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Occupational therapy for the upper limb after stroke:  
implementing evidence-based constraint induced  
movement therapy into practice

**Kathryn Jarvis**

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# Abstract

## Background

Constraint induced movement therapy (CIMT), an intervention to increase upper limb (UL) function post-stroke, is not used routinely by therapists in the United Kingdom; reasons for this are unknown. Using the Promoting Action on Research Implementation in Health Services (PARIHS) framework to analyse CIMT research and context, a series of related studies explored implementation of CIMT into practice.

## Methods and Findings

Systematic review: nineteen CIMT randomised controlled trials found evidence of effectiveness in sub-acute stroke, but could not determine the most effective evidence-based protocols. Further review of qualitative data found paucity of evidence relating to acceptability and feasibility of CIMT.

Focus group: perceptions of the feasibility, including facilitators and barriers, of implementing CIMT into practice were explored in a group of eight therapists. Thematic analysis identified five themes: personal characteristics; setting and support; ethical considerations; education and training; and practicalities, which need to be addressed prior to implementation of CIMT.

Mixed-methods, pilot study (three single cases): pre- and post-CIMT (participant preferred protocol) interviews explored perceptions and experiences of CIMT, with pre- and post-CIMT measurement of participation and UL function. Findings indicated: (i) provision of evidence-based

CIMT protocols was feasible, although barriers persisted; (ii) piloted data collection and analysis methods facilitated exploration of stroke survivors' perceptions and experiences, and recorded participation and UL function.

## **Conclusions**

Findings traversed PARIHS elements (evidence, context, facilitation), and should be considered prior to further CIMT implementation. Future studies of CIMT should explore: effects of CIMT protocol variations; characteristics of stroke survivors most likely to benefit from CIMT; interactions between CIMT and participation.

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# Abbreviations

ADL	activities of daily living
AOU	amount of use
ANOVA	analysis of variance
ANCOVA	analysis of covariance
ARAT	Action Research Arm Test
ATP	adaptive task practice
BATRAC	bilateral arm training with rhythmic auditory cueing
BI	Barthel Index
CASP	Critical Appraisal Skills Programme
CD-RISC	Connor-Davidson Resilience Scale
CFIR	Consolidated Framework for Implementation Research
CI	confidence interval
CIMT	constraint induced movement therapy
CIT	constraint induced therapy
CONSORT	Consolidated Standards of Reporting Trials
COPM	Canadian Occupational Performance Measure
COREQ	Consolidated Criteria for Reporting Qualitative Studies
CRD	Centre for Reviews and Dissemination
CVA	cerebrovascular accident
EMF	Emory Function Test
ESD	early supported discharge
ESRC	Economic and Social Research Council
EXCITE	Extremity Constraint Induced Therapy Evaluation
FIM	Functional Independence Measure
FMA	Fugl-Meyer Assessment
GPT	grooved peg test
HADS	Hospital Anxiety and Depression Scale
hr	hour
IADL	instrumental activities of daily living
ICF	International Classification of Functioning, Disability and Health
IP	interphalangeal joint
IPA	interpretative phenomenological analysis
Kg	kilograms
lnWMFT	log of WMFT time
m	metres
MAL	Motor Assessment Log
MAS	Motor Assessment Scale
MANOVA	multivariate analysis of variance
MCID	minimal clinically important difference
mCIMT	modified constraint induced movement therapy
MCP	meta-carpophalangeal joint
MD	mean difference
MDC	minimum detectable change
MeSH	Medical Subject Headings
MFT	Muscle Function Test
MI	Motricity Index
Min	minute

MMSE	Mini Mental State Examination
MoCA	Montreal Cognitive Assessment
MOHO	Model of Human Occupation
MRC	Medical Research Council
NDT	neurodevelopmental techniques
NEADL	Nottingham Extended Activities of Daily Living Scale
NHPT	nine hole peg test
NHS	National Health Service
NIHSS	National Institutes of Health Stroke Scale
NRES	National Research Ethics Service
NSA	Nottingham Sensory Assessment
OT	occupational therapist
OT-STAR	Occupational Therapy Stroke Arm and Hand Treatment Record
PARIHS	Promoting Action on Research Implementation in Health Services
PIOS	population, intervention, outcomes and study design
PNF	proprioceptive neuromuscular facilitation
PROM	passive range of motion
PT	physiotherapy
QIF	Quality Implementation Framework
QOM	quality of movement
QUORUM	Quality of Reporting of Meta-analyses
RCT	randomized controlled trial
RMA	Rivermead Motor Assessment
ROM	range of motion
RTP	repetitive task practice
SD	standard deviation
secs	seconds
SIS	Stroke Impact scale
SMD	standard mean difference
SPIDER	sample, phenomenon of interest, design, evaluation, research type
UL	upper limb
UK	United Kingdom
US	United States
VECTORS	Very Early Constraint-Induced Movement during Stroke Rehabilitation
wks	Weeks
WMD	weighted mean difference
WMFT	Wolf Motor Function Test

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Jarvis, K., Grant, E., Edelstyn, N. and Hunter, S. (2013) Facilitators and barriers to undertaking a constraint induced movement therapy (CIMT) protocol in sub-acute stroke: a synthesis of the literature. *Cerebrovascular Diseases*. 2013; 35 (Supp. 3): 21.

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# Chapter 1

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## Introduction

The purpose of this chapter is to provide an overview of stroke, its impact on the upper limb (UL) and the context in which stroke rehabilitation takes place. It will introduce Constraint Induced Movement Therapy (CIMT) as a complex UL intervention and will start to explore the relationship between CIMT and evidence-based practice. This thesis is primarily about implementation of CIMT; evidence of implementation of CIMT to date is examined. The chapter concludes with an overview of the thesis purpose, aims and objectives.

### 1.1 Stroke

Based on a World Health Organization classification (World Health Organization, 1978), stroke has been defined as “a clinical syndrome, of presumed vascular origin, typified by rapidly developing signs of focal or global disturbance of cerebral functions lasting more than 24 hours or leading to death” (Intercollegiate Stroke Working Party, 2012, p. 4). A stroke occurs when the blood flow to the brain is interrupted resulting in damage to the cells of the brain (National Audit Office, 2010). The blood flow is usually interrupted either as a result of a blockage of a blood vessel (from a thrombus or embolus), termed an ischaemic stroke, or as a result of a bleed into the brain from a blood vessel, termed a haemorrhagic stroke (National Audit Office, 2010). Approximately 85% of strokes are ischaemic and 15% haemorrhagic (National Audit Office, 2010).

Each year over 110,000 people in England have a first stroke (National Audit Office, 2005; National Institute for Health and Clinical Excellence, 2008). It is estimated that 25% of people living to 85 years of age will experience a stroke (National Audit Office, 2005), with 25% of strokes occurring in those younger than 65 (Department of Health, 2007). Stroke is the largest cause of disability in England and Wales, with a significant risk (estimated at 11% with one year and 26% within 5 years) of a recurrent stroke (Mohan et al., 2011). With 900,000 people living with stroke in England at any one time (National Audit Office, 2005; National Institute for Health and Clinical Excellence, 2008), and an estimate that approximately 300,000 people in England live with moderate to severe disability from their stroke (Department of Health, 2007), the impact of stroke is far reaching.

Stroke affects the ability to undertake valued activities causing long-term disability (activity limitation) for approximately a third of stroke survivors (Department of Health, 2007; National Institute for Health and Clinical Excellence, 2008); the range of potential effects depends on the functional area and extent of the brain damaged by the stroke (Department of Health, 2007; The University of Edinburgh, 2007). Stroke may impact on: emotional status; mental health, with stroke survivors being particularly at risk of depression; physical ability, including muscle weakness (paresis) of limbs and reduced sensation; communication, which may impact on the ability to produce or understand words; ability to swallow; cognitive abilities and behaviour; vision; and continence (Department of Health, 2007; Intercollegiate Stroke Working Party, 2012; Miao et al., 2015; Pinter & Brainin, 2012; The University of Edinburgh, 2007).

## **1.2 Rehabilitation context**

It is estimated that stroke costs the National Health Service (NHS) approximately £2.8 billion each year in direct care costs (Department of Health, 2007; National Audit Office, 2010), which is

approximately 4% of the total NHS budget (Department of Health, 2006; The Information Centre, 2007) with an additional £2.4 billion in informal care costs, including nursing home costs and other costs to the stroke survivors' families in order that the stroke survivors' care needs are met (Department of Health, 2007). Recovery from stroke is important for each stroke survivor for their quality of life, it is also important in a political and economic environment where there is continuous pressure on health and social care funding (Liberal Democrats, 2015; The Conservative Party, 2015; The Labour Party, 2014). In this environment stroke services must be effective and perceived as value for money.

Although a few studies have suggested that functional recovery can take place many months post-stroke (Miltner et al., 1999; Sterr et al., 2002a; Taub et al., 1993), the majority of the evidence indicates that most functional recovery takes place within 3 months (Dimyan & Cohen, 2011; Nakayama et al., 1994; Zeiler & Krakauer, 2013). The National Clinical Guideline for Stroke (Intercollegiate Stroke Working Party, 2012) recommends stroke survivors should be re-assessed by specialist professionals if their situation changes, or new issues have arisen, or where clear goals are established, and that in these circumstances further therapy may be appropriate. Current guidelines also recognise the value of employment services (Department of Health, 2007; Intercollegiate Stroke Working Party, 2012; Scottish Intercollegiate Guidelines Network, 2010) and psychological support (Department of Health, 2007; Intercollegiate Stroke Working Party, 2012); however, there is currently insufficient evidence to support longer term therapy for all stroke survivors (National Audit Office, 2010). Given this lack of evidence, and the current economic and political environment, it is inevitable that stroke rehabilitation mainly occurs in the first few months post-stroke (Desrosiers et al., 2005; Intercollegiate Stroke Working Party, 2012, p. 79). It is essential that therapists know which interventions are most likely to reap the best results in the first few months post-stroke (Desrosiers et al., 2005) since some stroke survivors

will be offered no additional therapy beyond this time. This thesis aims to address this rehabilitation window of opportunity, with a focus on the sub-acute phase of stroke.

### **1.2.1 Defining the sub-acute phase of stroke**

The terms acute, sub-acute and chronic phases of stroke are in common use in stroke literature, although these terms are rarely adequately defined. The acute phase indicates the first few hours to days after the stroke occurs, when a diagnosis is made and the pathological aspects of the stroke are managed (Intercollegiate Stroke Working Party, 2012). The chronic phase of stroke is usually considered to start somewhere between six months (Barzel et al., 2009; Brogårdh & Sjolund, 2006; Kitago et al., 2013) and one year post-stroke (Lin et al., 2007; Page et al., 2004; Taub et al., 1993). Between the acute and chronic phase is the sub-acute phase of stroke, in which stroke survivors with a non-functional UL are likely to access much of their rehabilitation (Intercollegiate Stroke Working Party, 2012). A previous large scale randomised controlled trial (RCT) (Wolf et al., 2006) defined the sub-acute phase as between three and nine months post-stroke. Whilst nine months is a reasonable estimate of an end point for the sub-acute phase, a substantial amount of rehabilitation takes place in the first few months following stroke, therefore for the purposes of this thesis, sub-acute was defined as from 14 days to nine months post-stroke. In doing this, the review focuses on the time frame in which most rehabilitation would occur, whilst excluding the acute phase where medical management of stroke is likely to be the priority.

## **1.3 UL impairment and rehabilitation**

Hemiparesis, impaired motor control on one side of the body (National Stroke Organisation, 2015), is well-recognised as a consequence of stroke (Intercollegiate Stroke Working Party, 2012). It occurs in about 80% of stroke survivors (Intercollegiate Stroke Working Party, 2012; Langhorne

et al., 2009). The UL, defined as “extending from the deltoid region to the hand, and including the arm; axilla; and shoulder” (National Center for Biotechnology Information, 2015) is affected in approximately 70% of stroke survivors (Intercollegiate Stroke Working Party, 2012; Nakayama et al., 1994; Parker et al., 1986). A reduced ability to use an UL may result from one or more impairments such as altered motor control (Carr & Shepherd, 1998; Intercollegiate Stroke Working Party, 2012; Pollock et al., 2014), altered muscle strength (Harris & Eng, 2007) reduced sensation (Doyle et al., 2013; Harris & Eng, 2007; Intercollegiate Stroke Working Party, 2012; Pollock et al., 2014), altered cognition (Intercollegiate Stroke Working Party, 2012; Pollock et al., 2014), oedema (Jackson et al., 2012), pain (Intercollegiate Stroke Working Party, 2012; Pollock et al., 2014; Taule & Raheim, 2014), or emotional state (Pollock et al., 2014).

UL use is important for many activities undertaken as part of everyday life. It provides dexterity combined with strength through a range of grips (Ritchie et al., 2011) and provides valuable sensory feedback about the environment and tasks being undertaken (Ritchie et al., 2011; Yekutieli, 2000). The ULs are also an important facilitator of communication through gesticulation, and physical contact with others (Ritchie et al., 2011). Reduced UL activity may impact on ability to participate in valued activities or occupations (Desrosiers et al., 2005; Nakayama et al., 1994; Olsen, 1990; Parker et al., 1986; Sarre et al., 2013; Sveen et al., 1999). Difficulty in using an UL in daily tasks has been associated with reduced quality of life (Hidaka et al., 2012) and emotional and behavioural changes (Poltawski et al., 2015). For these reasons it is crucial that recovery of UL function is addressed as part of a rehabilitation process.

Evidence indicates that recovery of the UL post-stroke is often not complete (Walsh et al., 2015a). It has been estimated that functional ability of the UL is not recovered in at least 40% of stroke survivors (Intercollegiate Stroke Working Party, 2012; Kong et al., 2011; Walsh et al., 2015a). Broeks et al. (1999) reported that 67% of their in-patient sample (N=54) continued to perceive

non-use and disuse of their more affected arm as a problem four years after the stroke.

Suggested reasons for this poor recovery include a focus on mobility and basic activities of daily living when a stroke survivor is in hospital in order to facilitate discharge (Brown et al., 2014; Cott, 2004), and insufficient therapy time or repetition of tasks to effect a change (Wolf et al., 2006). In summary, UL function is frequently affected following stroke. It is, therefore, essential that therapists use effective therapeutic interventions which are both feasible and acceptable to stroke survivors to address UL dysfunction.

### **1.3.1 Describing therapeutic interventions**

Establishing effectiveness of a therapeutic intervention is more complex than testing a new drug (Medical Research Council, 2008; Whyte & Hart, 2003). The active ingredients in a new drug are known, and processes for testing new drugs have been established; this is not the case for therapeutic interventions (Medical Research Council, 2008). Researchers have described a therapy 'black box' which needs unpacking (Pomeroy et al., 2001; Winter et al., 2011) in order to establish and understand the active ingredients in each therapeutic intervention. Whyte and Hart (2003) propose that the process would be better compared to opening a Russian doll. They propose that there are many layers to understanding a therapeutic intervention; the outer doll may be a description of the key elements of the intervention, whilst the smaller dolls (the deeper layers) may be a description of the intervention in greater detail, such as the intensity and duration of the intervention, or aspects of its delivery that might impact on outcome, for example, therapist experience or the setting in which it takes place. Whyte and Hart (2003) also note that, unlike dispensing a drug, the outcome of a therapeutic intervention may be dependent on the amount of patient engagement. Therapeutic interventions need to be clearly described to enable evaluation of the intervention and, where effectiveness is established, replication into clinical practice.

