms were formulated using the SPIDER search format to describe the sample, phenomenon of interest, design, evaluation, and research type (Cooke, Smith, & Booth, 2012). For search terms, refer to Table 2.2. The search terms within each category were combined using the Boolean operator of 'or' (Sampson et al., 2009) and the terms describing the sample, phenomenon, design and research type were combined with the Boolean operator of 'and' (Sampson et al., 2009). The search strategy included both free-text

terms and medical subject headings (MeSH terms) (Cooke et al., 2012). Five electronic databases were searched: Medline (1946 to 31st July 2016), EBSCO CINHAL (1981 to 31st July 2016), OVID EMBASE (1947 to 31st July 2016), PYSCHInfo OVID (1987 to 31st July 2016) and COCHRANE Central (to 31st July 2016). A search filter for each database (using free text and MeSH terms) (McKibbin et al., 2006; Walters, Wilczynski, & Haynes, 2006; Wilczynski & Haynes, 2004; Wilczynski, Marks, & Haynes, 2007) was used to identify studies with qualitative data. The first step before screening was to remove duplicate studies from the search findings.

Table 2.2

Qualitative Study SPIDER Search Strategy

	Sample	Phenomenon of interest	Design	Evaluation	Research type
	People who have had a stroke	Functional electrical stimulation	Questionnaire, survey, interview or focus groups	The use of FES	Qualitative and mixed method approaches
Search terms	Stroke or cerebrovascular accident or CVA	“functional electrical stimulation” or “electrical stimulation” or “neuromuscular electrical stimulation” or “transcutaneous electrical stimulation” or “FES” or “TENS” or “NMES” or “ES”	MeSH qualitative study design filter	Search terms not included in the search strategy	MeSH Qualitative study design Filter

Note. CVA = cerebrovascular accident; FES = functional electrical stimulation; TENS = transcutaneous electrical stimulation; NMES = neuromuscular electrical stimulation; ES = electrical stimulation; MeSH = medical subject headings.

Predetermined selection criteria were applied to all titles and abstracts by the student researcher. Ineligible studies were immediately excluded. Refer to Figure 2.1 for the details of the inclusion and exclusion criteria. The full-text of the remaining studies were obtained, and the student researcher examined the eligibility of these studies. The reason for exclusion was recorded, and then the eligible study's characteristics of participant type and methodology were extracted (Dixon-Woods et al., 2005). The methodological quality of included studies was examined by using the Joanna Briggs Institute Qualitative Review Template (Joanna Briggs Institute, 20). Finally, the themes and supporting qualitative statements of the eligible studies were extracted and recorded.

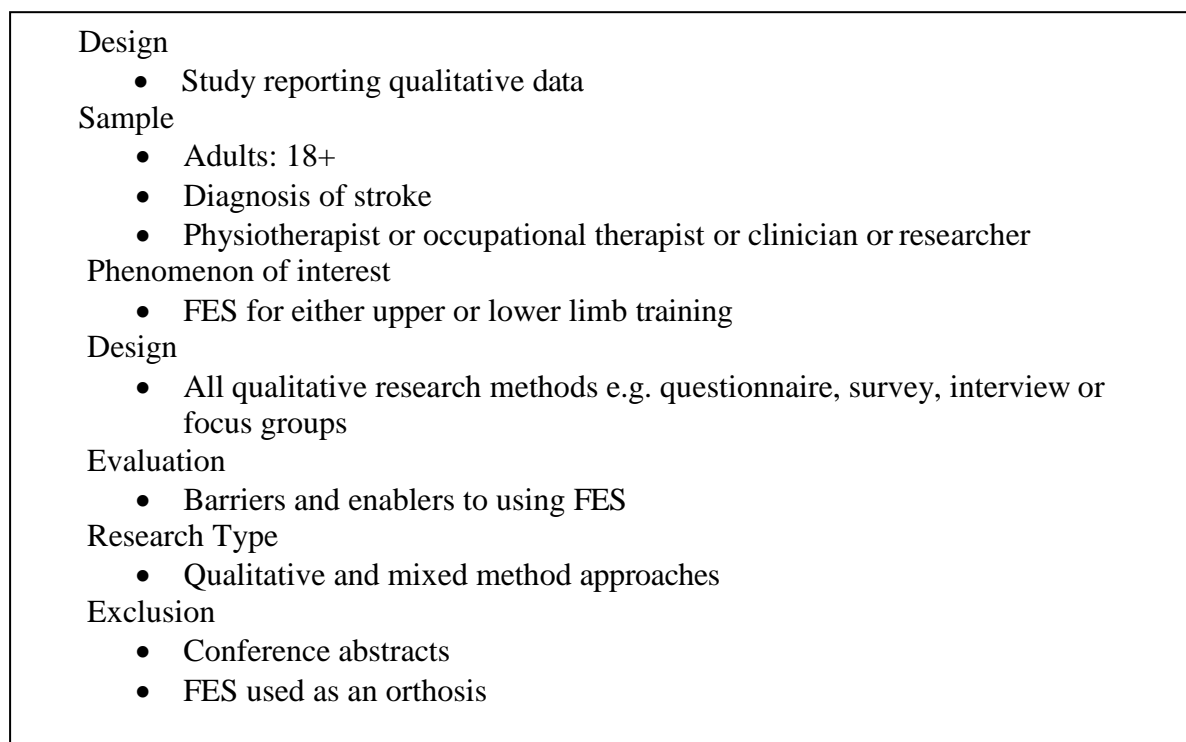


Figure 2.1. Qualitative Selection Criteria.

2.4.2 Results from qualitative search.

Of the initial 198 studies identified for possible inclusion, only four studies met the inclusion criteria (Auchstaetter et al., 2016; Hayward, Neibling, & Barker, 2015; Hughes et al., 2011; Roche & Coote, 2007). Refer to Figure 2.2 regarding the numbers of studies screened and reviewed. Refer to Table 2.3 for a summary of the included individual qualitative studies. All four eligible studies used thematic analysis to understand clinician's and stroke survivor's perspectives (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007). Three of the eligible studies (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011) used a mixed method approach while Roche et al. (2009) used a Grounded Theory qualitative approach. The perspectives of stroke survivors were captured in two studies (Hayward et al., 2015; Hughes et al., 2011), while the viewpoints of physiotherapists were also reported in two studies (Auchstaetter et al., 2016; Roche & Coote, 2007).

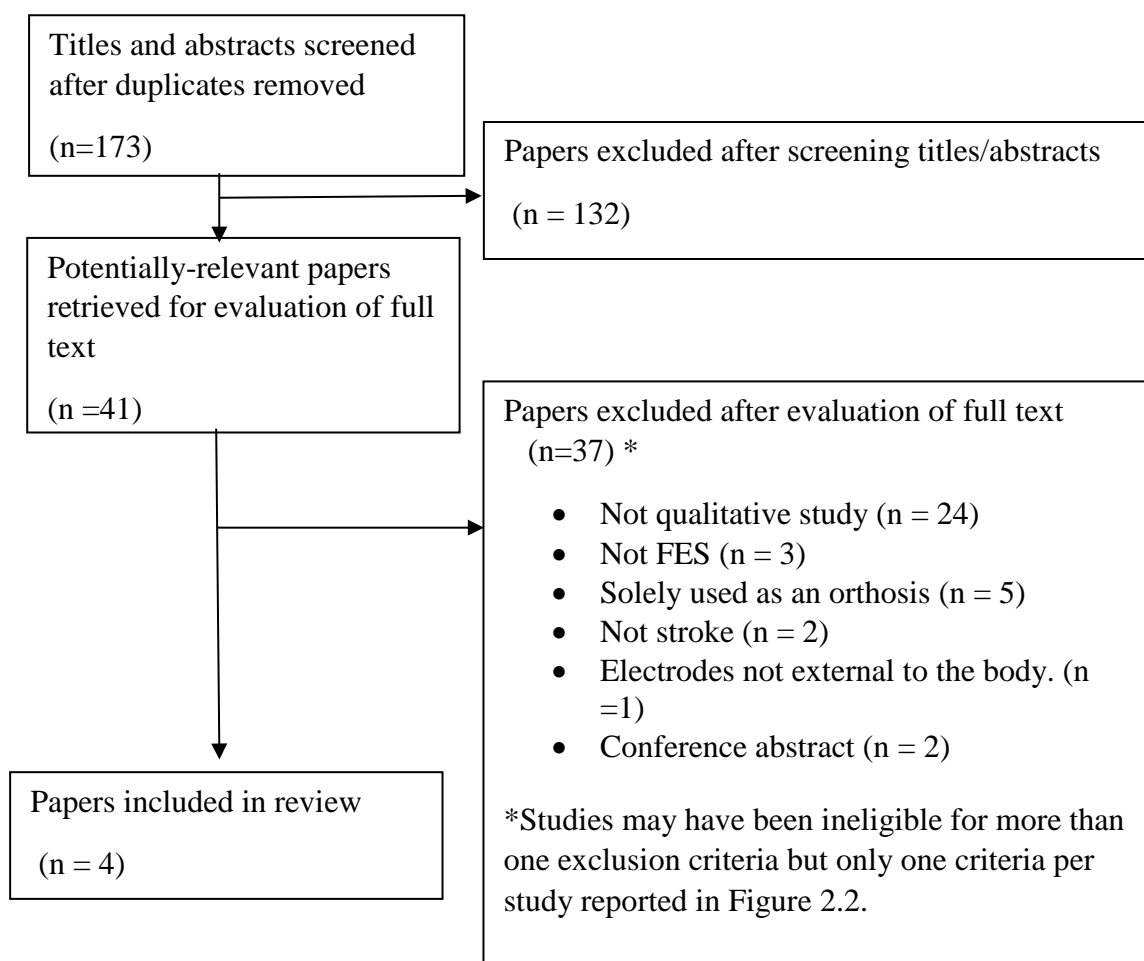


Figure 2.2. Flowchart of screening and reviewing of qualitative studies

Table 2.3

Summary of Features of the Included Qualitative Studies

Study	Subjects (n)	Study design	Participant(s) details				Data analysis method
			Age (years)	Female (%)	Time after stroke onset	Limb trained	
Hayward et al. (2015)	1	A single case study using a mixed method approach	57	0	9 months	UL	Thematic analysis of participants' and researchers' journals
Hughes et al. (2011)	5	Case series using a mixed method approach	38 to 77	2	8 months to 8.4 years	UL	Content analysis of structured interviews and recordings of statements made during FES intervention sessions
Roche and Coote (2007)	12	Grounded Theory	NA	NA	NA	LL	Thematic analysis of data collected from three focus groups
Auchstaetter et al. (2016)	298	Cross sectional survey using a mixed method approach	NA	NA	NA	UL	Thematic analysis of responses to open ended survey questions.

Note. NA = not applicable; LL = lower limb; UL = upper limb.

2.4.3 Discussion.

A predominant theme from the findings of studies reporting on clinicians' experience, was that multiple barriers are impeding the use of FES (Auchstaetter et al., 2016; Roche & Coote, 2007). For example, a physiotherapist in Roche and Coote's study (2007, p. 40) stated that "I was using it so infrequently that I would have to go back and read up on it again every single time before and that's a block of time for me." Another clinician commented that the FES device was challenging to use, saying "we ditched it because of the time and because of usability, it wasn't user friendly" (Roche & Coote, 2007, p. 40). Also, a physiotherapist stated, "in the end it's not worth the reward as far as I can see" (Roche & Coote, 2007, p. 41). These quotes demonstrate how the barriers to using FES can influence clinicians' use of an evidence-based intervention. The statements by a therapist in Roche and Coote's (2007) study were similar to the themes reported in the mixed methods study by Auchstaetter et al. (2016, p. 1000), which related to: "(1) lack of resources; (2) therapists lacking knowledge, training, or expertise in FES; (3) the perception of FES being inappropriate for certain patients with stroke; and (4) therapist preference." As reported in two studies (Auchstaetter et al., 2016; Roche & Coote, 2007;), there are multiple reported barriers to using FES by clinicians.

The frequent frustrations reported by clinicians (Auchstaetter et al., 2016; Roche & Coote, 2007) contrast with the positive outcomes reported by stroke survivors (Hayward et al., 2015; Hughes et al., 2011). For example, one stroke survivor was adamant that using FES was beneficial for him:

I've had people ask me, did the [FES device] do you any good? And I say bloody oath it did. It got my arm moving and in turn got my confidence going, which started to allow me to do things that I hadn't been able to do in a long time (Hayward et al., 2015, p. 4).

Another participant reported the positive impact of using FES on the ability to participate in daily living activities, commenting that he or she was "... able to grip things, hold on to bottles, as long as no fingers are required" (Hughes et al., 2011, p134). The improvements reported by stroke survivors were contradicted by quantitative data collected in the same study (Hughes et al., 2011), demonstrating that a favourable clinical outcome for a stroke survivor after FES may not be easily quantified.

Stroke survivors described a desire for a FES stimulated motor training program to be improved to enable better outcomes (Hayward et al., 2015; Hughes et al., 2011). Stroke survivors identified that a centre-based FES stimulated motor training program was not enough, with one participant stating that he or she "would have liked something to do at home" (Hughes et al., 2011, p. 135). Stroke survivors wanted to engage both the hand and the arm during a FES training session. For example, one stroke survivor wanted "help with fingers at the same time (if fingers don't work you can't use your arm)" (Hughes et al., 2011, p. 135). It was hoped FES would result in tangible outcomes, as exemplified by the quote from one stroke survivor, that "to pick up a cup would be major" (Hughes et al., 2011, p. 135). Stroke survivors reported experiencing benefits from using FES, however it was evident that FES was not completely meeting the needs of participants.

Clinicians predominantly described barriers to using FES, although they recognised that administering FES could be improved if enablement strategies were implemented. For example, a physiotherapist commented that "you have to have the ability to loan it out and let somebody try it out" (Roche & Coote, 2007, p. 41). The findings of the Auchstaetter et al. (2016) study identified enablement themes, including: (a) access to resources including equipment, time and support from others, (b) clinicians becoming comfortable in delivering FES through the support of others and through attendance at training courses, and (c) the availability of supporting evidence. Hayward et al. (2015) also identified enablement themes including: (a) the need for the

intervention to be focused on teaching the stroke survivor to complete the intervention independently rather than under the guidance of the clinician, (b) the device needs to be user friendly, (c) the need for clinicians to provide support to maintain the stroke survivors' motivations, (d) the need to link the exercise regimen of FES with daily activities to make it applicable to the participant, and (e) assistance with establishing daily practice. The findings of Hayward's et al. (2015) study identified a role for clinicians to support the stroke survivor to engage and participate with FES, which was not highlighted in other studies (Auchstaetter et al., 2016; Roche & Coote, 2007). The three studies describing how a FES stimulated motor training program could be improved, identified that FES might not be reaching its full potential during research or therapy (Auchstaetter et al., 2016; Hayward et al., 2015; Roche & Coote, 2007).

There is evidence to demonstrate that FES can be challenging to implement into practice by physiotherapists (Auchstaetter et al., 2016; Hayward et al., 2015; Roche & Coote, 2007). It is not known if occupational therapists experience the same difficulties as physiotherapists when implementing FES. Clinicians and stroke survivors have recommended enablers to using FES, however these were not tested nor linked to formal theories of knowledge translation.

The possible methodological biases of the identified qualitative studies will now be outlined. The dependability of a qualitative study relates to how a study is considered trustworthy by demonstrating processes which are replicable and are consistent with research aims (Lincoln & Guba, 2013). All four studies (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007) reported suitable qualitative approaches to answering the stated research question and formulated conclusions which applied to the research aim. For the studies using a mixed method approach (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011), the method of integrating the quantitative and qualitative approaches was not outlined, therefore uncertainty exists relating to the trustworthiness of the statements reporting on the relationship between the qualitative and quantitative data (Creswell, 2014; Pluye, 2015; Tashakkori & Teddie, 2003). While some aspects of dependability have been

reported in the four studies, biases may exist due to the methods of integration used or not used.

A further strategy to establish a study's dependability is reflexivity (Munn, Porritt, Lockwood, Aromataris & Pearson, 2014), which determines the extent a researcher's viewpoint influences the research findings (Berger, 2015). All four studies (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007) did not report how the researcher's opinion, culture, education or self-interest may have influenced what participants disclosed to the researcher (Tracy, 2010). It is possible that participants were influenced (positively or negatively) by previously established relationships between the researcher and participants (Roche & Coote, 2007). It is also possible that stroke survivors wanted to support the research project by being overly supportive (Hayward et al., 2015; Hughes et al., 2011) or that the researcher's perspective may have influenced how the coding elicited the themes in the study (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007). Due to a lack of reflexivity transparency, there may be potential bias towards the researcher's viewpoints when reporting and interpreting the data (Tracy, 2010).

A credible qualitative study demonstrates how the author's conclusions are an accurate representation of the stories told by the participants (Tobin & Begley, 2004). Credibility is demonstrated by the reporting of participant quotations (voice) which reflects the identified themes (Munn et al., 2014). The clinician's voice was evident in the Roche et al. (2007) study with each reported theme supported by statements generated by the participants, adding a thick description and credibility to the findings (Tracy, 2010; Munn et al., 2014). Contrastingly to Roche et al., Hayward et al. and Hughes et al. had limited examples (Hayward et al., 2015; Hughes et al., 2011) and Auchstaetter et al. had no examples (Auchstaetter et al., 2016) of participant quotes. While some evidence exists describing the barriers and enablers to using a FES stimulated motor training program (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes

et al., 2011; Roche & Coote, 2007), the varying levels of credibility results in uncertainty in the accuracy of the representation of participants' viewpoints, and in the overall reported findings (Munn et al., 2014).

In summary, limited evidence has demonstrated that barriers do exist to using a FES stimulated motor training program in a clinical context (Auchstaetter et al., 2016; Roche & Coote, 2007), potentially limiting the benefits of this intervention to stroke survivors. It is not known if this evidence is applicable to the Australian healthcare context.

2.5 Chapter Summary

Clinical practice guidelines have recommended that clinicians use FES in stroke rehabilitation, however guideline recommendations were inconsistent (Intercollegiate Stroke Working Party, 2012; Lindsay et al., 2012; Miller et al., 2010; National Institute for Health and Care Excellence, 2013; Stroke Foundation, 2010; Scottish Intercollegiate Guidelines Network, 2010). Relevant systematic reviews highlighted that FES was effective to improve walking speed, with both clinical and statistical significance being demonstrated (Pereira et al., 2012; Robbins et al., 2006). Clinical effectiveness was demonstrated for lower limb training, predominantly in the chronic stage after stroke onset (Pereira et al., 2012; Robbins et al., 2006), while the overall effectiveness for upper limb FES was yet to be established. There were 28 randomised controlled trials investigating FES use to improve the daily life of the stroke survivor (Alon et al., 2007; Alon et al., 2008; Barker et al., 2008; Bogataj et al., 1995; BurrIDGE et al., 1997; Cheng et al., 2010; Daly et al., 2005; Embrey et al., 2010; Hara et al., 2008; Johnson et al., 2004; Kojovic et al., 2009; Lin et al., 2011; Lo et al., 2012; Macdonell et al., 1994; Mangold et al., 2009; Mann et al., 2005; Mohamed Faisal et al., 2012; Ng et al., 2008; Page et al., 2012; Peurala et al., 2005; Popovic et al., 2004; Popovic et al., 2002; Popovic et al., 2003; Shindo et al., 2011; Tanovic et al., 2009; Tarkka et al., 2011; Thrasher et al., 2008 & Tong et al., 2006). The gap in the evidence was that the clinical effectiveness of a FES stimulated motor training program for both upper and lower limb at all time frames after stroke onset, had not been

described in a study of knowledge synthesis (systematic review with meta-analysis).

The intervention of FES is being used infrequently for stroke rehabilitation by Canadian physiotherapists (Auchstaetter et al., 2016), and when used, a FES stimulated motor training program was identified to be beneficial to improve the use of both the upper and lower limb. There was uncertainty if occupational therapists and orthotists were using FES therapeutically in stroke rehabilitation (Gustafsson & Yates, 2009; Scottish Stroke Allied Health Professionals Forum, 2014). A gap in the evidence identified that no knowledge inquiry studies had determined whether FES is being used in stroke rehabilitation by Victorian clinicians.

Research studies using qualitative methods have reported multiple barriers to using FES in clinical practice by physiotherapists (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007). These barriers were reported to be multifaceted and relate to the environment, the clinician, and the stroke survivor. Clinicians and stroke survivors have also reported enablement strategies for FES use (Auchstaetter et al., 2016; Hayward et al., 2015; Hughes et al., 2011; Roche & Coote, 2007). It is not known if the described behaviour change strategies of adequate resourcing, the inclusion of user friendly devices, providing FES training/education or the use of stroke survivor education, will change the knowledge translation practices of clinicians. There was no evidence guiding how a health setting could identify practice barriers and subsequent behaviour change strategies.

Chapter Two has described the gaps in the evidence relating to the research question: how do occupational therapists and physiotherapists use FES in stroke rehabilitation, to improve the daily life of a stroke survivor? A three-part research project was then established to address these gaps, and will now be described in Chapter Three.

Chapter 3. Method

3.1 Introduction

The following chapter details the methods used and the justification for the research program. The research questions will be stated and explained, followed by a description of the theoretical framework. The methods of each study will be reported in Chapters Four, Five and Six. A pragmatic multiple methods research design using a framework of knowledge translation will be described, investigating the use of a FES stimulated motor training program for stroke rehabilitation.

3.2 Research Questions That Guide the Thesis

The overarching research question was in response to an identified gap in the literature relating to the use of a FES stimulated motor training program in clinical practice. As outlined in Chapter Two, there was limited evidence to support clinicians' use of FES by either physiotherapists or occupational therapists in Victoria, Australia. Research evidence relating to the use of FES and the barriers to implementation were limited to Canadian physiotherapists. Thus this doctoral research program sought to determine how occupational therapists and physiotherapists use FES in stroke rehabilitation to improve the daily life of a stroke survivor. Exploratory questions were established to investigate the primary question from multiple viewpoints:

1. Is FES effective in improving daily life after stroke?
2. Is FES used in the clinical practice of occupational therapists and physiotherapists in Victoria, Australia?
3. What are the barriers to using FES in practice for occupational therapists and physiotherapists?

Enhancing understanding of how occupational therapists and physiotherapists use FES in clinical practice, could provide insights into how to establish the use of FES in stroke rehabilitation in a health setting, through using a theoretical framework of knowledge translation.

3.3 Theoretical Framework

The Knowledge to Action Framework (Graham et al., 2006) directed the investigation of how occupational therapists and physiotherapists have used a FES stimulated motor training program in stroke rehabilitation to improve the daily life of the stroke survivor. The research program was structured by applying the Knowledge to Action Framework's knowledge creation stage in study one, and the first four steps of the action cycle in study two and three. Refer to Figure 1.2 (page 5) for the structure of the Knowledge to Action Framework and to Table 3.1 for a summary describing how each stage of the Knowledge to Action Framework is related to the individual research questions. Three stages of the Knowledge to Action Framework were not used to structure the investigation of FES because the stages of monitoring, evaluating and sustaining are concerned with outcomes after implementation. The thesis describes how occupational therapists and physiotherapists currently use FES in clinical practice. The relevant aspects of the knowledge creation stage and the action cycle will now be described to justify the research program.

Table 3.1

Summary of Research Design as per the Knowledge to Action Framework

Thesis Study	Research question	Stage of KTA framework	Level of KTA framework
One	Is FES effective in improving daily life after stroke?	Knowledge Creation	Knowledge synthesis.
Two	Is FES used in the clinical practice of occupational therapists and physiotherapists in Victoria, Australia?	Action Cycle	Determine the knowledge to action gap.
Three	What are the barriers to using FES in practice for occupational therapists and physiotherapists?	Action Cycle	3a. Adapt to the local context. 3b. Assess the barriers and the facilitators to knowledge use. 3c. Select intervention

Note. KTA = Knowledge to Action; FES = functional electrical stimulation.

3.3.1 Knowledge creation.

The centrepiece of the Knowledge to Action Framework describes knowledge creation, from which the action cycle can be applied (Graham et al., 2006). The model takes a traditional view that knowledge creation is the result of formal research activities (Malone et al., 2016) and has three layers (Straus, Tetroe, & Graham, 2011a): (a) knowledge inquiry, (b) knowledge synthesis, and (c) knowledge tools and products. The diagrammatic representation of the Knowledge to Action Framework has the stages of knowledge creation situated in a funnel (see Figure 1.2 on page 5) and represents how each upper layer of knowledge creation informs the development of the next layer (Straus, Tetroe, & Graham, 2011a). Alternatively, a gap in the evidence informing the layer of knowledge requires clinicians to look to another layer to inform implementation. The gaps in the research evidence relating to the use of a FES stimulated motor training program (as described by the knowledge creation stage of the Knowledge to Action Framework) were described in the literature review chapter. The next two paragraphs will describe how the knowledge creation domain informed the research question of study one, is FES effective in improving daily life after stroke?

The layer of knowledge creation relating to knowledge product tools (Graham et al., 2006) refers to clinical guidelines which provide statements to assist clinicians in making decisions regarding what interventions should be used in their practice to improve clinical outcomes (Jackson & Feder, 1998). An audit of Australian stroke rehabilitation practice demonstrated that the use of clinical guidelines by rehabilitation health care professionals was highly correlated with better stroke survivor recovery outcomes (Hubbard et al., 2012). Clinical guidelines can also direct implementation efforts (Graham et al., 2006) and are recommended to be constructed by well-formed systematic reviews with meta-analysis (Guyatt et al., 2008). In Australia, there are well established clinical guidelines for stroke rehabilitation (Stroke Foundation, 2010) which were a logical starting point in examining the research evidence, however, as described in Chapter Two, clinical guidelines (product tools)

could not be relied upon to guide the effectiveness of a FES stimulated motor training program, therefore, the knowledge synthesis layer of the knowledge creation stage was chosen to investigate the effectiveness of a FES stimulated motor training program.

A knowledge synthesis study can identify if the accumulative evidence reports a treatment effect, thereby supporting intervention implementation (Graham et al., 2006; National Health and Medical Research Council, 2009; Bennett, Hannes & O'Connor, 2017). While the literature review chapter described two prior FES knowledge synthesis studies (Pereira et al., 2012; Robbins et al., 2006; Roche & Coote, 2007), their findings were limited to lower limb training, the chronic stage of recovery and studies published up to 2011. There were 28 available knowledge inquiry studies (upper layer of the knowledge creation stage), therefore conducting a knowledge synthesis study was a viable option. To understand the findings from knowledge inquiry studies, a systematic review with meta-analysis was to be conducted as the first study, to identify if FES is effective in improving daily life after stroke.

3.3.2 Action cycle (application).

The action cycle stage of the Knowledge to Action Framework was developed by Graham and colleagues, after they reviewed 35 practice models to identify how systems are theoretically understood to create change (Graham et al., 2006). The Knowledge to Action Framework's action cycle is initiated in practice when a problem is identified. A problem exists when an expected standard of health care intervention (as described by knowledge creation studies) is not being implemented into practice (Grimshaw & Russell, 1993). Problem identification can be achieved by auditing or surveying clinician practices (Feder, Eccles, Grol, Griffiths, & Grimshaw, 1999; Lennon, 2001) against the expected type of implementation, as described by patient decision aids (tools to assist patients to make a decision, after being informed of the risk and benefits of the intervention) (O'Connor, Llewellyn-Thomas, & Flood, 2004); clinical practice guidelines (Jackson & Feder, 1998); or by a systematic review of random controlled studies (Thomas & Harden, 2008). As

described in Chapter Two, the use of FES in clinical practice by Victorian occupational therapists and physiotherapists had not previously been investigated, thus justifying the need to understand the use of a FES stimulated motor training program within a Victorian context. It was unknown if a problem in using FES in Victoria existed. Study two was implemented to answer the research question: is FES used in clinical practice in Victoria, by occupational therapists and physiotherapists?

Once a practice problem is identified, it is recommended that the research evidence be understood as related to a local context to ensure that the desired behaviour change is both relevant and accepted within that setting (Harrison, Légaré, Graham, & Fervers, 2010; Moore et al., 2014; Straus, Tetroe, & Graham, 2011b). Examples of local considerations are organisational resources, policy statements and current clinical practices (Harrison et al., 2010). To understand the influence of a local context on using a FES stimulated motor training program, a case study involving a regional health service was undertaken in study three (reported in Chapter Six). The Knowledge to Action Framework provides guidance that by understanding the local context in which the research evidence is to be implemented, barriers to practice could be identified.

A difficulty with the translation of research evidence into practice is the existence of contextual practice barriers (Handley et al., 2016; Metzler & Metz, 2010). Barriers can be classified accordingly to knowledge, attitudes, or behaviour (Cabana et al., 1999). Examples of contextual practice barriers relevant to health care settings include clinicians being unaware of the preferred intervention, disagreement with expert recommendations, a lack of self-efficacy to facilitate change and an inability to carry out the recommendation (Harrison et al., 2010). Although some barriers to using FES in clinical practice were reported in the literature review chapter (Auchstaetter et al., 2016; Roche & Coote, 2007), the relevance of these barriers to the local context of a regional health service was not known. Therefore, study three

(Chapter Six) sought to investigate what are the barriers to using FES in practice for occupational therapists and physiotherapists in the local context of regional Victoria, Australia.

The next stage of the Knowledge to Action Framework describes the need to choose behaviour change strategies to overcome the barriers to implementing knowledge into practice (Straus et al., 2009). These strategies can include facilitation (Harvey & Kitson, 2015; Kitson & Harvey, 2016), mentoring (Abdullah et al., 2014), feedback and audit (Foy et al., 2002), education (Jones, Roop, Pohar, Albrecht, & Scott, 2015), educational materials provided in printed format (Freemantle et al., 2000), knowledge brokers (Bornbaum, Kornas, Peirson, & Rosella, 2015), toolkits (Yamada, Shorkey, Barwick, Widger, & Stevens, 2015), incentives, and local opinion makers (Flodgren et al., 2011). The use of barrier identification to create contextual behaviour change strategies is supported by a meta-analysis of 15 studies demonstrating a small to moderate treatment effect on professional practice (Barker et al., 2015). Therefore, study three also mapped the barriers to behaviour change strategies using the Behaviour Change Wheel (Michie et al., 2014) and in doing so demonstrated the feasibility of barrier and strategy identification in a local context.

3.4 Methodological Framework

A multiple methods research design (Morse, 2010; Brewer & Hunt, 2015) was used to understand the efficacy and use of FES by occupational therapists and physiotherapists from multiple viewpoints. This thesis program consists of three research studies, with one quantitative study, one mixed method study and one qualitative study. Each study addressed a specific research question with methods reported in three manuscripts in Chapters Four and Five, and in a report describing a case study in Chapter Six. Table 3.2 summarises the research questions and methods used in each study. The results from the individual studies were then synthesised (Morse, 2010) using the Knowledge to Action Framework,

highlighting the complementary relationships between the findings of each study as related to the primary research question, and are reported in Chapter Seven. A multiple methods design was used to understand how occupational therapists and physiotherapists use functional electrical stimulation in stroke rehabilitation to improve the daily life of a stroke survivor.

Table 3.2

Summary of the Individual Study's Research Design

Study	Research question	Methodology	Method	
			Data collection	Data analysis
One	Is FES effective in improving daily life after stroke?	Quantitative	Systematic review	Meta-analysis
Two	2a. Do survey questions collect accurate and valid data relating to the use of FES by clinicians?	Mixed	2a. Structured interviews via cognitive interviewing	2a. Descriptive analysis
	2b. Is FES used in the clinical practice of occupational therapists and physiotherapists in Victoria, Australia?		2b. Online survey tool	2b. Descriptive analysis
Three	What are the barriers to using FES in practice for occupational therapists and physiotherapists?	Qualitative	Focus groups	Thematic analysis

Note. FES = functional electrical stimulation.

A multiple methods approach is an alternative philosophy to the constructivism/interpretivism or positivism/postpositivism constructs of qualitative and quantitative approaches (Feilzer, 2010). Those using a positive/postpositive paradigm believe that one reality exists and this directs quantitative research to observe for replicable patterns of behaviour or events (Schutt, 2012). The constructive/interpretive paradigm considers a reality which is constructed by society or stakeholders and guides qualitative methods to investigate the meaning of these events or how these meanings are formed (Schutt, 2012). As an alternative to these constructivism and positivism paradigms, multiple methods research addresses the need to investigate multiple aspects of the research question, *while using the most suitable method* which may solely include or combine quantitative or qualitative approaches (Brewer and Hunt, 2006; Brewer and Hunt, 2015; Morse, 2010). This pragmatic use of a multiple methods approach enabled an exploratory investigation of three aspects of the primary research question (Creswell, Klassen, Plano Clark, & Smith, 2011, Brewer and Hunt, 2015; Small, 2011).

The pragmatic research design (Duram, 2010; Feilzer, 2010) aimed to understand the experience of using FES in clinical practice by conducting three individual studies. In study one, the quantitative method of a systematic review with meta-analysis (Higgins & Green, 2011) was applied to understand if therapists should be using FES in practice. In study two, a quantitative driven mixed method study (Creswell, 2014; Johnstone, 2004) was used to identify if therapists were using FES in clinical practice. Study two used a quantitative survey to collect data regarding FES use, and qualitative data was collected from individual interviews to test and refine the survey prior to administration. In study three, the qualitative method of inductive inquiry (Braun & Clarke, 2006) was used to identify the barriers and establish enablers to using FES in practice. Together the studies formed a pragmatic multiple methods research design to identify how occupational therapists and physiotherapist use a FES stimulated motor training program to improve the daily life of a stroke survivor.

Consideration was given to how the study designs were to be related and synthesised when planning the overall research program, and then again, after reporting the stand-alone studies (Fetters & Molina-Azorin, 2017). When planning the research program, consideration was given to how each research study would inform the subsequent study (Hunter & Brewer, 2015). The findings of study one justified study two and three, with study one establishing if FES should be used in clinical practice given the meta-analysed findings. The findings of study one also informed the draft design of the survey used in study two, ensuring the survey questions collected data relevant to study one's findings. For example, survey questions collected data describing both upper and lower limb FES stimulated motor training programs. Subsequently, study three extended the understanding of study two's findings to a local context. After all three studies were completed, the emerging themes spanning data from all three studies were synthesised (O'Cathain, Murphy & Nicholl, 2010) and are reported in the discussion chapter. The pragmatic design of the multiple methods research program ensured that the findings of the thesis were able to provide insights relating to the use of FES in clinical practice.

The use of a multiple methods approach enabled understanding of the research phenomenon from various viewpoints (Brewer and Hunter, 2006). The effectiveness of a FES stimulated motor training program was established in study one, the use of FES by Victorian clinicians was determined in study two, and in study three the further understandings of why FES may or may not be being used was reported. A multiple method approach also drew upon the strengths of the different research methods (Creswell, 2014). The quantitative method of study one (using meta-analysis of Level II research) supported the identification of the cause and effect of FES on outcomes of activity in stroke rehabilitation. The mixed methods used in study two identified a knowledge to practice gap by Victorian clinicians. Collecting qualitative data using focus groups in study three identified clinicians' viewpoints and perspectives relating to the barriers to using FES in clinical practice. A multiple methods

methodology was an appropriate research paradigm to investigate the use of FES for stroke rehabilitation by occupational therapists and physiotherapists.

3.5 Summary

The Knowledge to Action Framework (Graham et al., 2006) and a multiple methods methodology (Brewer and Hunt, 2006) were used to frame the thesis. The study designs were informed by quantitative, mixed and qualitative research methods. The research program was justified because there was no comprehensive knowledge synthesis of studies investigating the use of FES in stroke rehabilitation, and there was no understanding relating to the use of FES by clinicians in Victoria, Australia. There was also limited understandings of the barriers to using FES in stroke rehabilitation. The specific research methods used in the research program are described in Chapters Four, Five and Six of the thesis. Consistent with a multiple methods approach, the findings from the three standalone studies were synthesised (Moran-Ellis et al., 2006) and are described in Chapter Seven, thereby, examining how occupational therapists and physiotherapists use FES in rehabilitation to improve the daily life of a stroke survivor. The three individual studies will now be described in Chapters Four, Five and Six.

Chapter 4. Study One

Functional Electrical Stimulation Improves Activity after Stroke: A Systematic Review with Meta-Analysis

4.1 Introduction to Chapter

Chapter Four reports the results of study one involving a systematic review investigating the evidence to support or refute the use of FES to improve the daily life of a stroke survivor. The manuscript was published in the Archives of Physical Medicine and Rehabilitation (Howlett et al., 2015). The justification for the systematic review was outlined in Chapter Two and Chapter Three of the thesis. The synthesis of study one's findings with study two and three, will be described and discussed in Chapter Seven.

4.2 Manuscript Abstract

Objective: To investigate (i) the effect of functional electrical stimulation (FES) in improving activity and (ii) whether it is more effective than training alone?

Data Sources: Cochrane Central Register of Controlled Trials, Ovid MEDLINE, EBSCO CINHAL, Ovid EMBASE, Physiotherapy Evidence Database and Occupational Therapy Systematic Evaluation of Effectiveness database.

Study Selection: Randomized and controlled trials up to 22nd June 2014 were included following pre-determined search and selection criteria.

Data Extraction: Data extraction occurred by two people independently using a pre-determined data collection form. Methodological quality was assessed by 2 reviewers using the PEDro methodological rating scale. Meta-analysis was conducted separately for the two research questions.

Data Synthesis: Eighteen trials (19 comparisons) were eligible for inclusion in the review. FES had a moderate effect on activity (SMD 0.40, 95% CI 0.09 to 0.72) compared with no or placebo intervention. FES had a moderate effect on activity (SMD 0.56, 95% CI 0.29 to 0.92) compared with training alone. When sub group analyses were performed, FES had a large effect on upper limb activity (SMD 0.69, 95% CI 0.33 to 1.05) and a small effect on walking speed (MD 0.08 m/s, 95% CI 0.02 to 0.15) compared with any control.

Conclusions: FES appears to moderately improve activity compared with both no intervention and training alone. These findings suggest that FES should be used in stroke rehabilitation to improve the ability to perform activities.

Key Words: Hemiparesis, meta-analysis, rehabilitation, occupational therapy.

4.3 Manuscript

Howlett, O. A., Lannin, N. A., Ada, L., & McKinstry, C. (2015). Functional electrical stimulation improves activity after stroke: a systematic review with meta-analysis. *Archives of Physical Medicine and Rehabilitation*, 96(5), 934-943. doi:10. 1016/j.apmr.2015.01.013

4.3.1 Introduction.

Stroke is the leading cause of disability in the Western world (Mendis, 2013; World Health Organization, 2011). Such disability arises from limitations in activities of daily living such as walking, performing self-care tasks, managing household chores and property maintenance (Australian Institute of Health and Welfare, 2013b). With hemiplegia contributing significantly to this inability to perform meaningful activities and participate fully in life after stroke (Franceschini et al., 2010), improving outcomes after stroke is essential.

Electrical stimulation is an intervention that has the potential to improve activity and participation after stroke. However, there are various forms of electrical stimulation. Functional electrical stimulation (FES) stimulates muscles to contract during the

performance of an activity such as sitting, standing up from a chair, walking or reaching for and manipulating objects, with the goal of improving the performance of that activity (Peckham & Knutson, 2005). The perceived benefit of FES for stroke survivors is that it can facilitate practice of activities that would not otherwise occur because of hemiparesis. In addition, FES can engage the stroke survivor's attention, be repetitive, be challenging and can provide sensory and visual feedback to the participant. These are common attributes labelled as essential components of an effective intervention to promote motor recovery after stroke (Dobkin & Dorsch, 2013).

Three previous systematic reviews have investigated the effect of FES for increasing movement and activity after stroke, and all have investigated lower limb function (Pereira et al., (2012), Robbins, Houghton, Woodbury, & Brown, 2006; Roche, Laighin, & Coote, 2009). In 2006, Robbins et al. (2006) reported that FES resulted in 0.18 m/s (95% CI 0.08 to 0.28) faster walking speed than walking training alone or no intervention, based on a meta-analysis of three controlled trials in chronic stroke. Then in 2009, Roche et al. (2009) concluded that evidence for a therapeutic effect of FES was inconclusive, based on the individual examination of 30 studies of peroneal nerve stimulators ranging from case studies to randomised trials. Finally, in 2012, Pereira et al. (2012) reported that FES resulted in 0.38 SMD (95% CI 0.08 to 0.68) further walking distance than walking training alone or no intervention, based on six controlled trials. The Scottish Intercollegiate Guidelines Network (2010) identified that there was insufficient high level evidence to support the routine use of FES for both upper and lower limb function.

Therefore, the aim of this systematic review was to examine the latest evidence for the use of FES after stroke. The specific research questions were:

0. Is FES effective in improving activity after stroke?
1. Is it more effective than activity training alone?

In order to make recommendations based on the highest level of evidence, this review included only moderate to high-quality randomized or controlled trials of adults with stroke using FES to contract muscles during the performance of everyday activities with the aim of improving those activities. Review protocol is available from https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42012003054.

4.3.2 Method.

Identification and selection of trials.

Six electronic databases were searched: Cochrane Central Register of Controlled Trials (to 22nd June 2014), Ovid MEDLINE (1946 to 22nd June 2014), EBSCO CINHAL (1981 to 22nd June 2014), Ovid EMBASE (1947 to 22nd June 2014), Physiotherapy Evidence Database (www.pedro.org.au) (to 22nd June 2014), and Occupational Therapy Systematic Evaluation of Effectiveness database (www.otseeker.com.au) (to 22nd June 2014) for relevant articles without language restrictions using words related to stroke and randomized, quasi-randomized or controlled trials and words related to functional electrical stimulation (contact corresponding author for full search strategy). One author (OH) screened all trials based on title and abstract. Full text papers for potentially relevant trials were retrieved and their reference lists screened. Two authors (OH and NL) independently reviewed full text papers for eligibility using the inclusion criteria outlined in Figure 4. 1. Where inclusion could not be established based on the information provided in the publication, the author of the trial was contacted to ascertain missing information. All disagreements regarding inclusion into the review were resolved through discussion between two reviewers and if required a third reviewer. Articles reporting the same research data were linked together to ensure data from each trial was only included once in the analysis.

Design
<ul style="list-style-type: none"> • Randomised or controlled clinical trial • Methodological quality PEDro > 4 for meta-analysis
Participants
<ul style="list-style-type: none"> • Adults, 18+ • 80% of participants had a stroke, remaining 20% of participants had a stroke like condition.
Intervention
<ul style="list-style-type: none"> • Electrical stimulation via surface electrodes that produces a muscle contraction causing movement of a limb during practice of an activity • FES the primary intervention, ie, practice of activity for the majority of the intervention, eg, walking or grasp/release of objects
Outcome measures
<ul style="list-style-type: none"> • Measures of activity limitation without electrical stimulation
Comparisons
<ul style="list-style-type: none"> • FES versus nothing/placebo • FES versus training alone

Figure 4.1. Inclusion criteria

Assessment of characteristics of trials.

Quality.

The quality of included trials into the systematic review was assessed by the PEDro scale and the Jadad scale. One reviewer determined the risk of bias for each study using PEDro scores (de Morton, 2009) obtained from the Physiotherapy Evidence Database (www.pedro.org.au) (Maher et al., 2003). If a score was not available from the data base, it was calculated by two review authors independently (OH and NL) who had undergone the PEDro training program. Only trials of moderate (rating of 5-6) and high (rating of 7-8) quality (Harvey, Herbert, & Crosbie, 2002) were included in the review. One reviewer (OH) established a Jadad score (Clark et al., 1999) for each included trial.

Participants.

Trials involving adult participants with stroke of any level of disability and any chronicity were included. The number of participants, their mean age, gender distribution and time since the onset of stroke were recorded to assess the similarity of the trials.

Intervention.

The experimental intervention was functional electrical stimulation i. e., electrical stimulation producing muscle contraction delivered via surface electrodes during practice of an upper or lower limb activity. The control group intervention was categorised as either no intervention or placebo, or as ‘same activity training’, defined as the training of the same activity as the experimental group but without any electrical stimulation. Muscle(s) stimulated, activity trained, and duration and frequency of the intervention were recorded to assess the similarity of the trials.

Outcome Measures.

Measures of activity were used in analyses. Where more than one measure of activity was available for a single trial, reviewers chose the outcome measure that closest reflected the task being trained (e. g. if upper limb grasp and release were trained using FES, the Box and Block Test was selected). The outcome measure used in the analysis and timing of measurement were recorded to assess the similarity of the trials; all measures were recorded without electrical stimulation.

Data analysis.

Characteristics of participants, intervention, and outcome measures were recorded onto a pre-designed data extraction form. The mean (SD) of the outcome immediately after intervention, and number of participants were extracted. Data extraction and cross checking

of data occurred by two people (OH and KH). Authors were contacted where there was difficulty extracting and/or interpreting data from the paper.