## 1.4 Constraint induced movement therapy (CIMT)

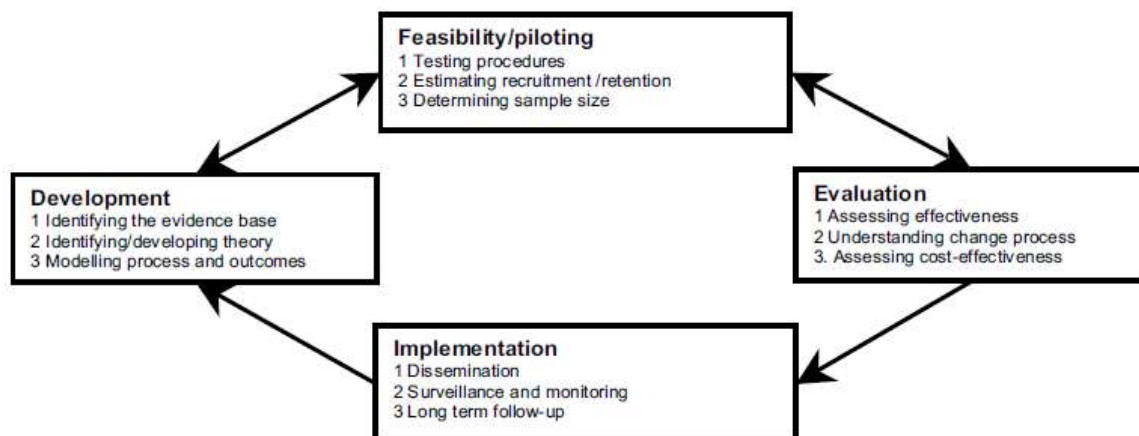
A variety of UL therapeutic interventions are reported in the published literature (Barreca et al., 2003; McHugh et al., 2013; Oujamaa et al., 2009). One intervention, CIMT, has gained a lot of interest due to a high volume of published research. CIMT has been described (Uswatte et al., 2006) as a collection of techniques that include two fundamental elements: 1. constraint or reduction of use of the ipsilesional (less affected) UL; 2. re-training of the contralesional (more affected) UL (Miltner et al., 1999; Nijland et al., 2013; Pollock et al., 2014). The CIMT protocols often involve a stroke survivor attending therapy each weekday over a two week period (Taub et al., 1993; Wolf et al., 2006). A detailed review of the development of CIMT and the subsequent studies is provided in the next chapter.

Based on large RCT (Wolf et al., 2006) and systematic review evidence (Nijland et al., 2011; Sirtori et al., 2009) indicating effectiveness of CIMT, the National Clinical Guideline for Stroke (Intercollegiate Stroke Working Party, 2012) currently advise that CIMT should be considered for stroke survivors who “have 20 degrees of active wrist extension and 10 degrees of active finger extension” (p. 84). Whilst the guideline (Intercollegiate Stroke Working Party, 2012) recognises the importance of training for a team prior to implementing CIMT, it has been proposed that, given the large evidence base, CIMT should be the intervention of choice for those who meet criteria to participate (Pomeroy et al., 2011). The research questions in this thesis originated from non-therapist healthcare professionals challenging the lack of implementation of CIMT on a stroke rehabilitation unit in the United Kingdom (UK). Whilst these questions were originally posed in 2007, there is evidence from recent surveys (McHugh et al., 2013; Pedlow et al., 2014) that this situation has not changed substantially in UK stroke services. McHugh et al. (2013) surveyed 53 stroke units in the UK and found that only 12 of these reported using CIMT with stroke survivors with mild UL impairment (active grip and release) and only 11 with stroke

survivors with a moderate impairment (poor gross skills). The survey indicates that only a small number of therapists are currently implementing CIMT into NHS practice, but the survey did not undertake any exploration of the reasons for the limited use of CIMT. Pedlow et al. (2014) used an online survey to investigate physiotherapist and occupational therapist (OT) knowledge and clinical practice of CIMT in the UK. From 489 (response rate of 17%) returned questionnaires, 62.6% of the respondents indicated that they had not used CIMT. Pedlow et al. (2014) also identified that therapists who were using CIMT were not using CIMT according to the protocols; the reasons for this were not explored. There was some evidence from closed questions that lack of training and limited resources were the main reservations to using CIMT; however, there was no opportunity for exploration of these issues in the questionnaire format. Additionally, the wording of the questionnaire indicated that reservations relating to the use of CIMT were expected from the participants. Due to this potential source of bias, and the lack of detail in responses as a result of the questionnaire design, the reasons for the limited implementation of CIMT remain unclear. In addition, where there is evidence of CIMT being used in practice in the UK, there is evidence that CIMT protocols are not being provided in line with published evidence (McHugh et al., 2013; Pedlow et al., 2014).

### **1.4.1 CIMT: a complex intervention**

Therapeutic interventions encompassing a number of potentially interacting components, such as CIMT, have been described as complex interventions (Medical Research Council, 2008; Pinter & Brainin, 2012). Guidance for Development and Evaluating Complex Interventions (Medical Research Council, 2008) first published in 2000 and updated in 2008 describes a process to establish effectiveness of an intervention and address implementation. To get to a point where an intervention can be tested for its effectiveness, a number of other non-linear, often iterative stages are required (Campbell et al., 2000). These are shown in the development-evaluation-implementation process (Medical Research Council, 2008) which is presented in Figure 1.1.

**Fig 1.1 The development-evaluation-implementation process**

*Reproduced from 'Developing and evaluating complex interventions: new guidance' with permission from the Medical Research Council and from 'Developing and evaluating complex interventions: the new Medical Research Council guidance', Craig, P, Dieppe, P, Macintyre, S, Michie, S, Nazareth, I, Petticrew, M, British Medical Journal (Clinical Research Edition), 337, 2008, with permission from BMJ Publishing Group Ltd.*

The Medical Research Council (MRC) (2008) proposes that planning for implementation of a complex intervention should start in the development stage. There is a need to establish whether an intervention is feasible and acceptable, and what might be the facilitators of and barriers to implementing the intervention (Medical Research Council, 2008); this work has not been undertaken during the development of CIMT.

Whilst quantitative RCT methods are often considered the gold standard when measuring effectiveness (Seers, 2007; Taylor, 2007, p. 16; Walshe, 2007), these methods are not sufficient when exploring issues of feasibility and acceptability (Campbell et al., 2000; Iltott, 2012; Walshe, 2007). Exploratory methods provide a means to collect rich qualitative data. These methods are inductive in nature and can be utilised to understand perceptions and experience of healthcare

(Taylor, 2007, pp. 86-104). Findings may be utilised in the generation of theory (Walshe, 2007) and should be used in addition to the deductive methods used in RCTs which aim to test theory through the testing of hypotheses (Medical Research Council, 2008; Walshe, 2007). Due to the nature of enquiry, the methods utilised within the programme of work, reported in this thesis, were predominantly qualitative. Where quantitative methods were incorporated, this was with the aim of better understanding the qualitative findings.

## 1.5 Implementation of innovations

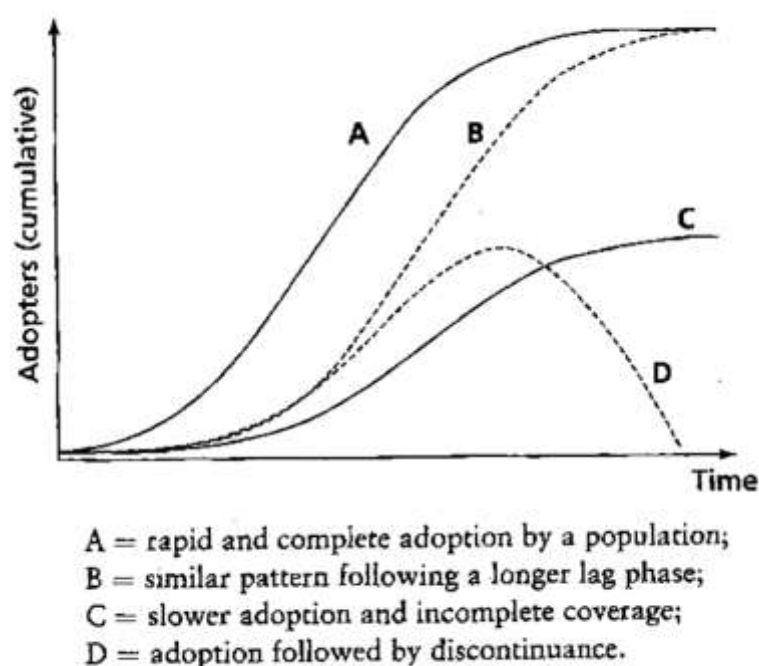
The process of successfully implementing an innovation has been described as an s-shaped curve (Greenhalgh et al., 2005). This curve is shown on Figure 1.2 as curve A where there is a lag at the start of the curve, with a gradual up-take which becomes more rapid at a point termed the 'take-off' curve; at this point there is acceleration in the number of people adopting the innovation. This is followed by a smoothing out of the curve as the majority of the population takes on the innovation and late adopters join the majority (Greenhalgh et al., 2005). This curve describes successful adoption of an innovation. Whilst this curve would be expected where there is an evidence-based innovation, some innovations may be supported by research, but still not adopted (Bayley et al., 2012; Damschroder et al., 2009).

CIMT is one such innovation, with evidence that therapists are not using CIMT based on the current evidence in their practice. Given that evidence of CIMT effectiveness has been available since the early 1990s, with systematic review evidence (Sirtori et al., 2009) available since 2009, it is clear that the stroke therapist population have not been quick to adopt CIMT. It is possible that the lag phase has been relatively long and that in the future there will be good adoption as represented by curve B in Figure 1.2. It is also possible that CIMT will be utilised by only a small number of therapists, for example due to feasibility issues and the practicalities of providing the

intervention; this is represented as curve C in Figure 1.2, where the gradient reflects adoption by fewer people and the curve flattens at a sub-optimum level.

Alternatively CIMT may be adopted by a few therapists, but over time the numbers using the innovation decrease and eventually it is discontinued; this may occur if the benefits are not perceived to outweigh the barriers to CIMT, or issues of acceptability or feasibility make the intervention unsustainable. This is represented in curve D in Figure 1.2. The adoption pattern and the reasons for the poor implementation of CIMT are unclear. To further implementation of evidence-based CIMT, the perceptions of therapists and stroke survivors, including an exploration of the acceptability and feasibility of CIMT, must be undertaken.

**Fig 1.2 Curves for different innovations and populations**



*Reproduced from 'Diffusion of innovations in health service organisations: a systematic literature review', Greenhalgh, T., Robert, G., Bate, P., Macfarlane, F., Kyriakidou, O., 2005, p. 21, with permission of John Wiley and Sons.*

### 1.5.1 Implementing CIMT into practice

Occupational therapists (OTs) work with stroke survivors to increase their participation in meaningful activities or occupations (Wolf et al., 2015). An important part of this work requires OTs to use interventions to assist stroke survivors regain the functional ability in the contralesional UL through the selection of effective, evidence-based and acceptable therapeutic interventions.

Evidence-based practice, defined as: “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient” (Sackett et al., 1996, pp. 71-2) requires that therapeutic interventions are based on best research evidence, clinical expertise and patient preferences (Sackett et al., 1996; Taylor, 2007, p. 2). Therapists are professionally required to utilise evidence-based practice (College of Occupational Therapists, 2010; Physiotherapy, 2015; Ryan, 2015), yet the reported implementation rate of CIMT indicates that the evidence-base for this intervention has not been integrated into practice. It is proposed that aspects of clinical expertise and perceived stroke survivor preference, for example a lack of therapist knowledge about CIMT or issues relating to the feasibility or acceptability of the CIMT protocols, may be preventing implementation. If implementation of CIMT is to be furthered, it is essential that not only the effectiveness of CIMT is understood, but also that therapist knowledge and perceptions (clinical expertise) alongside stroke survivor preference are explored.

CIMT was selected for study over other UL interventions for a number of reasons: CIMT has a well-established evidence-base (Nijland et al., 2011; Sirtori et al., 2009; Wolf et al., 2006), but as the previous sections indicate, the development process has not been comprehensive and gaps in knowledge remain regarding the feasibility and acceptability of CIMT. In addition, despite clinical guidelines recommending the use of CIMT therapeutic intervention following stroke, evidence indicates that therapists in the UK have not integrated evidence-based CIMT into their practice (McHugh et al., 2013; Pedlow et al., 2014); the reasons for this are not yet understood.

## **1.6 Overview of thesis**

The thesis comprises four individual studies, woven together with the intention of producing a cohesive narrative to explore the implementation of CIMT in a UK NHS stroke service. The research questions of each study evolved from conversations with and questions posed by

professionals and stroke survivors with an interest in implementing CIMT into practice and improving UL outcomes following stroke.

This first chapter sets out the overall purpose of the thesis and continues by offering an overview of the subsequent chapters.

### 1.6.1 Purpose and research questions

The overall purpose of the thesis is to explore the issues impacting the implementation of CIMT into a sub-acute UK NHS stroke service. The Promoting Action on Research Implementation in Health Service (PARIHS) framework (Rycroft-Malone, 2004) was utilised to assess the need for, and subsequently plan studies to further, implementation of CIMT into UK NHS stroke services. The thesis aims have been expressed as a series of research questions that address the three areas of implementation identified in the PARIHS framework, namely evidence, context and facilitation. These research questions are summarised below.

- 1 What is the evidence underpinning CIMT as a complex intervention to increase UL function in sub-acute stroke? **(evidence, Chapter 3)**
- 2 What is known about the acceptability and feasibility of CIMT in the sub-acute phase of stroke? **(evidence, Chapter 4)**
- 3 What are therapists' experiences and perceptions of providing CIMT in a UK NHS stroke service? **(context and facilitation, Chapter 5)**
- 4 What are stroke survivors' expectations, experiences and responses to receiving CIMT in a UK NHS stroke service? **(context and facilitation, Chapter 6)**

## 1.7 Organisation of thesis

Chapter 2 provides a review of the literature which explores and critically evaluates the history and development of CIMT and the theory underpinning it.

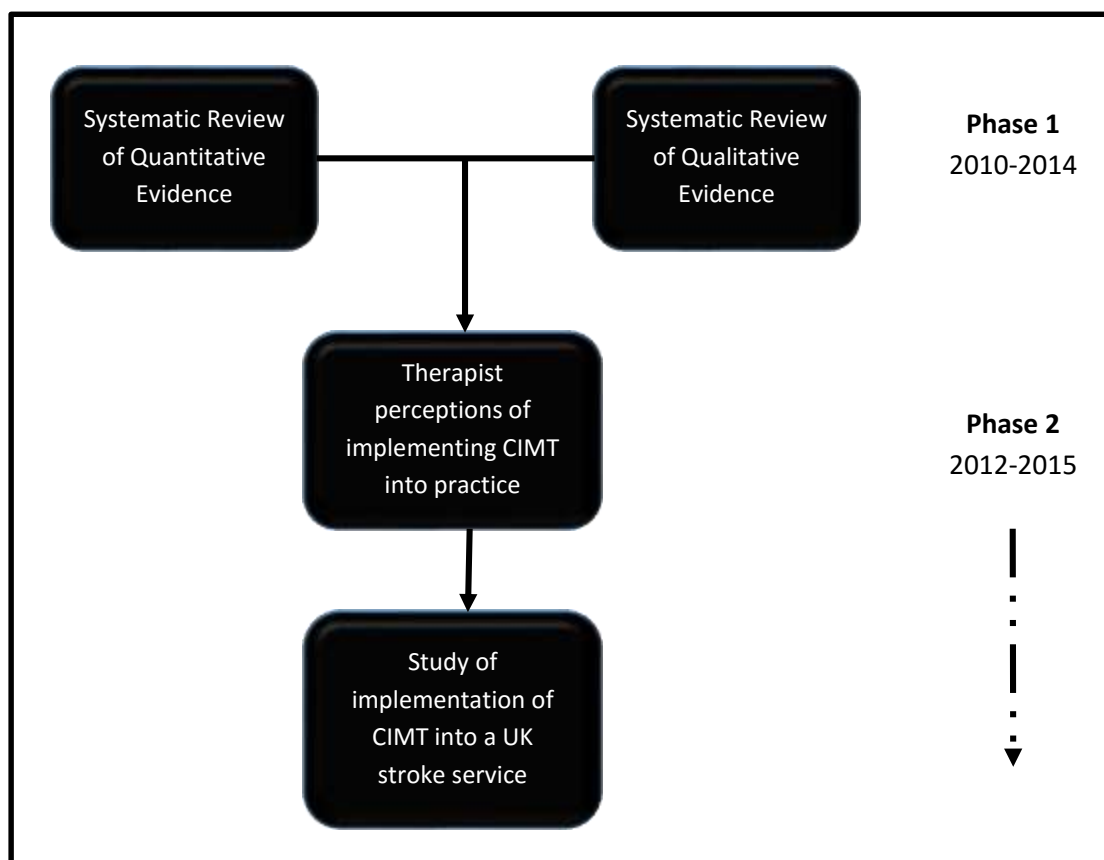
Four studies are reported in Chapters 3 through 6 and can be seen as two distinct phases, summarised in Table 1.1.

**Table 1.1 Summary of the phases, their focus and position in the thesis**

Phase	Focus	Study	Chapter
1	Systematic Reviews to evaluate current CIMT evidence-base	1 & 2	Chapter 3 & 4
2	Implementation of CIMT into a UK NHS Stroke Service	3 & 4	Chapters 5 & 6

The findings from Phase 1 informed the research design for Phase 2. The relationship and timeline is represented in Figure 1.3.

Fig 1.3 Diagram of relationship of studies



Chapter 3 and 4 respectively report the systematic review of quantitative and qualitative data relating to effectiveness and acceptability of CIMT. These studies critically evaluate the current evidence-base for CIMT in the sub-acute phase of stroke. They identify what is known, and establish the gaps in the understanding of CIMT. Chapter 3 reports a systematic review of the quantitative results of RCTs to evaluate the effectiveness of CIMT in increasing UL function in sub-acute stroke survivors, and Chapter 4 is a review and synthesis of the reported experiences of providing and undertaking CIMT from, respectively, a therapist and stroke survivor perspective. This included the identification of previously established facilitators of, and barriers to the provision of CIMT.

The findings from the two systematic reviews reported in Chapters 3 and 4 formed the foundation for two further studies. These two studies, reported in Chapters 5 and 6, sought to gain an understanding of the issues of implementing CIMT in a UK NHS stroke service. Therapist perceptions were sought and are reported in Chapter 5. The final study, a pilot study comprising three mixed methods single case studies, forms Chapter 6, in which the feasibility of providing CIMT in a sub-acute stroke service was explored, barriers and facilitators to the use of CIMT identified, and data collection and analysis methods were tested to inform a future study.

Chapter 7 is the Grand Discussion. This chapter critically reflects on the findings of the studies and discusses the wider implications of those findings for practice and future research. It also provides a discussion of the strengths and limitations of this body of work. Final conclusions are made in Chapter 8.

## **1.8 Personal Stance**

As a researcher's understanding of the world shapes the whole research process (Creswell, 1998, p. 8; Grix, 2004, pp. 100-3; Moon & Blackman, 2014; Moses & Knutsen, 2007), from designing questions, through selecting a methodology and methods, to interpreting the findings (Madill et al., 2000), a researcher's personal stance should be clearly articulated. It has been proposed that where there is an explicit philosophical stance, the research produced is more sophisticated (Creswell, 1998, p. 4). This is of particular importance in qualitative research, where there are numerous research traditions and perspectives (Creswell, 1998; Moses & Knutsen, 2007). Having an explicit philosophical stance helps researchers decide which data they should collect to examine their area of interest (Grix, 2004, p. 103) and facilitates a congruent and observable path so that a researcher can more clearly articulate their thought processes leading to a more rigorous approach (Creswell, 1998, p. 4). The following sections will, therefore, discuss the

ontological and epistemological assumptions that underpin four studies. The information presented in the subsequent sections is necessary to enable consumers of the research to understand the process undertaken and to critique the credibility of the research.

### **1.8.1 Ontology**

This thesis is based on an anti-foundationalist ontology which assumes that the world exists through the perception of humans (Moses & Knutsen, 2007, pp. 142-9) and that truth or knowledge is not independent of humans; therefore, understanding the interaction between humans and their environment is essential if a researcher is going to gain knowledge about a given construct (Moses & Knutsen, 2007, pp.142-9). Within this anti-foundationalist perspective, the work in this thesis assumes a bounded relativist stance (Moon & Blackman, 2014) which assumes that realities, or understandings, may be shared within groups of people (for example those connected by profession or culture), but that these realities are not necessarily shared with other groups or individuals; based on these assumptions, bounded relativism must recognise multiple realities (Moon & Blackman, 2014).

It is from this anti-foundationalist, relativist ontology, favoured by qualitative researchers and based on the premise of multiple realities that this work has evolved. The belief that there may be shared realities within professional groups (a bounded relativist stance) is also an important basic tenet of this work.

### **1.8.2 Epistemology**

Constructivism is an epistemological stance congruent with an anti-foundationalist, relativist ontology. It is based on the belief that knowledge and meaning are “created by the subject’s interaction with the world” (Gray, 2009, p. 18). Whilst meaning is constructed by a person (Gray,

2009, p. 18; Moses & Knutsen, 2007, p. 9), this construction is dependent on interactions with the environment which shape and develop a person's understanding and knowledge (Moon & Blackman, 2014). Constructivism has been described as "the view that all knowledge, and therefore all meaningful reality...is contingent upon human practices, being constructed in and out of interaction between human beings and their world, and developed and transmitted within an essentially social context" (Crotty, 1998, p. 42). This quotation recognises the fundamental role of the social environment in constructing knowledge and understanding.

A presence of power or influence, or specific pools of knowledge that have developed over time may impact on this knowledge through interactions with individuals, groups or society (Moses & Knutsen, 2007, pp. 183-5). In the case of a therapist, their professional knowledge, and understanding of the meaning of this, may be dependent on the place they trained, the environment in which they spent their formative professional years, or the involvement in other professional networks.

A constructivist epistemological stance is the foundation of the four studies in this thesis. In each study there is a premise that knowledge has been constructed and that this was influenced by context and environment.

### **1.8.3 Theoretical perspective**

Social constructionism is the theoretical lens through which the first three studies were viewed. Whilst the terms social constructivism and social constructionism are sometimes used interchangeably (Crotty, 1998, p. 63; Moon & Blackman, 2014; Robson, 2011, p. 24) propose that the latter tends to be used to describe a collective generation and sharing of meaning, whilst the former tends to be used to focus on the experience of individuals and their knowledge

acquisition. The term social constructionism is favoured throughout this thesis to recognise the focus of the generation of knowledge from within groups of CIMT implementation stakeholders.

Social constructionism is a theoretical perspective that aims to understand the interpretation of given constructs and the social context in which this knowledge has been gained through an inductive process (Andrews, 2012; Robson, 2011, p. 24). It emphasises the acquisition of knowledge through the use of language and conversation (Andrews, 2012, p. 44; Creswell, 2009, p. 8) and these assumptions structure the research process (Crotty, 1998, p. 17). Where social constructivism is perceived as a theoretical perspective stemming from a bounded relativist ontology, it also recognises the potential for shared knowledge. In this way there may be constructs for which there is a shared understanding. Studies viewed through a social constructionist lens look for the variety of meanings and consider whether there is a common understanding of these.

The final study maintained a constructivist epistemology, but was viewed through a phenomenological theoretical lens to explore stroke survivor's lived experiences (Hoffman et al., 2010, p. 224) of CIMT. A pragmatic phenomenological approach was undertaken. This approach required the most appropriate methods be chosen to address the research problem and aims (Creswell, 2009, p. 10). Pragmatism was evident in this final study which combined a phenomenological approach with quantitative data analysis.

#### **1.8.4 Overview of methodologies**

The ontological and epistemological stance remains constant throughout the thesis, as these represent the researcher's beliefs and assumptions. The research questions originated from these assumptions and are expressed through a congruent theoretical perspective. The research

design and methods were driven by both the research aim and the researcher's theoretical stance. The ontological, epistemological stance, the theoretical perspective, along with the associated methodology and methods for each of the four studies are summarised in Table 1.2. All studies within this thesis are inductive in nature. Whilst all four studies are predominantly qualitative in design, there is considerable variety in the methods employed, in order that the study aim can be met. The methodologies and research methods for each study are described in detail and justified in the relevant chapter.

**Table 1.2 Summary of theoretical perspectives for the thesis studies**

Study	Ontology	Epistemology	Theoretical Perspective	Aim of Study	Methodology	Methods
1	Anti-foundationalist  Bounded Relativist	Constructivist	Social construction	To identify and analyse randomised controlled trials to provide information that will assist therapists' clinical decision making about when and how they use a specific UL intervention in the sub-acute (14 days to 9 months post-stroke) phase of stroke.	Qualitative, narrative, inductive analysis of quantitative primary studies	Systematic Review with qualitative narrative analysis
2			Social construction	To explore what is known about the experience of providing and receiving a specific UL intervention in the sub-acute phase of stroke	Qualitative, narrative, inductive analysis of qualitative primary studies	Systematic Review with qualitative narrative analysis
3			Social construction	To explore therapist perceptions of implementing evidence-based protocols of a specific UL intervention in a United Kingdom (UK) stroke service.	Qualitative study underpinned by practice development theory	Focus Group

4			Pragmatic phenomenology	To investigate the feasibility of providing protocols of a specific UL intervention to individuals in the sub-acute phase of stroke as part of a UK stroke service, and to test the data collection methods and the data analysis to explore stroke survivors' perceptions and experiences of CIMT, to inform a larger study.	Mixed methods approach in a series of case studies	Interviews Observational Study
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### **1.8.5 An occupational therapist perspective**

OTs and physiotherapists provide the majority of the UL therapeutic interventions for stroke survivors (Lennon, 2011, p. 236). The work in this thesis has been undertaken by an OT; it is inevitable that occupational therapy philosophy is inextricably interwoven into the work. The philosophical roots of occupational therapy recognise the importance of a person interacting with their environment (American Occupational Therapy Association, 2010; Iwama et al., 2009; Kielhofner, 2011; Law, 2013; Law et al., 1996). A foundational tenet of occupational therapy is a belief that people interact with their environment constantly and that a person's environment changes his or her behaviour and understanding of the world (American Occupational Therapy Association, 2010; Iwama et al., 2009; Kielhofner, 2011; Law et al., 1996). A constructivist epistemological stance underpinned by the assumption that humans engage with their environment and construct their knowledge as part of this process, (social constructionism) fits comfortably with an OT's professional understanding of the world.

#### **1.8.5.1 Activity and Occupation**

The OT perspective will be evident throughout this thesis in the use of the terms activity and occupations. Influenced by occupational science (American Occupational Therapy Association, 2008), these concepts are separated in the occupational therapy literature (American Occupational Therapy Association, 2008; Pierce, 2001). An activity has been defined as “a culturally defined and general class of human actions” (Pierce, 2001, p. 139), or “the execution of a task or action by an individual” (World Health Organization, 2002, p. 10). An example of an activity might be eating, walking to school or playing tennis. Activities have different meanings to different people and they can be undertaken in an infinite number of ways. An individual does not have to undertake an activity to have an understanding of it (Pierce, 2001).

OTs use the term occupation to indicate the ‘doing’ that is specific to an individual; it is meaningful to an individual and is goal-directed (Pierce, 2001). There are a number of definitions of occupation (American Occupational Therapy Association, 2008), but they all share the concept that occupations are daily life activities that are meaningful, purposeful and have value to the person undertaking them (American Occupational Therapy Association, 2008). It has been proposed that an occupation is a one-off experience depending on the spatial, temporal and socio-cultural context (Pierce, 2001). Occupations may be undertaken because they are enjoyable or because they are part of a person’s roles and routine (American Occupational Therapy Association, 2008; Kielhofner, 2011). When summarising occupations, they can be described as self-care occupations (such as washing, dressing, oral care, eating, using the toilet), productivity occupations (such as house work, food preparation, child care, employment, or study) or leisure occupations (such as undertaking a sport or craft, socialising with friends, attending events such as concerts or theatre) (Law, 2002; Law et al., 1996). In this way, if an activity is meaningful to a person and they undertake it as part of their everyday lives, it can be considered to be an occupation. Implicit within this is an understanding that any occupation will be dependent on the context in which it is performed (American Occupational Therapy Association, 2008).

Occupational therapy is defined as enabling “people to achieve health, well-being and life satisfaction through participation in occupation” (College of Occupational Therapists, 2011, [www.cot.co.uk](http://www.cot.co.uk)). This definition emphasises the role of OTs as enablers of occupation. Whilst CIMT might be a part of both physiotherapy and occupational therapy practice, and indeed there are physiotherapist participants in one of the studies, the occupational therapy perspective described above is evident throughout.

### **1.8.6 Reflexivity**

Qualitative data by its nature requires interpretation; the researcher’s understanding of the world and their personal and social experiences will guide the collection and interpretation of the

data (Creswell, 2009, p. 8; Denscombe, 2007, p. 300). To ensure research is credible, there must be consideration of the relationship between what is being interpreted and the interpreter; Alvessen and Skoldberg (2009) in summarising this issue, stated “the relation between ‘reality’ and ‘text’ (the research results) is at best uncertain and at worst arbitrary or even non-existent” (p. 2). Exploring and defining this relationship poses substantial challenges to qualitative researchers.

Interpretation is an integral part of qualitative inquiry; in order to understand the relationship between the findings and the researcher, a reflective approach to designing a study, data collection and analysis is advocated (Alvesson & Skoldberg, 2009, p. 9). One aspect of qualitative research is reflexivity, a process which “entails the researcher being aware of his effect on the process and outcomes of research” (Anderson, 2008). Reflexivity can be seen to take a number of forms including epistemological debates (Anderson, 2008; Gomm, 2008, p. 292) and introspective analyses of how the researcher is interwoven with the research (Denscombe, 2007, p. 301; Gomm, 2008, p. 292). Reflexive processes have been put in place in the qualitative studies; the details of these are discussed in the relevant chapter.

## 1.9 Summary

Whilst national guidelines indicate that CIMT should be employed by therapists to improve UL function in a defined group of stroke survivors, therapists are not implementing evidence-based CIMT into practice. The reasons for this are unclear. Not enough is known about the acceptability and feasibility of CIMT to establish whether therapists are meeting the professional requirement for evidence-based practice in relation to CIMT. This thesis sets out to examine the current CIMT evidence-base, to explore therapists and stroke survivor perceptions and experience of CIMT

using predominantly qualitative methods, and to make recommendations to further the implementation of CIMT into practice.

# Chapter 2

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## Background Literature Review

The previous chapter described the prevalence of stroke and the impact of stroke on UL function. The chapter identified a need for therapists to undertake evidence-based practice and identified CIMT as an UL therapeutic intervention with evidence in support of its effectiveness. It presented evidence that, contrary to national guidance, CIMT is not being implemented into clinical practice. The development-evaluation-implementation process (Medical Research Council, 2008) was introduced as a means to guide and understand the process required to implement CIMT.

This chapter reports the background literature review on which this programme of work is based. Medical Subject Headings (MeSH) and key words were used in combination: cerebrovascular accident, stroke, CVA, CIMT, CIT, forced use, upper limb, upper extremity, arm, shoulder, hand, wrist, fingers, with the aim of establishing the historical development of CIMT and the theoretical basis on which it is based. Computer-based databases: MEDLINE, AMED, Scopus, CINAHL, PsychINFO, and Cochrane Central Register of Controlled Trials were utilised. The reference lists of the papers identified as relevant were examined for additional sources of information.