Data was entered into Review Manager Software (Morone, Fusco, Di Capua, Coiro, & Pratesi, 2012) and the effect of FES was calculated as the standardized mean difference (SMD) and 95% confidence interval (CI) of post-intervention scores, since different outcome measures were used across the trials. When a trial included three arms, analysis occurred on the two arms most applicable to the review question. For a cross over design, only the pre-crossover data was included in analysis. A fixed effect model was used in the initial analysis and heterogeneity was examined by visual inspection of the forest plot, the Chi-squared test and I² statistic. Where there was considerable heterogeneity as noted by the I² statistic, a sensitivity analysis to explore the source of the heterogeneity was carried out and a random effect model was then reported. Sub group analyses were planned for the limb that was trained (upper compared with lower limb) and time after stroke (acute: less than six months compared with chronic: greater than six months), as well as meta-regression to investigate the influence of all factors together provided that a minimum of n=10 trials for each characteristic were included (Higgins & Green, 2008).

4.3.3 Results.

Flow of trials through the review.

Citations for 4,921 trials were identified in the search. Of these, 4,614 were excluded after screening based on abstract and title. A total of 251 potentially relevant trials were identified from electronic databases and two from reference lists. Of these, 233 trials were excluded after full text review, leaving 18 trials for inclusion. One trial had three arms and so there were 19 comparisons in total (15). See Figure 4.2 for summary of flow of trials through the review.

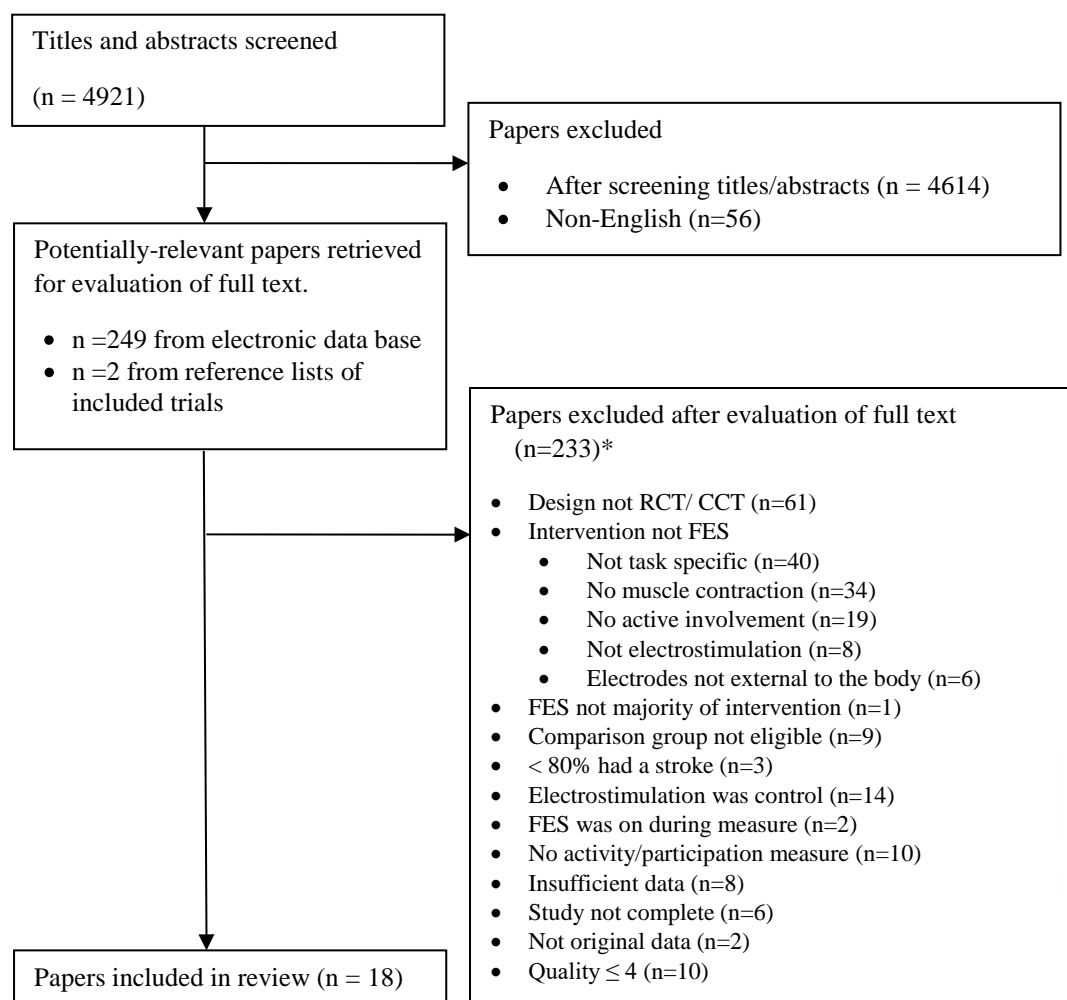


Figure 4.2. Flow of trials through the review. * Papers may have been excluded for failing to meet more than one inclusion criteria.

Characteristics of included trials.

The 18 trials (19 comparisons) included in the review comprised 485 participants (Table 4.1). Of these, there were 9 comparisons of FES against nil/placebo and 10 against training alone. Of these, seven comparisons were of acute participants, and eight involved the lower limb. 16 trials (17 comparisons) had data available for inclusion in a meta-analysis.

Table 4.1

Summary of Included Trials (n=18)

Study	Design	Participants	Intervention	Outcome measures
Barker et al. (2008)	RCT	n = 33 Age (yr) = 66 (SD 12) Gender = 22 M, 11 F Time since stroke = 46 mth	Exp 1 = FES to elbow ext during UL activity training 60 min x 3/wk x 4 wk Con 1 = Nil Con 2 = UL activity training 60 min x 3/wk x 4 wk	Activity = Motor Assessment Scale for Stroke: Item 6 Timing = 0, 4, 12 wk
Bogataj et al. (1995)	CT	n = 20 Age (yr) = 56 (SD 10) Gender = 11 M, 9 F Time since stroke = 4 mth	Exp = FES to ankle dorsi/plantarflex, knee flex/ext during LL activity training 30 min-1 hr x 5/wk x 3 wk Con = LL activity training 30 min-1 hr x 5/wk x 3 wk Both = Standard rehabilitation	Activity = Walking speed Timing = 0, 3 wk
Burridge et al. (1997)	RCT	n = 32 Age (yr) = 56 (SD 3) Gender = 23 M, 9 F Time since stroke = 51 mth	Exp = FES to ankle dorsiflex during LL activity training 60 min x 2/wk x 5 wk Con = LL activity training 60 min x 2/wk x 5 wk	Activity = Walking speed Timing = 0, 5, 13 wk
Cheng et al. (2010)	RCT	n = 15 Age (yr) = 56 (SD 7) Gender = 11 M, 3 F Time since stroke = 34 mth	Exp = FES to ankle dorsiflex during LL activity training 45 min x 3/wk x 4 wk Con = Placebo (LL range of motion and strengthening exercises) 45 min x 3/wk x 4 wk Both = Walking training	Activity = Walking speed Timing = 0, 4 wk
Daly et al. (2005)	RCT	n = 12 Age (yr) = 21-62 Gender = 9 M, 3F Time since stroke = 30 mth	Exp = FES to wrist/finger/thumb flex/ext during UL activity training 1.5 hr x 5/wk x 12 wk Con = Placebo (robotic shoulder/elbow flex/ext during UL activity training) 1.5 hr x 5/wk x 12 wk Both = UL activity training 3.5 hr x 5/wk x 12 wk	Activity = Arm Motor Ability Test Timing = 0, 12, 36 wk
Hara et al. (2008)	RCT	n = 20 Age (yr) = 58 Gender = 14 M, 6 F Time since stroke = 13 mth	Exp = FES to finger/wrist ext during UL activity training 30-60 min x 5/wk x 5 mth Con = UL activity training 30-60 min x 5/wk x 5 mth	Activity = Nine Hole Peg Test Timing = 0, 20 wk

Kojovic et al. (2009)	RCT	n = 13 Age (yr) = 59 Gender = 6 M, 7 F Time since stroke = < 1 mth	Exp = FES to hip/knee/ flex/ext during LL activity training 45 min x 5/wk x 4 wk Con = LL activity training 45 min x 5/wk x 4 wk Both = Standard rehabilitation	Activity = Walking speed Timing = 0, 4 wk
Lee et al. (2013)	RCT	n=15 Age (yr) =55 (SD 8) Gender = 22 M, 8 F Time since stroke = 5 mth	Exp = FES of ankle dorsiflex during LL activity training. 30 min x 5/wk x 4 wk Con = LL activity training. 30 min x 5/wk x 4 wk Both = Standard rehabilitation 1-2/wk x 12 wk	Activity = Walking speed Timing = 0, 4 wk
Mangold et al. (2009)	RCT	n = 22 Age (yr) = 70 Gender = 10 M, 12 F Time since stroke = 7 mth	Exp = FES to elbow/wrist/finger/thumb ext during UL activity training 30 min x 10/wk x 12 wk Con = Placebo (wrist and finger range of motion exercises) 30 min x 10/wk x 12 wk	Activity = Action Research Arm Test Timing = 0, 12, 24wk
Mann et al. (2005)	RCT	n = 23 Age (yr) = 60 (SD 17) Gender = 17 M, 6 F Time since stroke = 7 mth	Exp = FES to shoulder flex, elbow ext, finger flex/ext during UL activity training (grasp and release of objects) 45 min x 3-5/wk x 4 wk Con = Placebo (range of motion exercises) 45 min x 3-5/wk x 4 wk Both = standard rehabilitation	Activity = = Action Research Arm Test Timing = 0, 4 wk
Mohamed Faisal et al (2012)	RCT	n = 30 Age (yr) = 45-75 Gender = not reported Time since stroke = < 1 mth	Exp = FES to wrist flex/ext during UL activity training 20 min x 6/wk 4 wk Con = Nil	Activity = Box and Block Test Timing = 0, 4 wk
Ng et al. (2008)	RCT	n = 54 Age (yr) = 67 (SD 11) Gender = 34 M, 19 F Time since stroke = < 1 mth	Exp = FES to quadriceps during stance phase, knee flex and ankle dorsiflex during swing during LL activity training 20 min x 5/wk x 4 wk Con = LL activity training 20 min x 5/wk x 4 wk Both = Standard rehabilitation	Activity = Walking speed Timing = 0, 4, 24 wk
Page et al. (2012)	RCT	n = 32 Age (yr)= 18-85 Gender = not reported Time since stroke = > 6 mth	Exp = FES to wrist/finger ext/flex and thumb ext/abd during UL activity retraining 120 min x 5/wk x 8 wk Con = Placebo (home exercise program) 30 min x 5/wk x 8 wk	Activity = Box and block test Timing = 0, 8 wk

Peurala et al. (2005)	RCT	n = 45 Age (yr) = 52 (SD 8) Gender = 37 M, 8 F Time since stroke = 36 mth	Exp = FES to 2 individually selected LL muscles during LL activity training 20 min x 5/wk x 3 wk Con = LL activity training 20 min x 5/wk x 3 wk	Activity = Walking speed Timing = 0, 3, 24 wk
Popovic et al. (2003)	CT	n = 41 Age (yr) = 60 (SD 9) Gender = not reported Time since stroke = 1.5 mth	Exp = FES to finger/wrist flex/ext and thumb flex/abd UL activity training 30 min x 3/wk x 3 wk Con = UL activity training 30 min x 3/wk x 3 wk Both = Standard rehabilitation	Activity = Upper Extremity Function Test Timing = 0, 3, 26, 52 wk
Popovic et al. (2004)	RCT	n = 28 Age (yr) = 60 (SD 9) Gender = not reported Time since stroke = 2 mth	Exp = FES to finger flex/ext, thumb ext/abd/opp during UL activity training 30 min x 5/wk x 3 wk Con = UL activity training 30 min x 5/wk x 3 wk Both = Standard rehabilitation	Activity = Upper Extremity Function Test Timing = 0, 3, 6, 13, 26 wk
Sabut et al. (2010)	CCT	n = 30 Age (yr) = 48 (SD 11) Gender = 24 M, 6 F Time since stroke = 18 mth	Exp = FES to dorsiflexors during LL activity training 30-45 min x 5/wk x 12 wk Con = Nil Both = Standard rehabilitation	Activity = Walking speed Timing = 0, 12 wk
Tarkka et al. (2011)	RCT	n = 20 Age (yr) = 53 (SD 6) Gender = 13 M, 7 F Time since stroke = 29 mth	Exp = FES to wrist flex/ext, thumb flex/opposition during UL activity training 30 min x 10/wk x 2 wk Con = Placebo (voluntary movement exercises and passive manual stretching) 30 min x 10/wk x 2 wk	Activity = Wolf motor function test Timing = 0, 2, 24 wk

RCT = randomised clinical trial, CCT = controlled clinical trial, CT = cross-over trial, M/F = male/ female, Exp = experimental group,

Con = Control group, FES = Functional electrical stimulation, EMG = electromyography, UL = upper limb, LL = lower limb

Quality.

The mean Jadad score was 2.6 out of five. Double blinding was achieved in 0% of trials, randomisation in 94%, description of randomisation method in 76% and reporting an account of all subjects occurred in 100 %. The mean PEDro score of trials was 5.5 (SD 0. 6); only one trial was of high quality (Table 4.2). Point estimates and variability was present in 100% of trials, random allocation in 94%, base line comparability in 89%, between group comparisons in 88%, adequate follow up in 72%, assessor blinding in 50%, concealed allocation in 44%, and intention to treat analysis in 16%. Participants or therapists were blinded to intervention in zero trials.

Table 4.2

PEDro Scores for Included Trials (n=18)*

Study	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	< 15% dropouts	Intention to treat analysis	Between group difference	Point estimate & variability	Total (0 to 10)
Barker et al. (2008)	Y	Y	Y	N	N	Y	N	Y	Y	Y	7
Bogataj et al. (1995)	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Burridge et al. (1997)	Y	Y	N	N	N	N	Y	N	Y	Y	5
Cheng et al. (2010)	Y	Y	Y	N	N	Y	N	N	Y	Y	6
Daly et al. (2005)	Y	N	Y	N	N	Y	Y	N	N	Y	5
Hara et al. (2008)	Y	N	N	N	N	Y	Y	N	Y	Y	5
Kojovic et al. (2009)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Lee et al. (2013)	Y	N	Y	N	N	Y	Y	N	Y	Y	6
Mangold et al. (2009)	Y	N	Y	N	N	N	Y	Y	Y	Y	6
Mann et al. (2005)	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Mohamed Faisal et al. (2012)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Ng et al. (2008)	Y	N	Y	N	N	N	Y	Y	Y	Y	6
Page et al. (2012)	Y	Y	Y	N	N	Y	Y	N	N	Y	6
Peurala et al. (2005)	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Popovic et al. (2003)	Y	N	Y	N	N	Y	N	N	Y	Y	5
Popovic et al. (2004)	Y	N	Y	N	N	Y	N	N	Y	Y	5
Sabut et al. (2010)	N	N	Y	N	N	Y	Y	N	Y	Y	5
Tarkka et al. (2011)	Y	Y	Y	N	N	N	N	N	Y	Y	5

*PEDro scores from website www.pedro.org.au

Participants.

Across the trials, the mean age ranged from 48 to 70 years old, and 52% of participants were male. The mean time after stroke ranged from less than one month to 51 months, with 61% of the trials carried out after 6 months.

Intervention.

Seven trials investigated FES in the lower limb and 10 in the upper limb. Length of FES sessions ranged from 20 minutes to 6 hours, frequency ranged from 2-7 per week and the duration ranged from 2-12 weeks with the total dose of intervention ranging from 5-90 hours. The frequency of the electrical stimulation ranged from 25-50 hertz and pulse width from 200-400 microseconds. Electrical stimulation was triggered by the therapist or the participant – either mechanically (eg, by weight bearing on a foot switch) or physiologically (by reaching a predetermined amount of muscle activity). The number of movements stimulated during the activity (i. e. wrist extension, ankle dorsiflexion, etc) ranged from 1-6 movements. The control intervention was nil/placebo in 10 trials and training the same activity as the experimental intervention but without the FES in eight trials.

Outcome measures.

Lower limb activity was assessed as walking speed (m/s) in seven comparisons. Upper limb activity was assessed using Motor Assessment Scale, Arm Motor Ability Test, Nine-hole Peg Test, Action Research Arm Test, Box and Block Test, Upper Extremity Function Test and the Wolf Motor Function Test.

Effect of intervention.***FES vs placebo/nothing.***

The effect of FES on activity was examined by pooling data after intervention from eight trials comprising 168 participants using a random effect model (Barker et al., 2008; Cheng et al., 2010; Daly et al., 2005; Mann et al., 2005; Mohamed Faisal et al., 2012; Page et al., 2012; Sabut, Sikdar et al., 2010; Tarkka et al., 2011) (fig. 4.3). FES improved activity compared with nil/placebo (SMD 0.40, 95% CI 0.08 to 0.72, $I^2 = 5\%$). Due to incomplete data, two trials could not be included into the analysis (Hara et al., 2008; Mangold et al., 2009). The analysis included six trials of UL (Barker et al., 2008; Daly et al., 2005; Mann et al., 2005; Mohamed Faisal et al., 2012; Page et al., 2012; Tarkka et al., 2011) and two of LL training (Cheng et al., 2010; Sabut, Sikdar et al., 2010b). Of these, seven were chronic (Barker et al., 2008; Cheng et al., 2010; Daly et al., 2005; Mann et al., 2005; Page et al., 2012; Sabut, Sikdar et al., 2010b; Tarkka et al., 2011) and one was acute (Mohamed Faisal et al., 2012). Most trials involved the upper limb in the chronic stage, so a sub group analysis was not done.

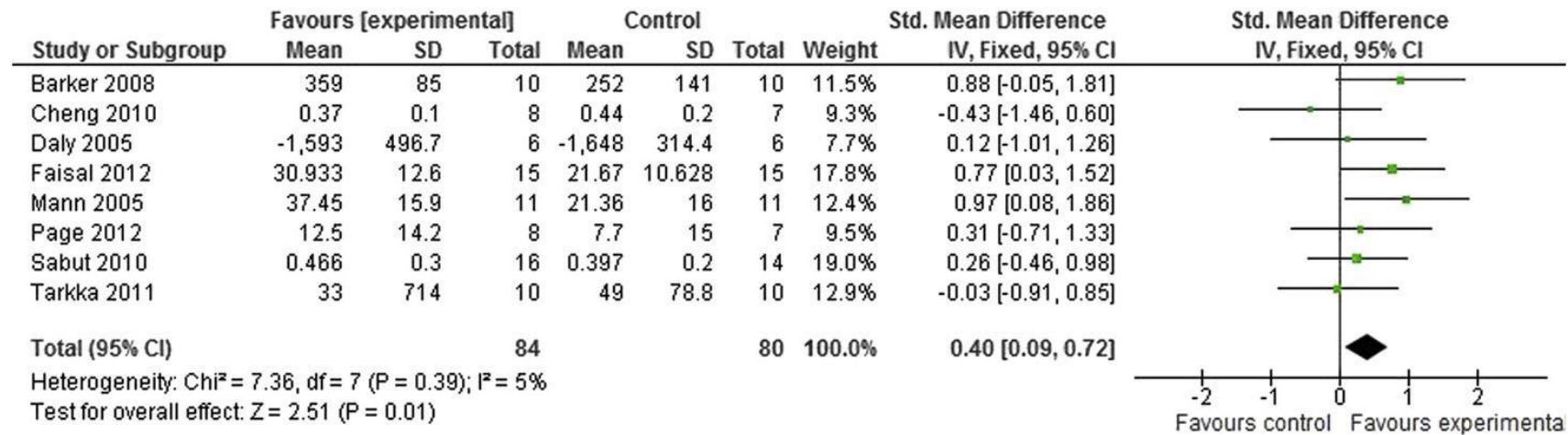


Figure 4.3. SMD (95% CI) of effect of functional electrical stimulation compared with nil/placebo on activity by pooling data from 8 comparisons ($n=164$).

FES vs training alone.

Whether FES was superior to training alone was examined by pooling data after intervention from nine trials comprising 241 participants using a random effect model (Barker et al., 2008; Bogataj et al., 1995; Burridge et al., 1997; Kojovic et al., 2009; Lee et al., 2013; Ng et al., 2008b; Peurala et al., 2005; Popovic et al., 2004; Popovic et al., 2003) (Fig. 4.4). FES improved activity compared with training alone (SMD 0.56, 95% CI 0.21 to 0.92, $I^2 = 44\%$). The analysis included three trials of upper limb (Barker et al., 2008; Popovic et al., 2004; Popovic et al., 2003) and six of lower limb training (Bogataj et al., 1995; Burridge et al., 1997; Kojovic et al., 2009; Lee et al., 2013; Ng et al., 2008b; Peurala et al., 2005). Of these, three were chronic (Barker et al., 2008; Burridge et al., 1997; Peurala et al., 2005) and six were acute (Bogataj et al., 1995; Kojovic et al., 2009; Lee et al., 2013; Ng et al., 2008b; Popovic et al., 2004; Popovic et al., 2003). Most trials involved the lower limb in the acute stage, so a sub group analysis was not done.

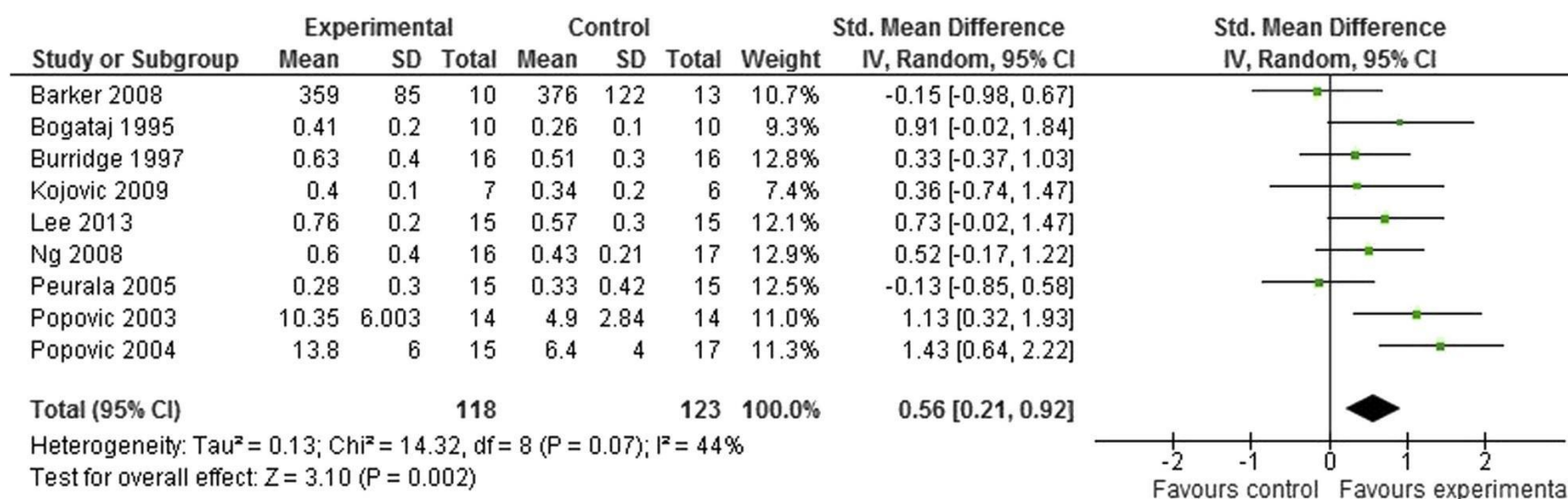


Figure 4.4. SMD (95% CI) of effect of functional electrical stimulation compared with training alone on activity by pooling data from 9 comparisons ($n=241$).

Sub group analysis.

Given that the effect size was similar for each analysis, trials were pooled into groups of either upper or lower limb FES training. The effect of FES after upper limb training was examined by pooling data after intervention from eight trials comprising 192 participants using a fixed effect model (Barker et al., 2008; Daly et al., 2005; Mann et al., 2005; Mohamed Faisal et al., 2012; Page et al., 2012; Popovic et al., 2004; Popovic et al., 2003; Tarkka et al., 2011) (fig. 4.5). For the trial of upper limb training which had three comparisons (one experimental and two controls) (Barker et al., 2008), the two control groups were averaged. FES improved upper limb activity compared with a control (SMD 0.69, 95% CI 0.33 to 1.05, $I^2 = 27\%$). The effect of FES after lower limb training was examined by pooling data after intervention from nine trials comprising 203 participants using a fixed effect model (Bogataj et al., 1995; BurrIDGE et al., 1997; Cheng et al., 2010; Kojovic et al., 2009; Lee et al., 2013; Ng et al., 2008; Peurala et al., 2005; Sabut, Sikdar et al., 2010b) (fig. 4.6). As all outcomes for lower limb training were walking reported in m/s, the mean difference (MD) was used to calculate the effect of intervention. FES improved lower limb activity (walking) compared with a control (MD 0.08 m/s, 95% CI 0.02 to 0.15, $I^2 = 5\%$).

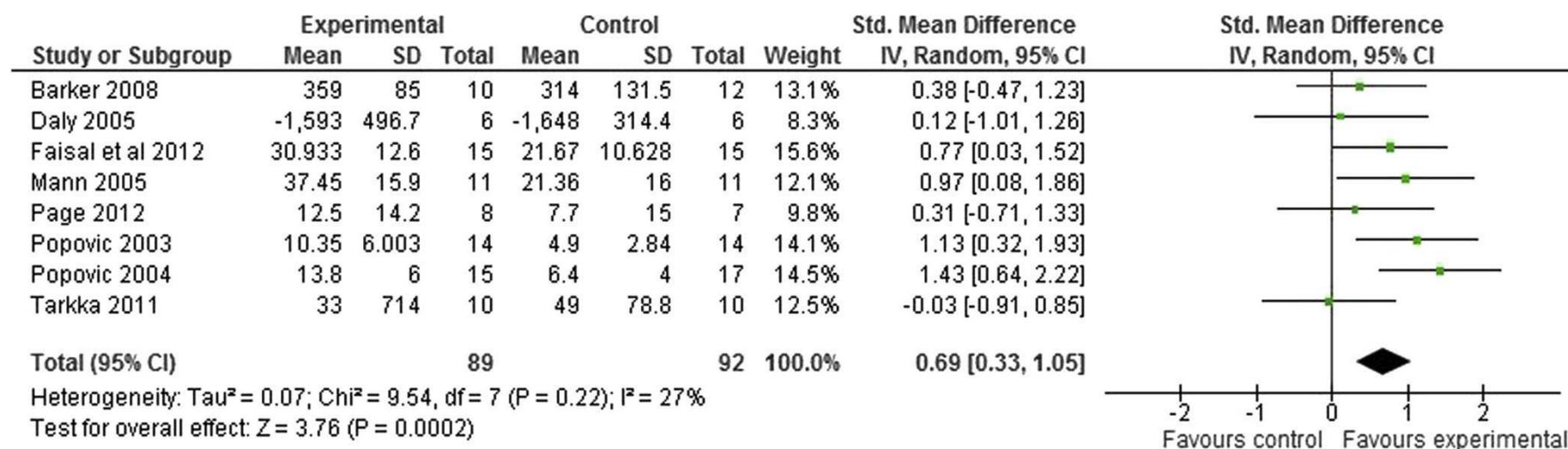


Figure 4.5. SMD (95% CI) of effect of upper limb functional electrical stimulation compared with a control on activity by pooling data from 8 comparisons (n=181).

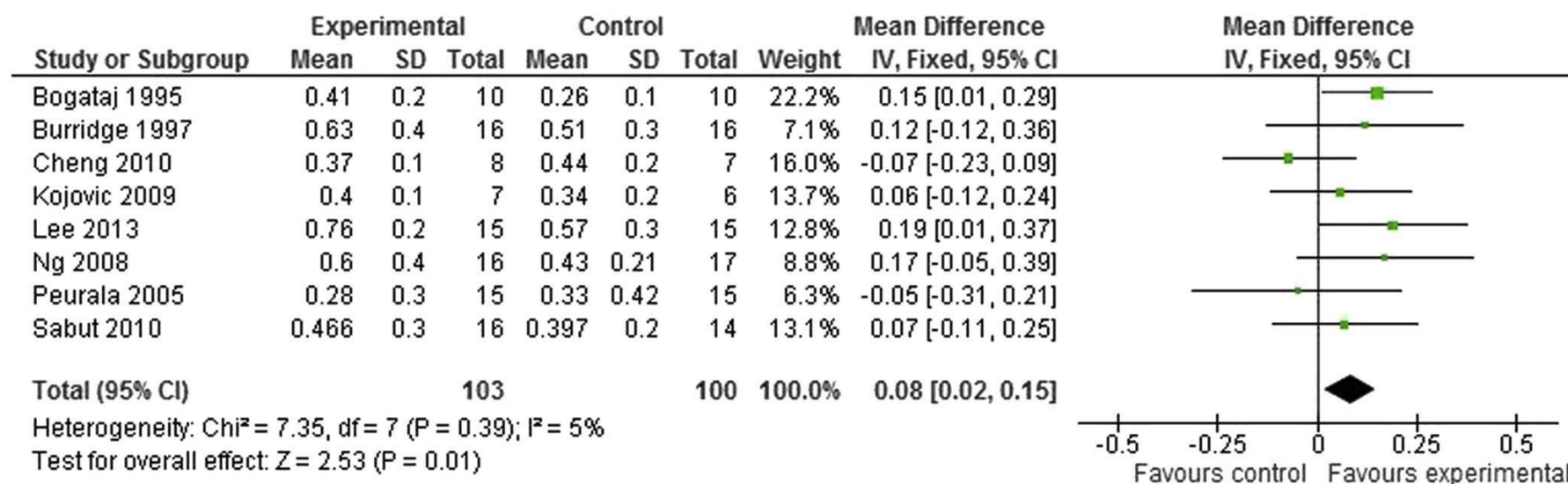


Figure 4.6. MD (95% CI) of effect of lower limb functional electrical stimulation compared with a control on activity by pooling data from 8 comparisons (n=203).

4.3.4 Discussion.

This systematic review provides evidence that FES has a small to moderate positive effect (Cohen, 2013) on activity compared with nil/placebo. It also provides evidence that FES is more beneficial than training alone with a moderate effect size. However, due to lack of available data, we were unable to examine whether FES improves participation or if the benefits of FES on activity are long lasting.

The use of the Jadad scale identified a lack of double blinding of group allocation, which is common amongst stroke rehabilitation trials. PEDro scores have then provided a method of breaking down the levels of blinding and investigated other methodological biases such as a lack of concealed allocation of subjects (Bhogal, Teasell, Foley, & Speechley, 2005). The mean PEDro score of 5.5 for the 18 trials included in this review represents moderate quality, adding to the credibility of the conclusions. Participants were similar in age and gender and the time after stroke was generally chronic (> 6 months after stroke), with seven trials examining participants in the acute/subacute phase of rehabilitation (< 4 months after stroke). There was a range of durations of intervention (2-12 weeks); however, the majority of trials examined interventions of 3-4 weeks duration. Furthermore, due to the diversity of intervention and subject factors which could not be accounted for in a sub group analysis, a random effect analysis has been presented. Taken together with the methodological quality of included trials, this suggests that the findings can be generalized cautiously.

There have been two previous systematic reviews examining the effect of FES after stroke, and both have investigated lower limb function (Pereira et al., 2012; Robbins et al., 2006). In 2006, Robbins et al. (2006) reported that FES resulted in 0.18 m/s (95% CI 0.08 to 0.28) faster walking speed than walking training alone or no intervention, based on a meta-analysis of three controlled trials in chronic stroke. Finally, in 2012, Pereira et al. (2012)

reported that FES resulted in 0.38 SMD (95% CI 0.08 to 0.68) further walking distance than walking training alone or no intervention, based on six controlled trials. Our analysis demonstrates that FES during walking training results in a difference of 0.08 m/s in walking speed. As the clinical significance of improved walking is 0.1 m/s (Chui et al., 2012), FES for lower limb training appears to have a small effect, nearing clinical significance. Therefore, the results of this systematic review provide stronger evidence of the efficacy of FES in improving activity because the conclusions are based on a meta-analysis of eight randomized trials of moderate quality. In contrast, FES during upper limb training resulted in a large effect size.

Study Limitations.

Our review has some limitations. First, the strongest source of bias is lack of blinding of therapists and participants in the clinical trials, since it is very difficult to blind them during the delivery of an intervention such as FES. Hence results may be influenced by observer bias (Schulz et al., 1995). Second, the results are potentially affected by small trial bias with an average number of 25 participants per trial. It is therefore possible that the estimated effect may be larger than the true effect (Dechartres, Trinquart, Boutron, & Ravaud, 2013). Third, since we combined data collected using different outcome measures, we calculated SMD in the meta-analysis. One of the problems associated with this is that an estimation of the benefit of FES in real terms cannot be expressed (Johnston et al., 2010). Lastly, only one person screened title and abstract, and no grey literature search was completed. Therefore caution is required when generalizing these results to the general population of stroke survivors.

As with most rehabilitation trials, there may have been many possible influences on the outcomes reported in the included studies other than the intervention of FES, including time after stroke, the limb that was trained, and the severity of stroke. Our review planned to conduct a sub group analysis to investigate the contribution of other factors to study findings, however insufficient studies have been conducted to warrant meta-regression (Higgins & Green, 2011). Therefore, the review is unable to hypothesise the influence of factors originating from the subject or the device; nor is this review able to investigate the influence of other factors on heterogeneity on the treatment effect. Future researchers are encouraged to do so with larger study numbers.

4.3.5 Conclusions.

There are implications for both clinicians and researchers from this review. Evidence from the meta-analysis suggests that FES is beneficial in improving activity after stroke. In the 18 trials, FES was administered by clinicians, with the exception of two trials which were home-based with no direct therapist supervision (Burridge et al., 1997; Page et al., 2012). Implementation of this review's findings will require a commitment from health services, both in terms resources and training. Future trials should include longer term follow up measures as well as measures that reflect participation, since there was not enough data in the 18 trials included in this study to address these questions.

Chapter 5. Study Two

The Use of Functional Electrical Stimulation by Occupational Therapists and Physiotherapists

5.1 Introduction to Chapter Five

Chapter Five outlines the methods and reports on the findings from study two investigating the use of FES by clinicians in the state of Victoria, Australia. The chapter is divided into two parts: (a) the design of the purposed design survey, and (b) the implementation of the survey with Victorian occupational therapists and physiotherapists. Part one and two of study two have been published as manuscripts in the Australian Journal of Occupational Therapy (Howlett et al., 2018a, 2018b). The methodological and theoretical justifications for study two, were described in Chapter Two and Three.

5.2 The Design of the FES Use Survey: Using the Cognitive Interviewing Process to Improve Survey Design by Allied Health: A Qualitative Study

5.2.1 Manuscript abstract.

Background/Aim: Allied health professionals frequently use surveys to collect data for clinical practice and service improvement projects. Careful development and piloting of purpose-designed surveys is important to ensure intended measuring (that respondents correctly interpret survey items when responding). Cognitive interviewing is a specific technique that can improve the design of self-administered surveys. The aim of this study was to describe the use of the cognitive interviewing process to improve survey design, which involved a purpose-designed, on-line survey evaluating staff use of functional electrical stimulation.

Methods: A qualitative study involving one round of cognitive interviewing with three occupational therapists and three physiotherapists.

Results: The cognitive interviewing process identified 11 issues with the draft survey,

which could potentially influence the validity and quality of responses. The raised issues included difficulties with: processing the question to be able to respond, determining a response to the question, retrieving relevant information from memory and comprehending the written question. Twelve survey amendments were made following the cognitive interviewing process, comprising four additions, seven revisions and one correction.

Conclusions: The cognitive interviewing process applied during the development of a purpose-designed survey enabled the identification of potential problems and informed revisions to the survey prior to its use.

Key words: Surveys; Questionnaires; Health Care Surveys; Allied Health.

5.2.2 Manuscript.

Howlett, O., McKinstry, C., & Lannin, N. (2018a). Using the cognitive interviewing process to improve survey design by allied health: a qualitative study. *Australian Journal of Occupational Therapy*, 65(2), 126-134. doi:10. 1111/1440-1630.12445.

Introduction.

Occupational therapists and physiotherapists frequently use surveys to evaluate clinical practice and inform improvements in service delivery (Boeije & G. Willis, 2013; Chang, Boots, Hodges, & Paratz, 2004; Koh, Hoffmann, Bennett, & McKenna, 2009). Where possible, validated surveys are used however there are occasions when the topic of interest is unique. In these instances, purpose-designed surveys may need to be developed. The validity and dependability of a survey's results is significantly influenced by survey design (Drennan, 2003). Development of a purpose-designed survey requires considerable attention to ensure that the survey measures what is intended, and respondents understand and correctly interpret survey items. Even with careful survey design and piloting, these processes do not necessarily ensure that the respondents will understand the questions in the manner in which the survey's authors intended (Garcia, 2011).

The cognitive interviewing process is a specific technique that can be used during the development and testing of surveys and questionnaires to help identify whether survey items generate the information that the investigator intends and thus, to inform revisions (Humann, Ridolfo, Virji, & Henneberger, 2013; Moore, 2009; Spark & Willis, 2014). The process identifies and analyses sources of response error within surveys by focusing on the cognitive processes that respondents use to answer the survey items or question. It concentrates on the items and questions within the survey, rather than how the survey is administered. Cognitive interviewing has its origins in cognitive psychology where it was proposed that survey respondents use distinct cognitive processes when reading and answering survey questions (Collins, 2014; Tourangeau, 1984). These processes include comprehension of the written question, retrieval from memory of relevant information, the decision and response processes (Willis, Royston, & Bercini, 1991). Based on these cognitive processes, two distinct cognitive interviewing strategies have been recommended to test survey questions (Boeije & Willis, 2013). The first is ‘think-aloud’ interviewing where the respondent explains to the interviewer what they are thinking in response to reading the question. The second strategy is ‘verbal probing’ and involves the interviewer asking the respondent pre-planned or spontaneous questions (after the think-aloud process) about their process of answering the question. These interviewing strategies help understand the respondent’s cognitive responses during testing, which can then be used to revise the survey and improve its validity and reliability (Aicken et al., 2013; Boeije & Willis, 2013; Ryan, Gannon-Slater, & Culbertson, 2012).

While the use of cognitive interviewing has received some attention in the fields of dietetics (Subar et al., 1995), pharmacy (Spark & Willis, 2014), sports science (Dietrich & Ehrlenspiel, 2010) and nursing (Izumi, Vandermause, & Benavides-Vaello, 2013), there is limited literature regarding its use by occupational therapists. Cognitive interviewing is a strategy that could enhance and improve robust data collection techniques by occupational

therapists.

The aim of this study was to describe the use of the cognitive interviewing process to develop a purpose-designed, on-line survey, using an example of investigating the use of functional electrical stimulation by occupational therapists and physiotherapists.

Methods.

Design.

A prospective qualitative study was undertaken whereby the cognitive interviewing process assisted in the development of an on-line survey evaluating the use of functional electrical stimulation by allied health professionals. The research ethics committee of Bendigo Health (reference LNR/ 15/ BHCG/ 82) and La Trobe University (reference SHE CHESC acceptance of Bendigo Health HREC approved project – LNR/15/BHCG/82) approved this study prior to commencement. A participant information statement was provided and all participating therapists provided written, informed consent.

Participants and setting.

A sample of convenience was sought from allied health professionals (occupational therapists or physiotherapists) working in health and known to have clinical experience with neurological rehabilitation of stroke survivors.

Study protocol.

The researchers first developed a draft survey investigating therapists' use of functional electrical stimulation. After the content of the draft version was finalised, the process of cognitive interviewing commenced. Each participant completed a one-on-one single session of cognitive interviewing with one of the researchers (OH) at a time and place that was convenient for the participant. Within each session of cognitive interviewing, the 'think-aloud' and 'verbal probing' strategies were used. All interviews were audio recorded and transcribed verbatim.

Think-aloud strategy.

For participants to understand the requirements of the ‘think-aloud’ process, they were given time to practise the technique using the training method suggested by Willis, Caspar, and Lessler (2013). This technique involved inviting the participant to respond to the following statement aloud: “Try to visualize the place where you live, and think about how many windows there are in that place. As you count up the windows, tell me what you are seeing and thinking about.” (Willis et al., 2013, p. 4). During the ‘think-aloud’ process, the interviewer, on noting any hesitation by participants during the interview, prompted the participant by saying ‘Tell me what you are thinking’. This open ended format of questioning is believed to reduce the likelihood of the interviewer’s bias being imposed onto the participant (Willis, 2004).

Verbal probing strategy.

‘Verbal probing’ was then undertaken to investigate each participant’s cognitive process whilst answering the survey questions (Collins, 2003). A variety of probing techniques were used throughout the testing of the functional electrical stimulation use survey as follows: comprehension, paraphrasing, recall, specific probing and general probing (Willis, 2004). To increase the richness of information gathered, the verbal probes were both spontaneous and pre-planned (Willis, 2004). Table 5.1 provides examples of the verbal probing techniques used during the interviews. The number of pre-planned probes was intentionally limited during the interviews because they can distract participants from the think-aloud process. All verbal probing was completed during the interview, rather than at its completion (Miller, Chepp, Willson, & Padilla, 2014). Care was taken to ensure that verbal probing by the interviewer did not lead the participant to select a response that reflected the interviewer’s beliefs rather than their own (Willis, 2004).

Table 5.1.

*Examples of Verbal Probing Used During Testing of the Functional Electrical Stimulation**Use Survey*

Verbal probing type	Verbal probing examples	
	Spontaneous	Pre-planned
Comprehension probe	Does that make sense?	How do you define the difference between the categories?
Paraphrasing probe	You are finding that hard, is that what I am hearing?	Not used
Recall probe	You find that timeframe quite easy to identify?	Is this hard to identify if it has been in the past two years?
Specific probe	Alright, if there was another way of asking that question that could be more accurate but easier, would you re-phrase it in any way?	Do you find it hard to define the difference between the three categories that we have there?
General probe	So, what are you thinking at the moment?	So, tell me what you are thinking.

Following completion of the think-aloud and verbal probing strategies for each question and to complement the cognitive interviewing process, each participant was asked to read the research aims of the functional electrical stimulation survey. These were to determine if: (1) occupational therapists and physiotherapists use functional electrical stimulation to improve the daily life of stroke survivors; and (2) functional electrical stimulation use depends on therapist's discipline, gender, training, location of practice, and/or years of experience with stroke survivors. Each participant was then asked to match a research aim to each survey item.

Outcome measures and data analyses.

A pre-designed data collection form was used during the interview to record the

verbalised concerns of participants and proposed solutions. At the completion of all the interviews, data were transcribed verbatim into a written format, and all participant perceived difficulties and their proposed solutions were recorded, and then summarised into a table format. The researchers, through a consensual process, agreed on which amendments were required. Once the survey amendments were finalised, the amendments were classified according to the cognitive process domains by one researcher while another researcher reviewed and agreed upon the domains allocated. For the matching of research aims to survey items, the agreement between participants' responses and the investigators' responses were measured. The participants were not asked to clarify their reasoning if the objectives were mismatched with the investigator's response. If mismatched, the researcher reviewed the participant's response to identify if the meaning of the question was not understood.

Results.

Participants.

Six participants were recruited to the study to take part in the cognitive interviewing process: three occupational therapists and three physiotherapists. The participants' mean (range) age was 28.3 (23 - 34) years and all were female. All therapists worked in the clinical area of neurological rehabilitation.

Cognitive interviewing process.

The mean (range) interview duration was 38.2 (28.43 to 53.87) minutes. The cognitive interviewing process resulted in the identification of 11 issues within the draft survey. A summary of these issues, the survey amendments and the supporting responses from participants are presented in Table 5.2. Each issue may have arisen from either an individual or multiple participants responses. Ten of the 11 problems resulted directly from the cognitive interviewing strategies of 'think out-loud' and 'probing'. The 11 problems identified were as follows.

- One issue was an error that had arisen during transcription from the paper version to the on-line version of the draft survey.
- Four issues related to where some participants had difficulty understanding the questions to enable a decision. For example, three participants were unable to respond to two questions because they had previously stated within the survey, that the clinical scenario was not relevant to them.
- Two issues arose when participants were determining a response to a question. For example, participants indicated that the survey's pre-determined answers did not accurately capture their response.
- One issue related to the process of participants recalling relevant information. For example, participants consistently identified that they had forgotten that their answers only related to the past two years.
- Three issues related to participants having difficulty in comprehending the question. For example, two participants could not decide if their student experiences should be included in their answers.

After the cognitive interviewing process, 12 amendments were made including changes to the survey format, sentence structure and answer format. These amendments comprised four additions; seven revisions and one correction (see Table 5.2).

Table 5.2.