This chapter aims to make three points fundamental to this thesis. Firstly, the historical and theoretical foundations, including some assumptions on which CIMT has been based, may have

implications for the effectiveness of CIMT post-stroke and its subsequent implementation into practice. Secondly, the presumed active ingredients of CIMT, and the most appropriate dose of these, have not been sufficiently explored in the development stage of CIMT and, therefore, require further study. To enable this there needs to be a method of documenting CIMT protocols and any comparison UL therapeutic interventions. Finally, the feasibility and acceptability of CIMT have not been sufficiently studied, which has implications for both evaluation and implementation.

The development-evaluation-implementation process described in Figure 1.1 has been used to structure this literature review. Development of CIMT has been addressed in two sections: 2.1 'Development of CIMT' and 2.2 'The active ingredients in CIMT'. Evaluation has been addressed in Section 2.3 'Evaluation of CIMT' and the potential implications of these for implementation has been summarised in Section 2.4.

## **2.1 Development of CIMT**

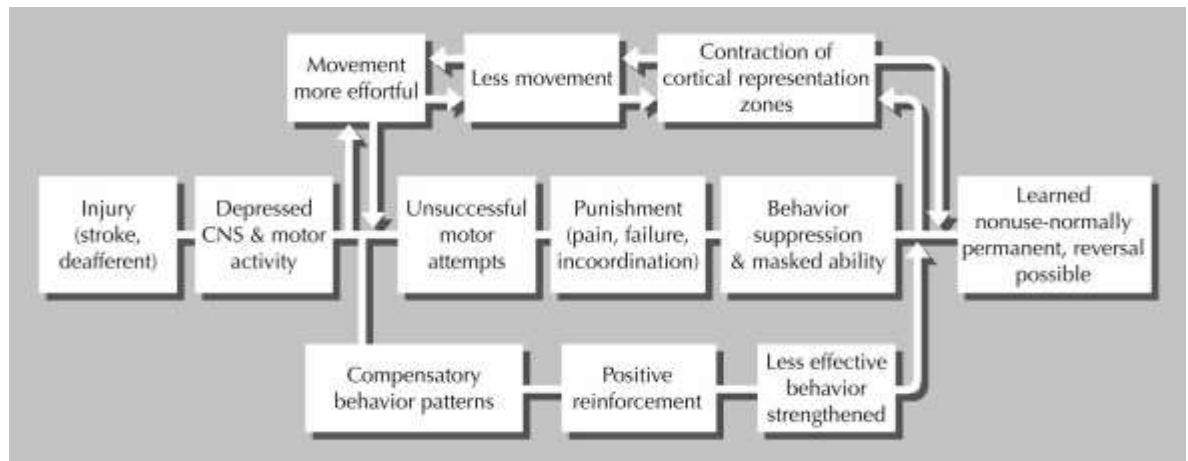
CIMT has developed over a number of decades and it is necessary to understand the development of CIMT for two reasons: 1) to enable a critical review of this process and, where appropriate, to challenge the assumptions made during this development process; 2) to consider the impact of these assumptions on implementation.

### **2.1.1 Development of learned non-use theory**

Learned non-use is the theory developed by Taub et al. (1993) to explain the reduced use of an UL following neurological insult, in spite of there being motor control sufficient for function in that limb. It is the theoretical basis on which CIMT is built.

During the 1960 and 70s, building on the work of others (Knapp et al., 1958; Knapp et al., 1963; Lassek, 1953; Twitchell, 1954), Taub et al. (1994) undertook studies exploring learning responses in monkeys unrelated to stroke, to explore the impact of performing dorsal rhizotomy on monkeys. Dorsal rhizotomy is a deafferentation (removal of afferent connections) procedure in which the dorsal (sensory) root of the spinal nerves innervating a limb is severed, whilst the ventral (motor) root remains intact (Taub et al., 1994); as a result, all sensory input from that limb to the somatosensory cortex is removed. Taub et al. (1993) reported that, following a unilateral dorsal rhizotomy, a monkey will stop using the lesioned limb, even though the motor pathways are intact. Following bilateral deafferentation of the forelimbs, monkeys regained the ability to make coordinated movements of the deafferented limbs after a period of two to six months (Taub, 1976). Based on this evidence, it was proposed (Taub et al., 1994; Taub & Morris, 2001; Taub et al., 1999) that immediately following the deafferentation procedure, spinal shock, a transient physiological depression of spinal cord function (Taub et al., 1993), reduced the activity of the motor neurones and prevents functional use of the limb. Taub et al. (1993) proposed that in monkeys who had undergone unilateral deafferentation, attempts to use the lesioned limb were unsuccessful due to spinal shock; after a number of unsuccessful attempts, the monkeys started to depend on the unaffected limb. As the spinal shock subsided, the unwillingness of the monkey to use the limb masked any returning movement. Taub et al. (Taub et al., 1994; Taub et al., 1993; Taub & Wolf, 1997) proposed this is a conditioned suppression of behaviour with the negative consequences from attempting movement leading to a reduction in the behaviour of using the deafferented limb (Kimble, 1998; Taub et al., 1994). The phenomenon was termed learned non-use (Taub et al., 1993), and was proposed as the mechanism that prevents recovery of movement in deafferented monkeys (Taub et al., 1994; Taub et al., 1993). If a monkey did not use the deafferented limb there would be no opportunity for re-learning to occur, even though motor activity may be possible after a few months have elapsed. The learned non-use would therefore persist (Taub et al., 1999).

To test this theory, the forelimbs of monkeys were restrained for three months immediately following unilateral deafferentation (Taub & Wolf, 1997). When the restraint was removed, the monkeys struggled to use either limb, but did start to use the deafferented limb immediately. No additional intervention was required for the monkey to use the limb again (Taub & Wolf, 1997). Taub and Wolf (1997) proposed that this was because the monkey did not try to use the limb until the spinal shock had reduced. In this way unsuccessful attempts to use the limb were avoided and a learned non-use did not occur. Taub and Wolf (1997) have presented a summary of learned non-use which is shown in Figure 2.1

**Fig 2.1 Diagram of learned non-use**

*Springer and Current Atherosclerosis Reports, (volume 3, 2001, p.280, Taub, E. and Morris, D.M., fig 1) original copyright notice is given to the publication in which the material was originally published with kind permission from Springer Science and Business Media.*

Whilst the reliability of the measurements undertaken was not established, and there was the assumption that the recovery processes following unilateral deafferentation and bilateral deafferentation are similar, the theory of learned non-use seems to adequately describe the response of monkeys to deafferentation.

### 2.1.2 Overcoming learned non-use

An exploration of the evidence to overcome learned non-use in monkeys is also presented here as it provides important insights into the development of CIMT, in order that the assumptions made during this process may be elucidated.

Taub's background as a behavioural psychologist (American Psychology Association, 2015) was evident in the strategies employed to overcome learned non-use. Before describing this work it is necessary to give some background about the development of behaviour theory. Current

behaviour theory is based on the work by Ivan Pavlov (1849-1936) on classical conditioning and by Edward Thorndike (1874-1949) and Burrhus Frederic (B.F.) Skinner (1904-1990) on operant conditioning (Gleitman et al., 2011a). In classical conditioning, a conditioned stimulus (e.g. a tone) is linked to an unconditioned stimulus (e.g. production of food) and the two are paired until the conditioned stimulus results in a conditioned response (e.g. salivation on the production of the tone) (Gleitman et al., 2011b, p. 264). In operant conditioning, a response (e.g. pressing a lever) is required to access the unconditioned stimulus (e.g. food) which, in turn, produces an unconditioned response (e.g. salivation) (Gleitman et al., 2011b, p. 281; Schwartz, 1989, pp. 27-8). There is no stimulus that precedes the response; the response is internally initiated (Blackman, 1974, p. 40). When the required action is performed it is rewarded, this positive reinforcement then increases the likelihood of the action being repeated and in this way behaviour is changed (Gleitman et al., 2011b, p. 281); once this is established, further actions can be added and rewarded. It is operant conditioning that has underpinned the development of strategies to overcome learned non-use.

Taub (1993) identified two ways to induce movement following deafferentation in monkeys: a restraint applied to the less affected limb to decrease its use, and the use of training following operant conditioning principles. Wearing a restraint on the unaffected limb for three days, nine weeks after the unilateral dorsal rhizotomy, resulted in use of the deafferented limb (Taub et al., 2006b); however, if the restraint was removed as soon as the deafferented limb was used, the effects were not retained in the colony environment. When the training was altered so that a food reward was used to 'shape' the desired action through a series of small goals, the behaviours shown in the laboratory were transferred to the colony environment (Taub, 2012). Whilst the measures of behaviour were observational and undertaken by non-blinded assessors, this study indicated that the type of training might be important for recovery of a functional limb

in deafferented monkeys, and it is this work that informed the development of CIMT comprising both a restraining element and a training element.

### **2.1.3 Translating the evidence to humans**

The work with monkeys described in the previous sections led to a proposal that the process of learned non-use may also occur in humans following acquired injury to the central nervous system (Ostendorf & Wolf, 1981), and that the interventions to overcome learned non-use in deafferented non-human primates may provide avenues to explore recovery in humans.

In transferring the evidence from monkeys to humans, two assumptions have been made: 1) that deafferentation of an UL and stroke are similar in terms of impact on UL function and the subsequent recovery processes; and 2) that a monkey's response to injury is similar to a human response.

The pathology of dorsal rhizotomy and stroke are different (Dobkin, 2007; Miltner et al., 1999). Surgical deafferentation of an UL produces a specific and controlled lesion of the spinal nerve root, affecting a defined area and removing sensation input from that limb. Stroke in comparison produces a diffuse, variable central lesion, affecting many functional areas of the brain (Dobkin, 2007). Stroke may impact on the sensation of an UL, but this would not usually result in the complete hemi-anaesthesia which is inevitable in the limb supplied by the deafferented nerves. In addition, following stroke, it is likely that there will be damaged efferent pathways leading to motor control impairments (Taub & Wolf, 1997). There may also be cognitive impairments (Dobkin, 2007; Intercollegiate Stroke Working Party, 2012) and emotional changes (Intercollegiate Stroke Working Party, 2012). In stroke, the lesion occurs in the brain rather than at spinal cord level, so the 'shock' that occurs is likely to be different. For these reasons, it is

unlikely that learned non-use is the only mechanism impacting on motor control following stroke. It has been proposed (Sterr et al., 2002b; Taub et al., 2006b) that learned non-use is different to both motor neglect, the underutilisation of a body part in the absence of paralysis or primary sensory deficit (Sampanis & Riddoch, 2013, p. 110) and to unilateral spatial neglect, a failure “to report, respond, or orient to novel or meaningful stimuli presented to the side opposite a brain lesion” (Heilman et al., 1993, p. 279). This proposition is based on evidence that motor neglect tends to reduce over time (Sampanis & Riddoch, 2013), whilst learned non-use is likely to become more marked (Sterr et al., 2002b), and that unilateral spatial neglect occurs more frequently with a right-sided lesion (Gialanella & Ferlucci, 2010), whilst learned non-use occurs equally with right and left sided lesions (Sterr et al., 2002b). Whilst it may be a separate mechanism, there is currently no means of identifying learned non-use in stroke survivors (Dobkin, 2007; van der Lee, 2001); it is, therefore, not yet possible to explore the relationship between learned non-use and recovery following stroke in humans.

The first study with a human participant (Ostendorf & Wolf, 1981) tested the concept of constraining (in a shoulder sling worn throughout the day) the ipsilesional limb of a 50 year old woman, 18 months post-stroke, with UL paresis, described as presenting with isolated movement at shoulder, elbow, wrist and fingers, but with a dominance of synergy in functional movements.

Descriptions of non-human primate research use the term ‘restraint’ to describe the immobilisation of a limb. The term reflects that there was neither collaboration with, nor choice available to, the participants in these studies. Once the research was transferred to humans the term ‘constraint’ has been used to reflect the active participation and the collaboration that occurs between the intervention provider and the stroke survivor (Russo, 1995). In this first study (Ostendorf & Wolf, 1981), a constraint sling was worn throughout the day during the intervention B-phase of an A-B-A quasi-experimental single system study (Ottenbacher, 1990), where each

phase lasted for seven days. Where an intervention comprises only constraint of the limb with no specified additional training, as in this study, it has been termed forced-use (Eugster-Buesch et al., 2012; Fuzaro et al., 2012; Pierce et al., 2003; Ploughman & Corbett, 2004). The study found an increase in participant-reported frequency of purposeful UL behaviours from a pre-defined list. It was unclear how these reports were rated and clinical significance of this finding was not discussed. A qualitative improvement in ability to use the contralesional hand to write name and use an iron were also reported. The functional assessment, a non-validated tool based on a protocol from Emory University Research and Teaching Center included 18 tasks such as moving hand from lap to table, straightening elbow, picking up cup, paper clip and pencil. These were timed and the video-recordings of the tasks were rated by blinded assessors for quality of movement on a 0-5 scale, where '0' was allocated for 'no visible movement of affected extremity' and '5' was allocated for 'isolated movements throughout the limb, but may be weak or uncoordinated'. The total time to complete all tasks reduced over the duration of the study; however, the biggest reduction in time was from day one of the baseline in Phase A to day seven in baseline Phase A, therefore the majority of the reduction occurred prior to the intervention phase, which indicated the reduction in time was likely to be a result of a practice effect. Quality of the movement did not change. The use of a non-validated functional assessment, the limited detail of the processes to establish the reliability of the reported purposeful UL behaviours, and the lack of blinding of the assessor to the phases indicate a number of potential sources of bias in this study.

In a larger study, (Wolf et al., 1989) studied the effects of forced-use with a sling constraint, which enclosed the fingers of the ipsilateral UL, over a period of two weeks in 25 chronic (greater than one year post-insult) stroke and head-injured participants, who had active finger and wrist extension. The participants wore the constraint for the majority of their waking hours. The study was not controlled, although, six once-weekly baseline measurements indicated that the

participants' UL function was stable prior to the forced-use. The measurements comprised 21 non-validated tasks which were similar, but not identical, to those used in the previous study; additions included lifting a basket and writing own name. The test was subsequently named the Emory Motor Function Test (Taub et al., 1993). Time taken to complete each task was measured and quality of movement was rated by blinded assessors observing the video-recordings and marking a non-validated matrix to indicate the presence or absence of isolated or synergistic movement for each task. Findings were only reported for the 21 participants (stroke n=16; head-injury n=5) who completed all measures. At post-intervention, compared to baseline, there was a statistically significant decreased median change time in 8 of the 21 upper limb functional tasks ( $p < 0.05$  for each of the 8 tasks). This increased to 19 out of 21 tasks at 4 months post-intervention ( $p < 0.05$  for each of the 19 tasks); these findings were maintained at one year post-stroke. There was no change in the quality of movement over time. This indicated that forced-use may have potential for reducing the time taken to complete UL tasks, and that this benefit may continue after the intervention is complete; however, as there was no control group there is a risk that changes may have been due to variables other than the intervention and that the same change may have occurred without the sling constraint. In addition, participants not completing all the measures were excluded and a non-validated measure of functional tasks was used; these may have impacted on the internal validity of the study.