Summary of the Issues Identified, Amendments and Participants' Responses during the Cognitive Interviewing Process

Cognitive process	Original question / statement	Identified issue	Resulting amendment	Participants' responses
Processing the question to make a decision.	Thinking about your use of FES when training the upper limb (shoulder, arm, and/or hand): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect.	Participants were confused as to why they were answering the question given that some participants had not used FES for upper limb training.	Added on-line rule to the electronic survey to allow participants to only answer the question if they had used FES for upper limb training.	<p>"I guess I have indicated in previous questions that I haven't used it in any of these situations."</p> <p>"So I'm just in a bit of a quandary. Because haven't actually used it but I believe that it can help with these things as to how to answer this."</p> <p>"So I guess I can still answer that base on theoretical knowledge but not actual clinical use."</p>
	Thinking about your use of FES when training the lower limb (hips, leg and/or foot): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect.	Participants were confused as to why they were answering the question given that some participants had not used FES for lower limb training.	Added on-line rule to the electronic survey to allow participants to only answer the question if they had used FES for lower limb training.	<p>"Don't know haven't done it."</p> <p>"So, because I ticked 'no', is this still going to come up?"</p> <p>"Don't know I'm not a physio."</p> <p>"Not sure, haven't seen it in action."</p>

	Reference cited at the end of the survey providing the definition of FES.	Participants were not sure if the survey was completed and if they needed to proceed to another page.	Reference was relocated from the end of the survey to appear at the time of the definition of FES.	“I think it would be more clear if this thankyou box popped up right at the very end rather than finishing with the reference and then finishing the survey.”
	Ranking options where participants were asked to: “Please rank the following reasons from 1 to 5, with 1 being the most common reason and 5 as the least common reason.”	Participants found it difficult to rank their answers.	Statement was revised to read: “Please select the statement which reflects the most common reason for you to use FES.”	<p>“Yeah, it kind of throws me thinking what are they trying to know, what are they wanting to know and it sort of feels a little bit like judgy (sic) on how you're being perceived as a therapist.”</p> <p>“Ranking is difficult because all of them are important. I suppose I just have back to well what was my reason for using it? Now, yeah, ranking them i hard. Things change around.”</p>
Determining a response to questions.	Question response: “Self-directed learning.”	Participants wanted to state what type of self-directed learning they had undertaken.	Added the option of a free text answer describing the type of self-directed learning.	<p>“Because self-directed learning could be - it could come under on-the-job training but it could also be doing your own research and that kind of thing.”</p> <p>“I kind of want an option to put what the self-directed learning was.”</p>
	Question: “How did you learn how to administer FES? Please rank each method of training from 1 to 5, with 1 ranked as the	Participants wanted to be able to answer the question to indicate that they	Added the question: “Have you spent time learning how to use FES?”	“Well, I have learnt how to administer it I just haven't done it.”

	method of training which was most useful and 5 as the least useful. Tick NA if you did not use this method at all.”	had received training for the use of FES, even if they had not used the intervention.	Added on-line rule to the electronic survey to skip all remaining questions if the answer selected was ‘no’.	
Retrieving relevant information from memory.	Question: “In the past two years, have you used FES in the following clinical scenarios?”	Participants forgot that this introductory statement related to more than one question.	Revised so that this statement was repeated for questions 11, 12 and 13.	<p>“For the person that has been in the last two years, I would add that in. Just so you're getting with the right timeframe.”</p> <p>“Now here I've kind of lost my stream of thought and I want that two year prompt at the top just as a reminder of what I'm focusing on.”</p>
Comprehending the written question.	Statement re effect of FES: “Stroke survivors will be able to use their weak upper limb in daily activities.”	Participant became confused regarding what the question was asking.	Revised statement to: “Stroke survivors will be able to use their weak upper limb in more daily activities.”	“I think, yeah, if you're trying to assess if they're able to do more daily activities then, yeah, that doesn't really ask that question well.”
	Question: “How many years have you worked with stroke survivors?”	Participants were unsure if they should include patients seen as a student.	Revised statement to: “How many years have you worked with stroke survivors? Do not include stroke survivors you saw as a student.”	<p>“I'd probably say, stipulate whether it was work as in working practicing or like eliminate that university student versus work clinician. If that makes sense.”</p> <p>“I would include a statement around working as a registered practitioner or</p>

				having in brackets this does not include time as a student maybe.”
Question: “What was the duration of the CPD?”	One participant was confused regarding how to answer the question, as she had completed multiple sessions of FES training.	Revised question to: “What was the total duration of your CPD?”	“So are we looking at that as you've done more than - are you looking a instance or all up?”	
Statement: “Electrodes connected to an electrostimulation device placed onto foot or leg muscles to assist the stroke survivor walk.”	The statement was incorrectly worded in the on-line survey.	Corrected statement to: “Why did you use FES to assist a stroke survivor to walk?”	No response recorded	

CPD – continuing professional development; FES – functional electrical stimulation; NA – not applicable.

Matching research aims and questions.

Participants were asked to match the research aims with individual survey items, with an agreement rate of 101 out of 108 (94 %) between the researchers and the participants' responses'. One response included an additional objective, which was not identified by the researchers, and six responses allocated one research objective for the question as compared to the researchers' choice of two objectives for the question. On review of mismatched responses, participants think aloud responses demonstrated an understanding of the questions; therefore, no adjustments to research objectives were required.

Discussion.

This study describes the use of a cognitive interviewing process to develop an allied health survey, involving an on-line survey investigating the use of functional electrical stimulation by occupational therapists and physiotherapists. The cognitive interviewing process was useful in identifying issues with the draft survey that may not have been otherwise identified. The resultant amendments improved the survey content and ensured that survey items generated the desired data for a future study. Whilst only six participants in the current study were included in the cognitive interviewing process, this number of participants was similar to other studies in health care (Pearson, Morris, & McKinstry, 2015; Ryan et al., 2012). Despite there only being a small number of participants, the cognitive interview process was able to identify issues with the draft surveys resulting in amendments and improvements.

Despite the lack of studies describing the use of cognitive interviewing with occupational therapists or physiotherapists, our findings are similar to studies investigating the use of cognitive interviewing by other allied health professionals. In a pharmacy based project investigating the development of people's perspectives on progesterone use (Spark

and Willis, 2014), results identified that respondents were not able to comprehend terminology about product information; thus the question format was modified to allow easier interpretation. In a study investigating functional electrical stimulation with people with spinal cord injury (Triccas et al., 2016), suggestions were made by health professionals to change the wording of statements within the question. Consistent with our study, one respondent was unable to understand a question related to functional electrical stimulation training, thus an additional word helped clarify the question. The current study has also demonstrated the use of cognitive interviewing by allied health professionals to improve the design of surveys to enhance the understanding of interventions (Pearson et al., 2015; Triccas et al., 2016).

In the current study, a single round of cognitive interviewing appeared to generate sufficient insight into the cognitive processes of survey respondents, consistent with suggestions by other researchers (Hall & Beatty, 2014). Other authors, however, have recommended that the process of cognitive interviewing should be repeated after amendments are made to further increase the likelihood that all major issues with the survey are identified and resolved (Willis & Artino, 2013; Willis et al., 2013). It is acknowledged that it may not be practical for small scale projects to undertake multiple rounds of cognitive interviewing because of restricted participant numbers and the human and financial resources required to collect and analyse the data (Ryan et al., 2012). An alternative to repeated rounds of cognitive interviewing is to analyse responses after each set of two or three interviews (Ryan et al., 2012; Spark & Willis, 2014). While only conducting six interviews, this method gave the researchers some ability to see if the amendments they had made had resolved the identified issues. Future research could investigate the optimal number of rounds of cognitive interviewing that are necessary to ensure saturation is reached (Guest, Bunce, & Johnson, 2006) whilst also conducting a cost effectiveness analysis based on the thematic saturation level of each interview round (Namey, Guest,

McKenna, & Chen, 2016). These investigations would identify if the cost of research methodology outweighs the benefits from the survey improvements.

Clinical implications.

As the process of cognitive interviewing relies on excellent inter-personal skills (Willis et al., 2013), allied health professionals are well placed to learn and utilise the process of cognitive interviewing and thus improve the content of the purpose-designed surveys. The cognitive interviewing process provides a simple but effective method that enables clinicians to identify problems with a survey prior to its implementation in practice. For example, a clinician may test a survey via cognitive interviewing prior to using the survey to identify a client's viewpoint about their involvement with an occupational therapy group or individual intervention. The strategies of 'think-aloud' and 'verbal probing' may also be used when developing brochures, pamphlets, protocols and educational handouts (Collins, 2014; Seligman et al., 2007) to ensure the key messages of these tools are understood by the readers consistent with the authors' intentions. Figure 5.1 provides an overview of the steps to conduct cognitive interviews in clinical practice.

The interviewee reads one survey question.

The interviewee thinks-aloud after they have read the question.

The interviewer asks probing questions to understand the issue.

Suggestions for solutions are given and recorded.

Repeat step 1 – 4 for each survey question.

After completion of multiple cognitive interviews, changes to the question or survey structure are made and then re-tested to ensure amendments have had desired effect.

Figure 5.1. Using cognitive interviewing process in clinical practice

Study limitations.

The main limitation of the current study was that a convenient and small sample of participants was used, which may have resulted in collection of insufficient data to achieve saturation (Guest et al., 2006). The concept of saturation indicates that no further new information will be obtained by conducting more interviews (Willis, 2015). While this is a limitation, it is important to acknowledge that the small sample in this study did identify necessary edits, and strengthened the quality of the survey. Data analysis in the current study used the transcribed interviews to capture participants' remarks, which were then summarised to identify issues and possible solutions. Our subjective process of analysis may have been improved by using a formalised analytical approach (Miller et al., 2014) such as thematic analysis, matrix display strategy or a systematic approach (Bobrovitz, Santana, Kline, Kortbeek, & Stelfox, 2015; Fisher, Falkner, Trevisan, & McCauley, 2000; Knafl et al., 2007). The use of a formalised analytical approach would improve replicability of any similar future studies or survey improvement studies.

Conclusion.

This study has demonstrated that the cognitive interviewing process can improve the quality of a purpose-designed on-line survey for use in an allied health setting. Through increased understanding of the participants' cognitive processes whilst responding to the

questions, issues with survey format and question structure and content can be identified and addressed improving accuracy and quality of data collected.

Key Points for Occupational Therapy.

- Survey questions may not be interpreted in the way the author intended.
- Survey questions may be tested by using a cognitive interviewing technique.
- Cognitive interviewing is practical in occupational therapy research and may strengthen survey design

5.3 The Implementation of the FES Use Survey: Using Functional Electrical Stimulation with Stroke Survivors: A survey of Victorian Occupational Therapists and Physiotherapists

5.3.1 Manuscript abstract.

Background/Aim: Functional electrical stimulation (FES) improves active movement of the hemiplegic upper and lower limbs following stroke. The use of FES by Australian allied health clinicians in stroke rehabilitation is, however, unknown. The purpose of this study was to understand the use of FES in clinical practice. Reasons for the use of FES and potential variables that influence decision-making were also investigated.

Method: Cross-sectional study of Victorian allied health clinicians, using a snowball recruitment method. Ninety-seven eligible therapists completed the anonymous online survey. Data were analysed using frequency distributions.

Results: The majority of respondents were occupational therapists (n=60; 62%). Approximately half of the respondents (n=50; 52%) reported using FES in the past two years to improve a stroke survivor's ability to use their arm in daily activities. Respondents suggested that receiving workplace training from colleagues to learn how to use FES is the preferred method of education. Of those who received education (n=80), 50 participants reported using FES in their practice.

Conclusions: There is variable use of FES in stroke rehabilitation to increase active movement after stroke. While there was moderate agreement about when to use FES and useful education approaches for learning to use FES, further research is needed to better understand strategies which could be implemented to support increased FES use in stroke rehabilitation.

Key words: Occupational therapy, physical therapy, electrical stimulation, stroke, translational medical research

5.3.2 Manuscript.

Howlett, O., McKinstry, C., & Lannin, N. (2018b). The use of functional electrical stimulation by occupational therapists and physiotherapists: A quantitative survey. *Australian Occupational Therapy Journal*, 65(4). doi:10.1111/1440-1630.12482

Introduction.

Stroke is a leading cause of disability worldwide (Feigin et al., 2014). A common impairment following stroke is motor weakness that leads to a loss of functional movement (typically affecting control of the arm and leg of one side of the body) (Langhorne et al., 2009). Much of the focus of stroke rehabilitation, and in particular that of physiotherapists and occupational therapists, is on recovery of impaired movement and functional ability to move the arm and leg. Functional electrical stimulation (FES), defined as electrically stimulating weak muscles to enable functional based movements during activities for therapeutic purposes (Peckham & Knutson, 2005), is able to improve the movement of the arm and leg after stroke (Howlett et al., 2015) and improve performance of activities of daily living for participants in the first 2 months after stroke (Eraifej, Clark, France, Desando, & Moore, 2017).

Clinical practice guidelines recommend the use of electrical stimulation interventions (including FES) to improve upper limb recovery (Hebert et al., 2016; National Institute for Health and Care Excellence, 2013; Stroke Foundation, 2017a; Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010), or to improve walking (Hebert et al., 2016; National Institute for Health and Care Excellence, 2009; Stroke Foundation, 2017a) after stroke. Importantly, the recommendations made within each clinical practice guideline vary in strength (as per the Grading of Recommendations Assessment Development and Evaluation [GRADE] framework [Schunemann, Brozek, Guyatt, & Oxman, 2013]) and wording, which may lead to clinician uncertainty about if

they should use FES. For example the strength level of ‘weak recommendation’ was prescribed by the Australian Stroke Foundation (Stroke Foundation, 2017a), meaning that “the guideline panel is uncertain about the balance between desirable and undesirable effects” (para. 1), while the UK guidelines recommend FES use for lower limb training based on best available evidence as described by guideline authors (National Institute for Health and Care Excellence, 2009, 2013). Recent meta-analysis of clinical trials, however, shows clear benefit (Howlett et al., 2015).

Despite research evidence and recommendations in clinical guidelines supporting the use of FES in clinical practice, clinicians do not use electrical stimulation interventions routinely in stroke rehabilitation (Auchstaetter et al., 2016; Scottish Stroke Allied Health Professionals Forum, 2014). In Australia, a survey identified that occupational therapists infrequently used electric stimulation interventions (including FES) in stroke rehabilitation (Gustafsson & Yates, 2009). This survey was completed nearly a decade ago, and it is not known if the more recent increase in research evidence has changed clinician use of electrical stimulation. Unfortunately, the recent Australian National Stroke Audit (Stroke Foundation, 2016) did not report if FES (as defined by Peckham and Knutson [2005]) was used commonly with stroke survivors, therefore the implementation of FES into clinical practice is not known.

Implementing research into clinical practice is notoriously difficult (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012; Menon, Korner-Bitensky, Monika Kastner, McKibbin, & Straus, 2009). Providing a summary of research in a clinical practice guideline (Hurdowar et al., 2007; Scott et al., 2007) or a systematic review (Tricco, Straus, & Moher, 2011) does not ensure uptake of the evidence into clinical practice (LaRocca, Yost, Dobbins, Ciliska, & Butt, 2012). To understand the implementation of FES by Australian physiotherapists and occupational therapists, we need to first identify the degree to which the research evidence

of FES is being translated into practice (Graham et al., 2006) and whether a gap exists between evidence recommendations and clinical practice.

Previous studies on the use of electrical stimulation have either not been specific to FES (Gustafsson & Yates, 2009), or were conducted outside of the Australian rehabilitation context (Auchstaetter et al., 2016; Scottish Stroke Allied Health Professionals Forum, 2014), therefore a study investigating current Australian clinical practices was undertaken. The objectives of our study were to: (1) determine the use of FES with stroke survivors by Victorian occupational therapists and physiotherapists and (2) identify factors that may influence a clinician's use of FES, such as practice setting, geographical location, clinical experience, professional discipline or participation in FES education sessions.

Method.

A quantitative cross-sectional study design was used. A closed response, online survey was designed and developed specifically for this study.

Survey Development: To validate both the overall survey and individual survey questions, the survey was piloted with six clinicians through an iterative process of survey completion and cognitive interviewing. Full details of the designing and piloting of the survey is published elsewhere (Howlet et al., 2018a). The content of the survey included use of FES in clinical rehabilitation, professional discipline, location and type of clinical practice, and years of practice working with stroke survivors. Further information were collected regarding indications, expected outcomes and use of education/ training to support the use of FES in practice. A full copy of the survey is available as an appendix in the supplementary on-line file.

Data Collection.

Invited participants were occupational therapists and physiotherapists practising in Victoria, Australia. This sample of convenience was selected to be able to investigate the

influence of the geographical and practice setting within the Victorian health care system. Following ethical approval from La Trobe University (HREC approval number S16-99), occupational therapists and physiotherapists were recruited by post, email and social media. The postal addresses of health services were obtained from the Victorian Department of Human Services and the Australian Medical Association's web sites (Australian Medical Association., 2016; Victorian State Government., 2014a, 2014b). Postal invitations were then sent to 123 occupational therapy and 123 physiotherapy services at 38 public metropolitan, 30 public rural, 15 public regional, and 21 private health care providers. Email invitations were also sent to members of an Australian neurology listserv for occupational therapists and 395 therapists registered as members of the Australian Occupational Therapy Association Ltd, Victorian Division neurological special interest group. Additionally, members of the research team posted the survey link on Twitter™. The survey was administered using the Qualtrics™ online platform.

Data Analysis.

Descriptive statistics were used to analyse the data using frequency distribution in numbers and percentages for each variable.

Results.

One-hundred and thirteen therapists responded to the survey; three participants were excluded because they were not employed by a Victorian health service. A further 13 responses were excluded, because not all questions were answered. The majority of participants were occupational therapists and female (see Table 5. 3 for full details of participant characteristics). Most worked in a metropolitan, publicly funded hospital, and were experienced clinicians (mean of 7. 9 years of experience of working with people who had had a stroke with a range of 0. 5 to 44 years).

Table 5.3

Demographics (N = 97)

Characteristic	Response n (%)
Profession	
Occupational Therapist	60 (61.8)
Physiotherapist	35 (36.1)
Allied Health Assistant	2 (2.1)
Gender	
Female	83 (85.6)
Male	14 (14.4)
Geographical Area	
Metropolitan	60 (61.9)
Regional	25 (25.8)
Rural	12 (12.3)
Facility Type	
Acute public hospital (inpatient)	16 (16.5)
Acute private hospital (inpatient)	0 (0)
Inpatient public hospital rehabilitation	22 (22.7)
Inpatient private hospital rehabilitation	4 (4.1)
Home-based rehabilitation (public funded)	6 (6.2)
Home-based rehabilitation (private funded)	2 (2.1)
Centre or clinic based outpatient rehabilitation (public funded)	38 (39.2)
Centre or clinic based outpatient rehabilitation (private funded)	3 (3.0)
Other	6 (6.2)
Years working with stroke survivors	
< 2 years of experience	10 (10.3)
≥2 to 5 years of experience	31(32.0)
≥5 to 10 years of experience	32 (33.0)
≥10 years of experience	24 (24.7)

The use of FES by occupational therapists and physiotherapists.

Over half of the clinicians reported using FES in the past two years; with 40 being occupational therapists (see Table 5.3). Of those using FES recently, nearly all clinicians had used FES for upper limb training (n=47) while only 5 clinicians had used FES for lower limb training. The mean years of working with stroke survivors was of 6.4 with a range of 0.5 to 30 years. Most therapists used FES to train grasp and release (such as when picking up a cup, n=47), or reaching (such as when reaching for an item on a shelf, n=32), or dexterous activity (n=17), suggesting the therapeutic goal was to engage a client in task oriented therapy and then to increase activity. For those clinicians who used FES for lower limb training, the most common reason was to improve the activity of walking (n=5). There was limited use of FES overall to manage impairments of pain, spasticity or weakness.

Clinicians reported that they expect a variety of outcomes when they use FES as one component of their rehabilitation program (see Table 5.4). These expected outcomes differed for upper limb versus lower limb rehabilitation, however both focused on addressing functional limitations rather than managing impairment.

Table 5.4

Characteristics of FES Use in Those Respondents Who Have Used FES the Past Two Years (n=50)

Characteristic	Use of FES in past two years n (%)	FES to train grasp and release n (%)	FES to train reaching n (%)	FES to train dexterous activity n (%)	FES to train walking n (%)
FES use	50 (100)	47 (94)	32 (64)	17 (34)	5 (10)
Profession					
Occupational Therapists	40 (80)	40(80)	27 (54)	15 (30)	1(2)
Physiotherapist	8 (16)	5 (10)	4 (8)	2 (4)	4 (8)
Allied Health Assistant	2 (4)	2 (4)	1(2)	0 (0)	0 (0)
Geographical Area					
Metropolitan	33 (66)	35 (70)	26 (51)	12 (24)	1(2)
Regional	11 (22)	9 (18)	3 (6)	3 (6)	4 (8)
Rural	4 (8)	4 (8)	3 (6)	2 (4)	0 (0)
Facility Type					
Acute public hospital (inpatient)	11 (22)	11 (22)	9 (18)	7 (14)	0 (0)
Acute private hospital (inpatient)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Inpatient public hospital rehabilitation	15 (30)	14 (28)	9 (18)	1(2)	3 (6)
Inpatient private hospital rehabilitation	1(2)	1(2)	1 (2)	0 (0)	0 (0)
Home-based rehabilitation (public funded)	3 (6)	3 (6)	3 (6)	0 (0)	0 (0)
Home-based rehabilitation (private funded)	1 (2)	1(2)	1(2)	0 (0)	0 (0)
Centre or clinic based outpatient rehabilitation (public funded)	16 (32)	14 (28)	7 (14)	8 (16)	2 (4)
Centre or clinic based outpatient rehabilitation (private funded)	2 (4)	2 (4)	1(2)	1(2)	0 (0)
Other	1 (2)	1 (2)	1(2)	0 (0)	0 (0)
Years working with stroke survivors					
< 2 years of experience	4 (8)				
≥2 to 5 years of experience	19 (38)				
≥5 to 10 years of experience	19 (38)				
≥10 years of experience	8 (16)				

Table 5.5

Expected Outcome When Using FES on Daily Activities

Characteristic	Use of FES in past two years n (%)	FES to train grasp and release n (%)	FES to train reaching n (%)	FES to train dexterous activity n (%)	FES to train walking n (%)
FES use	50 (100)	47 (94)	32 (64)	17 (34)	5 (10)
Profession					
Occupational Therapists	40 (80)	40(80)	27 (54)	15 (30)	1(2)
Physiotherapist	8 (16)	5 (10)	4 (8)	2 (4)	4 (8)
Allied Health Assistant	2 (4)	2 (4)	1(2)	0 (0)	0 (0)
Geographical Area					
Metropolitan	33 (66)	35 (70)	26 (51)	12 (24)	1(2)
Regional	11 (22)	9 (18)	3 (6)	3 (6)	4 (8)
Rural	4 (8)	4 (8)	3 (6)	2 (4)	0 (0)
Facility Type					
Acute public hospital (inpatient)	11 (22)	11 (22)	9 (18)	7 (14)	0 (0)
Acute private hospital (inpatient)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Inpatient public hospital rehabilitation	15 (30)	14 (28)	9 (18)	1(2)	3 (6)
Inpatient private hospital rehabilitation	1(2)	1(2)	1 (2)	0 (0)	0 (0)
Home-based rehabilitation (public funded)	3 (6)	3 (6)	3 (6)	0 (0)	0 (0)
Home-based rehabilitation (private funded)	1 (2)	1(2)	1(2)	0 (0)	0 (0)
Centre or clinic based outpatient rehabilitation (public funded)	16 (32)	14 (28)	7 (14)	8 (16)	2 (4)
Centre or clinic based outpatient rehabilitation (private funded)	2 (4)	2 (4)	1(2)	1(2)	0 (0)
Other	1 (2)	1 (2)	1(2)	0 (0)	0 (0)
Years working with stroke survivors					
< 2 years of experience	4 (8)				
≥2 to 5 years of experience	19 (38)				
≥5 to 10 years of experience	19 (38)				
≥10 years of experience	8 (16)				

FES, functional electrical stimulation; UL, upper limb; LL, lower limb

Clinician education to use FES

Of the ninety-seven participants, eighty (82%) had undertaken some form of education to learn to use FES, with 51 being occupational therapists, 27 physiotherapists and two allied health assistants. Clinicians rated workplace training from a colleague as the most valuable form of education for learning how to use FES (n=37, 46%), followed by formal continuing professional development (n=29, 36%), then entry-level (undergraduate) training (n=8, 10%), post-graduate university training (n=2, 2.5%), and self-directed learning (n=1, 1%).

Discussion.

The main finding of this study is that FES is being used in stroke rehabilitation, particularly by occupational therapists. When choosing to use FES, clinicians expected that it would increase the amount of upper limb activity, as well as the quality of movement in both the lower and upper limb during daily activities. In contrast, the clinicians did not expect that using FES would enhance a stroke survivor's ability to participate in life roles (such as worker, student, volunteer, parent or friend) suggesting that clinicians perceive that improving role performance will take more than simply learning to move that limb again. These clinical expectations are consistent with the results of Howlett et al.'s (2015) systematic review, which demonstrated that activity outcomes are improved after FES training. The review was however unable to support or refute the expectation that FES will improve the outcomes of participation, because studies to date have failed to collect measurement data at that level. Further research is therefore needed to understand the relationship between activity performance and role participation.

The findings of the current study suggest proportionally higher use of FES in metropolitan and regional locations in comparison to Victorian rural settings. As specialized stroke rehabilitation units and rehabilitation centres are predominately located in

metropolitan and regional areas (Australian Institute of Health and Welfare, 2013a), higher rates of FES use in these areas may reflect more consistent implementation of stroke rehabilitation guidelines (Faux et al., 2009). The lower use of FES in rural locations may have arisen because of unique barriers attributable to geographical location. The survey did not, however, investigate what these geographical barriers might be. Graham et al. (2006) proposed that barriers can be overcome by examining the local context in which an intervention will be administered. Findings from the current survey suggest that a specific implementation study for the use of FES in rural Victoria may be required to increase adherence to FES clinical practice guidelines.

Respondents in the current study who had graduated less than 10 years earlier were more likely to use FES. The time since graduation has been reported elsewhere to influence the behaviour of translating research knowledge into practice (Bennett et al., 2003; Dysart & Tomlin, 2002; Zipoli & Kennedy, 2005). Zipoli and Kennedy (2005) suggested that if an intervention was not taught in under graduate training or not practised within the first year after graduation, the use of research knowledge in practice was less likely to occur. Some clinicians may not use FES because their graduate training did not include skills training in using FES. An alternate explanation may be that therapists “with 15 or more years of clinical experience did not believe that research conclusions usually translated into treatment plans for individuals” (Dysart and Tomlin, 2002 p. 275). As the evidence to support FES use has only recently been demonstrated in two systematic reviews with meta-analysis (Eraifej et al., 2017; Howlett et al., 2015), staff members with 15 or more years of experience may not be aware of the knowledge to support FES, therefore have yet to support the translation of this intervention into their work setting.

Belief in the efficacy of an intervention will also influence clinician likelihood of using that intervention. As clinicians gain clinical experience, if they have not observed the

intervention of FES to produce tangible outcomes, they may be less inclined to use FES for stroke rehabilitation. Reasons for not experiencing positive outcomes may include the intervention not demonstrating implementation fidelity (Carroll et al., 2007) or the treatment effects being estimated from the systematic reviews may be inflated due to small trial bias (Howlett et al., 2015) or the methodological biases of included trials (Eraifej et al., 2017). To better understand why there is variability in use of FES between different therapists, future implementation studies should explore the effect of clinician clinical experience and undergraduate training on FES use.

The current study findings suggest that attending FES training does not necessarily enable a clinician to use FES in practice. Our findings are consistent with a systematic review that investigated the knowledge translation of training of occupational therapists and physiotherapists (Menon et al., 2009) and found that the type of education may influence the intervention being used in practice. Menon et al. (2009) identified that training involving multiple learning methods, combined with an active learning approach, were preferable to individual activities involving only an educational component. Victorian therapists identified that they valued workplace training most of all, while the second most valued activity was attending continuing professional development. Therapists in our study, on average, participated in two educational activities. Although, knowledge translation was not reported for all participants, by providing preferred training in future implementation strategies, may be key to supporting the use of FES.

We acknowledge that the defined scope of our population was both a strength (a high response rate was achieved) and a limitation (with potentially reduced applicability outside of Victoria). In addition to the limitation of geographical location, the size and make-up of the sample across settings and professions may also limit the applicability of the results. In particular, there was low representation in the sample with only $n=35$

physiotherapists which may not be a true representation of Victorian physiotherapists practising in stroke rehabilitation. The findings relating to lower limb FES use also need to be carefully considered given this sample's limitation. Although the number of female and male participants reflect the Victorian gender rates for physiotherapy and occupational therapy (Australian Institute of Health and Welfare, 2013a), we are unable to identify if the sample accurately reflects the number of clinicians employed across geographical locations and settings relating to stroke rehabilitation in Victoria. While the use of FES in public and private rehabilitation settings was proportionally consistent with survey participation, it is acknowledged that there were low numbers of respondents from the private sector. Australian hospital statistics suggest that 52% of rehabilitation admissions for people with strokes occurs in the private sector (Australian Institute of Health and Welfare, 2013a), therefore the low participation of those from the private sector limits the conclusions which can be drawn from this study.

Clinical Implications.

While FES may enable a clinician to engage stroke survivors with muscle weakness in repetitive task specific training, our findings suggest there is a tendency for clinicians to use only a limited number of FES training methods. Using only FES to train grasp and release, for example, may restrict engagement in all upper limb activity performance, potentially reducing likelihood of a full recovery from stroke. Approximately half of the responding therapists reported using FES, so large proportion of clinicians did not. Therefore, there may be workplace or individual barriers currently limiting the implementation of FES clinical practice guidelines into practice. A variety of factors may exist which may or may not be unique to the context of the Victorian health care industry. For example, undergraduate training may focus on teaching the knowledge of FES to students, however, the opportunity to practice and observe the required skills may be

limited. Secondly, rural therapists may be implementing FES less frequent due to low numbers of clients presenting with the need to use FES. Lastly, the influence of a senior staff member's skills and knowledge may influence which interventions are used in particular settings. Further research is recommended to identify and understand the contextual factors, which influence the implementation of FES in the state of Victoria, Australia.

Findings from our study provide useful implementation recommendations. Firstly, clinicians should be encouraged to actively plan how resources can be appropriately used to overcome barriers faced (potentially geographical, setting or caseload specific). Secondly, if the implementation of FES guidelines occurs, health care providers should be encouraged to support workplace peer learning and attendance at professional development activities, because these were the preferred method of learning reported by participants in this study.

Research implications.

We identified that Victorian clinicians are using FES in practice although its use varies depending on the health care setting, geographical location, professional discipline, clinical experience and prior access to education. Future research needs to identify and understand the factors that enable and impede the use of FES in clinical practice. Due to the differences in uptake of FES use between occupational therapists and physiotherapists, identification of barriers and enablers relating to the use of FES in practice for each professional group is recommended. Although clinical guidelines encourage the use of FES, the study findings indicate that the intervention is not necessarily being widely practised.

The reasons for the non-implementation of the guidelines are not fully understood. Future research needs to focus on appropriate and effective translation of clinical guidelines recommendations into practice, to maximise the benefits of the intervention for those receiving stroke rehabilitation. If clinical guidelines are recommending the use of FES based

on clinical trials with robust study designs, the recommendations may be translated with increased confidence by clinicians.

Conclusions.

Victorian occupational therapists and physiotherapists are using FES as an intervention to improve a person's ability to complete activities following stroke. While FES is not yet a routine intervention, occupational therapists surveyed used FES more frequently than the physiotherapists. Participation in education to learn how to use FES did not appear to increase translation of research findings, which supports the efficacy of FES for increasing upper and lower limb use after stroke (Howlett et al., 2015). Future knowledge translation studies investigating the implementation of FES into practice are thus recommended.

Key points for occupational therapy.

- Occupational therapists are using FES for stroke rehabilitation.
- Limited FES training methods (e. g. FES to train grasp, reach or dexterity), may restrict rehabilitation of the upper limb.
- Occupational therapists participation in FES education did not always lead to translation of FES research into practice.

Chapter 6. Study Three

Understanding the Barriers Preventing the Use of Functional Electrical Stimulation in Stroke Rehabilitation: A Single Site Case Study

6.1 Introduction to Chapter

Chapter Six details the background, method, results and findings of study three, which investigates the research question: what do clinicians perceive to be the barriers to using FES in practice? The findings from study three will be synthesised with the findings from study one and two in Chapter Seven to describe the use of FES by occupational therapists and physiotherapists to improve the daily life of a stroke survivor.

6.2 Introduction

In stroke rehabilitation, Australian occupational therapists and physiotherapists use FES with people who have difficulties using their upper or lower limb in activities (Howlett et al., 2018b) to facilitate motor activity. The Australian Stroke Management Guidelines (Stroke Foundation, 2017a) recommend the use of FES as a stand-alone intervention to improve activity performance of the upper limb, or as an adjunct therapy to improve the speed of walking. Despite this, a recent survey found that only half of the responding stroke rehabilitation therapists used FES in their clinical practice (Howlett et al., 2018b). Education alone did not appear to be an enabler for FES use because most of this survey's respondents had received some form of professional development or graduate training relating to FES (Howlett et al., 2018b). A more probable explanation for the variation in uptake of this guideline recommendation, is the impact of contextual practice barriers that are faced by clinicians which limits their ability to provide therapy that adheres to clinical practice guideline recommendations (Graham et al., 2006).

Contextual practice barriers have been shown outside of stroke rehabilitation to reduce the uptake of evidence-based interventions (Handley et al., 2016; Glasziou, 2005). Earlier studies of FES motor training programs have suggested barriers to using FES in the clinical setting include: inadequate access to resources, including the lack of suitable FES devices in the clinical setting, the time required to learn to use FES, and therapist's factors such as lack of motivation and clinician frustration (Auchstaetter et al., 2016; Roche & Coote, 2007). To reduce the impact of these barriers, behaviour change strategies have been shown to create small to moderate changes in the practices of healthcare professionals (Baker et al., 2010; 2015) and have been suggested to improve the use of FES in practice (Auchstaetter et al., 2016; Roche & Coote, 2007). Strategies have included providing resources in a clinical setting, having loan equipment to stroke survivors to allow FES home practice, and access to suitable clinician training. Alone however, these are unlikely to change clinical behaviour across all clinical settings (Auchstaetter et al., 2016; Roche & Coote, 2007). With the previous research literature describing the barriers and enablers to FES use as reported from the experiences of physiotherapists in Canada (Auchstaetter et al., 2016) and Ireland (Roche & Coote, 2007), it is not known if the reported barriers and enablers for using FES remain consistent within an Australian rehabilitation context.

The following two research questions were therefore asked to further understand the barriers and enablers to using a FES stimulated motor training program in the clinical setting in Victoria, Australia.

- (a) What are the barriers to using FES in stroke rehabilitation by occupational therapists and physiotherapists?
- (b) What strategies are recommended to increase the use of FES in practice with people following stroke?

The study had two specific aims:

- Aim 1: To identify the barriers to using FES by occupational therapists and physiotherapists practising in a local context.
- Aim 2: To identify implementation strategies relevant to the local, regional context.

This single site case study reports on the strategies that may be used to assist a health service to identify barriers and enablers to intervention implementation in a regional health service, and demonstrates the development of an implementation plan to improve use of FES in the clinical setting.

6.3 Methods

The study aimed to identify barriers and behaviour change strategies which may enable the clinical use of a FES stimulated motor training program in practice, reflecting stage three and four of the action cycle of the Knowledge to Action Framework (Graham et al., 2006, see Figure 1.2, page five). To identify knowledge translation barriers, a qualitative study design following an inductive inquiry process, used focus groups to collect data (Braun & Clarke, 2006). Procedures from The Behaviour Change Wheel (Michie et al., 2014) were also followed to map the identified barriers to behaviour change strategies which aim to increase the use of FES in a local context (Michie et al., 2011; 2012).

A purposive sample (Palinkas et al., 2015) of occupational therapists and physiotherapists working at one health care service (across acute care, inpatient rehabilitation and community-based settings), were invited via email to participate. Invitees were encouraged to forward the email invitation to other occupational therapists and physiotherapists employed at the same health service who may have been interested in participating (i.e. snowball sampling).

A focus group with each specific discipline was conducted to capture the professional reasoning and processes specific to either occupational therapists or physiotherapists (Barbour, 2007; Liamputtong, 2011). Demographic data of participants were recorded at the commencement of each group, including the participant's age, gender, number of years working with people who have had a stroke, professional discipline and clinical setting within the health service. Due to the many interchangeable terms for electric stimulation interventions (Pomeroy et al., 2006), a definition of FES (Howlett et al. 2015; Peckham & Knutson, 2005), was provided at the start of each focus group to ensure that there was a common understanding of the FES terminology amongst participants. The focus group topic schedule was generated using the Focus Group Exemplar Questionnaire (Michie et al., 2014). Refer to Table 6.1 for the topic schedule. The Focus Group Exemplar Questionnaire has previously been mapped to the Theoretical Domains Framework, therefore, was likely to generate data which could be linked to behaviour change strategies (Miche et al., 2014).

Table 6.1

Focus Group Topic Schedule

TDF domain	Interview questions
Skills	What are the challenges to learning the practical skills of how to administer FES?
Knowledge	Is the available knowledge about FES relevant to applying FES in practice?
Memory, attention and decision processes	Is it difficult to remember how to use FES? Is it challenging to decide who you should administer FES to?
Behavioural regulation	Do you ever review clients to see if there were patients you did not do FES with; however they would have been suitable?
Environmental context and resources	To what extent does the physical environment or resources hinder the use of FES?
Social influences	To what extent do the behaviours of your colleagues hinder your use of FES in practice?
Social/professional role and identity	Is using FES in conflict with your identity as an occupational therapists or physiotherapists?
Beliefs and capabilities	How difficult or easy is it for you to use FES in your setting?
Optimism	Does your level of enthusiasm make it harder to use FES?
Beliefs about consequences	Do you not to use FES because you don't believe it works?
Intentions	Have you made an active decision that the use of FES is not required in your practice?
Goals	Does not having a goal of using FES stop you from learning or using FES?
Reinforcement	Are there incentives to use other interventions in your workplace?
Emotion	Do your emotions ever stop you from using FES?

Note. FES = Functional electrical stimulation.

The focus groups were conducted at La Trobe University, Bendigo, Australia. The same moderator (OH) and the note taker (CM) participated in each of the focus groups. Apart from the participants, no other people were present. The student researcher was the moderator and was known to all the participants. To reduce the impact of possible bias, given the participants and the primary moderator were work colleagues, the note taker (CM) also acted as a second moderator to encourage equal participation by all (Liamputtong, 2011).

The moderator aimed to be reflexive during the interview (Råheim et al., 2016), in being aware of his position of power created by his postgraduate research studies and being in working relationships with all participants. It was also recognised that the previous working relationships might add to the thickness of descriptions which were collected (Liamputtong, 2011). During the focus groups, the moderator used behavioural and interactive communication strategies such as intentional verbal prompting, intentional questioning and purposeful eye contact (Carey & Asbury, 2016; Liamputtong, 2011). The note taker recorded any pertinent information observed. The roles of both the moderator and note-taker was made known to the participants at the beginning of the focus groups, and both focus groups were audio-recorded using a digital recorder. No repeat interviews were conducted.

Digital data were stored in a La Trobe University password-protected file, which was accessed by only the student researcher and supervisors. All hard copies of data were stored in a locked storage cabinet in the office of the student's supervisor (room 203) in the Clinical Teaching Building at La Trobe University. After data analysis, all hard copy data were transferred to a digital medium, and the hard copy data were shredded. Digital data is stored for seven years in the La Trobe University's Library Research Data File Storage facility.

Data from the focus groups were transcribed verbatim by the student researcher (OH). All spoken words, sounds, hesitations, pauses, laughter and strong emphasis were recorded (Braun et al., 2014). Common patterns of meaning were identified by conducting a thematic analysis as described by Braun and Clarke (2006), rather than imposing predetermined coding onto the data. Before coding, transcriptions were read and listened to by two researchers (OH and CM) independently to ensure transcripts reflected both the spoken and unspoken words, and to become familiar with the data. The two researchers independently generated initial qualitative codes with potential themes identified during coding. Themes were reviewed, and then a consensus agreement reached before finalising the major and minor themes. A spreadsheet was used to categorise and sort codes into themes and subthemes. Refer to Appendix U for a copy of study three's codebook.

Following coding, the Behaviour Change Wheel (Michie et al., 2014) guided the mapping of tailored interventions from the themes generated by the two researchers (OH and CM). Refer to Appendix V for mapping of barriers to the Behaviour Change Wheel. If an agreement was not reached, the two researchers discussed differences and reached consensus. Once the agreement was reached, one researcher (OH) summarised the mapped categories to the contextual behavioural strategies of the Behaviour Change Wheel domains of opportunity, capability and motivation (Michie et al., 2011) into a table format. Both researchers were novices with using the Behaviour Change Wheel, therefore the case study format allowed for the learning of the Behaviour Change Wheel whilst using printed materials to inform the process (Michie et al., 2014).

Approval from the Bendigo Health (approval number LNR/16/BHCG/69) and La Trobe University (reference SHE CHESC acceptance of Bendigo Health HREC approved project – LNR/16/BHCG/69) ethics committees was obtained prior to commencement of participant recruitment and data collection. Refer to Appendices K, L, M and N for copies of

the Participant Information Statement (PIS), informed consent form, ethics approval and a copy of the email invitation to potential participants.

6.4 Results

Participants.

Each focus group consisted predominantly of females, with one male in each of the two groups. One group comprised six occupational therapists, while the other group had four physiotherapists. Each focus group was conducted separately. The mean number of years working with people diagnosed with a stroke of participants was 7 years, with a range of 0.5 to 20 years. The workplace settings where participants worked included acute care, inpatient rehabilitation and outpatient rehabilitation. Each focus group went for over one hour (mean 66.5minutes). No participants withdrew from the study after providing informed consent.

Identified barriers to using FES for stroke rehabilitation.

In total, seven themes emerged common to both the occupational therapists and physiotherapists working in the same health care service. These themes were: expertise/confidence, professional development, consumer factors, perception of being time poor, scope of practice, interdisciplinary collaboration and organisational factors. Each will now be discussed in turn.

Expertise/Confidence.

Low levels of FES knowledge and skills was evident limiting clinicians' confidence as illustrated in the comment below:

Confidence is a huge part, if you don't have confidence about the equipment, the setting, the parameters, the anatomy, there's a lot of variables which could then mean you're not being effective with your treatment. So you stick with what you know. (FG2, P1)

Likewise, one clinician described a lack of confidence specifically in the FES equipment

available, therefore reducing motivation to use the intervention stating, “.... and the new devices, just I couldn’t work out how to work them and I just revert back to the old ones” (FG2, P2) and “I didn’t show [name of colleague], you know, that this machine has this capability because I didn’t feel I could do it” (FG2, P2). These statements demonstrated how therapist confidence could influence the use of FES for stroke rehabilitation.

Challenges were identified relating to confidence in their professional reasoning, and knowing why and how they were using FES. One clinician described being hesitant about using FES stating, “that made me nervous when trying upper limb stuff as going through the anatomy again, figuring out what exactly what we are actually trying to achieve” (FG2, P3). When a clinician had limited understanding about why and how FES was being used, therapist confidence appeared low.

Limited confidence in using FES was disclosed when the participant’s knowledge of the research evidence had not been maintained, saying “I guess with the length of time since I have used FES to now, I would be wanting to see current evidence because the evidence I would have been aware of in the past has probably developed and changed” (FG1, P1). Another clinician said that “there’s not strong evidence behind it (*FES*)” (FG2, P3), thereby reducing this clinician’s confidence and likelihood to use the intervention as a standard practice. Awareness of research evidence was identified to influence how a clinician used FES in practice.

The work practices of clinicians in the health care setting influenced the choice to use FES. A clinician described the influence of a colleague’s intervention choices on using or not using FES, saying that due to a senior staff member not using FES in the workplace, it resulted in them being “.... a bit shy about using it” (FG2, P3). Another clinician stated:

I think you are um very much driven by what everyone else is doing as well, cause I know personally I haven't used it (FES) recently and I can almost guarantee if you guys were using it all the time, I'm sure I would push myself to get back into using it and working out how. (FG2, P4)

A clinician described how the established standard practice in their setting influenced their choice of what intervention techniques to administer, stating that "in the past we have been very sort of manual or hands-on, just focusing on trying to regain active movement through assisting the patient. I think that's influenced a lot of what I have done" (FG1, P6). The current work practices were described to influence the use of FES.

Clinicians talked about feeling uneasy when learning to administer FES. One therapist commented:

It would feel pretty, um, terrible in the sense it would look like, yeah not sure of how to get it, or you're taking a long time to do it. It would make... me feel as though I am looking as though I am not competent in administering this for the patient. (FG1, P6)

Another stated:

The thing is that it is very different to a lot of our OT interventions, that we typically do and I am no means a neuro expert, um, so for me I find probably it very overwhelming, in which there is a sense of anxiety of about where do I start. I personally don't like using it on myself? And that makes me anxious. (FG1, P5)

Themes emerging from the analysis of focus groups indicated that barriers caused by reduced confidence and expertise may decrease the likelihood that FES will be implemented in stroke rehabilitation.

Professional development.

Focus group participants from both professional disciplines identified that it was

challenging to acquire skills across multiple stroke rehabilitation techniques, with one clinician commenting “there are so many interventions you can choose as therapists and to be experts in them all is not practical” (FG1, P6). Clinicians identified difficulties to prioritise the up-skilling of various interventions in stroke rehabilitation.

There’s so many different interventions that we could be looking at, and that is just one of the ones that probably on my list which I would like to be able to um to learn more about and have that confidence in administering (FG1, P4).

Prioritisation, in amongst everything else we are trying to learn, so that, it’s the payout. So if I invest the time in this, how frequently am I going to use it? Versus some other techniques that might actually be used more frequently that I still need to learn as well (FG2, P1).

Due to the variety of intervention techniques, clinicians expressed difficulties in choosing which intervention to learn and to administer.

Clinicians identified that if the teaching of FES in professional development activities was not comprehensive, FES use in a practice setting was less likely stating, “it (FES) will get referred to in gait courses for example, but it’s usually just, that’s where it stops; it gets referred to” (FG2, P1). Participants noted that it was difficult to find and access professional development activities which related directly to their needs, with one person commenting that “to find external training is very difficult from a physio perspective. There is a lot more probably around for upper limb perspective rather than lower limb use. I’ve been looking but haven’t been able to find and attend training” (FG2, P2). A similar concern was expressed by another, stating that, “the stroke sort of therapy I have done is only ever been in the PD I have attended and there has been a minute amount of FES, so I just go straight to what I have been taught” (FG2, P1).

A specific sub-theme uniquely identified by the physiotherapy group in the study, highlighted the importance of the credibility of the educators who train clinicians to use FES, commenting that they did not appreciate "... being trained by a person who doesn't have the physio or OT knowledge background, so you are learning how to use a piece of equipment but you are not actually learning the clinical reasoning behind the actual use" (FG2, P1). In contrast, the credentials of the professional development facilitator were not highlighted as an issue for occupational therapists. Instead, the occupational therapists identified a desire to learn from others within their workplace setting. One occupational therapist stating that they needed "... someone else to guide me and show me. So more that hands-on learning" (FG1, P4). Another occupational therapist stated that "... when I was working in rehab prior, my supervisor there had completed formal like PD opportunities on the use of FES, um so I felt confident in administering that with her present" (FG1, P6). The availability of relevant professional development may influence how FES is established in a health care setting.

Consumer factors.

Clinicians identified that a stroke survivor's abilities influenced a clinician's choice of when to decide to use FES with a stroke survivor. For example, one clinician identified that the stroke survivor's physical characteristics might influence FES use.

If they've got the right sensation to be able to tell if it's working or not, um good skin integrity um no pacemaker or any of the contraindications, that's a big thing in when we're deciding who to use it on (FG2, P3).

Another clinician agreed with this comment stating, "I feel that they need to have good cognition and good sensation to be able to feel it and know what they are feeling and understand how to use the machine and everything" (FG2, P4). Both occupational therapists and physiotherapists were in agreement that not all stroke survivors should receive FES.

Clinicians identified examples of consumer characteristics which decreased therapist

confidence in implementing FES as an intervention. For example, one person stated that “sending someone home using it on their tib ant (tibialis anterior), and they came back and they’ve been using it on their perennials. So I don’t think I ever sent it home again” (FG2, P3). Another clinician described feeling anxious about having a FES device being used in home practice with a stroke survivor who may not have the capability to use FES at home without a clinician’s assistance, saying they do not have “the confidence in someone who argh they’re a bit sketchy in coming, and giving them an asset of ours to take home” (FG1, P4). Clinicians discussed a nervousness regarding how the stroke survivor may administer the FES when the clinician was not present, which could lead to underutilisation of FES as an intervention.

Perception of being time poor.

Clinicians in both focus groups discussed time availability as being a perceived barrier for using FES with clients. If time was perceived to be a barrier due to the time required to establish the use of FES into clinical practice, clinicians are less likely to select FES as an intervention, even though being time poor may not be the originating cause of lack of use. One clinician stated:

When you are feeling time poor with lots of pressures you sort of go with the path of least resistance...., it’s just easier to go with the flow than swim upstream with this. I know that there is evidence here but there is a lot of effort to get there. (FG1, P6)

Another clinician echoed the issue of a perceived lack of time:

Is the time it takes to set it up um outweighed by the amount of time your patients can use it, therefore the benefits, like is it worth spending your time for you to be using it for 20 minutes that you are getting. (FG2, P4)

Clinicians recounted that it takes significant amounts of time to learn to use an intervention

which is unfamiliar to them with one stating, “I know personally I am not very good at finding and working through evidence in a time-efficient manner” (FG1, P2). The perception of having limited time may influence how clinicians are motivated to learn and implement a FES stimulated motor training program in stroke rehabilitation.

Scope of practice.

A major theme identified through the inductive process (Braun & Clarke, 2006), described how professional role and identity influences the behaviour of using a FES stimulated motor training program. The traditional practice boundaries of occupational therapy and physiotherapy were described to influence the use of FES for upper or lower limb rehabilitation. Clinicians stated, “OT has always focused on the upper limb and um physio has always focused on the lower limb” (FG1, P6) or “the OTs tend to more focus on the upper limb whilst we (physiotherapists) are doing more of the gait and balance stuff” (FG2, P2). Another clinician stated, “in terms of PT/OT assessment, there is definitely blurred lines there on who does what in regards to the upper limb” (FG1, P6). These perceived discipline practice boundaries may reduce the comprehensive use of FES for stroke rehabilitation.

A clinician talked about how they were uncertain if their employer required them to participate in further training or if they are credentialed to use FES in clinical practice:

Do we need further training, like what is the protocol around that, and there isn't anything really anything to clearly say? Like, is your university degree is suffice to administer this, or do you need an external qualifications to be able to use this. You know, is working with a supervisor that who is trained, is enough? (FG1, P6).

The uncertainty described, appeared to influence if a FES stimulated motor training program was used in practice.

Interdisciplinary collaboration.

Therapists commented that it would be desirable to have nursing, physiotherapists, allied health assistants and occupational therapists all working collaboratively to administer FES effectively. One clinician described the benefits of having clinicians from other disciplines help in the administration of a FES stimulated motor training program stating, “we have an allied health assistant who’s done it before, um so having that familiarity and helping with increasing dosing” (FG1, P4) or “working with additional therapists might elevate just that extra support to that you are doing it together and educating together um is sometimes easier” (FG1, P5). Nurses were also identified by the participants as being key within the delivery of a FES facilitated program in acute settings, although there was uncertainty if that practice currently existed in that particular work setting. A clinician posed the question, “do nurses have an awareness of what the (FES) unit is?” (FG2, P3). Interdisciplinary collaboration was viewed as a desired feature of practice for administering FES in the inpatient rehabilitation context.

Organisational factors.

A theme evident in the analysed data from both focus groups, was the influence of organisational support for the provision of equipment, has on the use of FES by clinicians. Two clinicians commented on reasons why FES was not used in their own inpatient caseloads. One clinician stated: “no, because we don’t have the units” (FG1, P6), while another commented, “You don’t want to get too enthusiastic if you’re not going to be able to get a unit (*FES device*) either” (FG1, P1).

The built environment was identified solely by the occupational therapists as influencing the ease of administering FES, and it was apparent that different work settings have their own unique barriers. A clinician stated, “I think in outpatients, it’s sort of moderately difficult because we do have an open plan gym which has a lot of background noise I just, I wouldn’t try to do it in that environment” (FG1, P4). A clinician working in a hospital setting also identified that built environment barriers also impeded using FES, commenting, “....those tables (tables in the patients’ room) I tend not to like so much that we have at the moment just because they’ve got a bit of a lip and they cause some other issues for the patients as well” (FG1, P2). Such quotes suggest that clinicians may need to modify the built environment to promote and enable the use of FES in stroke rehabilitation.

The use of FES in a health setting is likely influenced by the number of stroke survivors seen in a clinical setting. A clinician expressed concern that “if we’re not seeing stroke patients on a daily basis um, and finding patients that are appropriate for this intervention, we could be going weeks ...” (FG1, P6). Another clinician said, “if you are only doing it on the rare occasion, you don’t have the confidence” (FG2, P1). If clients who would benefit from FES are not admitted frequently to the organisation, clinicians may not get an opportunity to increase their confidence and FES skill level.

Strategies to increase use of FES in stroke rehabilitation.

The Behaviour Change Wheel was successfully used to map potential solutions to the barriers identified during thematic coding. Refer to Table 6.2 for summary of the mapping of the Behaviour Change Wheel domains to identified barriers. Refer to Appendix U for complete coding of the mapping of barrier themes to the theoretical domains framework. The first enabler was training to address the barriers mapped to the domains of physical skills (for example, the physical capability to perform the intervention), psychological capability (such as, the ability to know why the intervention is being implemented), physical opportunities (for example, having available time to administer FES) and the motivations of the clinician delivering FES in clinical practice (such as, does the clinician believe the intervention will be of benefit). The second enabler was education to address the barriers attributable to psychological capability and motivations to use FES for stroke rehabilitation. Thirdly, modelling was recommended to influence the barriers attributable to social interactions (for example, actions and beliefs of colleagues which may discourage the use of FES). The fourth enabler was restructuring the environment to overcome the barriers related to environmental resources and context (such as having the appropriate equipment available in the clinical setting).

Table 6.2

Mapping the 'Barriers to Using FES' to the Theoretical Domains Framework and the Behaviour Change Wheel (Michie, Atkins, & West, 2014)

	Behaviour Change Wheel Domains										
	Capability				Opportunity			Motivation			
	Physical	Psychological			Social	Physical		Reflective		Auto	
	Domains of the Theoretical Domains Framework										
	Skills	Knowledge	Memory, Behavioural	Social	Environmental	Beliefs	Belief about	Social	Optimism	Goals	Emotions
			attention regulation and decision process	influences	context and resources	about capability	consequence	professional role and identity			
Barriers to using FES											
Expertise/confidence	•	•	•	•	•	•	•		•	•	•
Professional development	•	•			•		•			•	
Consumer factors					•	•					
Time	•	•	•			•	•	•			
Scope of practice									•		
Interdisciplinary collaboration					•				•		
Organisational factors					•	•					

Note. COM-B = capability, opportunity, motivation and behaviour

6.5 Discussion

This single-site case study found that contextual practice barriers, including expertise/confidence, professional development, consumer factors, perception of being time poor, scope of practice, interdisciplinary collaboration and organisational factors influenced use of FES by occupational therapists and physiotherapists. By addressing such barriers, and by using behaviour change strategies (Michie et al., 2014; Shaw et al., 2005) the use of FES in the local context may be increased.

Behaviour change strategies have been used to increase the uptake of evidence into practice (outside of FES evidence) as demonstrated in a systematic review of 32 randomised controlled trials (Barker et al., 2015). The included meta-analysis of 15 trials reported that tailored interventions could improve professional behaviours as compared to the provision of printed materials or placebo intervention. The four behaviour change strategies mapped to the identified barriers in this study, suggest that skills training, education, clinician modelling and environmental restructure may have an influence on the use of a FES stimulated motor training program in a local health care context.

Skill-based training can teach therapists how to deliver a FES stimulated motor training program in their practice, including the effective use of the equipment and how to modify the surrounding built environment. Skill-based training starts by determining the key intervention characteristics which would guide the replication of FES as described in the research evidence (implementation fidelity) (Carroll et al., 2007; Hoffmann et al., 2014; Michie et al., 2014; Toomey & Hardeman, 2017). When an intervention is implemented with fidelity, the treatment outcome is more likely to reflect the treatment effect described in the research literature (Durlak & DuPre, 2008; Hasson, 2010). When an intervention is not delivered with fidelity, it is not possible to accurately determine why the intervention was not effective (Breitenstein et al., 2010). Hoffmann et al. (2014) described five characteristics to

support replication: how to use the equipment which is required to administer the intervention (for example, type of FES device and which activities are to be used for task-based training); how to conduct the processes required to deliver the intervention (such as, the setting of FES parameters, electrode positioning and client education); how the intervention was delivered in therapy (for example, how to conduct a home exercise program or a clinician-led session); dosage of the intervention (such as, how to establish duration and frequency of sessions) and how to adapt the intervention to the individual (for example, consideration of muscle fatigue, weakness or spasticity). The characteristics of implementation fidelity would help determine the content of training, and also that of education activities.

Education activities would aim to increase clinicians' understanding of how to administer a FES stimulated motor training program (Michie et al., 2011). For example, educational activities could impart knowledge relating to the various FES device parameters, which muscles should be stimulated to achieve specific movements, what precautions and contraindications need to be considered, and what outcomes can be expected after using FES with stroke survivors. Educational mediums may include workshops, seminars, printed materials, lectures or a visitation from a person proficient in the use of FES (Cochrane Effective Practice and Organisation of Care Group, 2005). The provision of FES education is proposed to increase the knowledge required to implement FES confidently, effectively and efficiently.

Education activities have been shown to produce a small treatment effect on the patient and health professional behavioural outcomes (Forsetlund et al., 2009; Giguère et al., 2012; O'Brien et al., 2007). *How* FES education is delivered needs to be considered to maximise the benefits of an educational session. The findings of study two demonstrated the clinician's primary preference was not for the traditional educational formats of continuing

professional development workshops, university training or self-directed learning, but that they preferred experiential learning in the workplace from a colleague (Howlett et al., 2018b). Thus this preference for experiential learning suggests there is likely benefit from incorporating modelling within educational activities.

Modelling involves an individual changing their behaviour in response to observed behaviours of others (Grimshaw et al., 2012). Modelling is thought to overcome contextual practice barriers created by social influences (Michie et al., 2014). The strategy of modelling is proposed to reduce the barriers to using FES as related to professional development, consumer factors, interdisciplinary collaboration, and organisational factors. For example, clinicians described a mistrust of professional development training when it was perceived that the facilitator did not demonstrate the necessary knowledge, skills or credentials; therefore, the clinician was not likely to engage in developing the desired skill set. It would be beneficial for clinicians to observe other clinicians demonstrating competent FES use, and to have access to previously used protocols and case studies modelling the development and use of FES treatment regimens.

Methods of modelling will be summarised to demonstrate how modelling could be used to support the sustainability (Proctor et al., 2015) of FES use in the regional health service. A community of practice can create change from individuals learning from each other whilst developing a new skill (Ranmuthugala et al., 2011). For example, as a group, clinicians would meet regularly to learn how to administer FES together, providing encouragement and support as the implementation efforts proceed. Another method of modelling would involve a local opinion leader as a person who displays social influence due to the “individual’s technical competence, social accessibility, and conformity to the system’s norms” (Flodgren et al., 2012, p. 4). A local opinion leader would need to be identified to provide clinical FES leadership and be in workplace social relationships, which enables

others to use FES. Lastly, mentoring uses interpersonal relationships to influence behaviour change (Abdullah et al., 2014). For example, formalised structures for a novice learner to receive guidance from an individual who has established skills of using FES. Regardless of which method of modelling is used to create change, consideration will need to be given to how the practice change will occur in the local environmental context.

Restructuring the environment could reduce barriers limiting the ability of clinicians to use FES due to a lack of opportunity within the rehabilitation setting (Michie et al., 2014). For example, clinicians identified that a lack of organisational infrastructure to maintain equipment, led to the non-use of FES when faults occurred. Environmental restructure would identify how to provide the most appropriate equipment, storage and maintenance schedules. Environmental restructure has been used successfully in health care to improve the translation of research evidence into practice (Lydon et al., 2017; Munroe, Curtis, Buckley, Lewis, & Atkins, 2018; Flodgren, Rojas-Reyes, Cole, & Foxcroft, 2012). Knowledge translation models provide further support that the environmental context (including both the built and organisational environment) should be considered, to overcome contextual practice barriers (Sudsawad, 2007).

Multifaceted interventions.

This case study reports the need to implement multiple interventions to create practice change. The finding is consistent with the frequent use of multifaceted tailored interventions as reported in studies translating the research evidence into practice (Jones et al., 2015; Menon et al., 2009; Scott et al., 2012). Importantly, it may not be the number of intervention strategies that is influencing the behaviour change, because a dose relationship does not reportedly exist between the number of knowledge translation activities and the effectiveness of the implementation (Squires, Sullivan, Eccles, Worswick, and Grimshaw, 2014). Empirical evidence is emerging suggesting that implementation effectiveness is not improved simply by

using multifaceted interventions, but when the behaviour change strategies adhere to behaviour change theory (Davis, Campbell, Hildon, Hobbs, & Michie, 2015; Dombrowski et al., 2012; Gourlan et al., 2016; Taylor, Conner, and Lawton, 2012). For example, a systematic review of 26 experimental and quasi-experimental studies identified that workplace interventions resulted in increased physical activity (Taylor et al., 2012). Subsequent sub-group analysis indicated that theory-driven studies, were more likely to create change as compared to an approach not driven by theory. In consideration of the evidence investigating multifaceted tailored intervention strategies and behaviour change models, future FES implementation studies could explore the outcomes of multifaceted strategies as compared to implementation efforts adhering to a behaviour change model such as the Behaviour Change Wheel (Michie et al., 2014).

Research strengths and limitations.

The credibility and dependability of this single site case study have been enhanced by data triangulation (Creswell & Miller, 2000), purposive sampling (Palinkas et al., 2015), reporting using of a thick description (Shenton, 2004), the use of a validated tool to guide data collection (Cane et al., 2012) and a structured method to guide analysis (Braun & Clarke, 2006; Braun et al., 2014). These strategies have resulted in findings which are representative of the phenomena being investigated (Creswell 2014) in a local context. Limitations relating to the research study exist. Firstly, the transferability of findings as described by Hesse-Biber, (2010) is restricted due to triangulation being limited to the professional disciplines of occupational therapy and physiotherapy. Secondly, due to the limited number of focus groups conducted, thematic saturation was not determined (Ando, Cousins & Young, 2014), thereby reducing transparency regarding how themes are consistent amongst varying settings or participants (Vasileiou, Barnett, Thorpe, & Young, 2018). Thirdly, the interview transcript were not checked for accuracy through respondent validation (Birt, Scott, Cavers, Campbell & Walter, 2016) or reported through audit trees (Cope, 2014). Lastly, two researchers

checked transcription accuracy, however, there is uncertainty relating to whether the reported findings were overly influenced by the student researcher's position of power during the data collection (Ayrton, 2019). The findings and limitations of the case study design will have implications for clinicians and future research.

Clinical Implications.

The findings of the current study highlight the complexity of establishing FES use in a local health service context. Health care managers are encouraged to collaborate with clinicians to identify barriers in their health care service by revisiting policies, resources and support mechanisms to enable examination of contextual practice barriers. To overcome or reduce the impact of the barriers, a health service must take a solution-focused approach, increasing the likelihood that consumers will receive rehabilitation which may achieve outcomes consistent to those reported in the research literature.

Research implications.

Further investigation relating to the barriers to using a FES stimulated motor training program is needed. Future comparison of barriers identified in various geographical settings, including metropolitan, regional and rural locations would be beneficial to confirm if recommendations of implementation can be made across health care settings, or that each context has a unique set of barriers. A qualitative study using focus groups to collect data is recommended to establish data saturation through a formalised process such as code occurrence rates (Ando et al., 2014). The dependability of the thematic accuracy of future findings should be checked through the use of respondent validation (Birt et al., 2016).

The multifaceted tailored interventions identified in this study could be tested in an implementation study to identify if they do increase the use of FES in stroke rehabilitation

(Stroke Foundation, 2017a). A pragmatic uncontrolled before and after trial design would be appropriate to identify if the use of the Behaviour Change Wheel could identify barriers and enablers in a regional health service or in other health services; and if these barriers and enablers correlated to beneficial practice change (Eccles, Grimshaw, Campbell, & Ramsay, 2003).

6.6 Conclusion

Multiple barriers for using FES for stroke rehabilitation in a regional health service were identified, including the perception of clinicians being time poor, lacking expertise, and issues with scope of practice, interdisciplinary collaboration, organisational factors, consumer factors and professional development. To overcome these barriers in this local context, the use of contextual behaviour change strategies of training, modelling, education and environmental restructure is recommended. Future research is needed to examine if the identified contextual behaviour change strategies are effective in implementing longterm change in a regional health service to improve stroke rehabilitation by occupational therapists and physiotherapists using a FES stimulated motor training program.

Chapter 7. Discussion

7.1 Introduction to Chapter

After restating the research hypothesis, the findings of the three research studies are discussed and synthesised in this chapter, highlighting the similarities and differences to previous research. This chapter compares the thesis justification for the use of a FES stimulated motor training program in clinical practice and then the thesis findings are discussed as related to how FES can be used to change the daily life of a stroke survivor. The Knowledge to Action Framework is also used to synthesise and discuss a finding which spans all three thesis research studies. The chapter will conclude by describing the limitations and strengths of the multiple methods methodology described in the thesis.

7.2 The Research Hypothesis

The primary research question was: how do occupational therapists and physiotherapists use FES in stroke rehabilitation to improve the daily life of a stroke survivor? The research program's primary aim was investigated over three studies with the findings reported in Chapter Four, Five and Six. Each study addressed three exploratory research questions. The first question, is FES effective in improving daily life after stroke? The second question, is FES used in the clinical practice of occupational therapists and physiotherapists in Victoria, Australia? The third question, what are the barriers to using FES in practice for occupational therapists and physiotherapists? At the commencement of the research program the student researcher hypothesised that the answer to these questions would indicate that some occupational therapists and physiotherapists use FES for stroke rehabilitation to assist a stroke survivor in reengaging with their daily life, however barriers existed which made it difficult for clinicians to establish and maintain the use of the intervention in practice. The synthesised findings from the thesis' three studies support the initial hypothesis.

7.3 Comparison of Thesis Findings to the Research Evidence Justifying the Use of a Functional Electrical Stimulation Stimulated Motor Retraining Program

Two previous systematic reviews reported that a lower limb FES stimulated motor training program is beneficial for those people with stroke onset greater than six months (Pereira et al., 2012; Robbins et al., 2009). The meta-analysis in this thesis relating to FES for lower limb training included four trials whose participants had a stroke onset of fewer than six months and four trials whose stroke onset was greater than six months. The thesis' findings suggest that FES treatment effect for lower limb training is beneficial at all time points after stroke onset (Howlett et al., 2015), therefore adding to the existing knowledge base.

Similar to previous reviews (Pereira et al., 2012; Robbins et al., 2009), the findings from study one (Howlett et al., 2015) were not able to recommend how and when FES should be implemented because there was a lack of detail provided by the source trials. Although clinicians can use written descriptions relating to how FES has been implemented in Level II trials (for example Page et al., 2012), there is still limited guidance from Level I evidence regarding FES dosage, parameters or participant type. Since the Howlett et al. (2015) systematic review was conducted, further randomised controlled trials have been published which continue to provide data that may guide clinical decision making regarding parameters, dosage and when to commence a FES stimulated motor training program (Barker, Hayward, Carson, Lloyd, & Brauer, 2017; Carda et al., 2017; Cho, Kim, Chung, & Hwang, 2015; de Sousa, Harvey, Dorsch, Leung, & Harris, 2016; Dujovic et al., 2017; Hwang, Lee, Lee, & Lee, 2015; Jonsdottir et al., 2017; Knutson, Gunzler, Wilson, & Chae, 2016; Lee et al., 2018; McCabe, Monkiewicz, Holcomb, Pundik, & Daly, 2015; Park & Wang, 2017; Peri et al., 2016; Sheffler et al., 2015; Wilkinson, Burrridge, Strike, & Taylor, 2015). The 14 recent randomised controlled trials have led to further systematic reviews with meta-analysis (Eraifej, Clark, France, Desando and Moore, 2017; Hong et al., 2018 and Prenton, Hollands,

Kenny & Onmanee, 2018). To elaborate on the description of how FES is used, each of these reviews will be described and then compared with the systematic review (Howlett et al., 2015) included in Chapter Four of the thesis.

Of the recent systematic reviews, two have synthesised the findings from randomised controlled trials investigating a FES stimulated motor training program for lower limb training (Hong et al., 2018; Prenton et al., 2018). The most recent systematic review, including 17 randomised controlled trials with 1,239 participants, synthesised trials of electrostimulated lower limb motor training (Hong et al., 2018). Within the review, a sub group analysis of nine studies applying FES calculated a mean increase in gait speed by 0.05 m/s (95% CI 0.00 to 0.09; I^2 ; 54%). Further sub group analysis (Hong et al., 2018) demonstrated that treatment effectiveness improved when combined with another intervention, suggesting that a FES stimulated lower limb motor training may be more suited as an adjunct therapy rather than a standalone intervention (National Stroke Guidelines, 2017). Unlike Hong et al. (2018), the findings reported in study one of this thesis (Howlett et al., 2015) did not complete a sub group analysis on FES when combined with another intervention as compared to a standalone intervention.

A second recent systematic review (Prenton et al., 2018) included a meta-analysis of 7 randomised controlled trials involving 464 participants and compared the use of a lower limb FES stimulated motor training program with an ankle-foot orthosis. The findings identified that both the use of a FES stimulated motor training program and the use of an ankle-foot orthosis had an equal therapeutic effect on gait speed (MD 0.02 m/s, CI 0.03 to 0.06). There are now three systematic reviews with a meta-analysis which have demonstrated that although improvements can be gained using a FES stimulated motor training program, the minimal clinical threshold for gait speed was not reached (Hong et al., 2018; Howlett et al., 2015; Prenton et al., 2018). Taken together, findings from multiple systematic reviews suggest that lower limb FES may be best used as an adjunct therapy as described in stroke

rehabilitation guidelines (National Stroke Guidelines, 2017).

Consistent with the systematic review reported in study one (Howlett et al., 2015), the third recent systematic review (Eraifej et al., 2017) has reported the treatment effect of a FES stimulated motor training program after upper limb training. Eraifej et al. (2017) synthesised 20 randomised controlled trials with a meta-analysis of 10 trials, including 132 participants. Similar to Howlett et al. (2015) many of the outcomes (six out of eight) demonstrated a measure of hand use or reach using either the Upper Extremity Function Test, Action Research Arm Test or the Box and Block Test. In contrast to Howlett et al., Eraifej et al. included two activity measures into the analysis, which demonstrated activity performance with activities of daily living (Functional Independence Measure [Kidd et al., 1995]). Similar to the findings in study one of this thesis, Eraifej's et al. analysis predominantly described activity performance.

The primary finding from Eraifej's et al. (2017) systematic review differed from the findings of the systematic review conducted as part of this thesis (Howlett et al., 2015). The recent review concluded that a FES motor training program did not improve upper limb activity any more than a control intervention (SMD 0.64, 95% CI -0.02 to 1.30, $I^2=66\%$) (Eraifej et al., 2017). An explanation of the non significant heterogeneous findings may be the inclusion of measures that reflect self-care, rather than upper limb activity. Unlike the Eraifej et al. review, the findings reported in study one did not identify heterogeneity within the reported meta-analysis, potentially due to the inclusion of measures of only upper limb activity, providing increased confidence that the treatment effect reported in study one, is reflective of the true effect.

When the thesis investigation commenced, the Clinical Guidelines for Stroke Management 2010 (Stroke Foundation, 2010) supported the use of electrostimulation interventions as an adjunct intervention for upper limb rehabilitation (Level II evidence). A FES stimulated lower limb motor training program was not recommended. The most recent clinical practice guideline (Stroke Foundation, 2017) has changed that recommendation. Australian clinicians are now encouraged to use FES for lower limb training to improve the outcome of walking speed, and the use of FES for upper limb training is supported as a standalone intervention. The changing of recommendations in clinical guidelines highlights the importance of clinicians having the capacity and capability to change their practices readily. The methods used in this research program demonstrate that the Knowledge to Action Framework (Graham et al., 2006) and the Behaviour Change Wheel (Michie et al., 2011), are feasible methods to create a plan for practice change.

7.4 The Use of Functional Electrical Stimulation to Improve the Daily Life of a Stroke Survivor

The definition of daily life used in the thesis was informed by using the activity and participation domains of the International Classification of Functioning (World Health Organization, 2001). It has been reported elsewhere, that a stroke survivors' ability to participate in real-life activities is associated with limitations of walking and using upper limbs to move, carry and hold objects (Ezekiel et al., 2018). Participation in daily life is also influenced by factors such as a person's cognition, mood, and environment (Ezekiel et al., 2018; Mole & Demeyere, 2018; Tse et al., 2017). For example, for a person to brush their teeth in their bathroom, they will need to have the motor function to stand and manipulate objects in front of a mirror and will need to organise and sequence multiple activities while focusing attention and watching for accuracy (World Health Organisation, 2018). For a FES stimulated motor training program to benefit a stroke survivors' daily life, it is imperative

that we not only understand how FES improves activity but also if FES can integrate the use of these activities into real-life environmental or social contexts.

The thesis has established that a FES stimulated motor training program can impact daily life at the level of activity (Howlett et al., 2015). None of the published systematic reviews investigating a FES stimulated motor training program (Eraifej et al., 2017; Hong et al., 2018; Howlett et al., 2015; Peurala et al., 2006; Prenton et al., 2018; Robbins et al., 2009) reported an analysis including participation outcomes. The inability of the systematic reviews to report on participation outcomes were due to source trials seldom reporting on participation, potentially because measuring participation is complex, and no singular instrument would capture all the characteristics of participation (Geyh et al., 2004; Tse et al., 2013). While it is currently not known if FES can increase participation levels after stroke, future research could examine how activity outcomes achieved with FES can be linked to changes in participation.

Study two confirmed that some Victorian clinicians expect that FES will improve a strokes survivor's ability to perform activities and reported little expectation that the intervention would change a person's participation in life roles. This expectation may be linked to current clinician practices of FES use rather than the inability of a FES stimulated motor training program to influence participation. To recover participation in life roles, task-oriented interventions (such as FES) may need to cease focusing solely on task repetition, and ensure task practise is linked to participation goals (Engel-Yeger, Tse, Josman, Baum & Carey, 2018) while having adequate practise intensity (Lohse et al., 2014; Schneider et al., 2016). A recent randomised control trial demonstrated that both activity and participation outcomes after a lower limb FES stimulated motor training program, for 10 stroke survivors, was achievable (Wilkinson et al., 2015). The FES program included repetitive task practise directed by client participation goals, performance feedback and contextual task practise.

Similar programs have been conducted for upper limb training resulting in improved activity performance when the trial had high practise intensity (McCabe et al., 2015; Page et al., 2012); however, they lacked a measure of participation. A task-oriented motor learning framework (delivered in a FES stimulated motor training program) may be well-positioned to achieve changes in participation if the intervention is delivered to promote the generalisation of skill acquisition in the context of daily life (Shishov, Melzer, & Bar-Haim, 2017).

7.5 A Synthesised Finding from the Three Studies Investigating the Use of a FES Stimulated Motor Training Program

By ‘following a thread’ (Moran-Ellis et al., 2006), Section 7.5 will further enhance the understanding of how occupational therapists and physiotherapists use a FES stimulated motor training program to improve the daily life of a stroke survivor. A thread is a synthesised finding which is present across all studies in a multi-method research program (O’Cathain et al., 2010). The described thread commences by discussing relevant findings representing the knowledge creation stage of the Knowledge to Action Framework (Graham et al., 2006), and will cease by discussing findings representative of the action stage of the select, tailor and implement interventions stage of the Knowledge to Action Framework. Refer to Figure 7.1 for the Knowledge to Action Framework. The thread is informed from study one, two and three. The finding which is present in all three studies indicates that the use and justification of a FES stimulated motor training program varied dependent on which limb was to be trained. The synthesised finding will be described by comparing and contrasting the finding to earlier research evidence.

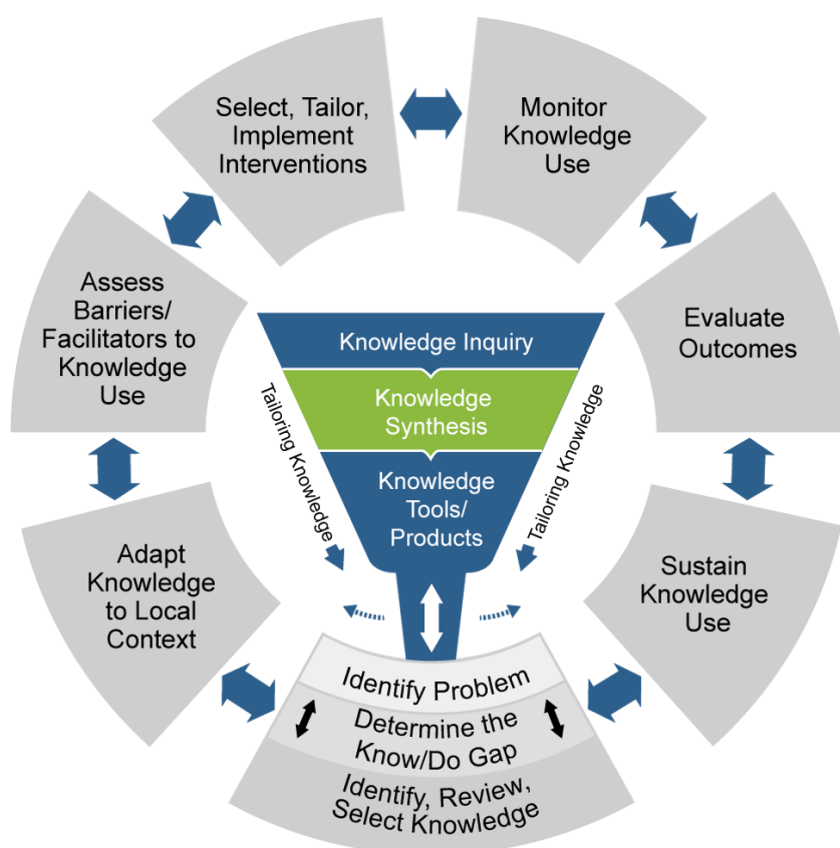


Figure 7.1. Knowledge to Action Cycle (Reprinted from *Knowledge translation in health care: moving from evidence to practice. 2nd ed* (p.10) by S.E Straus, J. Tetroe, & J. Graham, 2013, Oxford: BMJ Books. Copyright 2013 BMJ Books Wiley. Reprinted with permission).

Study one identified that an upper limb FES stimulated motor training program can create a moderate to large treatment effect for the outcome of activity (Howlett et al., 2015). Study one also identified that a positive treatment effect for activity outcomes after lower limb training was achievable (Howlett et al., 2015), even though the threshold for clinical significance was not reached (Chui et al., 2012). Different magnitudes of effect size were reported dependent on which limb was trained resulting in different recommendations for use. A FES stimulated motor training program for lower limb training has been recommended to be used as an adjunct therapy (Hong et al., 2018; Stroke Foundation, 2017), whereas, FES for upper limb motor training has been recommended as a standalone intervention (Stroke Foundation, 2017). The magnitude of treatment effect differs after lower and upper limb FES,

therefore it is plausible that the use and that the barriers to using FES are different dependent on which limb was trained.

The description of difference as related to findings about the use of a FES stimulated motor training program for upper versus lower limb FES, was also present in study two (Howlett et al., 2018b). Study two investigated the evidence to practice gap, which represents the extent that the research knowledge is implemented into practice (Lau et al., 2016). From study two, of the 50 (52%) clinicians who reported using FES in the previous two years, most clinicians used FES for upper limb motor retraining (98%), as compared to 10% of clinicians using FES for lower limb motor retraining. The only other study to have reported on the use of FES for both upper and lower limb training involved a Canadian cohort of physiotherapists (Auchstaetter et al., 2016). The findings from Auchstaetter and colleagues' study demonstrated that if FES was to be used by physiotherapists, there was a preference for using a FES stimulated motor training program for lower limb training. Study two (Howlett et al., 2018b) and the study by Auchstaetter et al., (2016) both identified that the use of FES varied depending on which limb is trained.

The description of difference as related to findings about upper versus lower limb FES, was also present in study three. This study was informed by the action stage of the Knowledge to Action Framework (assess barriers/facilitators to knowledge use) (Graham et al., 2006). Findings from study three supported the hypothesis that a clinician's professional identity influenced if they used FES for either upper or lower limb rehabilitation. Both physiotherapists and occupational therapists reported using FES for upper limb training, however, occupational therapists were identified to be more likely to use FES for upper limb training than their physiotherapy colleagues. Lower limb motor retraining was not considered to be a part of the occupational therapist's scope of practice, therefore occupational therapists did not report administering FES for lower limb motor training. The use of FES by occupational therapists for predominant upper limb training was also reported in the cross-

sectional data obtained in Victoria in 2016 (Howlett et al., 2018b). Findings demonstrated that only 1 out of the 40 occupational therapists used FES for lower limb training, whereas, all 40 of these occupational therapists used FES for upper limb training. Findings from study two and three demonstrate that the local context characteristics of a discipline's scope of practice, influences the use of a FES stimulated motor training program for both upper and lower limb rehabilitation.

Local contextual considerations will influence how a discipline delivers stroke rehabilitation, even though the disciplines of occupational therapy and physiotherapy have the capability to deliver similar motor retraining programs (De Wit et al., 2006). In 2005, a prospective observational cohort study identified that occupational therapists in the United States of America spent most of their time providing upper limb rehabilitation, whereas, in New Zealand, the physiotherapists predominantly provided upper limb therapy (McNaughton et al., 2007). Physiotherapists in both countries engaged stroke survivors in mobility activities, with occupational therapists engaging stroke survivors in these activities at a lesser rate (McNaughton et al., 2007). A similar study based in Europe identified that physiotherapists spent more time in gait retraining, while occupational therapists spent more time in retraining the upper limb (Horn et al., 2005). A similar pattern of stroke rehabilitation delivery was demonstrated in study two and three, indicating that the scope of a discipline (a contextual factor) influences who and how FES is delivered in the local context of a regional health service. These international studies (Horn et al., 2005; McNaughton et al., 2007; De Wit et al., 2006) highlight the importance of avoiding a one size fits all approach to implementation as intervention delivery will differ depending on the local context.

The discussion relating to the synthesised findings ends in stage four of the action domain of the Knowledge to Action Framework. This stage guides a health care service to consider how clinicians intend to change clinical practice towards the desirable behavioural

intervention (Graham et al., 2006). In study three, the seven barriers to implementing FES were mapped (Michie et al., 2011) to the contextual behavioural strategies of education, modelling, training and environmental restructure. The content of implementation strategies used for increasing the use of upper limb FES will be different to those used for increasing the use of a lower limb FES stimulated motor training. This is because the FES devices are different for both upper and lower limb training (Howlett et al., 2015) and different motor training activities are used for upper and lower limb motor training (Howlett et al., 2015; 2018b and study three). It will be necessary for the contextual behaviour change strategies to be delivered in a format appropriate for supporting the use of FES for either upper or lower limb motor training.

The synthesised findings from study one, two and three, highlights that the use of a FES stimulated motor training program varies dependent on the limb which requires training. Firstly, the magnitude of the effect is different for lower and upper limb training, leading to different recommendations for the use of FES for lower or upper limb rehabilitation. Secondly, a considerable variation of FES use was reported in a sample of Victorian rehabilitation clinicians, dependent on which limb was trained. Thirdly, local contextual factors in a regional health service influenced the choice to who uses FES for upper or lower limb training. Lastly, the limb to be trained will also need to be considered when delivering behaviour change strategies to improve the use of FES. The use of a FES stimulated motor training program varies depending on the research informing FES justification and the local contextual factors influencing clinical practice.

7.6 Research Strength and Limitations

The individual studies methodological rigour was described in Chapters Four (Howlett et al., 2015), Five (Howlett, McKinstry, & Lannin, 2018a, 2018) and Six. Section 7.6 will further report on the methodological rigour employed in the overall design and research methods.

7.6.1 Strengths and limitations of the multiple method approach.

The methodology of a multiple methods approach (Brewer & Hunt, 2015) was appropriate to understand how occupational therapists and physiotherapists can use FES to improve the daily life of the stroke survivor. Each study was designed to either explain or explore previous study findings (Creswell, 2014). The findings from individual studies were synthesised together using the theoretical Knowledge to Action Framework to identify a thread of meaning between all three data sets (Moran-Ellis et al., 2006). As demonstrated in this chapter, the multiple method approach gave rise to a common finding between all three individual studies.

A limitation of the multiple methods method used in the thesis was that data collected in the three studies were not integrated. The synthesis identified a thread of meaning between all three data sets (Brewer & Hunt, 2015; Moran-Ellis et al., 2006; Feters & Molina-Azorin, 2017; O’Cathain et al., 2010), which may be subject to author bias. An alternative method of data synthesis is integration. Data integration uses an analytical approach to understanding how the findings from individual studies relate and can be used to improve validity and credibility of overall findings (Maxwell, Chmiel & Rogers et al., 2015). An example of an integration method is the Triangulation Protocol (O’Cathain et al., 2010) which uses a coding matrix to identify similar and different findings across all three studies (Farmer, Robinson, Elliott, & Eyles, 2006). An integrative approach is recommended to improve the combined analysis of findings from all three studies.

7.6.2 Strengths and limitations of the study methods.

Study one.

A systematic review was an appropriate research method to identify and summarise the research evidence investigating the use of a FES stimulated motor training program. In knowledge translation research, a systematic review is a valuable tool to estimate a treatment effect and describe how an intervention should be implemented to maximise effectiveness (Mulrow, 1994). The systematic review reported in study one achieved these aims. The strength of the systematic review method used in study one was that the protocol was registered via PROSPERO (Howlett et al., 2012) to ensure that the data collection and analysis methods were transparent before administering (Ioannidis, 2016). Study one used Cochrane methodology to improve replicability and validity (Higgins & Green, 2011), for example, rules to explore treatment effect of continuous data and exploration of heterogeneity of results. The reporting of findings also adhered to the PRISMA reporting guidelines which facilitated the sharing of methods to achieve quality reporting of the systematic review findings (Moher et al., 2015).

A limitation of the systematic review method used in study one was that findings did not provide a recommendation for practice as guided by the quality of the evidence. The incorporation of a GRADE method into the systematic review would have generated a capacity of the review to state the level of confidence in the treatment effect and the strength of the evidence (Guyatt et al., 2008). The GRADE approach can achieve this by reporting the combined impact of heterogeneity, risk of bias, inconsistency, indirectness, imprecision and publication bias on the studies overall findings (Higgins & Green, 2011; Schünemann et al.,

2013). By reporting the strength of the recommendations, clinicians can report the risk and harms of the intervention to the health care consumer (Schünemann et al., 2013); and policymakers have a mechanism to identify the priority of resource allocation (Kothori & Wathen, 2017).

Study two.

The use of an online survey was an appropriate method to identify clinician's use of FES. The convenient sampling technique (De Vaus, 2013; Etikan, Musa & Alkassim, 2016) was appropriate to collect the viewpoints and opinions of participants across a large geographical setting; resulting in data representative of clinicians in numerous settings. To minimise measurement bias (Fricker, 2017; Presser et al., 2004), the use of the Tailored Design Survey Method ensured that the survey's questions, format, and structure collected data able to answer the research question (Dillman et al., 2014). To improve participant responsiveness (Snijkers et al., 2013), the FES Clinical Use Survey (Howlett et al., 2018c) was piloted and tested with a cognitive interview method (Drennan, 2003; Humann, Ridolfo, Virji, & Henneberger, 2013; Moore, 2009; Spark & Willis, 2014). Overall, the survey achieved the aim of obtaining the perspectives of clinicians who have delivered a FES stimulated motor training program in Victoria.

There are two predominant limitations in the use of an online survey method to understand the use of FES by clinicians in Victoria. Firstly, the discipline response rate was lower from physiotherapy as compared to occupational therapy, thus the findings may not be representative of the views of physiotherapists. In this way, the survey findings may have been influenced by coverage error, having a sample overly representative of occupational therapists introducing bias in the interpretation of findings (Fricker, 2017). Secondly, incomplete survey responses were excluded from our analyses, and so non-response bias may have also occurred in the final reporting of the survey (Rea & Parker, 2014). Thirdly, the

survey findings cannot justify that FES is or is not being implemented in a specific health service, because the specific local contextual barriers (Harvey & Kitson, 2015) were not investigated in the survey. To understand the extent FES is being implemented in a local context, an alternative research method would need to be chosen, such as an audit tool (Ivers et al., 2012; Janzen et al., 2016). Caution is recommended when interpreting the findings of the online survey due to potential sampling bias and limitations in how the findings can be generalised to a local context.

Study three.

The use of focus groups to collect data in study three was an appropriate research method to understand clinicians' perceptions relating to the barriers to using FES. A variety of perspectives relating to the phenomenon was collected by using a purposeful sampling technique (Barbour, 2010). The trustworthiness of data was enhanced using a topic schedule framework that had been validated to be used in studies investigating implementation barriers (Michie et al., 2014). The credibility of data was enhanced using inductive inquiry methods to generate patterns of meaning directly from the data (Braun et al., 2014; Braun & Clarke, 2006; Liamputtong, 2011). Specific methods were used in study three to enhance the credibility and trustworthiness of the study findings.

Social influence may have been a limitation to establishing credible themes from using focus groups to collect data in study three. Including the moderator, all participants were familiar with each other. There was potential that the group members might have altered their comments to meet social standards and to fit with the moderator's viewpoint (Barbour, 2010). The result may be a discourse which is not a true reflection of the phenomena, impacting coding, generation of themes and mapping to behaviour change strategies (Curtin & Fossey, 2007). To encourage a rich description from clinicians, data collection may be better suited to occur by individual interviews or by someone not situated in the social influence of the local context (Liamputtong, 2011).