Based on the work to overcome learned non-use in monkeys, described in section 2.1.2, Taub et al. (1993) introduced a training element to the forced-use intervention, developing what is now recognised as the original CIMT protocol, sometimes referred to as the signature CIMT protocol (Taub et al., 1999). In a small, randomised, controlled study of chronic stroke survivors, CIMT (n=4) was compared to an attention comparison (n=5). The two week CIMT intervention comprised six hours training of the contralesional UL each weekday and the wearing of a constraint on the ipsilesional UL for 90% of waking hours, allowing for a small allocation of time

without the constraint to undertake washing and toileting. The training included activities such as using cutlery, playing games and writing (Taub et al., 1993). The participants in the attention comparison: a) were told that they had greater ability in their ipsilateral UL; b) undertook two therapy sessions in which passive range of motion (ROM) and sensory loss were assessed; and c) undertook self-initiated ROM exercises for 15 minutes each day. Taub et al. (1993) reported that the participants in the CIMT group each had statistical significant or near significant reductions (nonparametric sign test,  $p < 0.06$ ) in mean performance times in Emory Motor Function Test (EMFT) (Wolf et al., 1989) and The Arm Motor Activity Test (AMAT), a test of activities involving the UL (McCulloch et al., 1988). This was not the case in the comparison group ( $p > 0.3$ ). Functional ability, rated by assessors blinded to group allocation, was also reported as significantly increased on both EMFT and AMAT for all participants in the CIMT group, but not for the comparison group; however the statistics to support this were not presented. Whilst the study indicates that CIMT may be beneficial when compared to an attention comparison of less than six hours, the interpretation of the measures is limited by a lack of reporting of the findings and the use of non-validated measures without an established Minimal Clinically Important Difference (MCID). A MCID is important as it indicates the smallest amount of change from an intervention that would be interpreted as important by a participant or patient (McGlothlin & Lewis, 2014), thereby indicating that change below this level would not be meaningful. In addition, the small sample size and a lack of detail of the randomisation procedures may have introduced bias. Whilst there was a clear need for further investigation of the intervention, the components of constraint and training described in this study continue to define CIMT.

Van der Lee et al. (1999) reported an observer-blinded RCT (N=66) of what was nominally forced-use, in chronic (greater than one year post stroke) stroke survivors. The experimental intervention comprised constraint of the ipsilesional UL for 12 consecutive days, excluding travelling, sleeping and self-care activities, in addition to six hours of training, five days a week for

12 days. Due to the inclusion of a training component, the intervention meets the definition of CIMT being used in this thesis. The comparison group undertook six hours of UL therapy according to neurodevelopmental theory, tasks were completed bimanually, and, where required, the ipsilesional UL was used to assist the contralesional UL. The training for both groups consisted of housekeeping activities, handicrafts and games, but the content of the sessions is not described. A mean difference in gain on the Action Research Arm Test (ARAT) in favour of the experimental group of 3.0 points (95% CI 1.3 to 4.8,  $p < 0.05$ ) was found; this gain was maintained at one year. The gain of 3.0 is, however, less than the ARAT MCID of 12 for the dominant hand and 17 for the non-dominant UL (Lang et al., 2008).

Van der Lee et al. (1999) also found a significant differential effect of treatment on the Action Research Arm Test (ARAT) in participants with sensory disorder and those without ( $F_{3,168}=5.95$ ,  $p=0.0001$ ). The mean improvement on the ARAT for the participants with sensory disorder (assessed by short non-standardised clinical assessment) ( $n=16$ ) and receiving the experimental intervention was 6.7 points greater than participants without sensory disorder ( $n=11$ ) receiving the comparison intervention, exceeding the MCID for the ARAT. They also found the Motor Activity Log Amount of Use rating (MAL AOU), a semi-structured interview to measure real life use of the UL (Taub et al., 1993) with established validity and reliability in stroke survivors (Uswatte et al., 2005; van der Lee et al., 2004), showed unilateral spatial neglect (assessed by cancellation and line bisection tests) to have a differential effect on treatment ( $F_{3,165}=4.93$ ,  $p=0.003$ ). The mean improvement of participants with unilateral spatial neglect ( $n=3$ ) receiving the experimental intervention was 1.16 points higher (exceeding the MCID) than that of participants with unilateral spatial neglect in the comparison group, although this effect was lost at one year follow-up. Further study of sub-groups is necessary, firstly to identify sub-groups that may respond differentially in RCTs potentially leading to a type II error (Sim & Wright, 2000, p.

205), and secondly, to assist therapists in deciding which stroke survivors are likely to benefit from, and therefore should be offered, CIMT.

Section 2.1 indicates that CIMT does have an established theoretical basis, as demanded by the development-evaluation-implementation process, although there are, as discussed, challenges in transferring this theoretical basis from monkeys to humans. The original protocol has been defined, but there is a need to explore which stroke survivors are likely to benefit from CIMT.

## **2.2 The active ingredients in CIMT**

The previous chapter stressed the need for active ingredients to be described, as part of the development process, to enable a complex intervention to be tested for effectiveness and implemented into practice (Medical Research Council, 2008). Where interventions comprise a number of components, these must be identified and tested to establish the role of each individual component (Pomeroy & Tallis, 2000).

In common with a number of other researchers (Brogårdh & Sjolund, 2006; Kitago et al., 2013; Miltner et al., 1999; Nijland et al., 2013; Pollock et al., 2014), the definition of CIMT used within this thesis is summarised as a therapeutic intervention of two components: 1) constraint of the ipsilesional UL; and 2) intense practice of tasks with the contralesional UL. This section will explore these two components and their role as active ingredients of CIMT.

## 2.2.1 Training

### 2.2.1.1 Shaping in humans following stroke

Shaping is often reported as the principles underpinning the training used in CIMT (Stevenson et al., 2012); the following sections challenge its use in CIMT.

Based on the work previously described with monkeys in section 2.1.2, Taub et al. (1994) explored ways to improve the effectiveness of forced-use, proposing that, in non-human primates, breaking the goal down into small steps formed a 'bridge' to facilitate transfer of skills gained in a laboratory to an extended environment. Although this research was based on deafferented monkeys, Taub et al. (1994) introduced the concept of shaping by successive approximation into the training of the contralesional UL in humans following stroke.

Shaping by successive approximation, usually referred to simply as shaping, emerged as an element of operant conditioning from work by Skinner in the 1950's (Atteya, 2004; Schwartz, 1989). There are two main concerns in transferring the concept of shaping to humans following stroke. Firstly, the role of shaping is not clear for humans following stroke; and, secondly, the definition of shaping (Taub & Morris, 2001), used throughout the CIMT literature, does not reflect the operant conditioning literature. Due to this lack of clarity of role and definition there is variation in the application of shaping between CIMT studies. These issues are described more fully below.

As established in section 2.1.2, operant conditioning rewards a desired, internally initiated response, as a means of changing behaviour. One of the challenges in operant conditioning is encouraging an organism to initiate the required response. Shaping by successive approximation, often referred to simply as shaping, was developed by Skinner (1953) as a means to alter

behaviour towards initiating the required response (Schwartz, 1989). In the original work, Skinner worked with pigeons and rats, providing food rewards for actions that indicated a change of behaviour towards the desired outcome (pecking a key or pressing a lever); the whole task is mapped out and the organism is encouraged through reward to get ever closer to the final goal of pecking a key or pressing a lever. Each step is clearly related to the final goal. Taub et al. (1994) identified shaping as a "slow stepwise procedure that could gradually lead an organism from a rudimentary initial response level to more complex responses" (p. 283). In this quotation there is recognition of the 'organism' being led, rather than the individual being responsible for their responses. Shaping is appropriate when behaviour change is required and it is difficult to elicit a response (Blackman, 1974, p. 35); examples of its use usually refer to the modification of behaviour in animals or children (Blackman, 1974; Schwartz, 1989). It is difficult to elicit the desired response when working with monkeys, but the same is not true when working with stroke survivors. A stroke survivor is able to actively engage in their rehabilitation, and communication between the therapist and stroke survivor is usually possible. Stroke survivors can, therefore, participate and collaborate in their rehabilitation; specific responses can be planned, discussed and practiced. This includes decisions to increase the complexity of task, length of time a task is undertaken, or adapt a final goal. Whilst learning theory supports the use of positive reinforcement as a means of changing behaviour (Gleitman et al., 2011a), shaping by successive approximation is unlikely to be necessary. The therapist does not need to rely on the stroke survivor internally generating a response, as the therapist can usually just ask the stroke survivor to undertake the required task. In spite of these issues, shaping continues to be a reported element of CIMT (Stevenson et al., 2012).

Taub and Morris (2001) describe shaping to increase UL function in humans as comprising 3 elements: 1) verbal reward through feedback for small improvements; 2) tasks to challenge identified motor deficits; 3) assistance in carrying out parts of a movement if required. It is

unclear whether this should still be counted as shaping; there has been no consideration of whether a verbal reward in humans will gain the same response as a food reward in monkeys or whether this form of shaping generates an internally generated response in stroke survivors.

A related complexity is that, whilst shaping has been consistently reported as a means to shape the required behaviour in CIMT literature (Miltner et al., 1999; Page et al., 2001; Taub et al., 1994; Taub & Wolf, 1997; Wolf et al., 2006), through tasks that are “approached in small steps of progressively increasing difficulty” (Page et al., 2001, p.586), there is a lack of consistency as to what this actually entails. There is agreement that the training should provide an achievable challenge (Brogårdh et al., 2009; Brunner et al., 2012; Page et al., 2002c; Taub et al., 1994; Wolf et al., 2006), but less agreement as to how this should be achieved. In line with Taub and Morris’ (2001) definition of shaping, many researchers report an emphasis on verbal reward, in the form of enthusiastic encouragement of any small improvements in performance, to be an important part of shaping (Atteya, 2004; Dromerick et al., 2000; Dromerick et al., 2009; Miltner et al., 1999; Page et al., 2002b; Taub et al., 2006b; Taub & Wolf, 1997; Uswatte et al., 2006). Some researchers indicate that shaping involves increasing the difficulty of tasks (Dromerick et al., 2009; Henderson & Wendt, 2010; Miltner et al., 1999; Uswatte et al., 2006), while some indicate that shaping involves providing, and gradually reducing, assistance to achieve a task (Taub et al., 1994; Taub & Wolf, 1997), which may also be termed assisted movement (Taub et al., 1994). The use of modelling (demonstration of a movement) and prompting in shaping has also been reported (Taub et al., 1994; Taub et al., 2006a; Taub & Wolf, 1997; Uswatte et al., 2006).

The development of shaping in CIMT has been described and this has cast doubt over the definition of shaping and its role for stroke survivors; however, shaping features prominently in the CIMT literature. The effectiveness of shaping alone in increasing UL function following stroke has received little attention. In a non-randomised study with chronic stroke survivors (N=17),

Uswatte et al. (2006) compared shaping of the contralesional UL with no constraint (n=4); sling constraint on the ipsilesional UL and task-practice (repetitive practice of individual functional tasks) with the contralesional UL (n=4); sling constraint on the ipsilesional UL and shaping with the contralesional UL (n=5); and half-glove constraint (with fingers removed from glove) on the ipsilesional UL and shaping of the contralesional UL (n=5). Shaping in this study included the provision of frequent feedback on movement, tasks selected to address individual goals, modelling, prompting and cueing during task performance, and increasing the task difficulty in small steps. The Motor Activity Log 14 (MAL-14), the original version of the MAL (Taub & Wolf, 1997; Uswatte et al., 2005), and the Wolf Motor Function Test (WMFT) (Wolf et al., 2001) both with established validity and reliability (Lin et al., 2009a; Morris et al., 2001; Nijland et al., 2010; Uswatte et al., 2005; Wolf et al., 2001) were used to measure real life UL use and UL activity respectively. Within groups there was a significant pre- to post-intervention increase in: MAL-14, (repeated measures analysis of variance (ANOVA)  $F(1, 13)=137.9$ ,  $p<0.0001$ ) for all groups, with an overall mean (standard deviation(SD)) increase from 1.5 (0.8) to 3.4 ( 0.7) points, and a significant decrease in WMFT time  $F(1,13)=9.8$ ,  $p<0.01$ . There was, however, no difference between groups, post-intervention or one month post-intervention. At two year follow up, the authors report a trend toward gains for the sling and task-practice compared to the sling and shaping group, mean (SD) of 2.2 (0.6) compared to 1.6 (0.2), ANOVA  $F(1,5)=3.1$ ,  $p=0.14$ ), and less gain for half-glove and shaping, compared to the sling and shaping group, mean (SD) of 0.7 (0.8) compared to 1.6 (0.2), ANOVA  $F(1,5)=3.0$ ,  $p=0.14$ ). Whilst the authors note that the differences in mean MAL exceed the MCID for the MAL-14, these differences were not statistically significant. This study suggests possible lines for future enquiry into the effectiveness of different training methods when combined with constraint as part of CIMT; however, the risk of bias in this study as a result of the small number of participants, a lack of clarity of the key aspects of each training method and a lack of randomisation and control group, do not allow any valid conclusions to be drawn.

One further paper explored shaping without constraint. Taub and Wolf (1997) undertook a series of six small studies (each group  $n < 6$ ) and reported that shaping without constraint was effective in increasing UL function, but that this function may not transfer into life situations as well as interventions including a constraint, but this was not substantiated. No numerical data were presented in this paper; therefore scrutiny of these findings is not possible.

Whilst shaping is frequently reported to be an essential part of CIMT, some other training methods, described previously as part of shaping, have also been used independent of shaping. Adapted task practice (Wolf et al., 2006) involves activities such as moving cones, grasping pegs and manipulating coins (Henderson & Wendt, 2010), and can be considered the practicing of performance components or part-practice (Gilmore & Spaulding, 2001; Hodges, 2007), whilst repetitive task practice (Henderson & Wendt, 2010; Wolf et al., 2006), client-centred tasks, sometimes termed whole-task practice (Gilmore & Spaulding, 2001; Hodges, 2007), includes functional activities such as setting tables, typing and playing games (Henderson & Wendt, 2010). Some studies (Henderson & Manns, 2012; Wolf et al., 2006) have combined adapted and repetitive task practice.

In a recent overview of systematic review of RCTs (Pollock et al., 2014), repetitive task training, was defined as “the repeated practice of functional tasks” (Pollock et al., 2014, p. 6) with an emphasis on whole-task practice. When CIMT evidence was excluded there was moderate quality evidence of no benefit or harm from repetitive task training, based on eight trials, involving 412 participants. Pollock et al. (2014) note that a lack of high quality research may have impacted on this finding, and suggest further study of task training with higher numbers of repetitions. In a systematic review of nine trials of 452 participants (van Delden et al., 2012), where bilateral training was compared to unilateral training, unilateral training and bilateral training were found to be broadly similarly effective in improving UL function; however, there was evidence of a

small, significant benefit of unilateral training over bilateral for stroke survivors with mild impairment in the chronic phase of stroke for UL activity, measured by WMFT and ARAT (SMD 0.30; 95%CI 0.02-0.58) and UL activity performance measured by MAL AOU (SMD 0.42; 95%CI 0.09-0.76) and Motor Activity Log Quality of Movement rating (MAL QOM) (SMD 0.45; 95%CI 0.12-0.78).

It is unclear which type of training should be used for best effect in CIMT in the sub-acute phase of stroke; this needs further exploration. Until the training component is better defined, any CIMT studies should aim to comprehensively describe the type of training used within the protocol.

### **2.2.2 Constraint**

A variety of constraint types have been reported in CIMT studies: splints (Barzel et al., 2009), mitts (Brogårdh et al., 2009; Hayner et al., 2010; Henderson & Manns, 2012; Page et al., 2005), or a combination of a splint or mitt with a sling (Kunkel et al., 1999; Miltner et al., 1999; Page et al., 2004; Taub et al., 2006a), with some studies using no material constraint (Krawczyk et al., 2012). However, current evidence (Brogårdh et al., 2009; Hammer & Lindmark, 2009a) indicates that the main concern is whether a constraint is actually an active ingredient in CIMT. Van der Lee et al. (1999) (reported in Section 2.1.3) found a small but significant gain in a constraint and training protocol compared with a training only protocol in chronic stroke survivors. However, no significant gains were found in sub-acute studies that compared the effects of a) a protocol of three hours training, for 12 days, combined with constraint wearing for 90% of waking hours (N=24) (Brogårdh et al., 2009); or b) 30-45 minute therapy sessions (number of sessions not specified) daily for two weeks with constraint wearing for six hours a day (N=30) (Hammer & Lindmark, 2009a); with an equivalent training without constraint on MAS (Brogårdh et al., 2009;

Hammer & Lindmark, 2009a), MAL (Brogårdh et al., 2009) or ARAT (Hammer & Lindmark, 2009a).