7.7 Conclusion to Chapter

The discussion chapter has compared research literature to the thesis' findings which justify using a FES stimulated motor training program in clinical practice to improve the daily life of a stroke survivor. A synthesised finding was then described outlining how FES use may vary depending on which limb is to be trained. The reported synthesised finding indicates that contextual factors influence the implementation of FES and are potentially difficult to overcome, however, solutions are available. The chapter concluded by identifying the strengths and limits of the multiple methods method. The following chapter will now conclude the thesis relating to how physiotherapists and occupational therapists use a FES stimulated motor training program in their clinical practice to improve the daily life of a stroke survivor, by providing a summary of overall findings and a listing of recommendations.

Chapter 8. Conclusion

The conclusion chapter is presented in three parts. Beginning with a summary of the thesis research design and findings, then the implications of the research findings for stroke survivors, the clinician, health services and educators are outlined. The chapter concludes with recommendations for future research.

8.1 Summary of the Research

To deliver a FES stimulated motor training program, a clinician uses a portable device which delivers an electrical impulse to a paretic muscle, eliciting a muscle contraction (Peckham & Knutson, 2005). The physiological response and the quality of muscle contraction will be influenced by the device's electrical parameters (Binder-Macleod & Snyder-Mackler, 1993; Doucet, Lam, & Griffin, 2012). It is the electrically stimulated muscle contraction which determines the stroke survivor's ability to engage in a task-oriented motor training program (French et al., 2016; Levac, Missiuna, Wishart, DeMatteo & Wright, 2011; Shumway-Cook & Woollacott, 2007). A clinician will determine the type of activity to be used in training, modify the task progression to suit the person, determine the intensity of the training schedule and vary the feedback depending on need (Bowden et al., 2013; Kuitago & Krakauer, 2013; Schaefer et al., 2013; Schneider et al., 2016). By combining the capabilities of the electrical stimulation device with a task-oriented motor retraining program, a clinician can engage a stroke survivor in a FES stimulated motor training program where previously it may have been challenging to do so (Page et al., 2012). The described research program was undertaken to investigate how clinicians use a FES stimulated motor training program to improve the daily life of a stroke survivor.

This multiple methods research program was framed by the International Classification of Functioning (World Health Organization, 2001) and The Knowledge to Action Framework (Graham et al., 2006). The International Classification of Functioning

(World Health Organization, 2001) domains of activity and participation were used to determine outcomes relating to stroke survivors' daily life outcomes throughout the thesis. The International Classification of Functioning describes activity as a person's ability to perform singular tasks, and participation is described as how the person can integrate activities in real-life contexts (Salter et al., 2005b; 2005c; World Health Organization, 2001). The Knowledge to Action Framework (Graham et al., 2006) was used to structure the research program to enable the findings from the individual studies to be synthesised together to inform the thesis conclusions. Three studies were used to investigate how occupational therapists and physiotherapists use FES to improve the daily life of a stroke survivor.

The findings of the systematic review with meta-analysis conducted in study one indicated that there is evidence to justify the use of a FES stimulated motor training program to support a stroke survivor recover the use of their arm or leg in motor activities. The systematic review included 18 controlled trials. The findings demonstrated that FES could moderately improve activity outcomes, as compared to a control group of the same task-oriented therapy without stimulation by a FES device (SMD 0.40, 95% CI 0.09 to 0.72). The systematic review findings also demonstrated that a FES stimulated motor training program can have a moderate treatment effect when compared to a control group of placebo or no training (SMD 0.56, 95% CI 0.29 to 0.92). When sub group analyses were conducted, activity outcomes were increased after upper limb training with FES (SMD 0.69, 95% CI 0.33 to 1.05) and after lower limb training with FES (MD 0.08, 95% CI 0.02 to 0.15). The review was unable to refute or support the use of FES to improve participation outcomes, therefore there is still uncertainty as to the extent FES can assist the stroke survivor in reengaging in their daily life.

In study two, some occupational therapists and physiotherapists were using FES in

stroke rehabilitation. Of the 97 Victorian clinicians who responded to the online survey (physiotherapists [n= 35], occupational therapists [n=60] or allied health assistants, [n=2]), 52% (n=50) reported using FES. Clinicians reported that they used FES predominantly to engage a stroke survivor in training grasp and release of an object (94%, n=47), in the training of reaching (63%, n=32), to train dexterous activity (34%, n=17) and to retrain walking (10%, n=5). When clinicians reported using FES for upper limb training, many clinicians indicated that a stroke survivor would be able to use their weak upper limb in more daily activities (74.5%, n=38). Similarly, clinicians agreed that the quality of limb movement improved after lower limb FES training (100%, n=5) or upper limb FES training (68.6 %, n=35). The use of FES varied depending on professional discipline, geographical region, years of clinical experience and the type of funding for the service; highlighting an evidence to practice gap for using FES in stroke rehabilitation which may be influenced by contextual factors.

The findings of study three confirmed the existence of barriers in a local context, influencing how clinicians in that context used FES in stroke rehabilitation. Qualitative data were collected from 10 clinicians via focus groups (six occupational therapists and four physiotherapists). After thematic analysis using an inductive inquiry method (Braun & Clarke, 2006), seven themes described barriers to using and implementing FES in clinical practice. The themes were: (a) expertise/confidence, (b) professional development, (c) consumer factors, (d) perceptions of being time poor, (e) scope of practice, (f) interdisciplinary collaboration, and (g) organisational factors. The seven themes were relevant to the disciplines of occupational therapy and physiotherapy. The four contextual behaviour change strategies of education, training, modelling and environmental restructure may improve the use and sustaining of a FES stimulated motor training program in stroke rehabilitation, in the context of the regional health care service. Study three confirmed that

contextual factors do appear to influence how FES is used by occupational therapists and physiotherapists in a local context, highlighting that the use of FES is not determined solely by the availability of evidence demonstrating effectiveness.

The synthesised research findings support the use of FES to improve activity outcomes for people after stroke, although contextual factors such as the scope of practice, will determine how the research knowledge is applied, established and maintained in practice. Contextual factors that create barriers to using FES can be potentially modified or minimised. In summary, clinician use of a FES stimulated motor training program, is influenced by both contextual factors and the evidence.

8.2 Implications of Research Findings

8.2.1 Implication for the stroke survivor.

The research findings outlined in this thesis have demonstrated that FES can enable recovery after stroke, however, that FES is not consistently used in Victorian health care settings. Stroke survivors may not have the opportunity to receive a FES stimulated motor training program due to contextual practice barriers. Strategies are required to facilitate stroke survivor awareness of how a FES stimulated motor training program may be beneficial for them, even when the intervention is not being used in that practice setting. Providing a FES specific patient decision aid may increase stroke survivors' awareness of their suitability to participate in a FES stimulated motor training program (O'Connor et al., 2004). Decision aids support stroke survivor choice by describing the resources needed, outlining benefits and harm while being in a format that can be understood by a lay person (Schunemann et al., 2013; Stacey et al., 2017). To enable stroke survivor access to a FES stimulated motor training program, the decision aid may need to be made available through existing educational platforms such as the Stroke Foundation Enable Me website (Stroke Foundation, 2018) or in a mobile phone application such as ViaTherapy (ViaTherapy, 2018). By

increasing stroke survivors' awareness of the benefits of a FES stimulated motor training program, the stroke survivor may influence how and if a clinician delivers a FES stimulated motor training program in practice.

8.2.2 Implication for the clinician.

The use of FES may be enhanced by clinicians identifying and overcoming the barriers relevant to their local practice setting (Barker et al., 2015; Graham et al., 2006; Harvey & Kitson, 2015). It is recommended that clinicians be active in identifying and addressing contextual practice barriers by using knowledge translation templates. The Theoretical Domains Framework Exemplar Questionnaire could guide the identification of contextual barriers impeding FES use (Cane et al., 2012). The use of the behaviour change mapping technique as described by the Behaviour Change Wheel (Michie et al., 2011) may guide clinicians to establish contextual behaviour change strategies (Barker et al., 2015) to improve how FES is used in practice. Clinicians wanting to use a FES stimulated motor training program can be equipped to overcome the negative contextual factors influencing their practices.

Additional consideration of the intervention's behaviour characteristics will be required to ensure the implemented intervention reflects a FES stimulated motor training program as recommended in clinical guidelines or a knowledge synthesis study (Graham et al., 2006). It is recommended that clinicians are not only skilled at identifying the treatment effect of an intervention as reported in the research literature, but also in identifying the characteristics of an intervention as described in the research literature (Carroll et al., 2007). Behaviour characteristics include the frequency of intervention application, what needs to be done to administer the intervention, when the intervention needs to happen, who needs to do the intervention and how the intervention has been modified (Hoffmann et al., 2014; Miche et al., 2011). To support the implementation of research evidence into clinical practice,

clinicians will need to understand the intervention as described by the research evidence.

8.2.3 Implication for health care organisations.

Overcoming contextual practice barriers is not the sole responsibility of individual clinicians working in stroke rehabilitation but also the responsibility of the organisation in which FES is administered (William, Perillo and Brown, 2015). Organisational policy, procedure and leadership can nurture the health care environment to support the implementation and sustaining of interventions which have been justified by research evidence (Barnes, Bullock and Warren, 2018; Cummings, Estabrooks, Midodzi, Wallin & Hayduk, 2007; Helfrich, Sharp & Sales, 2009; Novak and McIntyre, 2010), such as a FES stimulated motor training program. A professional development policy could outline and reinforce the need for a knowledge translation plan after attendance at professional development activities (Straus et al., 2011b). Quality assurance procedures may include a measure of knowledge translation to demonstrate how the uptake of evidence is being actioned and sustained (Lewis et al., 2015; Proctor et al., 2015; Tricco et al., 2016). Leadership can be provided to establish staffing and resources to enable allied health clinicians to identify when and how to implement research evidence (Bornbaum, Kornas, Peirson, & Rosella, 2015). By a health service providing organisational policy, procedures, and leadership to support knowledge translation actively, the aim would be to reduce the influence of contextual barriers to facilitate practices supported by research evidence.

8.2.3 Implication for educators.

The thesis has reported that it is recommended that clinicians receive education and training reflective of the research evidence. Educational workshops have been a traditional method of improving evidence-based practices of allied health professionals (Novak & McIntyre, 2010). Considering educational workshops have a small effect size to translate effective uptake of evidence-based interventions (Forsetlund et al., 2009; Giguère et al.,

2012; O'Brien et al., 2007), educational workshops may benefit from being delivered through a knowledge translation framework (Damschroder et al., 2019; Graham et al., 2006; Harvey & Kitson, 2015; Michie et al., 2011). In addition to educators teaching clinicians the skills and knowledge required to use FES, further consideration is recommended to equip clinicians during education sessions to identify and address the contextual factors impeding the learner to establish a FES stimulated motor training program to improve outcomes for stroke survivors.

8.3 Recommendations for Future Research

Findings from this program of studies confirms the initial hypothesis, that while some occupational therapists and physiotherapists are using FES in stroke rehabilitation to improve the daily life of a stroke survivor, local contextual barriers may influence FES use and uptake (as demonstrated in a regional health care context). To build upon the findings reported in the thesis, recommendations for future research are now outlined.

8.3.1 Recommendation one.

It is recommended that further research investigate the effectiveness of a FES stimulated motor training program on participation outcomes. Little is known about the impact FES can have on improving the ability of a stroke survivor to use their arm or leg in real-life activities (participation). To understand the impact of FES on participation outcomes, randomised controlled trials are recommended to include measures of participation as the primary outcome. Examples include an outcome measure demonstrating occupational performance as quantified by the Canadian Occupational Performance Measure (Martini & Polatajko, 1998), the Performance Quality Rating Scale (Yang, Lin, Lee, & Chang, 2017), or a hand and arm use outcome as measured by the Motor Activity Log (Uswatte, Taub, Morris, Vignolo, & McCulloch, 2005). The accumulated findings from multiple well-designed randomised

controlled trials, including measures of participation, could result in an international consensus relating to how participation can be enabled and measured. This may provide guidance regarding how a FES stimulated motor training program can improve the daily life of a stroke survivor.

8.3.2 Recommendation two.

Once sufficient numbers of randomised controlled trials that include participation outcomes are reported, future systematic reviews (Garner et al., 2016) should update the treatment effectiveness of FES while providing a complete description of the use of FES to restore daily life activities, as described by the International Classification of Functioning (World Health Organization, 2001). An updated review should retain the analysis of trials demonstrating activity limitations (e.g. picking up an object), but also expand to include an analysis of participation restrictions (e.g. shopping for groceries at the local supermarket) (Salter et al., 2005a; 2005b). If a meta-regression analysis (Higgins & Green, 2011) can be completed, it could identify if outcomes are dependent on FES treatment intensity, FES parameters, stroke severity, or time after stroke. A future updated systematic review would have the intention of revising the treatment effect of a FES stimulated motor training program and to provide further guidance relating to how and when clinicians should administer the intervention.

8.3.3 Recommendation three.

It is recommended that further research investigate the effectiveness of contextual behaviour change strategies to improve clinician use of a FES stimulated motor training program in practice. The effectiveness of the contextual behaviour change strategies of training, education, environmental restructure and modelling for creating practice change in a local context, is unknown. It was reported in Chapter Six, that the contextual behaviour change strategies which were recommended for the regional health service, need to be tested

in a before and after trial to establish if they do influence how clinicians use a FES stimulated motor training program to improve the daily life of a stroke survivor. If the trial was feasible and favourable outcomes were demonstrated, it may be beneficial to increase understanding of the cause and effect of contextual behaviour change strategies on the use of FES in a randomised, clustered control trial (Hemming, Eldridge, Forbes, Weijer, & Taljaard, 2017; Rebbeck, Maher, & Refshauge, 2006). An experimental study could identify if a formalised method of knowledge translation (as used in this thesis) is more effective than a non-formalised method of knowledge translation (as often occurs in standard practice). The findings from an experimental trial will identify if a knowledge translation process is effective for improving the use of a FES stimulated motor training program when guided by a formal method of behaviour change.

8.3.4 Recommendation four.

It is recommended that future research investigate stroke survivors' experience in engaging in a FES stimulated motor training program. The Knowledge to Action Framework (Graham et al., 2006) describes the need to understand the barriers to implementation prior to facilitating the use of an intervention in practice. None of the studies conducted in this thesis investigated the barriers to FES implementation from a stroke survivor's perspective. Neither has prior research extensively reported on the stroke survivors' experiences and perceptions of the value of using a FES stimulated motor training program (Hayward et al., 2015; Hughes et al., 2011). As a result, it is not known if there are unique barriers to using a FES stimulated motor training program which is only experienced by the stroke survivor. In identifying these barriers, behaviour change strategies could be formulated to improve the delivery of a FES stimulated motor training program. Data collection could occur by individual interviews (Jamshed, 2014) followed by thematic analysis (Braun & Clarke, 2006). Themes could then be mapped to enablement strategies as guided by the Behaviour Change Wheel (Michie et al., 2014). The findings from a qualitative study investigating the stroke survivor's experience of

using a FES stimulated motor training program, could inform the delivery of a FES stimulated motor training program which is designed to meet the needs of a stroke survivor, while providing an intervention which can help drive recovery.

8.4 Conclusion

It is the responsibility of health professionals to be aware of and to understand the evidence which guides their clinical practice and to effectively and efficiently use evidence-based interventions in their practice context. Occupational therapists and physiotherapists' use of a FES stimulated motor training program to improve the daily life of a stroke survivor is supported by research evidence, however, the use of a FES stimulated motor training program in a local context is influenced by contextual practice barriers. Opportunities exist for clinicians to use formal knowledge translation models to potentially improve the use of a FES stimulated motor training program, thereby reducing the limitations of stroke survivors to increase participation in their daily lives. To conclude "knowledge derived from research and experience may be of little value unless it is put into practice" (World Health Organisation, p. 5, 2015).

Appendix A1

Study One - Protocol

A systematic review of functional electrical stimulation to improve activity and participation
after stroke

Owen Howlett, Natasha Lannin, Louise Ada, Carol McKinstry

Citation

Owen Howlett, Natasha Lannin, Louise Ada, Carol McKinstry. A systematic review of functional electrical stimulation to improve activity and participation after stroke. PROSPERO 2012 CRD42012003054 Available from:
http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42012003054

Review question

Does functional electrical stimulation improve activity and participation after stroke?

Searches

Six electronic databases will be searched with pre-determined search terms. Data bases will be the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (Ovid), CINAHL (EBESCO), EMBASE (Ovid), the Physiotherapy Evidence Database (PEDRO), and Occupational Therapy Systematic Evaluation of Effectiveness database (OTseeker).

Reference list of eligible studies, will be examined to identify potential studies that were not identified through the initial search process. There will be no language restrictions.

Search strategy

http://www.crd.york.ac.uk/PROSPEROFILES/3054_STRATEGY_20120907.pdf

Types of study to be included

This review will include randomised controlled trials and quasi randomised controlled trials.

Condition or domain being studied

Survivors of stroke.

Participants/population

Population will include adults of age 18 plus. Only human subjects will be included. 80% of participants in studies will have had a stroke, and the remaining 20% of participants will have a stroke like condition.

Intervention(s), exposure(s)

The intervention of interest is functional electrical stimulation. Functional electrical stimulation for this review is defined as electrical stimulation that is applied during a task to improve the performance of that task.

Criteria established to define functional electric stimulation for this review:

- The stimulator must be external to the body with electrodes placed onto the skin.
- The stimulation must produce a muscle contraction that causes movement to either upper or lower limb
- Subject will have active involvement with a therapeutic task whilst device is activated.
- The intervention must include the practice of task or activities (eg, walking, standing up, reaching for or the manipulation of items) for the majority of the intervention rather than the practice of isolated movements.

Studies that use a mix of interventions within the study design will be allowed, however, functional electrical stimulation must be the primary therapeutic intervention. Studies will be excluded if the functional electrical stimulation is used only as an orthosis.

Comparator(s)/control

Studies will be included if the intervention group is compared with another group such as placebo, usual care or an alternative therapy. Studies will not be included if the comparison group is predominantly another functional electrical stimulation based protocol.

Context

Main outcome(s)

Primary outcomes will be measures that reflect the domains of activity or participation of the international classification of functioning.

Additional outcome(s)

None

Data extraction (selection and coding)

1. Author will screen eligibility based on title and abstract using predetermined criteria. All obviously ineligible studies will be immediately excluded. For all the remaining studies, full text, will be retrieved. Reports regarding the same study will be linked together to ensure that the data from that study, will only be included once in review and analysis.

2. Authors will then review eligibility of these full texts. Authors of studies may be contacted to collect any relevant missing data or clarify details of the study to ensure inclusion of study. If a disagreement regarding inclusion of a study into the review occurs, this will be resolved by the two authors reviewing eligibility, to discuss the issue. If not resolved, a third party will be involved in the discussion. If still not resolved, the author of the study in question will be contacted in an attempt to resolve disagreement. If still not resolved, the disagreement will be noted in the review. Authors reviewing inclusion criteria will not be masked to the study details, i.e. author, data or institution.

Data Extraction will be carried out by two review authors independently. Data will be collected from the eligible studies by using a predetermined data collection form and risk of bias tool. This data extraction form will record information regarding study, participants, interventions, outcome measures, continuous and dichotomous data, missing data that requires follow up and miscellaneous data of importance to this review such as funding sources.

Risk of bias (quality) assessment

One author will assess the risk of bias of each study, using the PEDro scale scores from the physiotherapy Evidence Database (www.pedro.org.au). If no score is available, the scale score will be calculated by two people independently. If disagreement occurs, discussion will occur to reach agreement. All studies that meet the eligibility criteria, irrespective of level of quality, will be included into this review. However, only studies determined to be of quality of a PEDro score greater than 4, will be eligible to be included in the meta-analysis.

Strategy for data synthesis

Data will be entered into REVMAN software.

Treatment effect for continuous data will be calculated using one of two methods.

1. If the same outcome measures are used, we will calculate mean difference and 95% CI.
2. If different outcome measures are used, we will calculate standardised mean difference and 95% CI.

Treatment effect for dichotomous data will be calculated using risk difference and 95% CI.

Heterogeneity will be examined by visual inspection of forest plot, Chi-squared test and I-squared statistic.

Sensitivity analysis will occur after the initial meta-analyses are completed. If more than 10 studies are included in the meta-analysis, a funnel plot test will occur to determine if small studies had an effect on the overall outcome.

Analysis of subgroups or subsets

Sub group analysis may occur on following groups if sufficient data available:

1. Upper limb as compared to lower limb outcomes.
2. Number of days after stroke.
3. Number of muscles stimulated by the functional electrical stimulation.

Contact details for further information

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Review team members and their organisational affiliations

PROSPERO
International prospective register of systematic reviews

Mr Owen Howlett. Latrobe University and Bendigo Health
Dr Natasha Lannin. Latrobe University and Alfred Health
Dr Louise Ada. University of Sydney
Dr Carol McKinstry. Latrobe University

Anticipated or actual start date

08 October 2012

Anticipated completion date

08 October 2013

Funding sources/sponsors

None

Conflicts of interest

None known

Language

English

Country

Australia

Stage of review

Review_Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Electric Stimulation Therapy; Gait Disorders, Neurologic; Humans; Stroke; Walking

Date of registration in PROSPERO

10 October 2012

Date of publication of this version

10 October 2012

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions

10 October 2012

PROSPERO

This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

Appendix A2

Study One - Search Strategy

CINAHL (EBSCO)

- S1 (MH "Stroke")
- S2 (MH "Cerebrovascular Disorders")
- S3 (MH "Hemorrhage") OR (MH "Intracranial Hemorrhage") OR (MH "Cerebral Hemorrhage") OR (MH "Subarachnoid Hemorrhage")
- S4 (MH "Infarction")
- S5 (MH "Cerebral Ischemia")
- S6 TX(stroke or cva or tia or post stroke or poststroke or post-stroke)
- S7 S1 or S2 or S3 or S4 or S5 or S6
- S8 (MH "Electric Stimulation")
- S9 (MH "Transcutaneous Electric Nerve Stimulation") OR (MH "Electrical Stimulation, Functional") OR (MH "Electrical Stimulation, Neuromuscular")
- S10 (MH "Electroacupuncture")
- S11 (MH "Electrodes")
- S12 TX(electrostimulation)
- S13 TX(electrotherapy)
- S14 TX(neuromuscular N5 stimulat*)
- S15 TX(transcutaneous nerve stimulation)
- S16 TX(tens or fes)
- S17 TX(electroacupuncture)
- S18 TX(electrode*)
- S19 TX(peroneal N5 stimulat*)
- S20 TX(electric N5 stimulat*)
- S21 TX(functional electric* stimulat*)
- S22 TX therapeutic electric* stimulat*
- S23 TX(emg N5 stimulat*)
- S24 S8 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23
- S25 S7 and S24 (limiters Human)

MEDLINE (OVID)

- 1 Stroke/
- 2 Cerebrovascular Disorders/
- 3 Subarachnoid Hemorrhage, Traumatic/ or Brain Hemorrhage, Traumatic/ or Basal Ganglia Hemorrhage/ or Cerebral Hemorrhage, Traumatic/ or Hemorrhage/ or Cerebral Hemorrhage/ or Subarachnoid Hemorrhage/ or Brain Stem Hemorrhage, Traumatic/
- 4 Brain Infarction/ or Infarction/ or Cerebral Infarction/
- 5 Brain Ischemia/
- 6 Ischemic Attack, Transient/
- 7 (stroke or poststroke or post-stroke or cerebrovasc\$ or cerebral vasc\$ or cva\$ or tia\$ or neurologic\$ deficit\$ or SAH or AVM).tw.
- 8 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9 randomized controlled trial.pt.
- 10 controlled clinical trial.pt.
- 11 randomized.ab.
- 12 placebo.ab.
- 13 drug therapy.fs.
- 14 randomly.ab.
- 15 trial.ab.
- 16 groups.ab.
- 17 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
- 18 exp animals/ not humans.sh.
- 19 17 not 18
- 20 Electric Stimulation/
- 21 Electric Stimulation Therapy/
- 22 transcutaneous electrical stimulation/
- 23 Electroacupuncture/
- 24 exp electrodes/
- 25 electrostimulation.tw.
- 26 electrotherapy.tw.

- 27 (tens or fes).tw.
- 28 (neuromuscular adj5 stimulat\$).tw.
- 29 transcutaneous nerve stimulation.tw.
- 30 electroacupuncture.tw.
- 31 electrode\$.tw.
- 32 (peroneal adj5 stimulation\$).tw.
- 33 (electric\$ adj5 stimulat\$).tw.
- 34 functional electric\$ stimulation\$.tw.
- 35 (electromyographic adj5 electric\$ stimulat*).tw.
- 36 (emg adj5 electric\$).tw.
- 37 therapeutic electric\$ stimulat\$.tw.
- 38 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
or 32 or 33 or 34 or 35 or 37
- 39 8 and 17 and 38

EMBASE (OVID)

- 1 stroke/
- 2 cerebrovascular disease/
- 3 subarachnoid hemorrhage/
- 4 brain hemorrhage/
- 5 brain infarction/
- 6 brain ischemia/
- 7 transient ischemic attack/
- 8 (stroke or poststroke or post-stroke or cerebrovasc\$ or cerebral
vasc\$ or isch?emi\$ or tia\$ or cva).tw.
- 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
- 10 electrostimulation/
- 11 electrostimulation therapy/
- 12 functional electrical stimulation/
- 13 transcutaneous nerve stimulation/
- 14 neuromuscular electrical stimulation/
- 15 exp electrode/
- 16 electrostimulation.tw.
- 17 electrotherapy.tw.
- 18 (tens or FES).tw.
- 19 (neuromuscular adj5 stimulat\$).tw.
- 20 transcutaneous nerve stimulation.tw.
- 21 electroacupuncture.tw.
- 22 electrode\$.tw.
- 23 (peroneal adj5 stimulat\$).tw.
- 24 (electric\$ adj5 stimulat\$).tw.
- 25 functional electric\$ stimulation\$.tw.
- 26 (electromyographic adj5 electric\$ stimulat\$).tw.
- 27 (emg adj5 stimulat\$).tw.
- 28 therapeutic electric\$ stimulat\$.tw.

29 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
or 22 or 23 or 24 or 25 or 26 or 27 or 28

30 controlled clinical trial/

31 randomization/

32 control group/

33 placebo/

34 (control or treatment or experiment\$ or intervention).tw.

35 30 or 31 or 32 or 33 or 34

36 9 and 29 and 35

37 limit 36 to human

Central

- #1 MeSH descriptor Stroke explode all trees
- #2 MeSH descriptor Cerebrovascular Disorders explode all trees
- #3 MeSH descriptor Brain Injuries, this term only
- #4 MeSH descriptor Brain Infarction explode all trees
- #5 MeSH descriptor Ischemic Attack, Transient explode all trees
- #6 MeSH descriptor Cerebral Infarction explode all trees
- #7 MeSH descriptor Basal Ganglia Hemorrhage explode all trees
- #8 MeSH descriptor Subarachnoid Hemorrhage explode all trees
- #9 stroke or poststroke or post-stroke or cerebrovasc* or cva* or "ischemi* or TIA* or "neurologic* deficit*" or SAH or AVM in Trials
- #10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
- #11 MeSH descriptor Electric Stimulation Therapy, this term only
- #12 MeSH descriptor Electric Stimulation, this term only
- #13 MeSH descriptor Electrodes, this term only
- #14 (electrostimulation):ti,ab,kw in Trials
- #15 (electrotherapy):ti,ab,kw in Trials
- #16 (tens or fes):ti,ab,kw in Trials
- #17 (neuromuscular near/5 stimul*):ti,ab,kw in Trials
- #18 (transcutaneous nerve stimulation):ti,ab,kw in Trials
- #19 (electroacupuncture):ti,ab,kw in Trials
- #20 (electrode*):ti,ab,kw in Trials
- #21 (peroneal near/5 stimulat*):ti,ab,kw in Trials
- #22 (therapeutic electric* stimulat*):ti,ab,kw in Trials
- #23 (functional electric* stimulat*):ti,ab,kw in Trials
- #24 (electric* near/5 stimulat*):ti,ab,kw in Trials
- #25 (electromyographic near/5 electric* stimulat*):ti,ab,kw in Trials
- #26 (emg near/5 stimulat*):ti,ab,kw in Trials
- #27 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26)
- #28 (#10 AND #27)

OT Seeker

Search	Subdiscipline	Neurology
	Method	Clinical Trial
		Electrical
	Key word	stimulation
	Number	87

PEDRO

Search type	Advanced
Therapy	
type	Electrotherapies
Subdiscipline	Neurology
Method	Clinical trial
	Pedro 396

Appendix A3

Study One - Data Extraction Form

Review title												
Review code												
Publication details												
Notes to extractor	<p>The data in the columns in blue will not need to be put into RevMan. If you have % event rates or standard errors enter these in the red columns, and the sheet will calculate the numbers needed for RevMan. Enter the data which is highlighted in green into RevMan; you will need to enter means, SDs and N, or mean differences and SEM for continuous data. Consult the RGC if you are not certain which parts of the worksheet require your input.</p> <p>Use the following rows and columns where study data are available as means and SEMs or SDs for individual treatment groups. If SDs are available enter them directly in the SD column for each group. If only SEMs are available enter them in column Treatment SEM/control SEM and the SD will be calculated for the SD columns.</p>											
Continous outcomes				Experimental			Control					
	UNIT	Sig	Extractor	Mean	SD	N	Mean	SD	N	Treatment SEM	Control SEM	Source of data
			#1									
			#2									
<p>Use the following rows and columns where study data are available as means and 95% confidence intervals or SEMs for differences between treatment groups. The columns in blue will generate the lower and upper limits of of confidence intervals so you can cross-check them against the original limits.</p>												
GIV outcomes			Extractor	Estimate (treatment - control)	SEM	N	N	Lower CI	Upper CI	Lower CI	Upper CI	
			#1		0					0	0	
			#2		0					0	0	
<p>Enter the n if known, or enter the % of participants experiencing the event to generate the number you need to enter in Revman. Round the numbers up or down as appropriate</p>												
Dichotomous outcomes												
Outcomes			Extractor	n	N	n	N	Treatment %	Control %			
			#1	0		0						
			#2	0		0						
Comments												

Appendix A4

Study One – Permission to Use Manuscript



Title: Functional Electrical Stimulation Improves Activity After Stroke: A Systematic Review With Meta-Analysis

Author: Owen A. Howlett, Natasha A. Lannin, Louise Ada, Carol McKinstry

Publication: Archives of Physical Medicine and Rehabilitation

Publisher: Elsevier

Date: May 2015

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Appendix A5

Study One - Manuscript

REVIEW ARTICLE (META-ANALYSIS)

Functional Electrical Stimulation Improves Activity After Stroke: A Systematic Review With Meta-Analysis



Owen A. Howlett, MaOT,^{a,b} Natasha A. Lannin, PhD,^{a,c,d} Louise Ada, PhD,^e Carol McKinstry, PhD^a

From the ^aDepartment of Occupational Therapy, La Trobe University, Bundoora, VIC; ^bBendigo Health, Bendigo, VIC; ^cOccupational Therapy Department, Alfred Health, Prahran, VIC; ^dThe John Walsh Centre of Rehabilitation Research, Sydney Medical School (Northern), University of Sydney, St Leonards, NSW; ^eDepartment of Physiotherapy, University of Sydney, Lidcombe, NSW; and La Trobe Rural Health School, La Trobe University, Bendigo, VIC, Australia.

Abstract

Objective: To investigate the effect of functional electrical stimulation (FES) in improving activity and to investigate whether FES is more effective than training alone.

Data Sources: Cochrane Central Register of Controlled Trials, Ovid Medline, EBSCO Cumulative Index to Nursing and Allied Health Literature, Ovid EMBASE, Physiotherapy Evidence Database (PEDro), and Occupational Therapy Systematic Evaluation of Effectiveness.

Study Selection: Randomized and controlled trials up to June 22, 2014, were included following predetermined search and selection criteria.

Data Extraction: Data extraction occurred by 2 people independently using a predetermined data collection form. Methodologic quality was assessed by 2 reviewers using the PEDro methodologic rating scale. Meta-analysis was conducted separately for the 2 research objectives.

Data Synthesis: Eighteen trials (19 comparisons) were eligible for inclusion in the review. FES had a moderate effect on activity (standardized mean difference [SMD], .40; 95% confidence interval [CI], .09–.72) compared with no or placebo intervention. FES had a moderate effect on activity (SMD, .56; 95% CI, .29–.92) compared with training alone. When subgroup analyses were performed, FES had a large effect on upper-limb activity (SMD, 0.69; 95% CI, 0.33–1.05) and a small effect on walking speed (mean difference, .08m/s; 95% CI, .02–.15) compared with control groups.

Conclusions: FES appears to moderately improve activity compared with both no intervention and training alone. These findings suggest that FES should be used in stroke rehabilitation to improve the ability to perform activities.

Archives of Physical Medicine and Rehabilitation 2015;96:934-43

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Stroke is the leading cause of disability in the Western world.^{1,2} Such disability arises from limitations in activities (eg, walking) and reduced participation in daily life tasks (eg, self-care, managing household chores, property maintenance).³ With hemiplegia contributing significantly to this inability to perform meaningful activities and participate fully in life after stroke,⁴ improving motor outcomes after stroke is essential.

To improve outcomes after stroke, intervention focuses on improving not only the impairment level, but addressing activity

limitations (eg, walking, moving objects) and participation restrictions.⁵ Electrical stimulation is one such intervention that has the potential to improve motor outcomes and as such, potentially lead to increased activity performance and participation after stroke. However, there are various forms of electrical stimulation. Functional electrical stimulation (FES) stimulates muscles to contract during the performance of an activity (eg, sitting, standing up from a chair, walking, reaching for and manipulating objects), with the goal of improving the performance of that activity.⁵ The perceived benefit of FES for survivors of stroke is that it can facilitate practice of activities that would not otherwise occur because of hemiparesis. In addition, FES can engage the stroke survivor's attention, be repetitive, be challenging, and can provide sensory and visual feedback to the participant. These are common

Presented to Occupational Therapy Australia, July 24–27, 2013, Adelaide, SA, Australia; and Occupational Therapy Australia, May 2–3, 2014, Melbourne, VIC, Australia.

Disclosures: none.

attributes labeled as essential components of an effective intervention to promote motor recovery after stroke.⁶

Three previous systematic reviews have investigated the effect of FES for increasing movement and activity after stroke, and all have investigated lower-limb function.⁷⁻⁹ In 2006, Robbins et al⁹ reported that FES resulted in .18m/s (95% confidence interval [CI], .08-.28) faster walking speed than walking training alone or no intervention, based on a meta-analysis of 3 controlled trials in chronic stroke. Then in 2009, Roche et al⁸ concluded that evidence for a therapeutic effect of FES was inconclusive, based on the individual examination of 30 studies of peroneal nerve stimulators ranging from case studies to randomized trials. Finally, in 2012, Pereira et al⁷ reported that FES resulted in .38 standardized mean difference (SMD) (95% CI, .08-.68) further walking distance than walking training alone or no intervention, based on 6 controlled trials in the chronic phase after stroke. Results of these prior systematic reviews demonstrate the previous focus in the research literature on the lower limb and conducting trials in the chronic population. In light of the limitations of these prior reviews, the clinical conclusion to date was that there was insufficient high-level evidence to support the routine use of FES for improving both upper- and lower-limb motor function.¹⁰

Therefore, the aim of this systematic review was to examine the latest evidence for the use of FES after stroke. The specific research questions were as follows: (1) Is FES effective in improving activity after stroke? (2) Is FES more effective than activity training alone?

To make recommendations based on the highest level of evidence, this review included only moderate-to-high-quality randomized or controlled trials of adults with stroke using FES to contract muscles during the performance of activities, with the aim of improving activity performance. Review protocol is available online (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=ZCRD42012003054).

Methods

Identification and selection of trials

The following 6 electronic databases were searched on June 22, 2014: Cochrane Central Register of Controlled Trials (studies to June 22, 2014), Ovid Medline (studies from 1946 to June 22, 2014), EBSCO Cumulative Index to Nursing and Allied Health Literature (studies from 1981 to June 22, 2014), Ovid EMBASE (studies from 1947 to June 22, 2014), Physiotherapy Evidence Database (PEDro) (www.pedro.org.au) (studies to June 22, 2014), and Occupational Therapy Systematic Evaluation of Effectiveness (www.otseeker.com) (studies to June 22, 2014) for relevant articles without language restrictions using words related to stroke and randomized, quasi-randomized, or controlled trials and words related to functional electrical stimulation (contact corresponding author for full search strategy). One author (O.H.) screened all trials based on the title and abstract. Full-text articles for potentially relevant trials were retrieved and their reference lists screened. Two authors (O.H.

- Design
- Randomised or controlled clinical trial
 - Methodological quality of PEDro >4
- Participants
- Adults: 18 +
 - 80% of participants to have a stroke, remaining 20% of participants to have a stroke like condition.
- Intervention
- Electrical stimulation via surface electrodes that produces a muscle contraction causing movement of a limb during practice of an activity
 - FES the primary intervention, i.e., practice of activity for the majority of the intervention, e.g., walking or grasp/release of objects
- Outcome measures
- Measures of activity limitation without electrical stimulation.
- Comparisons
- FES versus nothing/ placebo
 - FES versus same activity training

Fig 1 Inclusion criteria.

and N.A.L.) independently reviewed full-text articles for eligibility using the inclusion criteria outlined in figure 1. Where inclusion could not be established based on the information provided in the publication, the author of the trial was contacted to ascertain missing information. All disagreements regarding inclusion into the review were resolved through discussion between 2 reviewers and if required a third reviewer. Articles reporting the same research data were linked together to ensure data from each trial were only included once in the analysis.

Assessment of characteristics of trials

Quality

The quality of the included trials into the systematic review was assessed by the PEDro scale and Jadad scale. One reviewer determined the risk of bias for each study using PEDro scores¹¹ obtained from the PEDro.¹² If a score was not available from the database, it was calculated by 2 review authors independently (O.H. and N.A.L.) who had undergone the PEDro training program. Only trials of moderate (ratings of 5 or 6) and high (ratings of 7 or 8) quality¹³ were included in the review. One reviewer (O.H.) established a Jadad score¹⁴ for each included trial.

Participants

Trials involving adult participants with stroke of any level of disability and any chronicity were included. The number of participants, their mean age, their sex distribution, and their time since the onset of stroke were recorded to assess the similarity of the trials.

Intervention

The experimental intervention was FES (ie, electrical stimulation producing muscle contraction delivered via surface electrodes during practice of an upper- or lower-limb activity). The control group intervention was categorized as either no intervention or placebo or as same activity training, defined as the training of the same activity as the experimental group but without any electrical stimulation. Muscle(s) stimulated, activity trained, and duration and frequency of the intervention were recorded to assess the similarity of the trials.

Outcome measures

Only measures that reflected the International Classification of Function domain of activity performance were used in analyses because there were insufficient participation measures reported in the trials. In the trials where only 1 measure of activity was available, this measure was chosen. Where >1 measure of activity was available for a single trial, reviewers chose the outcome measure that closest reflected the task being trained

List of abbreviations:

- CI confidence interval
- FES functional electrical stimulation
- PEDro Physiotherapy Evidence Database
- SMD standardized mean difference

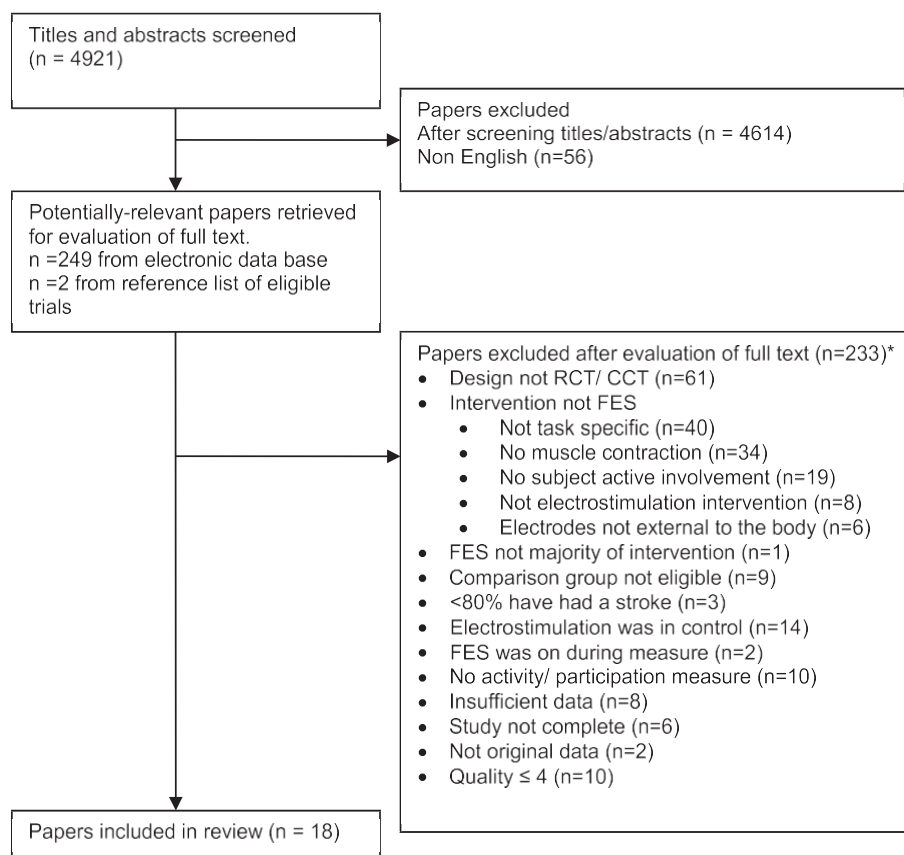


Fig 2 Flow of trials through the review. *Articles may have been excluded for failing to meet >1 inclusion criteria. Abbreviation: CCT, controlled clinical trial.

(eg, if upper-limb grasp and release were trained using FES, the Box and Block Test was selected). The outcome measure used in the analysis and timing of measurement were recorded to assess the similarity of the trials; all measures were recorded without electrical stimulation.

Data analysis

Characteristics of participants, intervention, and outcome measures were recorded onto a predesigned data extraction form. The mean \pm SD of the outcome immediately after intervention and number of participants were extracted. Data extraction and cross-checking of data occurred by 2 people (data extractors and cross-checkers: O.H. and an external data extractor). Authors were contacted where there was difficulty extracting and/or interpreting data from the article.

Data were entered into Review Manager software,^a and the effect of FES was calculated as the SMD and 95% CI of post-intervention scores because different outcome measures were used across the trials. When analyzing the data from multiple armed trials, analysis occurred on the 2 arms most applicable to the review question. If >2 arms were applicable to the review question, where 2 experimental groups (or control groups) contained eligible data, these were averaged and analyzed as 1 experimental (or control) group in the comparisons. If 1 arm in the trial was eligible for analysis in the FES vs nil/placebo comparison and the other arm was eligible for analysis in the FES vs same activity training comparison group, this occurred with the data only being counted once in the separate analyses.

For a crossover design, only the precrossover data were included in analysis. A fixed effect model was used in the initial analysis, and heterogeneity was examined by visual inspection of the forest plot, chi-square test, and I^2 statistic. Where there was considerable heterogeneity as noted by the I^2 statistic, a sensitivity analysis to explore the source of the heterogeneity was carried out, and a random effect model was then reported. Subgroup analyses were planned for the limb that was trained (upper compared with lower limb) and time after stroke (acute [<6 mo] compared with chronic [>6 mo]) and meta-regression to investigate the influence of all factors together provided that a minimum of 10 trials for each characteristic were included.¹⁵

Results

Flow of trials through the review

Citations for 4921 trials were identified in the search. Of these, 4614 were excluded after screening based on the abstract and title. A total of 251 potentially relevant trials were identified from electronic databases and 2 from reference lists. Of these, 233 trials were excluded after full-text review, leaving 18 trials for inclusion. Because 1 trial had 3 arms that could be counted as 2 separate comparison groups, there were 19 comparisons in total.¹⁶ See figure 2 for a summary of the flow of trials through the review.