The two sub-acute studies (Brogårdh et al., 2009; Hammer & Lindmark, 2009a) all had small sample sizes ( $n \leq 30$ ) and blinding was absent in one study (Hammer & Lindmark, 2009a); nevertheless, these studies do raise questions about the role of the constraint. Whilst the development of CIMT indicated that the constraint component was an integral part of the intervention, the role of the constraint in sub-acute stroke has not been substantiated.

Further work is clearly required to establish the active ingredients of CIMT. Whilst shaping is prominent in the CIMT literature, it is not well defined, and has been subject to limited testing. The most effective training method for CIMT is not known. High quality studies are required to establish the role of the training and constraint components of CIMT. If CIMT is to be implemented into practice, it must be possible to comprehensively and accurately document the intervention to allow replication.

## 2.3 Evaluation of CIMT

Studies indicate that retention to CIMT research is good with a large study ( $N=222$ ) of sub-acute stroke survivors undertaking the original protocol (six hours of training each weekday for two weeks and constraint wearing for 90% of waking hours) having a retention rate of 76.1% of participants at 12 months (Wolf et al., 2006). Additionally, a study of stroke survivors less than 28 days post-stroke undertaking a reduced protocol (two or three hours of training and six hours or 90% of waking hours of restraint) maintained a retention rate of 96% of participants at 90 days (Dromerick et al., 2009). The recruitment rate is less clear. Taub et al. (1993) noted that approximately 18% of chronic stroke survivors identified from physicians' files met the inclusion criteria of more than one digit with  $10^\circ$  active range of extension at the metacarpophalangeal (MCP) and interphalangeal (IP) joints and  $20^\circ$  at wrist joint, without severe cognitive deficits or

spasticity. By contrast, Brunner et al. (2011) found 21 out of 100 stroke survivors in an in-patients setting were found to meet CIMT inclusion criteria at one to two weeks post stroke; however, this dropped to 14 after four weeks, and six at three months. This reduction over time was due to increased function in the majority of cases and is supported by the EXCITE trial (Wolf et al., 2006) where only 6% of those screened (three to nine months post stroke) were ultimately recruited to a protocol including six hours of daily training. The VECTORS study (Dromerick et al., 2009) recruited only 3% of stroke survivors who were less than 28 days post-stroke. The difference in recruitment rate between the VECTOR study and the work by Brunner et al. (2011) may be explained by additional selection criteria in the VECTOR study including a requirement for preserved cognition, the ability to perform two step commands, and exclusion of stroke survivors with unilateral spatial neglect or sensory loss. Based on the above evidence, where sub-acute is defined as from 14 days to nine months post stroke, the recruitment rate of sub-acute stroke survivors to a CIMT study is likely to be between 3% and 14%.

Whilst it is possible to extrapolate the evidence to estimate recruitment and retention to CIMT, and a few studies state that provision of CIMT is feasible (Atteya, 2004; Barzel et al., 2009; Page et al., 2001), there has been very little qualitative exploration of the acceptability of the CIMT to stroke survivors and of therapists' views about the feasibility of providing the intervention.

One study (Page et al., 2002a) reported potential barriers and facilitators to using CIMT, by collecting views by questionnaire from therapists in the United States (US) who had not administered a CIMT protocol, but who did have knowledge of the intervention from in-service training or literature. OTs (n=26) and physiotherapists (n=59) completed the five-point Likert scaled questions; 68% felt that the CIMT protocol would be difficult to administer. A number of potential barriers were noted: length of therapy time (84.7% of participants indicated that the amount of contact time would cause difficulty), fatigue, decreased safety as a result of wearing a

constraint, transport to therapy, and insufficient resources within the service to administer CIMT. Stroke survivors (N=208) also completed a questionnaire: 68% indicated that they would not participate in CIMT which involved constraining the contralesional UL and undertaking training six hours a day for 10 consecutive weekdays. Reasons cited for not wanting to participate included length of time wearing constraint, number of daily hours of therapy and number of days of therapy. Whilst this study does provide some useful insights, data collected by questionnaire is restricted by the pre-determined questions, potentially limiting scope and detail of the findings.

One study (Gillot et al., 2003) utilised a phenomenological approach to explore the perceptions and experiences of CIMT of two chronic stroke survivors. The study used quantitative measures to provide additional description. One stroke survivor undertook the original CIMT protocol with six hours training over two weeks and wore the constraint for about eight hours a day, whilst the other participant, also a stroke survivor, undertook a protocol of three hours training a day for two weeks and 'occasionally' wore a constraint. Qualitative data were collected during two interviews, pre-CIMT and post-CIMT. Both participants indicated that they were participating in CIMT to increase the functional use of their contralesional UL. Both participants reported an increase in functional ability, but the participant undertaking the higher intensity protocol reported disappointment in the results, as she had read about CIMT and its "remarkable results" prior to undertaking the protocol. These qualitative data reporting increases in function were supported by descriptive quantitative findings. This study explored perceptions and experiences, but the interviews explored neither the acceptability of CIMT, nor the barriers to or facilitators of CIMT. Whilst the study design aimed to increase rigour through triangulated data, and member checking of the analyses, the independence of those analysing the data was unclear as was the interviewer's relationship with the participants, impacting negatively on the overall credibility of the study. In addition, this study was undertaken in the US, with chronic stroke survivors. An

exploration of the acceptability, and the barriers and facilitators of undertaking CIMT in the sub-acute phase of stroke in the UK is required.

Since most therapy occurs in the first few months post-stroke, and much of the rehabilitation will take place in the acute and sub-acute phase of stroke, Wolf et al. (2006) undertook the largest CIMT study (N=222) to date, with stroke survivors three to nine months post stroke. This multi-centred EXCITE trial compared the original CIMT protocol of six hours training for 10 weekdays combined with 90% daily constraint wearing (n=106) with customary care (n=116), in stroke survivors in the sub-acute (three to nine months) phase of stroke, where customary care ranged from no therapy to sessions of undescribed physiotherapy or occupational therapy. Wolf et al. (2006) reported that the CIMT group had significantly greater improvements in WMFT performance time and functional score than customary care group at post-intervention (ANOVA;  $p < 0.001$ ). The gains were significantly greater for the CIMT group than the customary care group at 12 months for performance time (ANOVA;  $p < 0.01$ ), but not functional score. There were small, but significant between group differences from baseline to 12 months in MAL AOU (SMD 0.43, 95% CI 0.05-0.80,  $p < 0.001$ ) and MAL QOM (SMD 0.48, 95% CI 0.13-0.84,  $p < 0.001$ ). This study was well designed and found some benefits of CIMT over customary care; however, there is a need to systematically review the CIMT evidence in sub-acute stroke to explore whether CIMT is more effective than an equal dose of other types of therapeutic interventions or whether it is the intensity, rather than the type of training, that is important.

Six systematic reviews have undertaken a quality assessment and analysis of CIMT studies post-stroke since 2008 (Corbetta et al., 2010; Nijland et al., 2011; Peurala et al., 2012; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012). A critical appraisal of these systematic reviews was undertaken. Assessment of the validity and methodological quality was made using the Critical Appraisal Skills Programme (CASP) systematic review checklist (Critical Appraisal Skills

Programme, 2013) and a checklist based on the Quality of Reporting of Meta-analyses (QUORUM) statement (Moher et al., 1999). The QUORUM checklist was designed, and has subsequently been used, to assess quality in stroke related systematic reviews (Intercollegiate Stroke Working Party, 2012, p. 7). The CASP checklist summarised the validity and relevance of the evidence to a local population, which is important where there is focus on implementation of an intervention (Rycroft-Malone, 2004), whilst the QUORUM checklist provided a numerical score based on the reporting of systematic review methodology. The 10 questions in the CASP and the 21 items on the QUORUM checklist are presented in Appendix 1. A decision about overall risk of bias took into account both assessments; the rating process is described in Table 2.1. The findings from these assessments, along with the main limitations or potential sources of bias which impacted on the quality rating, are presented in Table 2.2.

**Table 2.1 Summary of rating process for systematic reviews**

<b>Risk of Bias</b>	<b>Decision</b>
<b>High</b> risk of bias	QUORUM score of < 30 AND CASP with ≥ 4 identified areas of concern
<b>Moderate</b> risk of bias	QUORUM score of < 30 AND CASP with ≤3 identified areas of concern  <b>OR</b> QUORUM score of ≥ 30 AND CASP with ≥ 4 identified areas of concern
<b>Low</b> risk of bias	QUORUM score of > 30 AND CASP with ≤ two identified areas of concern

Where the traditional CIMT protocol has been altered, these protocols are sometimes referred to as modified CIMT (mCIMT) (Brunner et al., 2011; Nijland et al., 2013). As Section 2.2 identified

that the components of CIMT are not well established, it is likely that each protocol contains 'modifications', therefore throughout most of this thesis, the term CIMT has been used for all protocols, and the dose of each protocol described.

**Table 2.2 Summary of CIMT Systematic Reviews (chronological order)**

Author Date	Included Study Designs and Population	Included protocols	Outcomes	Findings	Comments on sub-acute phase analyses	Risk of Bias
Sirtori et al., 2009	19 RCTs and quasi-RCTs N=619  Time post-stroke range: 0-92 months.  ≥18 yrs of age; paresis of the UL	Included all CIMT and forced use protocols	Primary outcome: Disability outcomes (FIM, BI)  Secondary outcomes: WMFT, ARAT, AMAT, EMF, AMPS, MAL, FMA, CMII, NHPT, GPT	Comparison of disability post-intervention comprising FIM (5 RCTs) and BI (1 study) n=184. CIMT had a modest significant benefit on disability (SMD 0.36, 95% CI 0.06 to 0.65, Z=2.36, p=0.018).  Comparison of disability three and six month follow-up FIM (1 study) and BI (1 study), n=73, effect of CIMT non-significant.  Secondary outcomes indicated an significant effect in favour of CIMT:  UL motor function (SMD 0.72, 95% 0.32-1.12, Z=3.51, p=0.00045) -14 RCTs, n=436.  MAL AOU (WMD 0.1.16, 95% 1.05-1.27, Z=20.71, p=0.00001) -16 RCTs, n=541.  MAL QOM (WMD 0.87, 95% 0.75-0.98, Z=14.63, p=0.00001) -16 RCTs, n=541.  UL motor impairment (SMD 0.65, 95% 0.15-1.15, Z=2.54, p=0.011) -8 RCTs, n=161	0-3 months post stroke (2 studies, n=66) no statistically significant effect size.  3-9 months post stroke group not analysed (no studies used primary outcome)	<b>Moderate</b> risk of bias  QUORUM: 34/42  CASP: -Most included studies had small sample size -Participant & CIMT heterogeneity between studies -Validity of findings to UK unclear
Corbetta et al., 2010	18 RCT and quasi-RCTs N=674	Included all CIMT and forced use protocols compared with	Primary outcome: disability outcomes (FIM, BI)	Disability outcomes: 8 studies (n=276) measured disability immediately after intervention. CIMT showed no significant effect (SMD 0.21, 95% CI -0.08 to 0.50)	No sub-group analysis for sub-acute phase of stroke	<b>High</b> risk of bias  QUORUM: 27/42  CASP:

	Time post-stroke range: 14 days-92 months.	other rehabilitative techniques	Secondary outcomes: UL function outcomes (ARAT, WMFT, EMF, MAS)	UL function outcomes: 14 studies (n=479). CIMT had a moderate effect on UL function (SMD 0.44, 95% CI 0.03 to 0.84). Substantial heterogeneity ( $I^2=63\%$ ) found for UL function		-Most included studies had small sample size -Participant & CIMT heterogeneity between studies -Relationship with previous systematic review (Sirtori 2009) not clear -Validity of findings to UK unclear
Shi et al., 2011	13 papers reporting 12 RCTs N=278 Time post-stroke range: 2 days-60 months ≥18 yrs of age; diagnosis of stroke; ≥10° extension ICP and MCP joints; ≥20° wrist extension; <2.5 on MAL; ≥69 on MMSE	CIMT protocols comprised at least 30 mins and not more than 3 hrs training a day, combined with less than 6hrs constraint a day	Trials included at least one measure of UL function. The following were reported: FMA, ARAT, FIM, MAL, SIS, kinematic measures	Meta-analysis indicated higher scores in CIMT group vs traditional rehab in: FMA (MD=7.8; 95%CI, 4.21-11.38, Z=4.27, p<0.0001) - 6RCTs, n=116 ARAT (MD=14.15; 95%CI 10.71-17.59, Z=8.07, p<0.00001) - 5 RCTs, n=63 FIM (MD=7.0; 95%CI 0.75-13.26, Z=2.19, p=0.03) – 3 RCTs, n=88 MAL AOU (MD=1.09; 95% CI 0.26- 1.91, Z=2.59, p<0.001) - 6 RCTs, n=173 MAL QOM (MD=1.02; 95% CI 0.55-1.49, Z=4.23, p<0.01) - 6 RCTs, n=173 WMFT – results not pooled as sample size too small	No sub-group analysis for sub-acute phase of stroke	<b>Moderate</b> risk of bias QUORUM: 35/42 CASP: -Most included studies had small sample size -Participant heterogeneity between studies -Some studies not included that met selection criteria (eg Myint 2008 and Brogardh 2009) -Validity of findings to UK unclear
Nijland et al., 2011	5 RCTs N=106 10 weeks post-stroke or less at recruitment	CIMT protocols that focussed on UL	Not specified which were included, but the following were pooled and reported: FMA, ARAT, MAL, GPT	Significantly greater MD in CIMT group for two measures: FMA (MD=11.0; 95%CI, 2.50-19.49, Z=2.54, p=0.01) - 3 RCTs, n=34. ARAT (MD=7.88; 95%CI 1.09-14.66, Z=2.28, p=0.02) - 3 RCTs, n=82.	Theoretically addresses acute and sub-acute phases, but does not include any studies in the 14 days to 9 month	<b>Moderate</b> risk of bias QUORUM: 32/42 CASP: -Most included studies had small sample size

	≥18 yrs of age			<p>Non-significant for MAL AOU and MAL QOU -3 RCTs, n=34.</p> <p>GPT (MD 0.05, 95%CI 0.02-0.09, Z=2.86, p=0.004) – 2 RCTs, n=24</p> <p>Significant mean differences found for FMA and ARAT for low intensity protocols (constraint of less than 90% and less than 3hrs training per day), but not high intensity protocols (restraint of 90% per day and 3hrs or more training per day)</p>	post-stroke range	<p>-Small number of eligible studies</p> <p>-High reliance on VECTORS study</p> <p>-Validity of findings to UK unclear</p>
Peurala et al., 2011	<p>30 RCTs</p> <p>Sample size not stated</p> <p>Time post-stroke not specified.</p> <p>≥18 yrs of age</p>	Included all UL CIMT protocols, excluded forced use	<p>Activity and participation outcomes</p> <p>27 outcomes reported, most common were MAL, ARAT, WMFT, FIM, SIS (participation item), BI</p>	<p>13 studies included in meta-analysis. Non-significant MD for FIM and SIS, but significant difference in favour of the CIMT group was found for WMFT, MAL, ARAT:</p> <p>WMFT (MD=-0.46; 95%CI -0.59,-0.33, Z=6.93, p&lt;0.00001) – 2 RCTs, n=232.</p> <p>MAL AOU (MD=0.85; 95% CI 0.62- 1.08, Z=7.23, p&lt;0.00001) - 9 RCTs, n=458.</p> <p>MAL QOU (MD=0.73; 95% CI 0.46-0.99, Z=5.40, p&lt;0.00001) - 8 RCTs, n=442.</p> <p>ARAT where CIMT was compared to comparison intervention (MD=7.84; 95%CI 1.60-14.08, Z=2.46, p=0.01) - 5 RCTs, n=154.</p> <p>ARAT where CIMT is compared to no treatment (MD=15.34; 95%CI 4.05-26.63, Z=2.66, p=0.008) - 1 RCTs, n=23</p>	No sub-group analysis for sub-acute phase of stroke	<p><b>Moderate</b> risk of bias</p> <p>QUORUM: 27/42</p> <p>CASP:</p> <p>-Most included studies had small sample size</p> <p>-Participant heterogeneity between studies</p> <p>-Validity of findings to UK unclear</p>

Stevenson et al., 2012	22 RCTs N=665 Time post-stroke not specified Adult stroke survivors	Included all UL CIMIT protocols. Studies included if CIMIT compared do a dose-matched control group supervised therapy of equal time to CIMIT training)	UL capacity: FMA, kinematic analyses of movement, indirect indicators of neuro-physiological mechanisms.  UL ability: ARAT, NHPT, WMFT, FIM, BI  Comprehensive function: FIM, BI  Self-repoerted measures: MAL	Significant effect in favour of CIMIT in:  UL capacity (SMD=0.47, 95%CI, 0.27-0.66)-15 RCTs  UL ability (SMD=0.80, 95%CI, 0.57-1.02)-14 RCTs  FIM (MD=5.05, 95%CI, 2.23-7.87)-6 RCTs  MAL AOU (MD=1.05, 95%CI, 0.85-1.24)-12 RCTs  MAL QOM (MD=0.89, 95%CI, 0.69-1.08)-11 RCTs	Compared studies >6months & <6 months post-stroke. Found no significant difference in UL capacity, UL ability or comprehensive function	<b>Moderate</b> risk of bias  QUORUM: 32/42  CASP: -Did not include studies that compared CIMIT with a constraint and similar training without constraint (eg Hammer, Brogardh) -Most included studies had small sample size -Participant & CIMIT heterogeneity between studies -Validity of findings to UK unclear
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AOU Amount of use  
 ARAT Action Research Arm Test  
 BI Barthel Index  
 CI confidence interval  
 CIMIT Constraint induced movement therapy  
 EMF Emory Function Test  
 FIM Functional Independence Measure  
 FMA Fugl-Meyer Assessment

GPT Grooved Peg Test  
 hr hour  
 IP interphalangeal joint  
 MAL Motor Assessment Log  
 mCIMIT Modified constraint induced movement therapy  
 MCP meta-carpophalangeal joint  
 MD mean difference  
 Min minute

MMSE Mini Mental State Examination  
 QOM Quality of movement  
 RCT Randomised Controlled Trial  
 SIS Stroke Impact scale  
 SMD standard mean difference  
 UL Upper limb  
 WMD Weighted mean difference  
 WMFT Wolf Motor Function Test

Systematic reviews that included participants across the acute, sub-acute and chronic phases of stroke (Corbetta et al., 2010; Peurala et al., 2012; Sirtori et al., 2009; Stevenson et al., 2012) have found CIMT (where the evidence includes both the original and modified CIMT protocols) to be effective in improving UL function (Corbetta et al., 2010; Peurala et al., 2012; Stevenson et al., 2012) even when compared to a dosed-matched intervention (Stevenson et al., 2012). The picture is less clear for disability outcomes, measured by the Functional Independence Measure (FIM) and Barthel Index (BI). Four systematic reviews addressed disability (Corbetta et al., 2010; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012), three systematic reviews of moderate quality found benefit of CIMT in reducing disability (activity limitation) compared to alternative interventions (Shi et al., 2011; Sirtori et al., 2009) and dose-matched interventions (Stevenson et al., 2012), whilst a lower quality systematic review (Corbetta et al., 2010) found there to be no beneficial effect on FIM. This review did, however, have a higher proportion of studies in the acute and sub-acute phase of stroke than the other reviews, which may have impacted the outcome. In addition one study (Sirtori et al., 2009) found the benefit on disability was lost at three and six months post-intervention.

Lower intensity CIMT (30 minutes to three hours training with less than six hours restraint a day) appears to be more effective than traditional rehabilitation (Shi et al., 2011) in regaining ability to use the contra-lesional UL, although it is not known whether it is more effective than an intensity equivalent rehabilitation. Stevenson et al. (2012) found a benefit of CIMT (combining higher and lower intensity protocols) in increasing UL function compared to dose-matched interventions; however, studies that compared CIMT to an intervention comprising similar training, but without a restraint were not included, therefore, several potentially relevant studies were excluded (Brogårdh et al., 2009; Hammer & Lindmark, 2009a), which may have impacted on the findings in that review.

There is evidence that CIMT (where the evidence includes both the original and modified CIMT protocols) is effective in increasing UL activity in the first three weeks post stroke (Nijland et al., 2011), with some indicators that, in this group, lower intensity CIMT (less than three hours a day training and constraint for less than 90% of waking hours) may be more effective than higher intensity CIMT (three hours or more training a day and constraint for 90% of waking hours). This is contrary to the findings of Sirtori et al. (2009) who concluded that there was no significant difference between a total of 30 hours or less therapy compared to a total of more than 30 hours of therapy. This discrepancy is likely to be a consequence of the differences in the time post-stroke of the participants in the included systematic reviews. It is not yet known if some protocols are more effective than other protocols for a given stroke survivor; it may be that time post-stroke is an important factor when selecting a CIMT protocol.

It is unclear from the previous systematic reviews whether CIMT, either the original protocol or a modified version, is effective in increasing upper limb function in a sub-acute phase of stroke, defined as 14 days to nine months post-stroke. Three systematic reviews (Nijland et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012) purport to address the sub-acute phase of stroke. Nijland et al. (2011) theoretically included participants from the acute and sub-acute phase of stroke; however, four of the five studies included only participants who were less than 14 days post-stroke on recruitment, whilst only one study included participants who were up to 21 days post-stroke. The majority of the data summarised in that systematic review relates to the acute rather than the sub-acute phase of stroke. Two systematic reviews considered whether there was a difference in response to CIMT depending on time post-stroke. Based on two heterogeneous studies (Myint et al., 2008; Ploughman & Corbett, 2004) including 66 participants, Sirtori et al. (2009) did not find a significant difference in effect on disability between experimental and comparison groups (SMD 0.18, 95% CI -0.31 to 0.67) in studies with participants zero to three months post stroke; they were unable to undertake a similar analysis for the group that was

greater than three months post stroke, but less than nine months post stroke, due to a lack of studies in this group using the primary outcome of disability. Whilst Stevenson et al. (2012) supports this finding, reporting no significant difference in response to CIMT for participants greater than six months post-stroke compared to those less than six months post-stroke, it is likely that the selection process, as stated above, may have influenced this conclusion. For these reasons the impact of CIMT on UL function in the sub-acute phase of stroke requires further investigation.

A recent overview of systematic reviews of UL interventions (Pollock et al., 2014) analysed two previous systematic CIMT reviews (Corbetta et al., 2010; Sirtori et al., 2009) supporting the quality assessment and analysis above, concluding that “moderate-quality evidence showed a beneficial effect of constraint-induced movement therapy”. As only two of the previous systematic reviews were included, some of the analysis presented above was not available to the reviewers, and potentially valuable detail about specific outcomes and populations did not feature in the findings. Nonetheless, the overview of systematic reviews (Pollock et al., 2014), also found no high quality systematic review evidence to support CIMT, and recognised that there is a need for further high quality CIMT systematic reviews to gain a better understanding of the effects of the intervention on impairment and activities of daily living (ADL) (Pollock et al., 2014).

A part of describing an intervention is establishing its dose (Keith, 1997; Pomeroy et al., 2011). The dose of a therapeutic intervention has been described as the “intensity (number of repetitions or time per session), frequency (e.g. 5 sessions a week) and duration (e.g. for 6 weeks)” (Pomeroy et al., 2011, p. 36S). Where there is more than one component, as in CIMT, the dose must describe all components.

One systematic review (Sirtori et al., 2009) explored the impact of the training component dose of CIMT protocols by undertaking sub-group analyses of protocols including a training component of more than 30 hours and those less than or equal to 30 hours. Protocols with a training component based on greater than 30 hours (based on 2 studies, 73 participants) did not indicate a significant effect size (SMD 0.02; 95% CI -0.44 to 0.49) whereas for protocols with a training component of less than or equal to 30 hours (based on 4 studies, 111 participants) the effect size was significant (SMD 0.58; 95% CI 0.20-0.97). This analysis was based on a small number of studies of both CIMT and forced-use, and both sub-acute and chronic participants were included. In contrast, Stevenson et al. (2012) compared 10 week protocols with two or three week protocols and found no difference in response on UL capacity or function outcomes; however, no analysis of overall intensity was undertaken.

The VECTOR study (Dromerick et al., 2009), an RCT of stroke survivors (N=52) less than 28 days post stroke, offers some support of this finding. The participants were randomised to a high intensity CIMT group (three hours of training a day, for 10 days over two weeks, and constraint worn for 90% of day), a lower intensity (two hours of training a day for 10 days over two weeks and constraint worn for six hours a day) or an occupational therapy group (two hours therapy a day). The study found a significant time by group interaction ( $F=3.06$ ,  $p<0.01$ ) on the ARAT, with the higher intensity group having significantly lower gains than the occupational therapy group ( $p<0.006$ ) or the lower intensity group ( $p<0.01$ ) at 90 day follow-up. This implies that a lower intensity CIMT protocol may be more effective than a higher intensity protocol in increasing UL function in the acute and early sub-acute phase of stroke.

Two additional small studies (Barzel et al., 2009; Sterr et al., 2002a) have each compared two different CIMT protocols with contrasting findings. In a randomised trial (N=15; 13 chronic stroke participants, two chronic traumatic head injury participants), Sterr et al. (2002a) compared CIMT

protocols with six hours (n=7) and three hours (n=8) training. Within groups, the six hour training group showed significantly improved performance, pre- to post-intervention, on the Wolf Motor Function Test (WMFT) ( $t=3.5$ ,  $p<0.01$ , mean performance time gain 2.32 seconds), whilst the three hour group did not ( $t=2.0$ ,  $p=0.09$ , mean performance time gain 1.87 seconds). The interaction (ANOVA), between median pre- to post-intervention performance time gain of 2.34 seconds for the six hour group, and 0.64 for the three hour group was not, however, statistically significant. Between groups, there was a significantly greater treatment effect (ANOVA) for the six hour compared to the three hour training on the MAL AOU ( $F_{6,66}=2.8$ ,  $p<0.05$ ) and MAL QOM ( $F_{6,66}=2.6$ ,  $p<0.05$ ). The additional gains for the six hour group were relatively small. Whilst this study seems to offer some support for higher intensity training, and supports training as an active ingredient in CIMT, this was a very small, non-blinded study.

In contrast, the original CIMT protocol (six hours daily training over two weeks with constraint wearing for 90% of waking hours) has been compared to a four week, home-based protocol, with two hours a day training, and constraint wearing for 60% of waking hours, where the CIMT was supervised by a family member supported by a weekly visit from a physiotherapist (Barzel et al., 2009). Chronic stroke survivors (N=14) were matched for gender, initial motor deficit (WMFT score), concordance of hand dominance and laterality of stroke, age and time since stroke. Both the WMFT performance time and functional score showed an effect in time MANOVA (performance time:  $F=14.16$ ,  $p<0.0001$ ; functional score:  $F=14.04$ ,  $p<0.0001$ ), but there was no group effect (performance time:  $F=0.98$ ,  $p=0.34$ ; functional score:  $F=0.07$ ,  $p=0.79$ ), indicating no between group difference in performance time or functional score. This pattern was reflected in MAL with an effect in time (QOM:  $F=52.56$ ,  $p<0.0001$ ; AOU:  $F=57.38$ ,  $p<0.0001$ ), but no group effect (QOM:  $F=1.14$ ,  $p=0.26$  and AOU:  $F=1.66$ ,  $p=0.22$ ). Due to the small size of this study and the lack of blinded assessors this should be considered a preliminary study, with further research required.

It is difficult to draw conclusions about the relative effectiveness of the CIMT protocols due to a lack of strength of the evidence and poor methodological quality identified above. Additionally, the studies compare a variety of CIMT protocols, with participants at different times post-stroke. There are some indications that time post-stroke may be important when considering the intensity of the training aspect of CIMT; acute stroke survivors may gain greater benefit from a lower intensity protocol.

CIMT is a complex intervention, comprising a number of elements which has led to a variety of CIMT protocols, with a range of CIMT doses, being used in primary research studies. This poses challenges in summarising the CIMT evidence to inform clinical practice, an issue previous reviews have failed to address adequately. Future systematic reviews must take account of this to ensure that the effectiveness of the various protocols can be established and, where a protocol is effective, it can be replicated by therapists.

## **2.4 Implementation**

The previous sections have established that there has been substantial quantitative study of CIMT, but that there are aspects in both the development process and the evaluation of CIMT that may impact negatively on its implementation. These include: assumptions in the translation of evidence from deafferented, non-human primates to human stroke survivors; not being able to identify which stroke survivors are experiencing learned non-use; a lack of clarity about the components and dose of CIMT; and the limited qualitative study of the acceptability and feasibility of providing CIMT.

Previous study of implementation has found an innovation is more likely to be implemented if the relative advantage of the intervention and the guidelines and procedures are clear (Fleuren

et al., 2004), and there is sufficient information about the use and the expected outcomes of the intervention (Greenhalgh et al., 2004). The previous sections have shown that, for CIMT, each of these may be an issue. Previous work (Dopson et al., 2002; Rycroft-Malone et al., 2004b) also indicates that the production of evidence, even if it is good evidence, is not enough to ensure diffusion to practice. If the evidence is not completely convincing, as is the case for CIMT, it opens up debate and negotiation (Dopson et al., 2002), where different pieces of evidence can be interpreted in different ways by stakeholders (Greenhalgh et al., 2004). Interpretations of evidence and the involvement and views of others, particularly trusted colleagues, may impact on the implementation process (Dopson et al., 2002; Rycroft-Malone et al., 2004b), indicating a social element to the construction and use of evidence (Dopson et al., 2002; Rycroft-Malone et al., 2004b). Given the prolific reporting of CIMT studies, utilising a variety of protocols, interpretation of the evidence must be a consideration for its implementation.

This chapter has shown that there are a number of potential challenges to the implementation of CIMT into practice. Implementation models or frameworks provide tools to organise the evidence to date, analyse the gaps and plan future work. As no previous systematic analysis of the implementation of CIMT had been undertaken, conceptual frameworks were reviewed as a means of summarising the CIMT evidence to date and undertaking an analysis of its implementation.

Over the past two decades a number of conceptual frameworks have been developed to assist in understanding the factors impacting on implementation of evidence into practice (Damschroder et al., 2009; Meyers et al., 2012; Rycroft-Malone, 2004). Conceptual implementation frameworks have been described as a collection of concepts drawn together into a structure with the aim of being able to communicate the concepts to others (Meyers et al., 2012). A framework should give

an overview of the key elements or ideas and offer scaffolding for addressing implementation in a systematic manner (Meyers et al., 2012).

No framework addresses every aspect of implementation (Meyers et al., 2012); the choice of a framework should take into account how the framework will be used (Ilott et al., 2013), the focus of the work and the robustness of the framework. With this in mind a number of frameworks were reviewed for use in guiding further work on the implementation of CIMT.

The Consolidated Framework for Implementation Research (CFIR) was developed from a meta-synthesis of existing frameworks (Damschroder et al., 2009; Meyers et al., 2012). In developing the CFIR, Damschroder et al. (2009) attempted to standardise terminology and constructs, from which they developed a framework. The resultant framework consisted of five domains: intervention characteristics; outer setting, which included the economic, political, and social context surrounding the organisation; inner setting, which included the structural, political and cultural context of the organisation in which the implementation will take place; characteristics of the individuals; and process of implementation (Damschroder et al., 2009). This framework offers a systematic approach to implementation, with domains that are rooted in the literature. The CFIR was not the final choice of framework, as there was another framework with ‘domains’ that better described the current challenges to implementing CIMT into practice; however, an analysis was undertaken using the CFIR as part of the background work when planning this programme of work. This analysis summarises contextual aspects and offers additional insights for consideration in future studies; it is therefore presented in Appendix 2.