Characteristics of included trials

The 18 trials (19 comparisons) included in the review included 485 participants (table 1). Of these, there were 9 comparisons of

Table 1 Summary of included trials (NZ18)

Study	Design	Participants	Intervention	Outcome Measures
Barker et al ¹⁶	RCT	nZ33 Age (y): 66±12 Sex: 22 M, 11 F Time since stroke: 46mo	Exp 1: FES to elbow ext during UL activity training 60min x 3/wk x 4wk Con 1: nil	Activity: Motor Assessment Scale for Stroke: item 6 Timing: 0, 4, 12wk
Bogataj et al ³³	CT	nZ20 Age (y): 56±10 Sex: 11 M, 9 F Time since stroke: 4mo	Con 2: UL activity training 60min x 3/wk x 4wk Exp: FES to ankle dorsiflex/plantarflex, knee flex/ext during LL activity training 30min x 1h x 5/wk x 3wk Con: LL activity training 30min x 1h x 5/wk x 3wk	Activity: walking speed Timing: 0, 3wk
Burridge et al ³⁴	RCT	nZ32 Age (y): 56±3 Sex: 23 M, 9 F Time since stroke: 51mo	Both: standard rehabilitation Exp: FES to ankle dorsiflex during LL activity training 60min x 2/wk x 5wk Con: LL activity training 60min x 2/wk x 5wk	Activity: walking speed Timing: 0, 5, 13wk
Cheng et al ²⁵	RCT	nZ15 Age (y): 56±7 Sex: 11 M, 3 F Time since stroke: 34mo	Exp: FES to ankle dorsiflex during LL activity training 45min x 3/wk x 4wk Con: placebo (LL range of motion and strengthening exercises) 45min x 3/wk x 4wk	Activity: walking speed Timing: 0, 4wk
Daly et al ²⁶	RCT	nZ12 Age (y): 21±62 Sex: 9 M, 3 F Time since stroke: 30mo	Both: walking training Exp: FES to wrist/finger/thumb flex/ext during UL activity training 1.5h x 5/wk x 12wk Con: placebo (robotic shoulder/elbow flex/ext during UL activity training) 1.5h x 5/wk x 12wk	Activity: Arm Motor Ability Test Timing: 0, 12, 36wk
Hara et al ³²	RCT	nZ20 Age (y): 58 Sex: 14 M, 6 F Time since stroke: 13mo	Both: UL activity training 3.5h x 5/wk x 12wk Exp: FES to finger/wrist ext during UL activity training 30min x 5/wk x 5mo Con: UL activity training 30min x 5/wk x 5mo	Activity: nine-hole peg test Timing: 0, 20wk
Kojovic et al ³⁵	RCT	nZ13 Age (y): 59 Sex: 6 M, 7 F Time since stroke: <1mo	Exp: FES to hip/knee flex/ext during LL activity training 45min x 5/wk x 4wk Con: LL activity training 45min x 5/wk x 4wk	Activity: walking speed Timing: 0, 4wk
Lee et al ³⁶	RCT	nZ15 Age (y): 55±8 Sex: 22 M, 8 F Time since stroke: 5mo	Both: standard rehabilitation Exp: FES of ankle dorsiflex during LL activity training 30min x 5/wk x 4wk Con: LL activity training 30min x 5/wk x 4wk	Activity: walking speed Timing: 0, 4wk
Mangold et al ³¹	RCT	nZ22 Age (y): 70 Sex: 10 M, 12 F Time since stroke: 7mo	Both: standard rehabilitation 1h x 2/wk x 12wk Exp: FES to elbow/wrist/finger/thumb ext during UL activity training 30min x 10/wk x 12wk Con: placebo (wrist and finger range of motion exercises) 30min x 10/wk x 12wk	Activity: Action Research Arm Test Timing: 0, 12, 24wk

(continued on next page)

Table 1 (continued)

Study	Design	Participants	Intervention	Outcome Measures
Mann et al ²⁷	RCT	nZ23 Age (y): 60±17 Sex: 17 M, 6 F Time since stroke: 7mo	Exp: FES to shoulder flex, elbow ext, finger flex/ext during UL activity training (grasp and release of objects) 45min x 3e5/wk x 4wk Con: placebo (range of motion exercises) 45min x 3e5/wk x 4wk Both: standard rehabilitation	Activity: Action Research Arm Test Timing: 0, 4wk
Faisal and Priyabanani Neha ²⁸	RCT	nZ30 Age (y): 45e75 Sex: not reported Time since stroke: <1mo	Exp: FES to wrist flex/ext during UL activity training 20min x 6/wk x 4wk Con: nil	Activity: Box and Block Test Timing: 0, 4wk
Ng et al ³⁷	RCT	nZ54 Age (y): 67±11 Sex: 34 M, 19 F Time since stroke: <1mo	Exp: FES to quadriceps during stance phase, knee flex and ankle dorsiflex during swing during LL activity training 20min x 5/wk x 4wk Con: LL activity training 20min x 5/wk x 4wk Both: standard rehabilitation	Activity: walking speed Timing: 0, 4, 24wk
Page et al ¹⁷	RCT	nZ32 Age (y): 18e85 Sex: not reported Time since stroke: >6mo	Exp: FES to wrist/finger ext/flex and thumb ext/abd during UL activity retraining 120min x 5/wk x 8wk Con: placebo (home exercise program) 30min x 5/wk x 8wk	Activity: Box and Block Test Timing: 0, 8wk
Peurala et al ³⁸	RCT	nZ45 Age (y): 52±8 Sex: 37 M, 8 F Time since stroke: 36mo	Exp: FES to 2 individually selected LL muscles during LL activity training 20min x 5/wk x 3wk Con: LL activity training 20min x 5/wk x 3wk	Activity: walking speed Timing: 0, 3, 24wk
Popovic et al ³⁹	CT	nZ41 Age (y): 60±9 Sex: not reported Time since stroke: 1.5mo	Exp: FES to finger/wrist flex/ext and thumb flex/abd UL activity training 30min x 3/wk x 3wk Con: UL activity training 30min x 3/wk x 3wk Both: standard rehabilitation	Activity: Upper Extremity Function Test Timing: 0, 3, 26, 52wk
Popovic et al ⁴⁰	RCT	nZ28 Age (y): 60±9 Sex: not reported Time since stroke: 2mo	Exp: FES to finger flex/ext, thumb ext/abd/opp during UL activity training 30min x 5/wk x 3wk Con: UL activity training 30min x 5/wk x 3wk Both: standard rehabilitation	Activity: Upper Extremity Function Test Timing: 0, 3, 6, 13, 26wk
Sabut et al ²⁹	CCT	nZ30 Age (y): 48±11 Sex: 24 M, 6 F Time since stroke: 18mo	Exp: FES to dorsiflexors during LL activity training 30e45min x 5/wk x 12wk Con: nil Both: standard rehabilitation	Activity: walking speed Timing: 0, 12wk
Tarkka et al ³⁰	RCT	nZ20 Age (y): 53±6 Sex: 13 M, 7 F Time since stroke: 29mo	Exp: FES to wrist flex/ext, thumb flex/opp during UL activity training 30min x 10/wk x 2wk Con: placebo (voluntary movement exercises and passive manual stretching) 30min x 10/wk x 2wk	Activity: Wolf Motor Function Test Timing: 0, 2, 24wk

Abbreviations: abd, abduction; CCT, controlled clinical trial; Con, control group; CT, crossover trial, Exp, experimental group; ext, extension; F, female; flex, flexion; LL, lower limb; M, male; opp, opposition; UL, upper limb.

Table 2 PEDro scores* for included trials (NZ18)

Study	Random Allocation	Concealed Allocation	Groups Similar at Baseline	Participant Blinding	Therapist Blinding	Assessor Blinding	<15% Dropouts	Intention-to-Treat Analysis	Between-Group Difference	Point Estimate and Variability	Total (0e10)
Barker et al ¹⁶	Y	Y	Y	N	N	Y	N	Y	Y	Y	7
Bogataj et al ³³	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Burridge et al ³⁴	Y	Y	N	N	N	N	Y	N	Y	Y	5
Cheng et al ²⁵	Y	Y	Y	N	N	Y	N	N	Y	Y	6
Daly et al ²⁶	Y	N	Y	N	N	Y	Y	N	N	Y	5
Hara et al ³²	Y	N	N	N	N	Y	Y	N	Y	Y	5
Kojovic et al ³⁵	Y	N	Y	N	N	N	Y	N	Y	Y	5
Lee et al ³⁶	Y	N	Y	N	N	Y	Y	N	Y	Y	6
Mangold et al ³¹	Y	N	Y	N	N	N	Y	Y	Y	Y	6
Mann et al ²⁷	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Faisal and Priyabanani Neha ²⁸	Y	N	Y	N	N	N	Y	N	Y	Y	5
Ng et al ³⁷	Y	N	Y	N	N	N	Y	Y	Y	Y	6
Page et al ¹⁷	Y	Y	Y	N	N	Y	Y	N	N	Y	6
Peurala et al ³⁸	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Popovic et al ³⁹	Y	N	Y	N	N	Y	N	N	Y	Y	5
Popovic et al ⁴⁰	Y	N	Y	N	N	Y	N	N	Y	Y	5
Sabut et al ²⁹	N	N	Y	N	N	Y	Y	N	Y	Y	5
Tarkka et al ³⁰	Y	Y	Y	N	N	N	N	N	Y	Y	5

Abbreviations: N, no; Y, yes.

* PEDro scores from website (www.pedro.org.au).

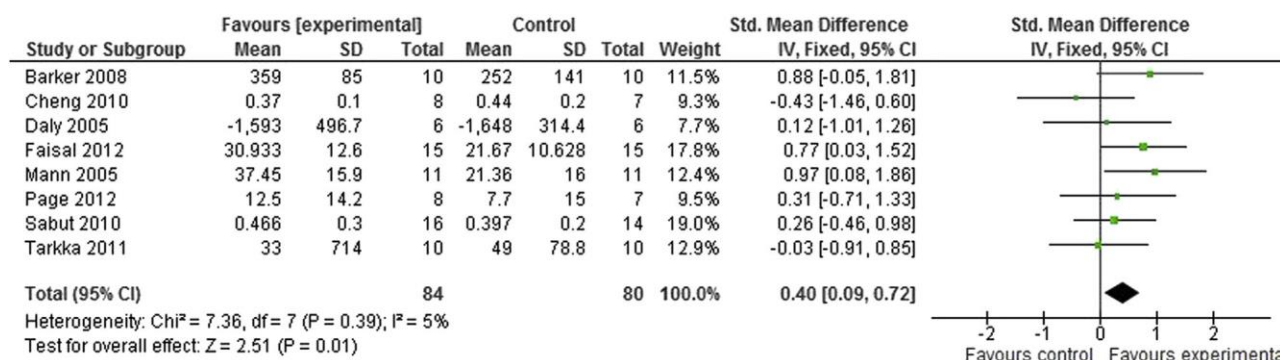


Fig 3 SMD (95% CI) of the effect of FES compared with nil/placebo on activity by pooling data from 8 comparisons (nZ164). Abbreviations: IV, inverse variance; Std., standard.

FES against nil/placebo and 10 against training alone. Of these, 7 comparisons were of acute participants, and 8 involved the lower limb. Sixteen trials (17 comparisons) had data available for inclusion in a meta-analysis.

Quality

The mean Jadad score was 2.6 (out of 5). Double blinding was achieved in 0% of trials, randomization was achieved in 94% of trials, description of the randomization method was achieved in 76% of trials, and reporting an account of all subjects occurred in 100% of the trials. The mean PEDro score of the trials was 5.5/6; only 1 trial was of high quality (table 2). Point estimates and variability were present in 100% of trials, random allocation was present in 94% of trials, baseline comparability was present in 89% of trials, between-group comparisons were present in 88% of trials, adequate follow-up was present in 72% of trials, assessor blinding was present in 50% of trials, concealed allocation was present in 44% of trials, and intention-to-treat analysis was present in 16% of trials. Participants or therapists were blinded to intervention in none of the trials.

Participants

Across the trials, the mean age ranged from 48 to 70 years old, and 52% of participants were men. All trials included only participants who had suffered a stroke. The mean time after stroke ranged from <1 to 51 months, with 61% of the trials carried out after 6 months.

Intervention

Seven trials investigated FES in the lower limb, and 10 trials investigated FES in the upper limb. Length of FES sessions ranged from 20 minutes to 6 hours. Frequency of sessions ranged from 2 to 7 sessions per week. The duration of sessions ranged from 2 to 12 weeks, with the total dose of intervention ranging from 5 to 90 hours. Of the 15 trials which included an experimental and an active control, 1 trial¹⁷ did not match the dose amount of FES intervention between the experimental and control groups. The frequency of the electrical stimulation ranged from 25 to 50Hz, and pulse width ranged from 200 to 400ms. Electrical stimulation was triggered by the therapist or the participant, either mechanically (eg, by weight bearing on a foot switch) or physiologically (eg, by reaching a predetermined amount of muscle activity). The number of movements stimulated during the activity (ie, wrist extension, ankle dorsiflexion) ranged from 1 to 6 movements. The control intervention was nil/placebo in 10 trials and training the

same activity as the experimental intervention but without the FES in 8 trials.

Outcome measures

Lower-limb activity was assessed as walking speed (m/s) in 7 comparisons. Upper-limb activity was assessed using Motor Assessment Scale,¹⁸ Arm Motor Ability Test,¹⁹ nine-hole peg test,²⁰ Action Research Arm Test,²¹ Box and Block Test,²² Upper Extremity Function Test,²³ and Wolf Motor Function Test.²⁴

Effect of intervention

FES vs placebo/nil

The effect of FES on activity was examined by pooling data after intervention from 8 trials of 168 participants using a random effect model (fig 3).^{16,17,25-30} FES improved activity compared with nil/placebo (SMD, .40; 95% CI, .08-0.72; $I^2=5\%$). Because of incomplete data, 2 trials could not be included in the analysis.^{31,32} The analysis included 6 trials of upper-limb training^{16,17,26-28,30} and 2 trials of lower-limb training.^{25,29} Of these, 7 trials included participants in the chronic stage of stroke,^{16,17,25-27,29,30} and 1 study included participants in the acute phase of stroke.²⁸ Most trials involved the upper limb in the chronic stage; therefore, a subgroup analysis was not done.

FES vs training alone

Whether FES was superior to training alone was examined by pooling data after intervention from 9 trials of 241 participants using a random effect model (fig 4).^{16,33-40} FES improved activity compared with training alone (SMD, .56; 95% CI, .21-0.92; $I^2=44\%$). The analysis included 3 trials of upper-limb training^{16,39,40} and 6 trials of lower-limb training.³³⁻³⁸ Of these, 3 trials included participants in the chronic stage of stroke,^{16,34,38} and 6 trials included participants in the acute stage of stroke.^{33,35-37,39,40} Most trials involved the lower limb in the acute stage; therefore, a subgroup analysis was not done.

Subgroup analysis

Given that the effect size was similar for each analysis, trials were pooled into groups of either upper- or lower-limb FES training. The effect of FES after upper-limb training was examined by pooling data after intervention from 8 trials of 192 participants using a fixed effect model (fig 5).^{16,17,26-28,30,39,40} For the trial of upper-limb training, which was previously included in both comparison groups,¹⁶ the 2 control groups were combined and

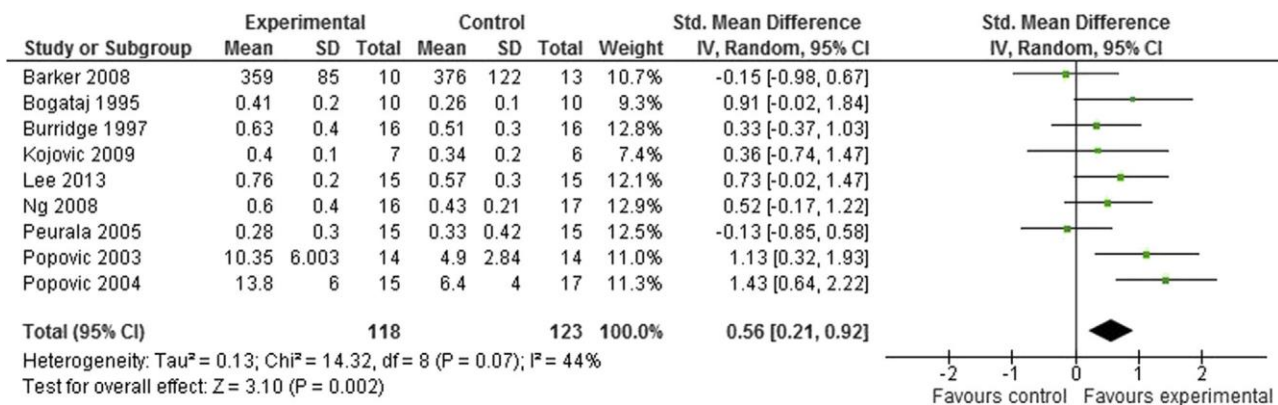


Fig 4 SMD (95% CI) of the effect of FES compared with training alone on activity by pooling data from 9 comparisons (nZ241). Abbreviations: IV, inverse variance; Std., standard.

averaged and included as 1 group into the subgroup analysis for upper-limb training. FES improved upper-limb activity compared with the control group (SMD, 0.69; 95% CI, 0.33–1.05; I^2 27%). The effect of FES after lower-limb training was examined by pooling data after intervention from 9 trials including 203 participants using a fixed effect model (Fig 6).^{25,29,33–38} Because all outcomes for lower-limb training were walking reported in meters per second, the mean difference was used to calculate the effect of the intervention. FES improved lower-limb activity (walking) compared with the control group (mean difference, .08m/s; 95% CI, .02–.15; I^2 25%).

Discussion

This systematic review provides evidence that FES has a small to moderate positive effect⁴¹ on activity compared with nil/placebo. It also provides evidence that FES is more beneficial than training alone, with a moderate effect size. However, because of a lack of available data, we were unable to examine whether FES improves participation or if the benefits of FES on activity are long-lasting.

The use of the Jadad scale identified a lack of double blinding of group allocation, which is common among stroke rehabilitation trials. PEDro scores then provided a method of breaking down the levels of blinding and investigated other methodologic biases (eg, a lack of concealed allocation of subjects).⁴² The mean PEDro score of 5.5 for the 18 trials included in this review represents moderate quality, adding to the credibility of the conclusions.

Participants were similar in age and sex, and the time after stroke was generally chronic (>6mo after stroke), with 7 trials examining participants in the acute/subacute phase of rehabilitation (<4mo after stroke). There was a range of durations of intervention (2–12wk); however, most trials examined interventions of 3 to 4 weeks in duration. Furthermore, because of the diversity of intervention and subject factors, which could not be accounted for in a subgroup analysis, a random effect analysis has been presented. Taken together with the methodologic quality of included trials, this suggests that the findings can be generalized cautiously.

There have been 2 previous systematic reviews with meta-analysis examining the effect of FES after stroke, and both have investigated lower-limb function.^{7,9} In 2006, Robbins⁹ reported that FES resulted in .18m/s (95% CI, .08–.28) faster walking speed than walking training alone or no intervention, based on a meta-analysis of 3 controlled trials in chronic stroke. Finally, in 2012, Pereira⁷ reported that FES resulted in a .38 SMD (95% CI, .08–.68) further walking distance than walking training alone or no intervention, based on 6 controlled trials. Our analysis demonstrates that FES during walking training results in a difference of .08m/s in walking speed. The meaningful change of walking speed has been previously reported as .10m/s in patients with stroke.⁴³ Therefore, a change of .08m/s after FES for lower-limb training represents a small effect, nearing clinical significance. The results of this systematic review provide stronger evidence of the efficacy of FES in improving activity because the conclusions are based on a meta-analysis of 8 randomized trials of moderate

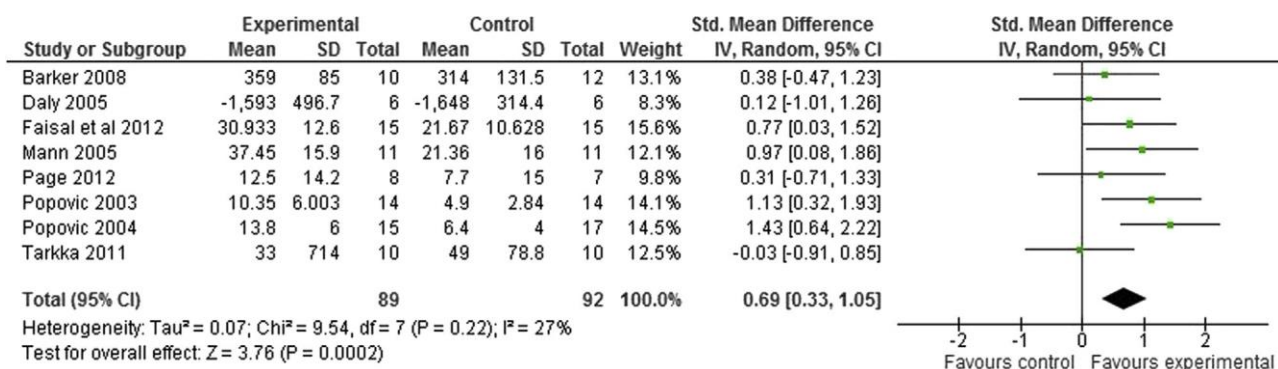


Fig 5 SMD (95% CI) of the effect of upper-limb FES compared with a control on activity by pooling data from 8 comparisons (nZ181). Abbreviations: IV, inverse variance; Std., standard.

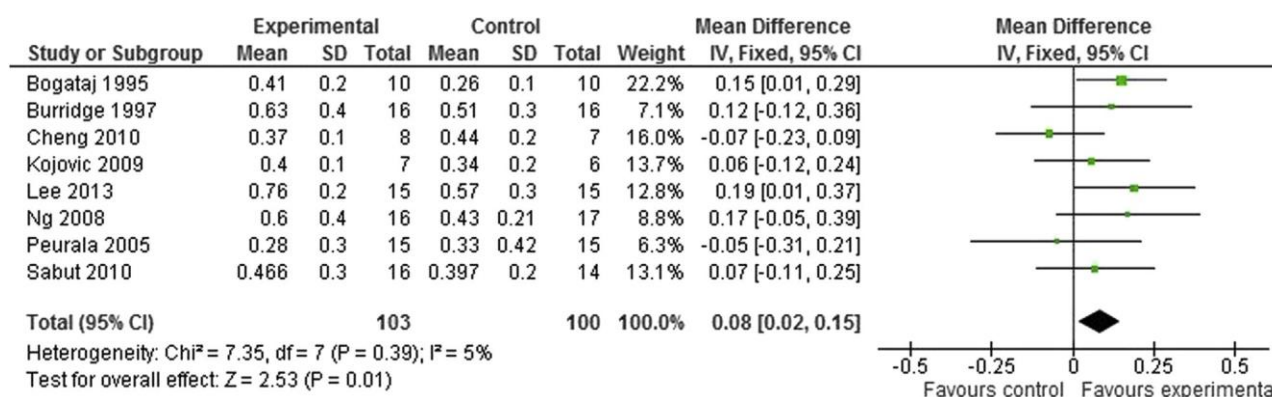


Fig 6 Mean difference (95% CI) of effect of lower-limb FES compared with a control on activity by pooling data from 8 comparisons (nZ203). Abbreviations: IV, inverse variance; Std., standard.

quality. In contrast, although FES during upper-limb training resulted in a large effect size, the clinical significance is not yet known.

Study limitations

Our review has some limitations. First, the strongest source of bias is lack of blinding of therapists and participants in the clinical trials because it is very difficult to blind them during the delivery of an intervention such as FES. Hence results may be influenced by observer bias.⁴⁴ Second, the results are potentially affected by small trial bias, with an average number of 25 participants per trial. It is therefore possible that the estimated effect may be larger than the true effect.⁴⁵ Third, because we combined data collected using different outcome measures, we calculated the SMD in the meta-analysis. One of the problems associated with this is that an estimation of the benefit of FES in real terms cannot be expressed.⁴⁶ Finally, only 1 person screened title and abstract for inclusion, and no gray literature search was completed.

As with most rehabilitation trials, there may have been many possible influences on the outcomes reported in the included studies other than the intervention of FES, including time after stroke, the limb that was trained, and the severity of stroke. Our review planned to conduct a subgroup analysis to investigate the contribution of other factors to study findings; however, insufficient studies have been conducted to warrant meta-regression.¹⁵ Therefore, the review is unable to hypothesize the influence of factors originating from the subject or the device; this study is also not able to investigate the influence of other factors on heterogeneity on the treatment effect. Future researchers are encouraged to do so with larger study numbers.

Conclusions

There are implications for both clinicians and researchers from this review. Evidence from the meta-analysis suggests that FES is beneficial in improving aspects of everyday activity performance after stroke. Implementation of this review's findings will therefore require a commitment from health services, both in terms of resources and clinician training. It is recommended that future trials include longer-term follow-up measures and measures that reflect participation because there were insufficient data in the 18 trials included in this study to address these questions.

Supplier

a. Review Manager; The Nordic Cochrane Centre.

Keywords

Meta-analysis [publication type]; Occupational therapy; Rehabilitation; Review [publication type]

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Appendix B1

Study Two Phase One – HREC Approval Bendigo Health

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC
PO Box 126
Bendigo
Victoria, 3552
SAMcCarthy@bendigohealth.org.au

Dr Carol McKinstry
La Trobe University
P.O. Box 199
Bendigo
Vic 3552

27 January 2016

Dear Dr McKinstry

Study title: The use of functional electrical stimulation by physiotherapists and occupational therapists in stroke rehabilitation – development of an electronic survey tool.

HREC Reference Number: LNR/15/BHCG/82

The Bendigo Health Care Group HREC reviewed the above application at the meeting held on 27 January 2016.

Decision of the HREC

The HREC approved the above application on the basis of the information provided in the application form and supporting documentation.

Approval

The HREC approval is from the date of this letter and *expires on 02 July 2016*.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses: Bendigo Health.

You must comply with the following conditions:

- a. *Limit of Approval:* approval is limited strictly to the research proposal as submitted in your application. In addition, approval by the HREC *does not* guarantee that an individual BHCG unit or service will agree to provide resources or support to your research. Such assistance will need to be negotiated separately.
- b. *Start date:* You are responsible for advising the HREC of the date when the project starts at this site.

- c. *Variation to Project*: any subsequent variations or modifications you might wish to make to your project must be notified formally to the committee for further consideration and approval. If the committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised project.
- d. *Incidents of Adverse Effects*: researchers must report immediately to the committee anything which might affect the ethical acceptance of the protocol including adverse effects on subjects or unforeseen events that might affect continued ethical acceptability of the project.
- e. *Progress Reporting*: please be aware that the Human Research Ethics Committee requires all researchers to submit a report on each of their projects yearly and at the conclusion of the project. Failure to submit a progress report may mean approval for this project will lapse. Researchers must inform the committee if the project is discontinued before the expected date of completion. **The first and final progress report for this project is due on 31/08/2016.** Please refer to Bendigo Health HREC website for template. http://www.bendigohealth.org.au/World_Class_Healthcare.asp?PageID=12
- f. *Auditing*: all projects may be subject to audit by members of the committee.
- g. *Research Reports*: please be aware that Bendigo Health reserves the right to include research project information in internal research reports.
- h. Please ensure that any requests to extend HREC approval are submitted at least **twelve weeks** prior to the date of HREC approval expiry.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Officer.

Approved documents

Documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	V1	30 November 2015
Application – LNR	V1	02 December 2015
Application –LNRSSA	V1	03 December 2015
Protocol: Current ethics application is for phase one only. The protocol outlines both phase one and two.	V1	19 November 2015
Participant Information Sheet/Consent Form: Bendigo Health	V1	04 November 2015
Letter of invitation to participant:	V1	21 January 2016
Questionnaire: Copy of the FES usage survey tool	V1	30 November 2015
Investigator CV: Natasha Lannin		
Investigator CV: Carol McKinstry		23 November 2015
Investigator CV: Owen Howlett		23 November 2015
Response to Request for Further Information		
Application– LNR	V2	21 January 2016
Questionnaire: V2 of the FES usage survey tool	2	21 January 2016
Participant Information Sheet/Consent Form:Bendigo Health with changes made as per reviewers' request.	V2	21 January 2016
Letter of invitation to participant: Changes made as requested by reviewers.	V2	21 January 2016

Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

If you should have any queries about your project please contact Ms Sally McCarthy by email.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely



Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC

E-mail: SAMcCarthy@bendigohealth.org.au

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	Yes/No/NA
Ethics approval notification The PI must send a copy to the RGO at that study site.	YES – completed
CTN notification The PI must sign the CTN and forward to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	NA
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g. CTRA) to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	YES – completed
Radiation If applicable, the RGO must contact the Medical Physicist to notify DHS, Radiation Safety Section to list the project on the Institute's licence.	NA
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	NA

Ms Sally McCarthy
Bendigo Health Care Group
PO Box 126 Bendigo, Vic 3552
SAMcCarthy@bendigohealth.org.au

Dr Carol McKinstry
La Trobe University
P.O. Box 199
Bendigo
Vic 3552

27 January 2016

Dear Dr McKinstry

Study title: The use of functional electrical stimulation by physiotherapists and occupational therapists – development of an electronic survey tool
HREC Reference Number: LNR/15/BHCG/82
SSA Reference Number: LNRSSA/15/BHCG/84

Thank you for submitting a Site Specific Assessment Form for authorisation of the above project at Bendigo Health. I can confirm that the submission was received on 06 December 2015.

I am pleased to inform you that authorisation has been granted for this project to be conducted at Bendigo Health.

The same conditions apply to this research project at your site as those imposed by the Human Research Ethics Committee that granted ethical approval:

List authorised document/s and version number

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	V1	30 November 2015
Application – LNR	V1	02 December 2015
Application –LNRSSA	V1	03 December 2015
Protocol: Current ethics application is for phase one only. The protocol outlines both phase one and two.	V1	19 November 2015
Participant Information Sheet/Consent Form: Bendigo Health	V1	04 November 2015
Letter of invitation to participant:	V1	21 January 2016
Questionnaire: Copy of the FES usage survey tool	V1	30 November 2015
Investigator CV: Natasha Lannin		
Investigator CV: Carol McKinstry		23 November 2015
Investigator CV: Owen Howlett		23 November 2015
Response to Request for Further Information		
Application– LNR	V2	21 January 2016

Questionnaire: V2 of the FES usage survey tool	2	21 January 2016
Participant Information Sheet/Consent Form: Bendigo Health with changes made as per reviewers' request.	V2	21 January 2016
Letter of invitation to participant: Changes made as requested by reviewers.	V2	21 January 2016
Bendigo Health HREC Approval Letter		27 January 2016

If you have any matters that arise regarding conduct of the research at this site, please ensure you contact the Research Manager.

Bendigo Health Care Group wishes you and your colleagues every success in your research.

Yours sincerely



Ms Sally McCarthy
Research Manager
Bendigo Health Care Group

E-mail: SAMcCarthy@bendigohealth.org.au

Appendix B2

Study Two Phase One – HREC Approval La Trobe University

MEMORANDUM

To: Carol McKinstry
Student: Owen Howlett
From: Secretariat, SHE College Human Ethics Sub-Committee (SHE CHESC)
Reference: SHE CHESC acceptance of Bendigo Health HREC approved project – LNR/15/BHCG/82.
Title: The use of functional electrical stimulation by physiotherapists and occupational therapists in stroke rehabilitation – development of an electronic survey tool
Date: 16 February, 2016

Thank you for submitting the above protocol to the SHE College Human Ethics Sub-Committee (SHE CHESC). Your material was forwarded to the SHE CHESC Chair for consideration. Following evidence of a full review and subsequent final approval by the **Bendigo Health HREC**, the SHE CHESC Chair agrees that the protocol complies with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and is in accordance with La Trobe University's *Human Research Ethics Guidelines*.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by The Bendigo Health HREC.

Limit of Approval. La Trobe SHE CHESC endorsement is limited strictly to the research protocol as approved by The Bendigo Health HREC.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by The Bendigo Health HREC for the project should be notified formally to the SHE CHESC

Annual Progress Reports. Copies of all progress reports submitted to The Bendigo Health HREC are to be forwarded to the SHE CHESC. Failure to submit a progress report will mean that endorsement for your involvement in this project will be rescinded. An audit related of your involvement in the study may be conducted by the SHE CHESC at any time.

Final Report. A copy of the final report is to be forwarded to the CHESC within one month of it being submitted by The Bendigo Health HREC.

If you have any queries related to the information above or require further clarifications, please contact chesc.she@latrobe.edu.au. Please quote reference number **LNR/15/BHCG/82 – McKinstry/Howlett**.

On behalf of the College Human Ethics Sub-Committee, best wishes with your research!

Ms Kate Ferris
Human Ethics Officer
Secretariat – SHE College Human Ethics Sub-Committee
Ethics and Integrity / Research Office
La Trobe University Bundoora, Victoria 3086
E: chesc.she@latrobe.edu.au
P: (03) 9479 – 3370
<http://www.latrobe.edu.au/researchers/ethics/human-ethics>

Appendix B3

Study Two Phase One - HREC Final Report

Progress reports are **required annually**, on the anniversary of initial approval for the project, and at the completion of the project. Please ensure that **any requests to extend HREC approval are submitted at least twelve weeks prior** to the date of HREC approval expiry. Failure to comply with reporting requirements may result in suspension of approval for your research project.

To complete this form electronically save the form, and complete it using Microsoft Word. Alternatively, you may print this form out and complete it manually.

Please submit 2 hard copies of this form and a soft to the Secretary, Human Research Ethics Committee, Bendigo Health Care Group, P.O. Box 126, Bendigo, Victoria, 3552 (samccarthy@bendigohealth.org.au)

Please indicate: [double click on box, fill 'checked' default value in 'Properties'. then 'OK']

Annual Progress Report ☒

Extension Requested Yes ☐ No ☒

Final Progress Report ☐

Researcher Details

Project Title: The use of functional electrical stimulation by physiotherapists and occupational therapists in stroke rehabilitation - development of an electronic survey tool.

HREC Reference No	LNR/15/BHCG/82
Date of HREC approval	27 th January 2016
Expiry date of HREC approval	3P ¹ AuQ 2016
Progress report due date	
Progress report submission date	
Contact name	Owen Howlett
Contact phone number	5454 8505

Address Details

Bendigo Health, PO Box 126, Bendigo Health 3552

If this is a supervised project please indicate:

1. Level of project:

Honours <input checked="" type="checkbox"/>	Masters <input checked="" type="checkbox"/>	PhD <input type="checkbox"/>
Other <input type="checkbox"/>	Please specify: Doctorate of Clinical Science	

2. Supervisor name

[Dr Carol McKinstry

3. Supervisor Position and Qualification (e.g. PhD, M.D.)

Senior Lecturer of Occupational Therapy, PhD

Research Progress

Current status of project

Has the project commenced?	Yes [8] Date of commencement March 2016	No0 Expected commencement date	
Data collection:	not started <input type="checkbox"/>	continuing <input type="checkbox"/>	completed [8]
Data analysis:	not started <input type="checkbox"/>	continuing <input type="checkbox"/>	completed [8]
Has the project been completed?	Yes [8] Date of completion	No0 Expected completion date	
Has the project been discontinued?	Yes D	Date project discontinued Provide reasons (attach further information if required)	
Other (please describe):			

Adverse event

- a. Have any adverse events been reported for this project?
- b. If yes, have reports been forwarded to the Bendigo Health HREC?
- c. If no, why not? Please provide details.

	No [8]
Yes <input type="checkbox"/>	No <input type="checkbox"/>

- d. Have any participants withdrawn from the project?
- e. If yes, please provide details.

Yes ☐ No [8]

Complaints

- a. Have any participants lodged a complaint regarding this project?
- b. If yes, have copies of the complaints been forwarded to the HREC?
- c. If no, why not?

Yes <input type="checkbox"/>	No [8]
Yes	No

Research protocol

- a. Have you deviated from the research methodology as detailed in the original protocol or approved amendments?
- b. If yes, please explain.

Yes D No [8]

Participant information

- a. Have all research participants received and read (or had read to them) the required participant information?
- b. Have all research participants (or appropriate approved representatives) signed consent forms?
- c. If no, please explain.
-

Yes [8J] No ☐

Yes [8J] No

Data security

- a. Is the data stored securely with due regard to privacy concerns?
- b. If no, please explain
-

Yes [8J] No ☐

Other issues

- a. Were there any other issues concerning this project that the HREC should be aware of?
- b. If yes, please explain.
-

/ Yes ☐ No [8J]

Research summary

- a. Please attach a summary of research project progress. This summary should be no more than one page and should include:
- b. A brief statement of the aims of the research project.

This project aimed to test the FES Use Survey by using the cognitive interview technique of think aloud and verbal probing.

- c. A brief overview of the method, including number of participants and reasons for withdrawal of participants, if applicable.

All rehabilitation outpatient and inpatient physiotherapists and occupational therapists at Bendigo Health were contacted by email. Participants who replied to the invitation were provided a participant information sheet and an opportunity to ask the interviewer questions. Once the consent forms were signed, a time was organised to conduct the interviews. Cognitive interviewing was conducted with all participants. Participants were asked to read each question and explain to the interviewer what they were thinking in response to the question. In total 3 occupational therapists and 3 physiotherapists were recruited. The interviewer then asked questions to clarify the meaning of their statement or state a solution for the identified problem. All interviews were audio recorded and transcribed verbatim. Data was then organised into an excel spread sheet. The difficulties were then classified into themes of cognitive processing. Amendments were made to the draft FES Use Survey. Data is stored in a locked filing cabinet in La Trobe university.

- d. A summary of any research findings.

11 identified difficulties of completing the survey were categorised into five themes:

- Processing the question to make a decision.
- Determining a response to questions.
- Retrieving relevant information from memory.
- Comprehending the written question.

These difficulties resulted in 12 amendments to the FES Use Survey.

- e. A summary of future work to be conducted on the project, if applicable.

The testing of the survey is now complete and the survey was finalised ready to be used in future research.

- f. A summary of problems that have arisen during the conduct of the research project, particularly those that bear on the capacity of the project to be completed within the approved time frame.

No problems arose whilst conducting the project. The project was completed on time.

- g. A list of publications or conference presentations of the research project. The committee would appreciate a copy of any research publications.

Results of the projects were presented as a project to the Victorian Occupational Therapy Australia conference as a poster presentation, titled "Improving survey design through using cognitive interviewing". A copy of the poster has been attached. A manuscript titled "Using the cognitive interviewing process to improve survey design by allied health: a qualitative study" is about to be submitted for publication to the Australian Journal of Occupational Therapy Journal. If the manuscript is approved, this will be forwarded to the committee.

Request for Extension

Yes ☐

No [81

a. Do you require an extension to the current HREC approval?

b. If yes, until what date?

c. For what reason/s is an extension to HREC approval required?

DrCarol McKinst!Y

Principal Investigator Name

Supervisor name (if applicable)

£

Signature

13/1a/11

Date

Signature

Date

Improving survey design through using cognitive interviewing

Owen A Howlett^{a,b} (MaOT), Carol McKinstry^a (PhD), Natasha Lannin^{a,c} (PhD)

a. La Trobe University; b. Bendigo Health; c. Alfred Health

Introduction

- To answer a survey question, respondents need to:
- comprehend the written question
 - process the question to make a decision
 - retrieve relevant information from memory
 - determine a response to the question.

(Wills, Casper, & Lessler, 2010)

Prior to administering a survey it is important to ensure that surveys are understood in the way you intend.

In response to this need, survey designers have used the technique of cognitive interviewing to improve the ease of answering the questions.

Methods

Objectives

To pilot and improve a survey seeking to understand clinical skills and training.

Participants

Cognitive interviewing was conducted with three physiotherapists and three occupational therapists.

Data Collection

Two cognitive interviewing techniques were used:

- **Think-out loud**
Each participant was asked to read the questions out loud. The participant was then asked to articulate their thoughts out loud whilst answering the questions.
- **Probing**
After the think-out loud step, the interviewer asked specific questions to gain an exact understanding of the issues which may have arisen. The participant was invited to suggest solutions.

Analysis

The identified difficulties and amendments were tabulated into an excel spreadsheet. The authors then discussed the identified difficulties and the proposed changes. The survey was then finalised.

Results

Think out loud and probing identified 11 issues with survey format and question structure, 12 amendments were made, which included one correction, four additions and seven revisions. Interviewing took between 17 and 32 minutes per interview.

Cognitive Process	Issue	Example
Comprehending the written question	One participant was confused how to answer the question.	"So are we looking at that as you've done revise them - are you looking at one instance or all up?"
Processing the question to make a decision	Participants found it difficult to rank their answers.	"Ranking is difficult because all of them are important. I suppose I just have to go back to well what was my reason for using it? Now yeah, ranking them is hard. Things change around."
Retrieving relevant information from memory	Participants forgot the period of time as related to the question.	"Now here I've kind of lost my stream of thought and I want that two year prompt at the top just as a reminder of what I'm focusing on."
Determining a response to the question	Participants wanted to see what the self-directed learning was.	"I kind of want an option to put what the self-directed learning was."

Figure 1: Examples of the identified issues

Clinical Implication

Cognitive interviewing

- strengthened the survey, increasing the likelihood that respondents will understand the questions
- is practical in a clinical setting, and could be used to test educational materials and brochures.

Conclusion

Cognitive interviewing can improve the survey respondents understanding of the intended meaning of a survey's question.

Allied health staff can use cognitive interviewing to remedy the issues with question structure and survey format.

Reference

Wills, G. B., Casper, R., & Lessler, J. (2010). Cognitive Interviewing: A "How To" Guide. 1996. Paper presented at the Short course presented at the meeting of the American Statistical Association.

Corresponding Author: Owen Howlett, Bendigo Health, ohowlett@bendigohealth.org.au, PO Box 128, Bendigo, Australia 3550



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Appendix B4

Study Two Phase One - Participant Information and Consent Form



Mailing address

PO Box 199
Bendigo Victoria 3552
Australia

T + 61 3 5444 7411

F + 61 3 5444 7977

E health@latrobe.edu.au

latrobe.edu.au/health

Participant Information Sheet

Bendigo Health

Title	The use of functional electrical stimulation by physiotherapists and occupational therapists – development of an electronic survey tool.
Short Title	FES usage survey tool
Coordinating Principal Investigator	<i>Dr Carol McKinstry</i>
Principal Investigators	<i>Owen Howlett</i> <i>Associate Professor Lannin</i>
Location	<i>Bendigo Health</i>

1 Introduction

You are invited to take part in this research project titled “The use of functional electrical stimulation by physiotherapists and occupational therapists – development of an electronic survey tool”.

This Participant Information Sheet tells you about the research project. Knowing what is involved will help you decide if you want to take part in the research. You will be given a copy of this Participant Information Sheet to keep. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

2 Consent

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read.
- Consent to take part in the research project.

3 What is the purpose of this research?

The purpose of this study is to test and develop an electronic survey investigating the use of functional electrical stimulation by occupational therapists and physiotherapists. Your participation in the study will assist us make amendments to the survey design to ensure the survey meets its intended purpose; whilst minimising misinterpretation of meaning by the person completing the survey. The completed survey will allow us to investigate if occupational therapists and physiotherapists use the evidence based practice of functional electrical stimulation. Currently we do not know if therapists in Victoria are doing this. The research is being conducted as a part of Owen Howlett’s Doctorate of Clinical Science post graduate studies; supervised by Dr McKinstry and Associate Professor Lannin.

4 What does participation in this research involve?

As a participant in this study, you will be interviewed about the proposed electronic survey. The interview will take no longer than 1 hour to complete. This time can be taken within Bendigo Health work hours, however you will be asked to choose a time which is least disruptive to providing direct care. The interview will take place in a private room at a convenient location and time at Bendigo Health. The interview will be conducted by the student researcher; Owen Howlett. You will be asked to read the survey questions and explain to the student researcher what you are thinking whilst reading the survey. The student researcher may ask you to elaborate on the meanings of your statements, or ask you to provide suggestions for changes to the survey questions. You will be asked to match each of the questions to the surveys predetermined research objective. If you choose an objective which does not match the researchers intended purpose, the student researcher will invite you to suggest changes to the question so it will match the research objective. If you consent, the interview will be audio taped to allow the research student to review your statements. Rest breaks are allowed during the interview. There are no costs associated with participating in this research project, nor will you be paid.

5 Other relevant information about the research project

In total we are seeking 3 physiotherapists and 3 occupational therapists at Bendigo Health to test the electronic survey. To be eligible to test our survey you must be a practicing occupational therapist or physiotherapist employed at Bendigo Health.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your employment at Bendigo Health.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research.

8 What are the possible risks and disadvantages of taking part?

It is not expected that you will experience distress through the interview however if this does occur, an appropriate counselling service will be recommended by the student researcher.

9 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing

10 What will happen to information about me?

During the interview, information about your age, professional discipline, along with comments regarding the survey will be recorded. Your name will not be identified by any written data. Your first name may be audio recorded during the interview, your surname will not be audio recorded. When completed, all data will be transferred to electronic files and stored on the La Trobe University password protected research storage facility. Prior to transfer to electronic media, paper and audio copies will be stored in a locked filing cabinet located at La Trobe Rural Health School, clinical teaching building, room 203. Once this has been done, all paper copies will be shredded, and audio copies will be erased. You will not be able to retrieve specific information about yourself, as the data will be de-identified. It is anticipated that the results of this research project will be presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. The results will be reported in Owen Howlett's Doctorate of Clinical Science thesis. If you wish to obtain a copy of the finalised survey, you may contact Owen Howlett. His contact details are listed below.

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Bendigo Health (insert HREC ref no.) and La Trobe University (insert HREC ref no.). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 Further information and who to contact

If you want any further information concerning this project which may be related to your involvement in the project you can phone Owen Howlett on (03) 5454 8505 or email ohowlett@bendigohealth.org.au.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Sally McCarthy
Secretary Bendigo Health Human Research Ethics Committee
Collaborative Health Education and Research Centre
Bendigo Health
Telephone (03) 5454 6412
Email: samccarthy@bendigohealth.org.au
Please quote HREC reference number_____.

Senior Human Ethics Officer
Ethics and Integrity
Research Office
La Trobe University
Telephone: 03 9479 1443
Email: humanethics@latrobe.edu.au
Please quote the HREC reference number_____.

Consent Form - Adult providing own consent

Title The use of functional electrical stimulation by physiotherapists and occupational therapists – development of an electronic survey tool.

Short Title FES usage survey tool

Protocol Number

Project Sponsor La Trobe University

Coordinating Principal Investigator Owen Howlett

Principal Investigator Dr Carol McKinstry

Associate Investigator(s) Associate Professor Lannin

Location Bendigo Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _

Name of Witness* to Participant's

Signature (please print) _____

Signature _____ Date _

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher[†] (please print) _____

Signature _____ Date _

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

Appendix B5

Study Two Phase One - Participant Invitation

Phase 1 email invitation

Dear [Insert name of contact]

We would like to invite you to participate in our research. We are seeking 3 physiotherapists and 3 occupational therapists to help us test and further develop an online survey. The finalized survey will identify if therapists use functional electrical stimulation (FES) in their practice, and if there are factors which influence the uptake of FES. Your help will identify if the current survey is matching its intended purpose whilst minimising potential issues with the survey design.

We have attached the Participant Information Statement (PIS) which outlines the requirements of the project. Ethical approval has been granted from Bendigo Health (insert number) and La Trobe University (insert number). To complete this project, we will need to spend 30 – 60 minutes with you, at a location convenient for you.

If you would like to be involved, please let Owen know via email and he will discuss further arrangements. Owen can be contacted on 5454 8505 if you have further questions or concerns. We thank you for your time.

Yours sincerely

Dr Carol McKinstry

Senior Lecturer

La Trobe Rural Health School, La Trobe University

Owen Howlett

Research Student/ Occupational Therapist

La Trobe University/ Bendigo Health

Appendix B6

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Appendix B7

Study Two Phase One - Manuscript

Feature Article

Using the cognitive interviewing process to improve survey design by allied health: A qualitative study

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Background/aim: Allied health professionals frequently use surveys to collect data for clinical practice and service improvement projects. Careful development and piloting of purpose-designed surveys is important to ensure intended measuring (that respondents correctly interpret survey items when responding). Cognitive interviewing is a specific technique that can improve the design of self-administered surveys. The aim of this study was to describe the use of the cognitive interviewing process to improve survey design, which involved a purpose-designed, online survey evaluation staff use of functional electrical stimulation.

Methods: A qualitative study involving one round of cognitive interviewing with three occupational therapists and three physiotherapists.

Results: The cognitive interviewing process identified 11 issues with the draft survey, which could potentially influence the validity and quality of responses. The raised issues included difficulties with: processing the question to be able to respond, determining a response to the question, retrieving relevant information from memory and comprehending the written question. Twelve survey amendments were made following the cognitive interviewing process, comprising four additions, seven revisions and one correction.

Conclusions: The cognitive interviewing process applied during the development of a purpose-designed survey enabled the identification of potential problems and informed revisions to the survey prior to its use.

KEY WORDS allied health, health-care surveys, questionnaires, surveys.

INTRODUCTION

Occupational therapists and physiotherapists frequently use surveys to evaluate clinical practice and inform improvements in service delivery (Boeije & Willis, 2013; Chang, Boots, Hodges & Paratz, 2004; Koh, Hoffmann, Bennett & McKenna, 2009). Where possible, validated surveys are used, however, there are occasions when the topic of interest is unique. In these instances, purpose-designed surveys may need to be developed. The validity and dependability of a survey's results are significantly influenced by survey design (Drennan, 2003). Development of a purpose-designed survey requires considerable attention to ensure that the survey measures what is intended, and respondents understand and correctly interpret survey items. Even with careful survey design and piloting, these processes do not necessarily ensure that the respondents will understand the questions in the manner in which the survey's authors intended (Garcia, 2011).

The cognitive interviewing process is a specific technique that can be used during the development and testing of surveys and questionnaires to help identify whether survey items generate the information that the investigator intends and thus, to inform revisions (Humann, Ridolfo, Virji & Henneberger, 2013; Moore, 2009; Spark & Willis, 2014). The process identifies and analyses sources of response error within surveys by focussing on the cognitive processes that respondents use to answer the survey items or question. It concentrates on the items and questions within the survey, rather than how the survey is administered. Cognitive interviewing has its origins in cognitive psychology where it was proposed that survey respondents use distinct cognitive processes when reading and answering survey questions (Collins, 2014; Tourangeau, 1984).

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Conflict of Interest
None declared.

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These processes include comprehension of the written question, retrieval from memory of relevant information, the decision and response processes (Willis, Royston & Bercini, 1991). Based on these cognitive processes, two distinct cognitive interviewing strategies have been recommended to test survey questions (Boeije & Willis). The first is 'think-aloud' interviewing where the respondent explains to the interviewer what they are thinking in response to reading the question. The second strategy is 'verbal probing' and involves the interviewer asking the respondent pre-planned or spontaneous questions (after the think-aloud process) about their process of answering the question. These interviewing strategies help understand the respondent's cognitive responses during testing, which can then be used to revise the survey and improve its validity and reliability (Aicken *et al.*, 2013; Boeije & Willis; Ryan, Gannon-Slater & Culbertson, 2012).

While the use of cognitive interviewing has received some attention in the fields of dietetics (Subar *et al.*, 1995), pharmacy (Spark & Willis, 2014), sports science (Dietrich & Ehrlenspiel, 2010) and nursing (Izumi, Vandermause & Benavides-Vaello, 2013), there is limited literature regarding its use by occupational therapists. Cognitive interviewing is a strategy that could enhance and improve robust data collection techniques by occupational therapists.

The aim of this study was to describe the use of the cognitive interviewing process to develop a purpose-designed, online survey, using an example of investigating the use of functional electrical stimulation by occupational therapists and physiotherapists.

Methods

Design

A prospective qualitative study was undertaken whereby the cognitive interviewing process assisted in the development of an online survey evaluating the use of functional electrical stimulation by allied health professionals. The research ethics committee of Bendigo Health (reference LNR/15/BHCG/82) and La Trobe University (reference SHE CHESC acceptance of Bendigo Health HREC approved project – LNR/15/BHCG/82) approved this study prior to commencement. A participant information statement was provided and all participating therapists provided written informed consent.

Participants and setting

A sample of convenience was sought from allied health professionals (occupational therapists or physiotherapists) working in health and known to have clinical experience with neurological rehabilitation of stroke survivors.

Study protocol

The researchers first developed a draft survey investigating therapists' use of functional electrical stimulation.

After the content of the draft version was finalised, the process of cognitive interviewing commenced. Each participant completed a one-on-one single session of cognitive interviewing with one of the researchers (OH) at a time and place that was convenient for the participant. Within each session of cognitive interviewing, the 'think-aloud' and 'verbal probing' strategies were used. All interviews were audio recorded and transcribed verbatim.

Think-aloud strategy

For participants to understand the requirements of the 'think-aloud' process, they were given time to practise the technique using the training method suggested by Willis, Caspar and Lessler (2013). This technique involved inviting the participant to respond to the following statement aloud: "Try to visualize the place where you live, and think about how many windows there are in that place. As you count up the windows, tell me what you are seeing and thinking about." (Willis *et al.*, p. 4). During the 'think-aloud' process, the interviewer, on noting any hesitation by participants during the interview, prompted the participant by saying 'Tell me what you are thinking'. This open-ended format of questioning is believed to reduce the likelihood of the interviewer's bias being imposed onto the participant (Willis, 2004).

Verbal probing strategy

'Verbal probing' was then undertaken to investigate each participant's cognitive process while answering the survey questions (Collins, 2003). A variety of probing techniques were used throughout the testing of the functional electrical stimulation use survey as follows: comprehension, paraphrasing, recall, specific probing and general probing (Willis, 2004). To increase the richness of information gathered, the verbal probes were both spontaneous and pre-planned (Willis). Table 1 provides examples of the verbal probing techniques used during the interviews. The number of pre-planned probes was intentionally limited during the interviews because they can distract participants from the think-aloud process. All verbal probing was completed during the interview, rather than at its completion (Miller, Chepp, Willson & Padilla, 2014). Care was taken to ensure that verbal probing by the interviewer did not lead the participant to select a response that reflected the interviewer's beliefs rather than their own (Willis).

Following completion of the think-aloud and verbal probing strategies for each question and to complement the cognitive interviewing process, each participant was asked to read the research aims of the functional electrical stimulation survey. These were to determine if: (i) occupational therapists and physiotherapists use functional electrical stimulation to improve the daily life of stroke survivors, and (ii) functional electrical stimulation use depends on therapist's discipline, gender,

TABLE 1: *Examples of verbal probing used during testing of the functional electrical stimulation use survey*

Verbal probing type	Verbal probing examples	
	Spontaneous	Pre-planned
Comprehension probe	Does that make sense?	How do you define the difference between the categories?
Paraphrasing probe	You are finding that hard, is that what I am hearing?	Not used
Recall probe	You find that timeframe quite easy to identify?	Is this hard to identify if it has been in the past two years?
Specific probe	Alright, if there was another way of asking that question that could be more accurate but easier, would you rephrase it in any way?	Do you find it hard to define the difference between the three categories that we have there?
General probe	So, what are you thinking at the moment?	So, tell me what you are thinking.

training, location of practice and/or years of experience with stroke survivors. Each participant was then asked to match a research aim to each survey item.

Outcome measures and data analyses

A pre-designed data collection form was used during the interview to record the verbalised concerns of participants and proposed solutions. At the completion of all the interviews, data were transcribed verbatim into a written format, and all participant perceived difficulties and their proposed solutions were recorded, and then summarised into a table format. The researchers, through a consensual process, agreed on which amendments were required. Once the survey amendments were finalised, the amendments were classified according to the cognitive process domains by one researcher while another researcher reviewed and agreed upon the domains allocated. For the matching of research aims to survey items, the agreement between participants' responses and the investigators' responses was measured. The participants were not asked to clarify their reasoning if the objectives were mismatched with the investigator's response. If mismatched, the researcher reviewed the participant's response to identify if the meaning of the question was not understood.

Results

Participants

Six participants were recruited to the study to take part in the cognitive interviewing process: three occupational therapists and three physiotherapists. The participants' mean (range) age was 28.3 (23–34) years and all were women. All therapists worked in the clinical area of neurological rehabilitation.

Cognitive interviewing process

The mean (range) interview duration was 38.2 (28.43–53.87) minutes. The cognitive interviewing process

resulted in the identification of 11 issues within the draft survey. A summary of these issues, the survey amendments and the supporting responses from participants are presented in Table 2. Each issue may have arisen from either an individual or multiple participants responses. Ten of the 11 problems resulted directly from the cognitive interviewing strategies of 'think out-loud' and 'probing'. The 11 problems identified were as follows.

- One issue was an error that had arisen during transcription from the paper version to the online version of the draft survey.
- Four issues were related to where some participants had difficulty in understanding the questions to enable a decision. For example, three participants were unable to respond to two questions because they had previously stated within the survey, that the clinical scenario was not relevant to them.
- Two issues arose when participants were determining a response to a question. For example, participants indicated that the survey's pre-determined answers did not accurately capture their response.
- One issue related to the process of participants recalling relevant information. For example, participants consistently identified that they had forgotten that their answers only related to the past two years.
- Three issues related to participants having difficulty in comprehending the question. For example, two participants could not decide if their student experiences should be included in their answers.

After the cognitive interviewing process, 12 amendments were made, including changes to the survey format, sentence structure and answer format. These amendments comprised four additions; seven revisions and one correction (see Table 2).

Matching research aims and questions

Participants were asked to match the research aims with individual survey items, with an agreement rate of 101 out of 108 (94%) between the researchers and the

TABLE 2: Summary of the issues identified, amendments and participants' responses during the cognitive interviewing process

Cognitive process	Original question/statement	Identified issue	Resulting amendment	Participants' responses
Processing the question to make a decision	Thinking about your use of FES when training the upper limb (shoulder, arm, and/or hand): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect.	Participants were confused as to why they were answering the question given that some participants had not used FES for upper limb training.	Added online rule to the electronic survey to allow participants to only answer the question if they had used FES for upper limb training.	<ul style="list-style-type: none"> • "I guess I have indicated in previous questions that I haven't used it in any of these situations." • "So I'm just in a bit of a quandary. Because I haven't actually used it but I believe that it can help with these things as to how to answer this." • "So I guess I can still answer that based on theoretical knowledge but not actual clinical use."
	Thinking about your use of FES when training the lower limb (hips, leg and/or foot): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect.	Participants were confused as to why they were answering the question given that some participants had not used FES for lower limb training.	Added online rule to the electronic survey to allow participants to only answer the question if they had used FES for lower limb training.	<ul style="list-style-type: none"> • "Don't know haven't done it." • "So, because I ticked 'no', is this still going to come up?" • "Don't know I'm not a physio." • "Not sure, haven't seen it in action."
	Reference cited at the end of the survey providing the definition of FES.	Participants were not sure if the survey was completed and if they needed to proceed to another page.	Reference was relocated from the end of the survey to appear at the time of the definition of FES.	"I think it would be more clear if this thank you box popped up right at the very end rather than finishing with the reference and then finishing the survey."
	Ranking options where participants were asked to: "Please rank the following reasons from 1 to 5, with 1 being the most common reason and 5 as the least common reason."	Participants found it difficult to rank their answers.	Statement was revised to read: "Please select the statement which reflects the most common reason for you to use FES."	<ul style="list-style-type: none"> • "Yeah, it kind of throws me thinking what are they trying to know, what are they wanting to know and it sort of feels a little bit like judgy (sic) on how you're being perceived as a therapist." • "Ranking is difficult because all of them are important. I suppose I just have to go back to well what was my reason for using it? Now, yeah, ranking them is hard. Things change around."

TABLE 2: (Continued)

Cognitive process	Original question/statement	Identified issue	Resulting amendment	Participants' responses
Determining a response to questions	Question response: "Self-directed learning."	Participants wanted to state what type of self-directed learning they had undertaken.	Added the option of a free text answer describing the type of self-directed learning.	<ul style="list-style-type: none"> • "Because self-directed learning could be – it could come under on-the-job training but it could also be doing your own research and that kind of thing." • "I kind of want an option to put what the self-directed learning was."
	Question: "How did you learn how to administer FES? Please rank each method of training from 1 to 5, with 1 ranked as the method of training which was most useful and 5 as the least useful. Tick NA if you did not use this method at all."	Participants wanted to be able to answer the question to indicate that they had received training for the use of FES, even if they had not used the intervention.	Added the question: "Have you spent time learning how to use FES?" Added online rule to the electronic survey to skip all remaining questions if the answer selected was 'no'.	"Well, I have learnt how to administer it. I just haven't done it."
Retrieving relevant information from memory	Question: "In the past two years, have you used FES in the following clinical scenarios?"	Participants forgot that this introductory statement related to more than one question.	Revised so that this statement was repeated for questions 11, 12 and 13.	<ul style="list-style-type: none"> • "For the person that has been in the last two years, I would add that in. Just so you're getting with the right timeframe." • "Now here I've kind of lost my stream of thought and I want that two year prompt at the top just as a reminder of what I'm focussing on."

TABLE 2: (Continued)

Cognitive process	Original question/statement	Identified issue	Resulting amendment	Participants' responses
Comprehending the written question	Statement re-effect of FES: "Stroke survivors will be able to use their weak upper limb in daily activities." Question: "How many years have you worked with stroke survivors?"	Participant became confused regarding what the question was asking. Participants were unsure if they should include patients seen as a student.	Revised statement to: "Stroke survivors will be able to use their weak upper limb in more daily activities." Revised statement to: "How many years have you worked with stroke survivors? Do not include stroke survivors you saw as a student."	"I think, yeah, if you're trying to assess if they're able to do more daily activities then, yeah, that doesn't really ask that question well." <ul style="list-style-type: none"> "I'd probably say, stipulate whether it was work as in working practicing or like eliminate that university student versus work clinician. If that makes sense." "I would include a statement around working as a registered practitioner or having in brackets this does not include time as a student maybe."
	Question: "What was the duration of the CPD?"	One participant was confused regarding how to answer the question, as she had completed multiple sessions of FES training.	Revised question to: "What was the total duration of your CPD?"	"So are we looking at that as you've done more than – are you looking at one instance or all up?"
	Statement: "Electrodes connected to an electrostimulation device placed onto foot or leg muscles to assist the stroke survivor walk."	The statement was incorrectly worded in the online survey.	Corrected statement to: "Why did you use FES to assist a stroke survivor to walk?"	No response recorded.

CPD = continuing professional development; FES = functional electrical stimulation; NA = not applicable.

participants' responses'. One response included an additional objective, which was not identified by the researchers, and six responses allocated one research objective for the question as compared to the researchers' choice of two objectives for the question. On review of mismatched responses, participants think-aloud responses demonstrated an understanding of the questions; therefore, no adjustments to research objectives were required.

Discussion

This study describes the use of a cognitive interviewing process to develop an allied health survey, involving an online survey investigating the use of functional electrical stimulation by occupational therapists and physiotherapists. The cognitive interviewing process was useful in identifying issues with the draft survey that may not have been otherwise identified. The resultant amendments improved the survey content and ensured that survey items generated the desired data for a future study. While only six participants in the current study were included in the cognitive interviewing process, this number of participants was similar to other studies in health care (Pearson, Morris & McKinstry, 2015; Ryan *et al.*, 2012). Despite there only being a small number of participants, the cognitive interview process was able to identify issues with the draft surveys resulting in amendments and improvements.

Despite the lack of studies describing the use of cognitive interviewing with occupational therapists or physiotherapists, our findings are similar to studies investigating the use of cognitive interviewing by other allied health professionals. In a pharmacy-based project investigating the development of people's perspectives on progesterone use (Spark & Willis, 2014), results identified that respondents were not able to comprehend terminology about product information; thus the question format was modified to allow easier interpretation. In a study investigating functional electrical stimulation with people with spinal cord injury (Triccas *et al.*, 2016), suggestions were made by health professionals to change the wording of statements within the question. Consistent with our study, one respondent was unable to understand a question related to functional electrical stimulation training, thus an additional word helped clarify the question. The current study has also demonstrated the use of cognitive interviewing by allied health professionals to improve the design of surveys to enhance the understanding of interventions (Pearson *et al.*, 2015; Triccas *et al.*).

In the current study, a single round of cognitive interviewing appeared to generate sufficient insight into the cognitive processes of survey respondents, consistent with suggestions by other researchers (Hall & Beatty, 2014). Other authors, however, have recommended that the process of cognitive interviewing should be repeated after amendments are made to further increase

the likelihood that all major issues with the survey are identified and resolved (Willis & Artino, 2013; Willis *et al.*, 2013). It is acknowledged that it may not be practical for small-scale projects to undertake multiple rounds of cognitive interviewing because of restricted participant numbers and the human and financial resources required to collect and analyse the data (Ryan *et al.*, 2012). An alternative to repeated rounds of cognitive interviewing is to analyse responses after each set of two or three interviews (Ryan *et al.*; Spark & Willis, 2014). While only conducting six interviews, this method gave the researchers some ability to see if the amendments they had made had resolved the identified issues. Future research could investigate the optimal number of rounds of cognitive interviewing that are necessary to ensure saturation is reached (Guest, Bunce & Johnson, 2006) while also conducting a cost effectiveness analysis based on the thematic saturation level of each interview round (Namey, Guest, McKenna & Chen, 2016). These investigations would identify if the cost of research methodology outweighs the benefits from the survey improvements.

Clinical implications

As the process of cognitive interviewing relies on excellent interpersonal skills (Willis *et al.*, 2013), allied health professionals are well placed to learn and utilise the process of cognitive interviewing and thus improve the content of the purpose-designed surveys. The cognitive interviewing process provides a simple but effective method that enables clinicians to identify problems with a survey prior to its implementation in practice. For example, a clinician may test a survey via cognitive interviewing prior to using the survey to identify a client's viewpoint about their involvement with an occupational therapy group or individual intervention. The strategies of 'think-aloud' and 'verbal probing' may also be used when developing brochures, pamphlets, protocols and educational handouts (Collins, 2014; Seligman *et al.*, 2007) to ensure the key messages of these tools are understood by the readers consistent with the authors' intentions. Box 1 provides an overview of the steps to conduct cognitive interviews in clinical practice.

Study limitations

The main limitation of the current study was that a convenient and small sample of participants was used, which may have resulted in collection of insufficient data to achieve saturation (Guest *et al.*, 2006). The concept of saturation indicates that no further new information will be obtained by conducting more interviews (Willis, 2015). While this is a limitation, it is important to acknowledge that the small sample in this study did identify necessary edits, and strengthened the quality of the survey. Data analysis in the current study used the transcribed interviews to capture participants' remarks, which were then summarised to identify issues and

Box 1: Using cognitive interviewing process in clinical practice

1. The interviewee reads one survey question.
2. The interviewee thinks-aloud after they have read the question.
3. The interviewer ask probing questions to understand the issue.
4. Suggestions for solutions are given and recorded.
5. Repeat step 1–4 for each survey question.
6. After completion of multiple cognitive interviews, changes to the question or survey structure are made and then re-tested to ensure amendments have had desired effect.

possible solutions. Our subjective process of analysis may have been improved by using a formalised analytical approach (Miller *et al.*, 2014) such as thematic analysis, matrix display strategy or a systematic approach (Bobrovitz, Santana, Kline, Kortbeek & Stelfox, 2015; Fisher, Falkner, Trevisan & McCauley, 2000; Knafl *et al.*, 2007). The use of a formalised analytical approach would improve replicability of any similar future studies or survey improvement studies.

Conclusion

This study has demonstrated that the cognitive interviewing process can improve the quality of a purpose-designed online survey for use in an allied health setting. Through increased understanding of the participants' cognitive processes while responding to the questions, issues with survey format and question structure and content can be identified and addressed improving accuracy and quality of data collected.

Key points for occupational therapy

- Survey questions may not be interpreted in the way the author intended.
- Survey questions may be tested by using a cognitive interviewing technique.
- Cognitive interviewing is practical in occupational therapy research and may strengthen survey design.

Acknowledgments

We declare that all authors have contributed significantly, and that all authors are in agreement with the content of the manuscript.

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Appendix B8

Study Two Phase Two - HREC Approval La Trobe University

-----Original Message-----

From: ResearchMasterEthics@latrobe.edu.au <ResearchMasterEthics@latrobe.edu.au>
Sent: Monday, 8 August 2016 1:29 PM
To: ResearchMasterEthics <ResearchMasterEthics@latrobe.edu.au>; Carol McKinstry <C.McKinstry@latrobe.edu.au>
Cc: Owen Howlett <O.Howlett@latrobe.edu.au>; Natasha Lannin <N.Lannin@latrobe.edu.au>
Subject: S16-99 (Finalised - Approved) - Application finalised as Approved

Dear Carol McKinstry,

The following project has been assessed as complying with the National Statement on Ethical Conduct in Human Research. I am pleased to advise that your project has been granted ethics approval and you may commence the study.

Application ID: S16-99

Application Status/Committee: Finalised - Approved

Project Title: Is functional electrical stimulation used by physiotherapists and occupational therapists in Victoria, Australia?

Chief Investigator: Carol McKinstry

Other Investigators: Natasha Lannin, Mr Owen Andrew Howlett

Date of Approval: 08/08/2016

Date of Ethics Approval Expiry: 30/06/2017

The following standard conditions apply to your project:

- Limit of Approval. Approval is limited strictly to the research proposal as submitted in your application.
- Variation to Project. Any subsequent variations or modifications you wish to make to your project must be formally notified for approval in advance of these modifications being introduced into the project.
- Adverse Events. If any unforeseen or adverse events occur the Chief Investigator must immediately notify the UHEC immediately. Any complaints about the project received by the researchers must also be referred immediately to the UHEC.
- Withdrawal of Project. If you decide to discontinue your research before its planned completion, you must inform the relevant committee and complete a Final Report form.
- Monitoring. All projects are subject to monitoring at any time by the University Human Ethics Committee.
- Annual Progress Reports. If your project continues for more than 12 months, you are required to submit a Progress Report annually, on or just prior to 12 February. The form is available on the Research Office website. Failure to submit a Progress Report will mean approval for this project will lapse.
- Auditing. An audit of the project may be conducted by members of the UHEC.
- Final Report. A Final Report (see above address) is required within six months of the completion of the project.

You may log in to ResearchMaster (<https://rmenet.latrobe.edu.au>) to view your application.

If you have any further questions, please contact the:

UHEC at humanethics@latrobe.edu.au

SHE College Human Ethics Sub-Committee at chesc.she@latrobe.edu.au ASSC College

Human Ethics Sub-Committee at chesc.assc@latrobe.edu.au

Appendix B9

Study Two Phase Two - HREC Final Report

FINAL REPORT FORM – HUMAN RESEARCH ETHICS

1. Approval Number	S16-99	
2. Project Title	Is functional electrical stimulation used by physiotherapists and occupational therapists in Victoria.	
3. Chief Investigator / Supervisor: (academic staff members only)	Name: Dr Carol McKinstry Email address: C.McKinstry@latrobe.edu.au	
4. Student (if applicable)	Name: Owen Howlett Email address: oahowlett@students.latrobe.edu.au	
5. Project Duration:	Project commenced: 1/ 08/ 2016	Project concluded: 01/ 05 /2017

Status of project

6. Please tick or highlight whichever is applicable:

- ☒ Data collection completed
☐ Project discontinued – please explain:

7. Indicate whether your project occurred as planned or if any variations were required:

- ☒ Project proceeded as approved
☐ Modifications were submitted and approved
☐ Project procedures varied from those approved. Please provide details:

Project summary

8. Provide a brief summary of your project findings and whether your project met the original aims (maximum one page):

The survey investigated the use of functional electrical stimulation (FES) by Victorian clinicians in stroke rehabilitation. 97 clinicians responded to the online survey. Of which 62% of respondents were occupational therapists. The remaining clinicians were either physiotherapists or allied health assistants. FES was predominantly used for upper limb rehabilitation for stroke rehabilitation. 52% of respondents had used FES in the past two years to improve the daily life of a stroke survivor. Variation of use was evident depending on work place setting, geographical location and years of experience. Education and training did not appear to influence uptake of FES. The project meet the aims of obtaining an overview of clinicians use of FES (in Victoria) and demonstrates variation of use

exists. The findings support the need for future research to gain an understanding to whether or not implementation strategies are required to improve the uptake of FES in clinical practice.

9. Provide the details of all publications to date which contain findings from this research project.

Findings have been submitted to Occupational Therapy Australia Journal submitted on 17th Oct 2017.

Results presented as a poster at the 2017 National Occupational Therapy Conference on the 19 – 21st July 2017. Poster titled: The Use of Functional Electrical Stimulation (FES) by Victorian Occupational Therapists and Physiotherapists.

10. Provide the details of all conferences at which findings from the research project have been presented.

Data Security

11. Are data secure and stored as advised in your initial application and any approved modifications?

- ☒ Yes
☐ No - Please explain:

Recruitment of participants

12. Specify your participant numbers in the table below.

Target number of participants	Number of participants recruited in total	Number of participant withdrawals
200	98	0

13. Provide reason(s) for participant withdrawal if applicable.

14. If the project was discontinued, please explain how participants were informed.

Incidents and Complaints

15. Did any ethically significant incidents arise during your research?

- ☐ Yes - Please specify whether the incidents were reported to the UHEC:
☒ No

16. Specify whether any complaints were received from participants and provide details.

Nil complaints received.

Chief Investigator Declaration

By submitting this report;

I, the Chief Investigator, confirm that the information contained in this report is true and accurate.

I, the Chief Investigator, confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007) or as amended.

The report must be submitted electronically by the Chief investigator from the La Trobe University staff email account. If the Chief Investigator is unable to submit the form, please ensure they are copied into the email to demonstrate they are aware of the submission.

Please submit all forms to humanethics@latrobe.edu.au

Website: <http://www.latrobe.edu.au/researchers/research-office/ethics/human-ethics>

Appendix B10

Study Two Phase Two - Participant Invitation

Email to occupational therapy and physiotherapy special interest group

Dear [Insert name of the SIG Convenor here]

As per previous correspondence, the below email text is inviting your members to participate in an online survey. If possible can you please distribute the following email to your members?

Thank you for your time. Please let me know if you have questions and I will do my best in answering them.

Owen Howlett
Research Student
Doctorate of Clinical Science Candidate
La Trobe Rural Health School | La Trobe University | P.O Box 199 Bendigo VIC 3552 Australia
T: 03 54 44 9111 | F: 03 5444 7977 | E: oahowlett@latrobe.edu.au | W: www.latrobe.edu.au

Dear [insert either occupational therapist or physiotherapist]

You are invited to participate in an online survey investigating the use of functional electrical stimulation (FES) to improve the daily life of a stroke survivor.

The aim of this survey is to identify if occupational therapists and physiotherapists use functional electrical stimulation in their practice; and to determine if there are factors which determine the use of FES. The results of the survey will inform future research investigating the enablers and barriers to implementing FES in clinical practice.

The survey is online, and will take no longer than 15 minutes to complete.

You can access this survey and the Participant Information Statement via the following link.

https://latrobe.co1.qualtrics.com/SE/?SID=SV_2g9a2C279eNUOyx

This research is being conducted as apart of Owen Howlett's Doctorate of Clinical Science. Ethical approval has been granted from La Trobe University (SHE-CHESC No. *S16-99*) for this study to proceed.

We thank you for your time, in this matter. If required, Owen Howlett can be contacted on 03 5448 9144 if you have further questions or concerns.

Yours sincerely

Dr Carol McKinstry
Principal Investigator
Senior Lecturer Occupational Therapy
La Trobe Rural Health School | La Trobe University | PO Box 199 Bendigo 3552
T: 03 5448 9111 | W: www.latrobe.edu.au

Owen Howlett
Research Student
Doctorate of Clinical Science Candidate
La Trobe Rural Health School | La Trobe University | P.O Box 199 Bendigo VIC 3552 Australia
T: 03 54 44 9111 | F: 03 5444 7977 | E: oahowlett@latrobe.edu.au | W: www.latrobe.edu.au

Email invitation to Occupational Therapy List-serve

Dear Occupational Therapy List serve member,

You are invited to participate in an online survey investigating the use of functional electrical stimulation (FES) to improve the daily life of a stroke survivor.

The aim of this survey is to identify if Victorian occupational therapists and physiotherapists use functional electrical stimulation in their practice; and to determine if there are factors which determine the use of FES. The results of the survey will inform future research investigating the enablers and barriers to implementing FES in clinical practice.

The survey is online, and will take no longer than 15 minutes to complete.

You can access this survey and the Participant Information Statement via the following link.

https://latrobe.co1.qualtrics.com/SE/?SID=SV_2g9a2C279eNUOyx

This research is being conducted as apart of Owen Howlett's Doctorate of Clinical Science. Ethical approval has been granted from La Trobe University (SHE-CHESC No. *S16-99*) for this study to proceed.

We thank you for your time, in this matter. If required, Owen Howlett can be contacted on 03 5448 9144 if you have further questions or concerns.

Yours sincerely

Dr Carol McKinstry
Principal Investigator
Senior Lecturer Occupational Therapy
La Trobe Rural Health School | La Trobe University | PO Box 199 Bendigo 3552
T: 03 5448 9111 | W: www.latrobe.edu.au

Owen Howlett
Research Student
Doctorate of Clinical Science Candidate
La Trobe Rural Health School | La Trobe University | P.O Box 199 Bendigo VIC 3552 Australia
T: 03 54 44 9111 | F: 03 5444 7977 | E: oahowlett@latrobe.edu.au | W: www.latrobe.edu.au

Invitation via social media – Twitter (140 character length)

Do OTs and PTs use FES in practice in Victoria, Aus? Help us find out by completing the survey at https://latrobe.co1.qualtrics.com/SE/?SID=SV_2g9a2C279eNUOyx please RT

Do OTs and PTs use FES in Victoria, Aus? Help us by completing the survey at https://latrobe.co1.qualtrics.com/SE/?SID=SV_2g9a2C279eNUOyx

Mail invitation to health services

[Insert Date]

[Recipient's Title + First Name + Family Name]

[Address Line 1]

[Address Line 2]

[Address Line 3]

[Suburb + State + Postcode]

[Country]

Dear [Click here to enter Salutation]

You and your department staff are invited to participate in an online survey investigating the use of functional electrical stimulation (FES) to improve the daily life of a stroke survivor. The aim of this survey is to identify if occupational therapists and physiotherapists use functional electrical stimulation in their practice; and to determine if there are factors which determine the use of FES. The results of the survey will inform future research investigating the enablers and barriers to implementing FES in clinical practice.

The survey is online, and will take no longer than 15 minutes to complete.

You can access the survey and the Participant Information Statement via the following link.

https://latrobe.col.qualtrics.com/SE/?SID=SV_2g9a2C279eNUOyx

This research is being conducted as apart of Owen Howlett's Doctorate of Clinical Science. Ethical approval has been granted from La Trobe University (SHE-CHESC No. *S16-99*) for this study to proceed.

We thank you for your time, in this matter. If required, Owen can be contacted on 03 5448 9144 if you have further questions or concerns.

Yours sincerely

Dr Carol McKinstry

Principal Investigator/ Senior Lecturer of Occupational Therapy

Owen Howlett

Doctorate of Clinical Science Candidate

Appendix B11

Study Two Phase Two – Survey Including Participant Information Statement

Block 4



La Trobe Rural Health School
Faculty of Health Sciences

Mailing address

La Trobe University
Victoria 3086 Australia
E:
oahowlett@students.latrobe.edu.au
MELBOURNE CAMPUSES
Bundoora
Collins Street CBD
Franklin Street CBD
REGIONAL CAMPUSES
Bendigo
Albury-Wodonga
Mildura
Shepparton

Participant Information Statement

IS FUNCTIONAL ELECTRICAL STIMULATION USED BY PHYSIOTHERAPISTS AND OCCUPATIONAL THERAPISTS IN VICTORIA, AUSTRALIA?

You are invited to participate in this research project titled "Is functional electrical stimulation used by physiotherapists and occupational therapists in Victoria, Australia?" You are able to print a copy of this Participant Information Statement by using the print function in your web browser.

Chief investigator: Dr. Carol McKinstry, La Trobe University
c.mckinstry@latrobe.edu.au

Associate Researcher: Associate Professor Natasha Lannin
N.Lannin@latrobe.edu.au

Student Researcher: Owen Howlett, La Trobe University
oahowlett@students.latrobe.edu.au

Purpose of this research

This study is investigating if occupational therapists and physiotherapists use functional electrical stimulation (FES) with stroke survivors in clinical practice. Your participation in the study will assist us identify if the evidence based intervention of FES is being used in Victorian healthcare. The benefit of this study will identify if further research is required to assist establish the use of FES in stroke rehabilitation. This study is being conducted as a part of Owen Howlett's post graduate studies of a Doctorate of Clinical Science; supervised by Dr McKinstry and Associate Professor Lannin.

Research requirements

To be eligible for completing this survey, you must be a practicing occupational therapist or physiotherapist, registered with AHPRA, working in the state of Victoria, Australia.

What does participation in this research involve?

This study requires you to complete an online survey. Your participation is voluntary. The survey has 20 multiple choice questions. It is anticipated the survey should take no longer than 15 minutes to

complete.

What will happen to information about me?

Your answers to the questions will be collated and analyzed by the research team using the online data platform "Qualtrics". All of the data will be stored on a La Trobe University password protected computer. The data will be stored for 7 years. There will be no identifiable information about you recorded. Your name or your organizations name will not be collected by us. There will be no identifiable information about you in any reports, published articles or presentations. The results of this survey may be presented at state, national or international health conferences. The results may be published in a health journal and will be included in Owen Howlett's Doctoral thesis. Results from the survey will be made available to you on request by contacting Owen Howlett on telephone (03) 5448 9144 or oahowlett@students.latrobe.edu.au. Results are likely to be available in 2017.

Can I withdraw for participating in this project?

You have the right to withdraw from active participation in this project whilst completing the survey. However, once you submit the survey, it will not be possible to withdraw that information from this project.

What are the possible risks and disadvantages of taking part?

There are no foreseen disadvantages, penalties or adverse consequences for not participating in or withdrawing from the survey. There are no foreseen risks, harms or discomforts which will result from this project.

Further information

If, you require any further information about this project or wish to clarify any aspects of this project the primary contact for this project is Owen Howlett. You can contact him on (03) 5448 9144 or oahowlett@students.latrobe.edu.au.

If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (P: 03 9479 1443, E: humanethics@latrobe.edu.au) . Please quote the application reference number S16-99.

Block 1**What is your profession?**

- ☐ Occupational therapist registered with AHPRA
- ☐ Physiotherapist registered with AHPRA
- ☐ Allied health assistant
- ☐ Other. State your profession.

Is the location of your primary workplace, in Victoria, Australia?

- ☐ Yes

☐ No

What is your gender?

- ☐ Male
- ☐ Female

How many years have you worked with stroke survivors? (do not include stroke survivors you saw as a student)

What is the location of your primary workplace? (i.e. the workplace where you spend the most time)

- ☐ Metropolitan
- ☐ Regional
- ☐ Rural

What is the setting of your primary workplace? (i.e. the workplace where you spend the most time)

- ☐ Acute public hospital (inpatient)
- ☐ Acute private hospital (inpatient)
- ☐ Inpatient public hospital rehabilitation
- ☐ Inpatient private hospital rehabilitation
- ☐ Home-based rehabilitation (public funded)
- ☐ Home-based rehabilitation (private funded)
- ☐ Centre or clinic based outpatient rehabilitation (public funded)
- ☐ Centre or clinic based outpatient rehabilitation (private funded)
- ☐ Other

Block 3

For the purpose of this survey functional electrical stimulation is defined as the following, “Functional electrical stimulation (FES) stimulates muscles to contract during the performance of an activity (eg, sitting, standing up from a chair, walking, reaching for and manipulating objects), with the goal of improving the performance of that activity” (Howlett et al. 2015, p. 934).

Reference

Howlett, O. A., et al. (2015). "Functional electrical stimulation improves activity after stroke: A systematic review with meta-analysis." Archives of physical medicine and rehabilitation **96**(5): 934-943.

In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto hand, thumb or forearm muscles to assist the stroke survivor use their weak hand to grasp and release objects. *For example, to assist a stroke survivor pick up a cup or put down a tooth brush.*

- ☐ Yes
- ☐ No

Why did you use FES to grasp and release objects? *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the fingers, thumb and wrist effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to use their hand in daily activities.
- ☐ To reduce an impairment of either weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state.

In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto shoulder or arm muscles to assist the stroke survivor reach. *For example to assist a stroke survivor move their arm to reach an object off a shelf or to place a jumper into a draw.*

- ☐ Yes
- ☐ No

Why did you use FES to assist a person to reach? *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the arm and shoulder effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to use their hand and arm in daily activities.
- ☐ To reduce the impairments of weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state.

In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto thumb or hand muscles to assist the stroke survivor use their weak hand in dexterous activity. *For example to assist a stroke survivor take a nut off a bolt or to put a stamp on an envelope.*

- ☐ Yes
- ☐ No

Why did you use FES to assist a stroke survivor to manipulate objects? *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the fingers, thumb and wrist effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to use their hand in daily activities.
- ☐ To reduce the impairments of weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state.

In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto foot or leg muscles to assist the stroke survivor to walk.

- ☐ Yes
- ☐ No

Why did you use FES to assist a stroke survivor to walk? *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the foot effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to walk.
- ☐ To reduce body structure impairments of either weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state.

Block 3

Thinking about your use of FES when training the upper limb (shoulder, arm, and / or hand): *Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect*

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Stroke survivors will complete daily activities faster	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Stroke survivors will be able to use their weak upper limb in more daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improvements in activity will only be maintained when the electrostimulation device (FES machine) is active	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
During daily activities, the quality of movement of the weak upper limb will improve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Thinking about your use of FES when training the lower limb (hips, leg and/or foot): *Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect*

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
Stroke survivors will walk faster.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stroke survivors will be able to walk more often.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Improvements in walking will only be maintained when the electrostimulation device (FES machine) is in use and is active.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When the stroke survivor walks, the quality of movement of the weak lower limb will improve.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Block 3

Have you spent time learning how to use functional electrical stimulation?

- ☐ Yes
- ☐ No

Please select the training you participated in.

- ☐ Entry Level (Undergraduate) training at University
- ☐ Postgraduate training at University
- ☐ Continuing professional development (CPD)
- ☐ On the job training from colleague
- ☐ Self-directed learning. Please state what this was.
- ☐ Other. Please state what this was.

Please rank each method of training, with 1 ranked as the method of training which was most useful.

- » Entry Level (Undergraduate) training at University
- » Postgraduate training at University
- » Continuing professional development (CPD)

☐

» On the job training from colleague

☐

» Self-directed learning. Please state what this was.

☐

» Other. Please state what this was.

What was the total duration of your continuing professional development (CPD)?

- ☐ 1 – 2 hours
- ☐ Half day
- ☐ Full day
- ☐ More than one day

Appendix B12

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Appendix B13

Study Two Phase Two – Manuscript

Feature Article

Using functional electrical stimulation with stroke survivors: A survey of Victorian occupational therapists and physiotherapists

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Background/aim: Functional electrical stimulation (FES) improves active movement of the hemiplegic upper and lower limbs following stroke. The use of FES by Australian allied health clinicians in stroke rehabilitation is, however, unknown. The purpose of this study was to understand the use of FES in clinical practice. Reasons for the use of FES and potential variables that influence decision-making were also investigated.

Methods: Cross-sectional study of Victorian allied health clinicians, using a snowball recruitment method. Ninety-seven eligible therapists completed the anonymous online survey. Data were analysed using frequency distributions. **Results:** The majority of respondents were occupational therapists ($n = 60$; 62%). Approximately half of the respondents ($n = 50$; 52%) reported using FES in the past two years to improve a stroke survivor's ability to use their arm in daily activities. Respondents suggested that receiving workplace training from colleagues to learn how to use FES is the preferred method of education. Of those who received education ($n = 80$), 50 participants reported using FES in their practice.

Conclusion: There is variable use of FES in stroke rehabilitation to increase active movement after stroke. While there was moderate agreement about when to use FES and useful education approaches for learning to use FES, further research is needed to better understand strategies which could be implemented to support increased FES use in stroke rehabilitation.

KEY WORDS electric stimulation, occupational therapy, physical therapy modalities, stroke rehabilitation, translational medical research.

Introduction

Stroke is a leading cause of disability worldwide (Feigin *et al.*, 2014). A common impairment following stroke is motor weakness that leads to a loss of functional movement (typically affecting control of the arm and leg of one side of the body) (Langhorne, Coupar & Pollock, 2009). Much of the focus of stroke rehabilitation, and in particular that of physiotherapists and occupational therapists, is on recovery of impaired movement and functional ability to move the arm and leg. Functional electrical stimulation (FES), defined as electrically stimulating weak muscles to enable functional based movements during activities for therapeutic purposes (Peckham & Knutson, 2005), is able to improve the movement of the arm and leg after stroke (Howlett, Lannin, Ada & McKinstry, 2015) and improve performance of activities of daily living for participants in the first two months after stroke (Eraifej, Clark, France, Desando & Moore, 2017).

Clinical practice guidelines recommend the use of electrical stimulation interventions (including FES) to improve upper limb recovery (Hebert *et al.*, 2016; National Institute for Health and Care Excellence, 2013; Stroke Foundation, 2017; Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010), or to improve walking (Hebert *et al.*; National Institute for Health and Care Excellence, 2009; Stroke Foundation) after stroke. Importantly, the recommendations made within each clinical practice guideline vary in strength (as per the Grading of Recommendations Assessment Development and Evaluation (GRADE) framework (Schunemann, Brozek, Guyatt & Oxman, 2013)) and

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wording, which may lead to clinician uncertainty about if they should use FES. For example, the strength level of 'weak recommendation' was prescribed by the Australian Stroke Foundation (Stroke Foundation), meaning that "the guideline panel is uncertain about the balance between desirable and undesirable effects" (para. 1), while the UK guidelines recommend FES use for lower limb training based on best available evidence as described by guideline authors (National Institute for Health and Care Excellence). Recent meta-analysis of clinical trials, however, shows clear benefit (Howlett *et al.*, 2015).

Despite research evidence and recommendations in clinical guidelines supporting the use of FES in clinical practice, clinicians do not use electrical stimulation interventions routinely in stroke rehabilitation (Auchstaetter *et al.*, 2016; Scottish Stroke Allied Health Professionals Forum, 2014). In Australia, a survey identified that occupational therapists infrequently used electric stimulation interventions (including FES) in stroke rehabilitation (Gustafsson & Yates, 2009). This survey was completed nearly a decade ago, and it is not known if the more recent increase in research evidence has changed clinician use of electrical stimulation. Unfortunately, the recent Australian National Stroke Audit (Stroke Foundation, 2016) did not report if FES (as defined by Peckham and Knutson (2005)) was used commonly with stroke survivors, therefore the implementation of FES into clinical practice is not known.

Implementing research into clinical practice is notoriously difficult (Grimshaw, Eccles, Lavis, Hill & Squires, 2012; Menon, Korner-Bitensky, Kastner, McKibbin & Straus, 2009). Providing a summary of research in a clinical practice guideline (Hurdwar *et al.*, 2007; Scott *et al.*, 2007) or a systematic review (Tricco, Straus & Moher, 2011) does not ensure uptake of the evidence into clinical practice (LaRocca, Yost, Dobbins, Ciliska & Butt, 2012). To understand the implementation of FES by Australian physiotherapists and occupational therapists, we need to first identify the degree to which the research evidence of FES is being translated into practice (Graham *et al.*, 2006) and whether a gap exists between evidence recommendations and clinical practice.

Previous studies on the use of electrical stimulation have either not been specific to FES (Gustafsson & Yates, 2009), or were conducted outside of the Australian rehabilitation context (Auchstaetter *et al.*, 2016; Scottish Stroke Allied Health Professionals Forum, 2014), therefore a study investigating current Australian clinical practices was undertaken. The objectives of our study were to (i) determine the use of FES with stroke survivors by Victorian occupational therapists and physiotherapists and (ii) identify factors that may influence a clinician's use of FES, such as practice setting, geographical location, clinical experience, professional discipline or participation in FES education sessions.

Methods

A quantitative cross-sectional study design was used. A closed response, online survey was designed and developed specifically for this study.

Survey development

To validate the overall survey and individual survey questions, the survey was piloted with six clinicians through an iterative process of survey completion and cognitive interviewing. Full details of the designing and piloting of the survey is published elsewhere (Howlett, McKinstry & Lannin, 2018). The content of the survey included use of FES in clinical rehabilitation, professional discipline, location and type of clinical practice, and years of practice working with stroke survivors. Further information was collected regarding indications, expected outcomes and use of education/ training to support the use of FES in practice. A full copy of the survey is available as an appendix in the supplementary on-line file (Data S1).

Data collection

Invited participants were occupational therapists and physiotherapists practising in Victoria, Australia. This sample of convenience was selected to be able to investigate the influence of the geographical and practice setting within the Victorian health-care system. Following ethical approval from La Trobe University (HREC approval number S16-99), occupational therapists and physiotherapists were recruited by post, email and social media. The postal addresses of health services were obtained from the Victorian Department of Human Services and the Australian Medical Association's web sites (Australian Medical Association, 2016; Victorian State Government, 2014a,b). Postal invitations were then sent to 123 occupational therapy and 123 physiotherapy services at 38 public metropolitan, 30 public rural, 15 public regional and 21 private health-care providers. Email invitations were also sent to members of an Australian neurology listserv for occupational therapists and 395 therapists registered as members of the Australian Occupational Therapy Association Ltd, Victorian Division neurological special interest group. Additionally, members of the research team posted the survey link on Twitter™. The survey was administered using the Qualtrics™ online platform.

Data analysis

Descriptive statistics were used to analyse the data using frequency distribution in numbers and percentages for each variable.

Results

One-hundred and thirteen therapists responded to the survey; three participants were excluded because they

were not employed by a Victorian health service. A further 13 responses were excluded, because not all questions were answered. The majority of participants were occupational therapists and female (see Table 1 for full details of participant characteristics). Most worked in a metropolitan, publicly funded hospital, and were experienced clinicians (mean of 7.9 years of experience of working with people who had had a stroke with a range of 0.5–44 years).

The use of FES by occupational therapists and physiotherapists

Over half of the clinicians reported using FES in the past two years; with 40 being occupational therapists (see Table 2). Of those using FES recently, nearly all clinicians had used FES for upper limb training ($n = 47$) while only five clinicians had used FES for lower limb training. The mean years of working with stroke survivors was of 6.4 with a range of 0.5–30 years. Most therapists used FES to train grasp and release (such as

when picking up a cup, $n = 47$), or reaching (such as when reaching for an item on a shelf, $n = 32$), or dexterous activity ($n = 17$), suggesting that the therapeutic goal was to engage a client in task oriented therapy and then to increase activity. For those clinicians who used FES for lower limb training, the most common reason was to improve the activity of walking ($n = 5$). There was limited use of FES overall to manage impairments of pain, spasticity or weakness.

Clinicians reported that they expect a variety of outcomes when they use FES as one component of their rehabilitation program (see Table 3). These expected outcomes differed for upper limb vs. lower limb rehabilitation, however, both focused on addressing functional limitations rather than managing impairments.

Clinician education to use FES

Of the ninety-seven participants, 80 (82%) had undertaken some form of education to learn to use FES, with 51 being occupational therapists, 27 physiotherapists and two allied health assistants. Clinicians rated work-place training from a colleague as the most valuable form of education for learning how to use FES ($n = 37$, 46%), followed by formal continuing professional development ($n = 29$, 36%), then entry-level (undergraduate

training ($n = 8$, 10%), post-graduate university training ($n = 2$, 2.5%), and self-directed learning ($n = 1$, 1%).

Discussion

The main finding of this study is that FES is being used in stroke rehabilitation, particularly by occupational therapists. When choosing to use FES, clinicians expected that it would increase the amount of upper limb activity, as well as the quality of movement in both the lower and upper limb during daily activities. In contrast, the clinicians did not expect that using FES would enhance a stroke survivor's ability to participate in life roles (such as worker, student, volunteer, parent or friend) suggesting that clinicians perceive that improving role performance will take more than simply learning to move that limb again. These clinical expectations are consistent with the results of Howlett *et al.*'s (2015) systematic review, which demonstrated that activity outcomes are improved after FES training. The review was however unable to support or refute the expectation that FES will improve the outcomes of participation, because studies to date have failed to collect

measurement data at that level. Further research is therefore needed to understand the relationship

TABLE 1: *Demographics* (N = 97)

Characteristic	n (%)	Response
Profession		
Occupational Therapist	60 (61.8)	
Physiotherapist	35 (36.1)	
Allied Health Assistant	2 (2.1)	
Gender		
Female	83 (85.6)	
Male	14 (14.4)	
Geographical area		
Metropolitan	60 (61.9)	
Regional	25 (25.8)	
Rural	12 (12.3)	
Facility type		
Acute public hospital (inpatient)	16 (16.5)	
Acute private hospital (inpatient)	0 (0)	
Inpatient public hospital rehabilitation	22 (22.7)	
Inpatient private hospital rehabilitation	4 (4.1)	
Home-based rehabilitation (public funded)	6 (6.2)	
Home-based rehabilitation (private funded)	2 (2.1)	
Centre or clinic based outpatient rehabilitation (public funded)	38 (39.2)	
Centre or clinic based outpatient rehabilitation (private funded)	3 (3.0)	
Other	6 (6.2)	
Years working with stroke survivors		
<2 years of experience	10 (10.3)	
≥2 to 5 years of experience	31 (32.0)	

≥5 to 10 years of experience	32 (33.0)
≥10 years of experience	24 (24.7)

between activity performance and role participation.

The findings of the current study suggest proportion-ally higher use of FES in metropolitan and regional locations in comparison to Victorian rural settings. As specialised stroke rehabilitation units and rehabilitation centres are predominately located in metropolitan and regional areas (Australian Institute of Health and

TABLE 2: *Characteristics of FES use in those respondents who have used FES the past two years (n = 50)*

Characteristic	Use of FES in past two years n (%)	FES to train grasp and release n (%)	FES to train reaching n (%)	FES to train dexterous activity n (%)	FES to train walking n (%)
FES use	50 (100)	47 (94)	32 (64)	17 (34)	5 (10)
Profession					
Occupational therapists	40 (80)	40 (80)	27 (54)	15 (30)	1 (2)
Physiotherapist	8 (16)	5 (10)	4 (8)	2 (4)	4 (8)
Allied Health Assistant	2 (4)	2 (4)	1 (2)	0 (0)	0 (0)
Geographical area					
Metropolitan	33 (66)	35 (70)	26 (51)	12 (24)	1 (2)
Regional	11 (22)	9 (18)	3 (6)	3 (6)	4 (8)
Rural	4 (8)	4 (8)	3 (6)	2 (4)	0 (0)
Facility type					
Acute public hospital (inpatient)	11 (22)	11 (22)	9 (18)	7 (0)	0 (0)
Acute private hospital (inpatient)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Inpatient public hospital rehabilitation	15 (30)	14 (28)	9 (18)	1 (2)	3 (6)
Inpatient private hospital rehabilitation	1 (2)	1 (2)	1 (2)	0 (0)	0 (0)
Home-based rehabilitation (public funded)	3 (6)	3 (6)	3 (6)	0 (0)	0 (0)
Home-based rehabilitation (private funded)	1 (2)	1 (2)	1 (2)	0 (0)	0 (0)
Centre or clinic based outpatient rehabilitation (public funded)	16 (32)	14 (0)	7 (14)	8 (16)	2 (4)
Centre or clinic based outpatient rehabilitation (private funded)	2 (4)	2 (4)	1 (2)	1 (2)	0 (0)
Other	1 (2)	1 (2)	1 (2)	0 (0)	0 (0)
Years working with stroke survivors					
<2 years of experience	4 (8)				
≥2 to 5 years of experience	19 (38)				
≥5 to 10 years of experience	19 (38)				
≥10 years of experience	8 (16)				

Welfare, 2013), higher rates of FES use in these areas may reflect more consistent implementation of stroke rehabilitation guidelines (Faux *et al.*, 2009). The lower use of FES in rural locations may have arisen because of unique barriers attributable to geographical location. The survey did not, however, investigate what these geographical barriers might be. Graham *et al.* (2006) proposed that barriers can be overcome by examining the local context in which an intervention will be administered. Findings from the current survey suggest that a specific implementation study for the use of FES in rural Victoria may be required to increase adherence to FES clinical practice guidelines.

Respondents in the current study who had graduated less than 10 years earlier were more likely to use FES. The time since graduation has been reported elsewhere to influence the behaviour of translating research knowledge into practice (Bennett *et al.*, 2003; Dysart & Tomlin, 2002; Zipoli & Kennedy, 2005). Zipoli and Kennedy (2005) suggested that if an intervention was not taught in under graduate training or not practised

within the first year after graduation, the use of research knowledge in practice was less likely to occur. Some clinicians may not use FES because their graduate training did not include skills training in using FES. An alternate explanation may be that therapists “with 15 or more years of clinical experience did not believe that research conclusions usually translated into treatment plans for individuals” (Dysart & Tomlin, 2002 p. 275). As the evidence to support FES use has only recently been demonstrated in two systematic reviews with meta-analysis (Eraifej *et al.*, 2017; Howlett *et al.*, 2015), staff members with 15 or more years of experience may not be aware of the knowledge to support FES, therefore have yet to support the translation of this intervention into their work setting.

Belief in the efficacy of an intervention will also influence clinician likelihood of using that intervention. As clinicians gain clinical experience, if they have not observed the intervention of FES to produce tangible outcomes, they may be less inclined to use FES for stroke rehabilitation. Reasons for not experiencing

TABLE 3: *Expected outcome when using FES on daily activities*

Expected outcome from using FES	Responses <i>n</i>	Strongly disagree <i>n</i> (%)	Disagree <i>n</i> (%)	Undecided <i>n</i> (%)	Agree <i>n</i> (%)	Strongly agree <i>n</i> (%)
Primary reason for using FES for UL training						
Stroke survivors will complete daily activities faster	49	0 (0)	16 (31.4)	19 (37.3)	13 (25.5)	1 (2)
Stroke survivors will be able to use their weak upper limb in more daily activities	49	0 (0)	1 (2)	4 (7.8)	38 (74.5)	6 (11.8)
Improvements in activity will only be maintained when the electrostimulation device (FES machine) is active	49	5 (9.8)	29 (56.9)	10 (19.7)	4 (7.8)	1 (2)
During daily activities, the quality of movement of the weak upper limb will improve	49	0 (0)	1 (2)	4 (7.8)	35 (68.6)	9 (17.6)
Primary reason for using FES for LL training						
Stroke survivors will walk faster	5	0 (0)	1 (20.0)	1 (20.0)	3 (60.0)	0 (0)
Stroke survivors will be able to walk more often	5	0 (0)	3 (60.0)	0 (0)	2 (40.0)	0 (0)
Improvements in walking will only be maintained when the electrostimulation device (FES machine) is in use and is active	5	0 (0)	3 (60.0)	0 (0)	2 (40.0)	0 (0)
When the stroke survivor walks, the quality of movement of the weak lower limb will improve	5	0 (0)	0 (0)	0 (0)	5 (100.0)	0 (0)

FES, functional electrical stimulation; UL, upper limb; LL, lower limb.

positive outcomes may include the intervention not demonstrating implementation fidelity (Carroll *et al.*, 2007) or the treatment effects being estimated from the systematic reviews may be inflated due to small trial bias (Howlett *et al.*, 2015) or the methodological biases of included trials (Erafeij *et al.*, 2017). To better understand why there is variability in use of FES between different therapists, future implementation studies should explore the effect of clinician clinical experience and undergraduate training on FES use.

The current study findings suggest that attending FES training does not necessarily enable a clinician to use FES in practice. Our findings are consistent with a systematic review that investigated the knowledge translation of training of occupational therapists and

physiotherapists (Menon *et al.*, 2009) and found that the type of education may influence the intervention being used in practice. Menon *et al.* identified that training involving multiple learning methods, combined with an active learning approach, were preferable to individual activities involving only an educational component. Victorian therapists identified that they valued workplace training most of all, while the second most valued activity was attending continuing professional development. Therapists in our study, on average, participated in two educational activities. Although, knowledge translation was not reported for all participants, by providing preferred training in future implementation strategies, may be key to supporting the uptake of FES.

We acknowledge that the defined scope of our population was both a strength (a high response rate was achieved) and a limitation (with potentially reduced applicability outside of Victoria). In addition to the limitation of geographical location, the size and make-up of the sample across settings and professions may also limit the applicability of the results. In particular, there was low representation in the sample with only $n = 35$ physiotherapists which may not be a true representation of Victorian physiotherapists practising in stroke rehabilitation. The findings relating to lower limb FES use also need to be carefully considered given this sample's limitation. Although the number of female and male participants reflect the Victorian gender rates for physiotherapy and occupational therapy (Australian Institute of Health and Welfare, 2013), we are unable to identify if the sample accurately reflects the number of clinicians employed across geographical locations and settings relating to stroke rehabilitation in Victoria. While the use of FES in public and private rehabilitation settings was proportionally consistent with survey participation, it is acknowledged that there were low numbers of respondents from the private sector. Australian hospital statistics suggest that 52% of rehabilitation admissions for people with strokes occurs in the private sector (Australian Institute of Health and Welfare), therefore the low participation of those from the private sector limits the conclusions which can be drawn from this study.

Clinical implications

While FES may enable a clinician to engage stroke survivors with muscle weakness in repetitive task specific training, our findings suggest there is a tendency for clinicians to use only a limited number of FES training methods. Using only FES to train grasp and release, for example, may restrict engagement in all upper limb activity performance, potentially reducing likelihood of a full recovery from stroke. Approximately half of the responding therapists reported using FES, so large proportion of clinicians did not. Therefore, there may be workplace or individual barriers currently limiting the implementation of FES clinical practice guidelines into practice. A variety of factors may exist which may or may not be unique to the context of the Victorian healthcare industry. For example, undergraduate training may focus on teaching the knowledge of FES to students, however, the opportunity to practice and observe the required skills may be limited. Secondly, rural therapists may be implementing FES less frequent due to low numbers of clients presenting with the need to use FES. Lastly, the influence of a senior staff member's skills and knowledge may influence which interventions are used in particular settings. Further research is recommended to identify and understand the contextual factors, which influence the implementation of FES in the state of Victoria, Australia.

Findings from our study provide useful implementation recommendations. Firstly, clinicians should be encouraged to actively plan how resources can be appropriately used to overcome barriers faced (potentially geographical, setting or caseload specific). Secondly, if the implementation of FES guidelines occurs, healthcare providers should be encouraged to support workplace peer learning and attendance at professional development activities, because these were the preferred method of learning reported by participants in this study.

Research implications

We identified that Victorian clinicians are using FES in practice although its use varies depending on the healthcare setting, geographical location, professional discipline, clinical experience and prior access to education. Future research needs to identify and understand the factors that enable and impede the use of FES in clinical practice. Due to the differences in uptake of FES use between occupational therapists and physiotherapists, identification of barriers and enablers relating to the use of FES in practice for each professional group is recommended. Although clinical guidelines encourage the use of FES, the study findings indicate that the intervention is not necessarily being widely practised. The reasons for the non-implementation of the guidelines are not fully understood. Future research needs to focus on appropriate and effective translation of clinical guidelines recommendations into practice, to maximise the benefits of the intervention for those receiving stroke rehabilitation. If clinical guidelines are recommending the use of FES based on clinical trials with robust study designs, the recommendations may be translated with increased confidence by clinicians.

Conclusion

Victorian occupational therapists and physiotherapists are using FES as an intervention to improve a person's ability to complete activities following stroke. While FES is not yet a routine intervention, occupational therapists surveyed used FES more frequently than the physiotherapists. Participation in education to learn how to use FES did not appear to increase translation of research findings, which supports the efficacy of FES for increasing upper and lower limb use after stroke (Howlett *et al.*, 2015). Future knowledge translation studies investigating the implementation of FES into practice are thus recommended.

Key points for occupational therapy

- Occupational therapists are using FES for stroke rehabilitation.
- Limited FES training methods (e.g. FES to train grasp, reach or dexterity), may restrict rehabilitation of the upper limb.

- Occupational therapists participation in FES education did not always lead to translation of FES research into practice.

Acknowledgments

We declare that all authors made substantial contributions to conception and design of the study, analysis and interpretation of data, drafting the article or revising it critically for important intellectual content and give final approval of the version submitted. We declare that the research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflict of interest

None declared.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Data S1. Functional Electrical Stimulation (FES) clinical use survey.

Appendix B14

Study Two Phase Two - Manuscript Supplement

Functional Electrical Stimulation (FES) Clinical Use Survey

La Trobe University, Alfred Health
Owen Howlett, Dr. Carol McKinstry, Associate Professor Natasha Lannin
Correspondence: o.howlett@latrobe.edu.au

1. What is your profession?

- ☐ Occupational therapist registered with AHPRA
- ☐ Physiotherapist registered with AHPRA
- ☐ Allied health assistant
- ☐ Other. State profession _____

2. Is the location of your primary workplace, in Victoria, Australia?

- ☐ Yes
- ☐ No

If No Is Selected, Then Skip To End of Survey

3. What is your gender?

- ☐ Female
- ☐ Male

4. How many years have you worked with stroke survivors? *(Do not include stroke survivors you saw as a student)*

Free text answer (numerical) _____

5. What is the location of your primary workplace? *(i.e. the workplace where you spend the most time)*

- ☐ Metropolitan
- ☐ Regional
- ☐ Rural

Functional Electrical Stimulation (FES) Clinical Use Survey

La Trobe University, Alfred Health
Owen Howlett, Dr. Carol McKinstry, Associate Professor Natasha Lannin
Correspondence: o.howlett@latrobe.edu.au

6. What is the setting of your primary workplace? (*i.e. the workplace where you spend the most time*)

- ☐ Acute public hospital (inpatient)
- ☐ Acute private hospital (inpatient)
- ☐ Inpatient public hospital rehabilitation
- ☐ Inpatient private hospital rehabilitation
- ☐ Home-based rehabilitation (public funded)
- ☐ Home-based rehabilitation (private funded)
- ☐ Centre or clinic based outpatient rehabilitation (public funded)
- ☐ Centre or clinic based outpatient rehabilitation (private funded)
- ☐ Other: _____

For the purpose of this survey functional electrical stimulation is defined as the following,
“Functional electrical stimulation (FES) stimulates muscles to contract during the performance of an activity (eg, sitting, standing up from a chair, walking, reaching for and manipulating objects), with the goal of improving the performance of that activity” (Howlett et al. 2015, p. 934).

Reference

Howlett, O. A., et al. (2015). "Functional electrical stimulation improves activity after stroke: A systematic review with meta-analysis." Archives of physical medicine and rehabilitation **96**(5): 934-943.

Functional Electrical Stimulation (FES) Clinical Use Survey

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Owen Howlett, Dr. Carol McKinstry, Associate Professor Natasha Lannin
Correspondence: o.howlett@latrobe.edu.au

7. In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto hand, thumb or forearm muscles to assist the stroke survivor use their weak hand to grasp and release objects. *For example, to assist a stroke survivor, pick up a cup or put down a tooth brush.*

☐ No

☐ Yes



Why did you use FES to grasp and release objects? *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the fingers, thumb and wrist effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to use their hand in daily activities.
- ☐ To reduce the impairments of weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state:_____. *If no other reason please state nil.*

Functional Electrical Stimulation (FES) Clinical Use Survey

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8. In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto shoulder or arm muscles to assist the stroke survivor to reach. *For example to assist a stroke survivor move their arm to reach an object off a shelf or to place a jumper into a draw.*

☐ No

☐ Yes



Why did you use FES to assist a person to reach? *Please select the statement which reflects the most common reason for you to use FES.*

☐ To position the arm and shoulder effectively to engage the stroke survivor in task-oriented therapy.

☐ To increase the stroke survivor's ability to use their hand and arm in daily activities.

☐ To reduce the impairments of weakness, pain, or spasticity.

☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.

☐ Other. Please state:_____. *If no other reason please state nil.*

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Correspondence: o.howlett@latrobe.edu.au

9. In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto thumb or hand muscles to assist the stroke survivor use their weak hand in dexterous activity. *For example to assist a stroke survivor take a nut off a bolt or to put a stamp on an envelope.*

☐ No

☐ Yes



Why did you use FES to assist a stroke survivor to manipulate objects? *Please select the statement which reflects the most common reason for you to use FES.*

☐ To position the fingers, thumb and wrist effectively to engage the stroke survivor in task-oriented therapy.

☐ To increase the stroke survivor's ability to use their hand in daily activities.

☐ To reduce the impairments of weakness, pain, or spasticity.

☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.

☐ Other. Please state:_____. *If no other reason please state nil.*


Functional Electrical Stimulation (FES) Clinical Use Survey

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Correspondence: o.howlett@latrobe.edu.au

10. In the past two years, have you used FES in the following clinical scenario?

Electrodes (connected to an electrostimulation device) placed onto foot or leg muscles to assist the stroke survivor to walk.

- ☐ No
- ☐ Yes

**Why did you use FES to assist a stroke survivor to walk?** *Please select the statement which reflects the most common reason for you to use FES.*

- ☐ To position the foot effectively to engage the stroke survivor in task-oriented therapy.
- ☐ To increase the stroke survivor's ability to walk.
- ☐ To reduce body structure impairments of either weakness, pain, or spasticity.
- ☐ To increase the stroke survivor's ability to participate in life roles such as worker, parent, friend, student or volunteer.
- ☐ Other. Please state:_____. If no other reason please state nil.

Functional Electrical Stimulation (FES) Clinical Use Survey

La Trobe University, Alfred Health
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Correspondence: o.howlett@latrobe.edu.au

11. Only answer, if either question 7, 8 or 9 was answered YES. Thinking about your use of FES when training the upper limb (shoulder, arm, and / or hand): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect

		Strongly disagree	Disagree	Undecided	Agree	Strongly Agree
11a.	Stroke survivors will complete daily activities faster	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11b.	Stroke survivors will be able to use their weak upper limb in more daily activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11c.	Improvements in activity will only be maintained when the electrostimulation device (FES machine) is active	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11d.	During daily activities, the quality of movement of the weak upper limb will improve	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Functional Electrical Stimulation (FES) Clinical Use Survey

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12. Only answer, if question 10 was answered YES. Thinking about your use of FES when training the lower limb (hips, leg and/or foot): Please indicate your level of agreement with the below statements by ticking the box which best represents the outcome you expect

		Strongly disagree	Disagree	Undecided	Agree	Strongly Agree
12a.	Stroke survivors will walk faster.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12b.	Stroke survivors will be able to walk more often.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12c.	Improvements in walking will only be maintained when the electrostimulation device (FES machine) is in use and is active.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12d.	When the stroke survivor walks, the quality of movement of the weak lower limb will improve.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Functional Electrical Stimulation (FES) Clinical Use Survey

La Trobe University, Alfred Health
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Correspondence: o.howlett@latrobe.edu.au

13. Have you spent time learning how to use functional electrical stimulation?

- ☐ Yes
☐ No

If No Is Selected, Then Skip To End of Survey

14. Please select the training you participated by ranking each method of training from 1 to 5, with 1 ranked as the method of training which was most useful and 5 as the least useful. Tick NA if you did not use this method at all.

☐ NA ☐ Rank **Entry Level (Undergraduate) training at University**

☐ NA ☐ Rank **Postgraduate training at University**

☐ NA ☐ Rank **Continuing professional development (CPD)**

What was the total duration of your CPD?

- ☐ 1 – 2 hours
☐ Half day
☐ Full day
☐ More than one day

☐ NA ☐ Rank **On the job training from colleague**

☐ NA ☐ Rank **Self-directed learning**

Please state what this was _____

☐ NA ☐ Rank **Other.**

Please state what this was _____

Appendix C1

Study Three – HREC Approval Bendigo Health

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC
Bendigo Health Care Group
PO Box 126
Bendigo, Victoria, 3552

Dr Carol McKinstry
La Trobe University
PO Box 199
Bendigo
Vic 3552

15 March 2017

Dear Dr McKinstry

Study title: Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study

HREC Reference Number: LNR/16/BHCG/69

Protocol version: 5

The Bendigo Health Care Group HREC reviewed the above application at the meeting held on 15 March 2017.

Decision of the reviewing HREC

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

Approval

The HREC approval is from the date of this letter *and expires on 30 March 2018*.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses: Bendigo Health.

You must comply with the following conditions:

- a. *Limit of Approval*: approval is limited strictly to the research proposal as submitted in your application. In addition, approval by the HREC *does not* guarantee that an individual BHCG unit or service will agree to provide resources or support to your research. Such assistance will need to be negotiated separately.
- b. *Start date*: You are responsible for advising the HREC of the date when the project starts at this site.
- c. *Variation to Project*: any subsequent variations or modifications you might wish to make to your project must be notified formally to the committee for further consideration and approval. If the committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised project.

- d. *Incidents of Adverse Effects*: researchers must report immediately to the committee anything which might affect the ethical acceptance of the protocol including adverse effects on subjects or unforeseen events that might affect continued ethical acceptability of the project.
- e. *Progress Reporting*: please be aware that the Human Research Ethics Committee requires all researchers to submit a report on each of their projects yearly and at the conclusion of the project. Failure to submit a progress report may mean approval for this project will lapse. Researchers must inform the committee if the project is discontinued before the expected date of completion. **The first and final progress report for this project is due on 30/04/2018.** Please refer to Bendigo Health HREC website for template.
http://www.bendigohealth.org.au/World_Class_Healthcare.asp?PageID=12
- f. *Auditing*: all projects may be subject to audit by members of the committee.
- g. *Research Reports*: please be aware that Bendigo Health reserves the right to include research project information in internal research reports.
- h. Please ensure that any requests to extend HREC approval are submitted at least **twelve weeks** prior to the date of HREC approval expiry.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Officer.

Approved documents

Documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter	1	28 November 2016
Application - LNR	1	29 December 2016
Application - LNRSSA	1	03 January 2017
Protocol	3	
Email invitation to participate	1	28 November 2016
Participant Information Sheet/ Consent Form	1	04 November 2016
Investigator CV: Carol McKinstry CV		
Investigator CV: Natasha Lannin CV		
Investigator CV: Owen Howlett CV		
Response to Request for Further Information		
Cover Letter for amended HREC	2	04 March 2017
Application - LNR	2	04 March 2017
Protocol: FES Barriers study protocol	4	
Participant Information Sheet/ Consent Form	2	04 November 2016
Response to Request for Further Information		
Application - LNR	3	09 March 2017
Protocol: FES Barriers study protocol	5	09 March 2017
Participant Information Sheet/ Consent Form	3	09 March 2017

Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

If you should have any queries about your project please contact Ms Sally McCarthy by email.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely

A handwritten signature in grey ink, appearing to read 'SMcCarthy'.

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group

E-mail: SAMcCarthy@bendigohealth.org.au

Copy: Mr Owen Howlett

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	Yes/No/NA
Ethics approval notification The PI must send a copy to the RGO at that study site.	Y
CTN notification The PI must sign the CTN and forward to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	NA
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g. CTRA) to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	Y
Radiation If applicable, the RGO must contact the Medical Physicist to notify DHS, Radiation Safety Section to list the project on the Institute's licence.	NA
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	NA

Ms Sally McCarthy
Research Manager
Bendigo Health Care Group HREC
PO Box 126
Bendigo
Victoria, 3552
SAMcCarthy@bendigohealth.org.au

Dr Carol McKinstry
La Trobe University
PO Box 199
Bendigo
Vic 3552

31 March 2017

Dear Dr McKinstry

Study title: Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study
HREC Reference Number: LNR/16/BHCG/69
SSA Reference Number: LNRSSA/17/BHCG/1

Thank you for submitting a Site Specific Assessment Form for authorisation of the above project at Bendigo Health. I can confirm that the submission was received on 04 January 2017.

I am pleased to inform you that authorisation has been granted for this project to be conducted at Bendigo Health.

The same conditions apply to this research project at your site as those imposed by the Human Research Ethics Committee that granted ethical approval: Bendigo Health

[List authorisation document/s and version number]

Document	Version	Date
Cover Letter	1	28 November 2016
Application - LNR	1	29 December 2016
Application - LNRSSA	1	03 January 2017
Protocol	3	
Email invitation to participate	1	28 November 2016
Participant Information Sheet/ Consent Form	1	04 November 2016
Investigator CV: Carol McKinstry CV		
Investigator CV: Natasha Lannin CV		
Investigator CV: Owen Howlett CV		
Response to Request for Further Information		
Cover Letter for amended HREC	2	04 March 2017
Application - LNR	2	04 March 2017
Protocol: FES Barriers study protocol	4	
Participant Information Sheet/ Consent Form	2	04 November 2016

Response to Request for Further Information		
Application - LNR	3	09 March 2017
Protocol: FES Barriers study protocol	5	09 March 2017
Participant Information Sheet/ Consent Form	3	09 March 2017
HREC approval letter: Bendigo Health HREC Approval		15 March 2017

If you have any matters that arise regarding conduct of the research at this site, please ensure you contact the Research Governance Officer.

Bendigo Health Care Group wishes you and your colleagues every success in your research.

Yours sincerely



Ms Sally McCarthy
Research Manager
Bendigo Health Care Group
E-mail: SAMcCarthy@bendigohealth.org.au

Copy: Mr Owen Howlett

Appendix C2

Study Three – HREC Approval La Trobe University

MEMORANDUM

To: Dr Carol McKinstry – School of Rural Health, College of SHE

Student: Owen Howlett

From: Secretariat, SHE College Human Ethics Sub-Committee (SHE CHESC)

Reference: SHE CHESC acceptance of Bendigo Health HREC approved project – LNR/ 16/ BHCG/ 69.

Title: Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study.

Date: 5 April, 2017

Thank you for submitting the above protocol to the SHE College Human Ethics Sub-Committee (SHE CHESC). Your material was forwarded to the SHE CHESC Chair for consideration. Following evidence of a full review and subsequent final approval by **The Bendigo Health HREC**, the SHE CHESC Chair agrees that the protocol complies with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and is in accordance with La Trobe University's *Human Research Ethics Guidelines*.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by The Bendigo Health HREC.

Limit of Approval. La Trobe SHE CHESC endorsement is limited strictly to the research protocol as approved by The Bendigo Health HREC.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by The Bendigo Health HREC for the project should be notified formally to the SHE CHESC

Annual Progress Reports. Copies of all progress reports submitted to The Bendigo Health HREC are to be forwarded to the SHE CHESC. Failure to submit a progress report will mean that endorsement for your involvement in this project will be rescinded. An audit related of your involvement in the study may be conducted by the SHE CHESC at any time.

Final Report. A copy of the final report is to be forwarded to the CHESC within one month of it being submitted by The Bendigo Health HREC.

If you have any queries related to the information above or require further clarifications, please contact chesc.she@latrobe.edu.au. Please quote reference number **LNR/ 16/ BHCG/ 69 - McKinstry**.

On behalf of the College Human Ethics Sub-Committee, best wishes with your research!

Ms Kate Ferris
Human Ethics Officer
Secretariat – SHE College Human Ethics Sub-Committee
Ethics and Integrity / Research Office
La Trobe University Bundoora, Victoria 3086
E: chesc.she@latrobe.edu.au
P: (03) 9479 – 3370
<http://www.latrobe.edu.au/researchers/ethics/human-ethics>

Appendix C3

Study Three – HREC Final Report

Ms Sally McCarthy
Research Manager
Research and Development
Bendigo Health Care Group
PO Box 126 Bendigo
Victoria, 3552
SAMcCarthy@bendigohealth.org.au

Dr Carol McKinstry
La Trobe University
PO Box 199
Bendigo
Vic, 3552

22 January 2018

Dear Dr McKinstry

Study title: Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study
HREC Reference Number: LNR/16/BHCG/69
Protocol version: 5

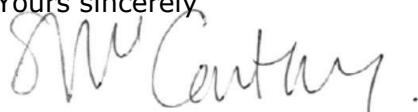
Thank you for sending the summary of the final research report for the above study. The report was reviewed at the meeting of the HREC held on 19 January 2018.

LNR/16/BHCG/69

Please quote this number on all correspondence

Congratulations on the successful outcome of the study.

Yours sincerely,



Ms Sally McCarthy
Research Manager
Bendigo Health Care Group
E-mail: SAMcCarthy@bendigohealth.org.au

Copy to: Mr Owen Howlett, Bendigo Health

Appendix C4

Study Three – Participant Information and Consent Form



Mailing address

PO Box 199
Bendigo Victoria 3552
Australia

T + 61 3 5444 7411

F + 61 3 5444 7977

E health@latrobe.edu.au

latrobe.edu.au/health

Participant Information Sheet

Bendigo Health

Title	Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study
Short Title	Barriers to using FES
Coordinating Principal Investigator	<i>Dr Carol McKinstry</i>
Principal Investigators	<i>Owen Howlett</i> <i>Associate Professor Natasha Lannin</i>
Location	<i>Bendigo Health</i>

1 Introduction

You are invited to take part in this research project titled “The barriers to using functional electrical stimulation with people who have had a stroke: A qualitative study”.

This Participant Information Sheet tells you about the research project. Knowing what is involved will help you decide if you want to take part in the research. You will be given a copy of this Participant Information Sheet to keep. Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Participation in this research is voluntary. If you do not wish to take part, you do not have to.

2 Consent

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read.
- Consent to take part in the research project.

3 What is the purpose of this research?

This project aims to identify barriers to using the intervention of functional electrical stimulation (FES) in a public healthcare setting. Your participation in the study will allow us to further understand the perspectives of occupational therapists and physiotherapists, about the use of FES with people who have had a stroke. We are not only seeking the clinicians perspectives about what encourages the use of FES in practice, but also the factors which make the implementation of this evidence-based intervention difficult. In doing so, the research findings will inform implementation strategies to enable the use of FES in a public health service. The research is being conducted as a part of Owen

4 What does participation in this research involve?

As a participant in this study, you be interviewed about FES in a focus group format. The focus group will take between 60 and 90 minutes. There will be up to 7 other people in the focus group. There will be two individual focus groups, one focus group for physiotherapists and one for occupational therapists. All group participants will be employees of Bendigo Health. The focus groups will be conducted in the during normal work hours. We will endeavour to choose a time which will minimise the impact on the provision of direct clinical care. The focus groups will be conducted at the La Trobe University Clinical Teaching Building in Arnold St. The focus groups will be facilitated by the student researcher: Owen Howlett. A note taker - Dr Carol McKinstry - will be present during the focus group. The facilitator will provide a brief presentation on the evidence supporting the use of FES for people who have had a stroke. The facilitator will then ask the group a range of questions which will identify the factors influencing the use of FES in healthcare. The focus group will be audio taped to allow the accurate analysis of the discussions. There are no costs associated with participating in this research project, nor will you be paid.

5 Other relevant information about the research project

We are seeking 10 to 16 clinicians to participate in this project. To be eligible you must be a practicing occupational therapist or physiotherapist employed at Bendigo Health working with people who have had a stroke.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your employment at Bendigo Health.

7 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research.

8 What are the possible risks and disadvantages of taking part?

It is not expected that you will experience distress through the interview however if this does occur, an appropriate counselling service will be recommended by the student researcher. For example, the Bendigo Health Employee Assistance Program.

9 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing

10 What will happen to information about me?

Prior to the focus group the following demographic data will be recorded about you: your age, professional discipline, clinical setting and the years of experience working with people who have had a stroke. Your first name may be audio recorded during the interview, your surname will not be audio recorded. When data is transcribed, pseudonyms will be used. Your name will not be identified in any written data. During the project all digital data will be kept on a La Trobe University password protected computer and paper and audio copies will be stored in a locked filing cabinet located at La Trobe Rural Health School, clinical teaching building, room 203. At the completion of the project, all paper and audio data will be transferred to a digital medium. The originals will be shredded, and audio copies will be erased. When completed, all data will be transferred to electronic files and stored in the La Trobe University's Library Research Data File Storage facility. You will not be able to retrieve specific information about yourself, because the data will be de-identified. It is anticipated that the results of this research project will be presented in a variety of forums. In any publication and/or presentation,

information will be provided in such a way that you cannot be identified. The results will be reported in Owen Howlett's Doctorate of Clinical Science thesis. If you wish to obtain a copy of the finalised survey, you may contact Owen Howlett. His contact details are listed below.

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Bendigo Health (insert HREC ref no.) and La Trobe University (insert HREC ref no.). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 Further information and who to contact

If you want any further information concerning this project which may be related to your involvement in the project you can phone Owen Howlett on (03) 5454 8505 or email ohowlett@bendigohealth.org.au.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Sally McCarthy
Secretary Bendigo Health Human Research Ethics Committee
Collaborative Health Education and Research Centre
Bendigo Health
Telephone (03) 5454 6412
Email: samccarthy@bendigohealth.org.au
Please quote HREC reference number_____.

Senior Human Ethics Officer
Ethics and Integrity
Research Office
La Trobe University
Telephone: 03 9479 1443
Email: humanethics@latrobe.edu.au
Please quote the HREC reference number_____.

Consent Form - *Adult providing own consent*

Title Understanding the barriers preventing the use of functional electrical stimulation with people who have had a stroke: A qualitative study

Short Title Barriers to using FES

Protocol Number

Project Sponsor *La Trobe University*

Coordinating Principal Investigator *Dr Carol McKinstry*

Principal Investigator *Owen Howlett*

Associate Investigator(s) *Associate Professor Natasha Lannin*

Location *Bendigo Health*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _

Name of Witness* to Participant's

Signature (please print) _____

Signature _____ Date _

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher[†] (please print) _____

Signature _____ Date _

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

Appendix C5

Study Three – Participant Invitation

Email to occupational therapists and physiotherapists

Dear [Insert name]

You are invited to participate in a research project titled: Understanding the barriers to using functional electrical stimulation with people who have had a stroke: A qualitative study. We are seeking to identify and understand the barriers and enablers to using functional electrical stimulation (FES) in clinical practice. In doing so we will be able to identify if implementation strategies are required to maximise the use of FES by allied health staff.

You are being invited to participate in a focus group with 5 to 7 other clinicians, and discuss the use of FES in a healthcare setting. The focus group will run between 60 to 90 minutes. The attached participant information sheet outlines the project details.

This research is being conducted as part of Owen Howlett's Doctorate of Clinical Science research project. Ethical approval for the study has been obtained from Bendigo Health (no. xxxx) and La Trobe University (SHE-CHESC no. xxxx).

If you know of other occupational therapists or physiotherapists employed by Bendigo Health who may wish to be involved in this study, please feel free to forward them this email.

If you are interested in participating, please contact, Owen on 5454 8505 or by replying to this email. Alternatively if you have further questions, you can contact Carol on her phone or email as listed below.

Yours sincerely

Owen Howlett
Research Student/ Occupational Therapist
Doctorate of Clinical Science Candidate
La Trobe Rural Health School | La Trobe University | P.O Box 199 Bendigo VIC 3552 Australia
T: 03 5454 8505 | E: ohowlett@bendigohealth.org.au

Dr Carol McKinstry
Principal Investigator
Senior Lecturer Occupational Therapy
La Trobe Rural Health School | La Trobe University | PO Box 199 Bendigo 3552
T: 03 5448 9111 | E: C.McKinstry@latrobe.edu.au | W: www.latrobe.edu.au

Appendix C6

Study Three - Codebook

Study three codebook: codes used by individual coders for focus group one.

Focus Group One	
Coder 1	Coder 2
Limited confidence in using intervention	Credentialing within an organisation
Limited knowledge/ skills of using equipment	OT UL, PT LL
Reduced confidence in reasoning skills	Interdisciplinary collaboration between physio and OT
Clinician wants to avoid appearing incompetent	
Limited confidence and awareness of the evidence	
Individual therapy expertise and preference	
FES is different to other interventions	
Access to PD for FES use	
Absence of mentors	
Priorities for learning	
Access to practicing skills	
Frequency of appropriate clients is limited	
Appropriate patient presentation	
Efficiency in therapy delivery	
To learn how to effectively use FES in practice	
Credentialing within an organisation	
OT UL, PT LL	
Not seen as routine scope of practice	
Challenges of using a multi D approach	
Access to equipment is limited	
Change of staff due to rotations/ leave/ job change	
Appropriate environmental setting to deliver intervention	

Study three codebook: codes used by individual coders for focus group two.

Focus Group Two	
Coder One	Coder Two
Need for machine maintenance	Limited knowledge of using existing equipment
Limited knowledge/ skills of using existing equipment	Of the evidence
Clinical reasoning	Eagerness to learn and try new things
of the evidence	Anatomy knowledge
Eagerness to learn new things	Individual therapy expertise and preference
Individual therapy expertise and preference	FES or muscle stimulation
FES or muscle stimulation	Access to PD for FES use
Outcomes not seen	Gait / LL specific
Access to PD for FES use	Credibility - who is providing the training
Priority for learning	Appropriate patient
Credibility of trainers	To learn how to effectively use FES in practice
Appropriate Patient	For setting up FES with patients
Motivation of clients	Efficiency in therapy delivery
Frequency of clients	Setting: Preference to Inpatient setting
Efficiency in therapy delivery	Access to contemporary equipment
For setting up FES with patients	
Priority against other intervention	
To administer	
To learn how to use FES in practice	
OT UL, PT LL	
Challenges of using a multi D approach	
Practice setting, ins vs out	
Client frequency	
Setting	
Routine Practice	
Access to equipment	
Staff turnover	

Consensus agreement on common codes between groups and subsequent themes.

Consensus agreement with Individual coder codes	Theme	Theme
Limited knowledge/ skills of using equipment	<i>Expertise/ Confidence</i>	1
Reduced confidence in reasoning skills		
Limited confidence and awareness of the evidence		
Individual therapy expertise and preference		
Varying anatomy knowledge		
FES or muscle stimulation		
Eagerness to learn to try new things #		
Need for ongoing device maintenance		
Tangible outcomes not experienced #		
Limited confidence in using FES*		
Clinicians want to avoid appearing incompetent*		
FES is different to other intervention		
Access to PD for FES use	<i>Professional Development</i>	2
Priorities for learning		
Absence of mentors*		
Access to practicing skills		
Credibility of the professional development training #		
Appropriate patient presentation	<i>Consumer Factors</i>	3
Efficiency in therapy delivery	<i>Time</i>	4
To learn how to effectively use FES in practice		
Traditional practice boundaries of OT/ PT	<i>Scope of practice</i>	5
Credentialing within an organisation*		
Challenges of using an interdisciplinary approach (nursing/ OT/ PT/ AHA)	<i>Interdisciplinary Collaboration</i>	6
Access to equipment is limited	<i>Organisational Factors</i>	7
Appropriate environmental setting to deliver intervention		
Frequency of appropriate clients is limited		
Practice setting, ins vs out		
Change of staff due to rotations/ leave/ job change*		
Change of staffing#		

Appendix C7

Study Three – Mapping of Barrier Themes to the Theoretical Domains Framework

Study Three. Mapping of Barrier Themes to the Theoretical Domains Framework.

[illegible]

Professional development	Access to PD for FES use	1, 3	1, 3		1, 3	2		
	Priorities for learning						2, 3	1, 3
	Absence of mentors*		2, 3		1, 3			
	Credibility of the professional development training #					1, 3	2, 3	
	Access to practising skills	1, 3				2, 3		
Consumer factors	Appropriate patient presentation				1, 3	1, 2, 3		
Time	Efficiency in therapy delivery	3	2, 3	1, 3		1, 3	1, 3	
	To learn how to use FES in practice effectively	1, 2, 3	1, 3	1, 3		1, 3	1, 3	1
Scope of practice	Traditional practice boundaries of OT/ PT						2, 3	1, 3
	Credentialing within an organisation*					2		1, 3
Interdisciplinary collaboration	Challenges of using an interdisciplinary approach (nursing/ OT/ PT/ AHA)				1, 3	2		1, 3
Organisational factors	Access to equipment is limited					1, 2, 3		
	Appropriate environmental setting to deliver intervention					1, 2, 3		
	Frequency of appropriate clients is limited					1, 2, 3		
	Practice setting, ins vs out				1, 3	1, 2, 3		
	Change of staff due to rotations/ leave/ job change*		2, 3		1, 3	1, 3		
	Change of staffing#		2, 3		1, 3	1, 3		

Note. 1 = Owen Howlett; 2 = Carol McKinstry; 3 = consensus agreement; # = physiotherapy; FES = functional electrical stimulation; * = occupational therapy; OT = occupational therapy; PT = physiotherapy; AHA = allied health assistant; PD = professional development

Appendix D

Knowledge to Action Framework Permission to Use

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Nov 28, 2019

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Expected completion date	Jun 2019
Expected size (number of pages)	300
Requestor Location	Bendigo Health 22 Penhallurick St Campbells Creek, Victoria 3451 Australia Attn: Owen Howlett
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