The Quality Implementation Framework (QIF) (Meyers et al., 2012), was also considered. This framework summarises 14 ‘critical steps’ organised into four phases: initial considerations, structure for implementation, on-going support strategies, and improving future applications.

The issues raised in this chapter would all need to be addressed as part of the ‘initial considerations’ phase. It was felt that whilst the QIF offered an evidence-based structure which promoted analysis of significant implementation issues, only the first phase of the QIF would currently be relevant to CIMT implementation.

The final framework that was considered was the Promoting Action on Research Implementation in Health Service (PARIHS) framework (Rycroft-Malone, 2004), a framework developed by a team with a strong nursing representation. Originally published by Kitson in 1998 (Kitson et al., 1998), it comprises three core elements: evidence, context and facilitation. The framework has subsequently undergone a concept analysis of the core concepts (elements) and testing of the framework in practice (Rycroft-Malone, 2013, p. 133). The use of the core elements was supported and the testing provided additional information to augment the sub-elements contained within the framework (Rycroft-Malone, 2013, p.133). Although the PARIHS does not have the strong evidence base of the CFIR and QIF, it has been used to good effect in a number of studies (Rycroft-Malone, 2013; Rycroft-Malone et al., 2004a) indicating it has utility as a structure for implementing innovation. It was felt that a systematic and rigorous approach, recommended in the practice development literature (McCormack et al., 2004), to developing CIMT practice, would be best achieved through the elements of the PARIHS framework. The framework has a strong emphasis on research and recognises the importance of stakeholder experience in the ‘evidence’ element; it was anticipated that this would facilitate a means of articulating the challenges with the CIMT research to date, and assist in planning future work. Whilst the ‘Context’ element would enable an exploration of the services and settings in which CIMT might take place, ‘Facilitation’ recognises that it is likely that implementation will require an active process to enable change. For these reasons, PARIHS was selected as the underpinning conceptual framework for this programme of work, and an analysis of the current CIMT evidence-base in the sub-acute population was undertaken using the framework. A summary is presented

in Table 2.3. The 'core elements' of PARIHS are defined in the left hand column. The central column reports the PARIHS 'sub-elements' that, following the analysis, were considered most relevant to the implementation of CIMT. The final column reports a summary of the analysis. The aim of this analysis was to use the PARIHS framework to present the current CIMT evidence-base reported in the former part of this chapter, and to identify the gaps in knowledge that may impact on implementation of CIMT into practice. This structured approach provided a logical and coherent process to design and plan the studies reported within this thesis.

**Table 2.3 The current evidence-base of CIMT in sub-acute stroke analysed using the PARIHS**

Core Element	Sub-elements	Summary of CIMT Implementation
<b>Evidence</b>	<p>Research</p> <p>Clinical Experience</p> <p>Patient Experience</p> <p>Local Data/Information</p>	<p>Analysis based on the evidence reviewed and evaluated in this chapter:</p> <ul style="list-style-type: none"> <li>• There is a clear development process for CIMT, although some assumptions have been made during this process.</li> <li>• There is evidence from systematic reviews that CIMT is effective in increasing UL function in stroke survivors. There are a variety of CIMT protocols in the published literature; it is not known which CIMT protocols are most effective. There needs to be a method of accurately and comprehensively recording UL therapeutic interventions to facilitate research and transfer of evidence to practice.</li> <li>• Whilst therapists predominantly work with stroke survivors in the sub-acute phase of stroke; it is not clear whether CIMT is effective in sub-acute stroke. The role of the constraint in sub-acute stroke is not established. A systematic review of CIMT in the sub-acute phase of stroke is required.</li> <li>• It is not clear whether stroke survivors experiencing sensory loss, unilateral spatial neglect, or other impairments benefit more than those who do not.</li> <li>• There is a lack of qualitative study of CIMT and the patient's (stroke survivor) and clinician's experience of CIMT in the sub-acute phase of stroke has not been established through a systematic review process. This means that factors such as facilitators and barriers to implementing CIMT have not been summarised.</li> <li>• There is a need to establish if there is good quality qualitative research relevant to the implementation of CIMT involving stroke survivors and therapists, to enable a greater understanding of factors that may impact implementation. Where there are gaps in this knowledge, well-designed qualitative research involving patients (stroke survivors) and clinicians (therapists) is required.</li> <li>• It is unclear how the current research evidence is perceived by therapists.</li> </ul>

		<ul style="list-style-type: none"> <li>It is unclear how the evidence relates to UK stroke services and whether local data/information has been a part of the implementation process in UK stroke services to date.</li> </ul>
<b>Context</b>	Culture Leadership Evaluation	<p>Analysis based on the evidence reviewed and evaluated in this chapter:</p> <ul style="list-style-type: none"> <li>Evaluation of effectiveness of the intervention has taken place in a number of settings; however little CIMT research has taken place in the UK.</li> <li>The majority of stroke rehabilitation occurs in the sub-acute phase of stroke, there is a need to evaluate implementation of CIMT in this context.</li> </ul> <p>As the 'Evidence' element above indicates, there is a need to establish factors that may impact implementation:</p> <ul style="list-style-type: none"> <li>The impact of culture and environment on stroke survivor and therapist beliefs about CIMT are unclear.</li> <li>It is not clear what type of leadership might be required and available to implement CIMT.</li> <li>The aspects of teamwork required to implement CIMT have not been explored.</li> </ul> <p>Further study is required to understand the impact of context on the implementation of CIMT</p>
<b>Facilitation</b>	Purpose Role Skills and Attributes	<p>Although two studies (Gillot et al., 2003; Page et al., 2002a) explored the perceptions of stroke survivors and therapists, the actual barriers to CIMT, that facilitation would need to overcome to implement the interventions, has not been fully explored:</p> <ul style="list-style-type: none"> <li>It is not known what form facilitation should take to further the implementation of CIMT into practice.</li> <li>The support therapists might need in order to gain the necessary knowledge and skills to implement CIM T is not known.</li> </ul>

To start to address the gaps identified in this analysis, two systematic reviews were planned. Firstly a systematic review of RCTs to explore the effectiveness of CIMT protocols in sub-acute phase of stroke. Secondly a systematic review of the qualitative evidence to explore what is known about the acceptability of CIMT and the feasibility of providing it as a therapeutic intervention. These systematic reviews were subsequently undertaken and are reported in Chapters 3 and 4.

## **2.5 Summary**

The previous chapter established that UL function is important for many activities and loss of this function can impact on well-being; UL function should therefore be addressed as part of rehabilitation following stroke. There is a need to establish which UL interventions are most likely to produce the best UL recovery in the first few months post-stroke.

This chapter has summarised the development and subsequent evaluation of CIMT using the development-evaluation-implementation process (Medical Research Council, 2008). CIMT developed from laboratory work and has a theoretical basis; however, assumptions have been made in transferring this evidence to stroke survivors. This may impact on the effectiveness of the intervention in stroke survivors and the implementation of CIMT into practice.

The components comprising CIMT have not been clearly described. This is particularly true of the training component; although shaping has been proposed as a key element of training in CIMT, it is unclear whether the training articulated in the CIMT should be defined as shaping, or whether it is the most effective means of training. The training component in future studies should be clearly articulated. This chapter discussed the importance of standardising and describing each component and the dose of an intervention. High quality studies must be replicable and

therefore there needs to be a means of comprehensively and accurately documenting UL interventions and any comparison interventions.

The evaluation of CIMT has included a variety of CIMT protocols. This variety, along with the limited evidence about which are effective, acceptable and feasible may impact on implementation. There remain some gaps in the development of CIMT and therefore further qualitative investigation of the feasibility of providing the intervention and the acceptability of the intervention to stroke survivors is required.

As the context is an important consideration in implementation, and the majority of rehabilitation takes place in the sub-acute phase of stroke, this timeframe will be the focus of this thesis. Whilst a number of CIMT systematic reviews have been undertaken, these neither give a clear picture of the effectiveness of CIMT in sub-acute stroke, nor summarise what is known about the qualitative experience of CIMT. Systematic reviews are required to address these gaps and underpin future work.

An analysis using the PARIHS framework was undertaken and a predominantly qualitative programme of work was proposed to address some of the gaps established above. The next chapter will explore the theoretical perspectives that underpin this work

# Chapter 3

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## Effectiveness of CIMT Protocols in Sub-acute Stroke: a Systematic Review

Chapter 2 critically reviewed the CIMT systematic reviews to date, and concluded that the effectiveness of CIMT in sub-acute stroke is unclear. It identified a need for a further systematic review to address this gap and to consider the potential for differential effectiveness in sub-groups of stroke survivors. To further the implementation of CIMT, a systematic review to critically review the effectiveness of CIMT to increase UL function in sub-acute stroke (defined in this thesis as 14 days to nine months post-stroke) was undertaken. The purpose of this chapter is to report this systematic review.

### 3.1 Background

#### 3.1.1 Summary of previous research findings

Chapter 2 identified that previous systematic reviews indicate that CIMT has the potential to improve UL outcomes and reduce disability (Hakkennes & Keating, 2005; Peurala et al., 2012; Sirtori et al., 2009). There is evidence from a large RCT (Wolf et al., 2006) and a systematic review (Shi et al., 2011) that CIMT, at the intensity of the original protocol and at a lower intensity

respectively, is more effective in increasing UL function than customary care. There is evidence that time post-stroke may have an impact on response to CIMT, with some indications that acute stroke survivors may benefit from lower intensity CIMT protocols (less than three hours a day training and constraint for less than 90% of waking hours) compared to higher intensity protocols (three hours or more training a day and constraint for 90% of waking hours) (Nijland et al., 2011). There is evidence from a large RCT (Wolf et al., 2006) that participants in the sub-acute phase of stroke do benefit from CIMT; however, this is poorly explored in the systematic reviews due to a lack of studies recruiting sub-acute participants (Nijland et al., 2011). Where studies of sub-acute stroke survivors were available, sub-group analysis of these participants was not undertaken (Sirtori et al., 2009).

CIMT has been identified as a complex intervention in Chapter 2; the inconsistency of the dose of the comprising elements has led to a variety of CIMT protocols being investigated in primary research studies. This poses challenges in summarising the CIMT evidence to inform clinical practice, an issue previous systematic reviews have failed to address adequately.

A further gap in the current systematic review evidence is the limited consideration of sub-group response to CIMT. Van der Lee et al. (1999) found some differential effects of CIMT for chronic stroke survivors with sensory loss and unilateral spatial neglect; the response of sub-groups in the sub-acute phase of stroke also needs systematically analysing.

It has been established in Chapter 2 that the lack of current clear guidance, procedures or information about the expected outcome is likely to impact on implementation (Fleuren et al., 2004). The gaps in the CIMT evidence summarised above must be addressed if CIMT implementation is to be furthered.

### 3.1.2 Systematic review and its role in evidence-based practice

Evidence-based practice has been identified in Chapter 1 as comprising research evidence, patient preference and clinical experience (Sackett et al., 1996). Systematic reviews are often considered the highest level of research evidence (Taylor, 2007, p. 15) as they aim to systematically retrieve all studies relevant to a given research question, assess the studies for quality and then, based on the quality of the studies, pool the findings to draw conclusions (Centre for Reviews and Dissemination, 2009; Khan et al., 2011; Taylor, 2007). Well-designed systematic reviews may be particularly helpful where there is a large amount of evidence and the findings contradictory or inconclusive (Taylor, 2007, p. 66). As identified above, this is the situation for CIMT evidence in sub-acute stroke; there is a need to understand the current evidence to be able to establish whether CIMT should be implemented in a UK stroke service and, if so, which protocols should be offered and to whom.

This systematic review aims to identify and critically review RCT evidence of CIMT in the sub-acute (14 days to nine months post-stroke) phase of stroke, to address the overarching question ‘what is the evidence underpinning CIMT as a complex intervention to increase UL function in sub-acute stroke?’ thereby providing information to assist therapists’ clinical decision-making about when and how they use CIMT.

The primary question for this review is:

1. Do CIMT (original and modified) protocols increase UL function in sub-acute stroke survivors (14 days to nine months post-stroke)?

The secondary questions are:

2. Which of the CIMT (original and modified) protocols are effective in increasing UL function in sub-acute stroke survivors?
3. Is there evidence that CIMT is effective in increasing UL function for definable sub-groups of sub-acute stroke survivors?

## 3.2 Methodology

A systematic review of RCTs was undertaken utilising the Centre for Reviews and Dissemination (CRD) guidance (Centre for Reviews and Dissemination, 2009). Whilst this review aimed to assess and synthesise quantitative data, the bounded relativist stance, described in Chapter 1 is evident through research questions that articulate an aspiration to gain a broader understanding of the current evidence and to identify what is known, rather than searching for one conclusive ‘truth’. This stance is supported by a narrative data synthesis facilitating the reporting of the range of findings from the included studies. The Economic and Social Research Council (ESRC) guidance (Popay et al., 2006) was used to guide the narrative synthesis, as recommended by established systematic review guidance (Centre for Reviews and Dissemination, 2009).

A constructivist approach as discussed in Chapter 1 underpinned the synthesis of data; there was recognition that even where the primary studies were quantitative in design, the findings and the interpretation of the findings will be influenced by the context of the study and the researchers constructing the conclusions. The constructivist stance recognises this as an important part of the subsequently constructed reality (Moses & Knutsen, 2007), rather than a potential bias.

### 3.3 Method

Population, Intervention, Outcome, Study Design (PIOS) (Khan et al., 2011, p. 10) was used to develop a table (Table 3.1) from the primary research question. This table and a scoping search, to determine the size and nature of the evidence base (Centre for Reviews and Dissemination, 2009), were utilised in refining search terms. A final search strategy was developed in collaboration with a Health Sciences Subject Librarian at the University of Liverpool. Previous systematic reviews indicate that disability (activity limitation) (Sirtori et al., 2009) and impairment (Pollock et al., 2014) outcomes have not been widely reported in previous CIMT studies. In order to clearly report the outcomes within this systematic review, the International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2002) was used to report UL function. The ICF is a framework that classifies health-related domains (World Health Organization, 2014), and was selected so that outcomes could be reported clearly through the ICF categories of body function, activity and participation.

**Table 3.1 PIOS Table for systematic review of quantitative studies**

<b>Research Question: Population, Intervention, Outcomes and Study Design</b>	
<b>Population</b>	<p>Studies with stroke survivor participants who have experienced ischaemic or haemorrhagic stroke</p> <p>Studies whose participants are 18 years or older</p> <p>Studies where the participants are in the sub-acute phase of stroke, defined as more than 14 days and not more than 9 months post-stroke on recruitment to the study</p> <p>Studies of mixed diagnoses, where the outcomes are reported separately for stroke</p> <p>Studies of mixed ages, where the outcomes are reported separately for participants of 18 years or more</p> <p>Studies where participants are mixed phases post-stroke, where the outcomes for the sub-acute phase (as defined above) are reported separately</p>
<b>Intervention</b>	<p>Intervention must include constraint or reduction in use of less affected upper limb and re-training of the more affected upper limb</p> <p>CIMT</p> <p>Modified CIMT or shortened CIMT</p> <p>forced use if it included a training aspect</p>
<b>Outcome</b>	<p>Upper limb recovery must be measured in terms of one of the following:</p> <ul style="list-style-type: none"> <li>-Body function</li> <li>-Activity</li> <li>-Participation</li> </ul>
<b>Study Design</b>	<p>Study designs that randomise participants to one or more groups, and where a CIMT group is compared to an alternative intervention and/or a control</p>

### 3.3.1 Search strategy

A computer-assisted search was conducted of MEDLINE (1966-2014), AMED (1985-2014) Scopus (1966-2014), CINAHL (1982-2014), PsychINFO (1967-2014) and Cochrane Central Register of

Controlled Trials (1993-2014). Databases were searched from their inception; a final search was completed on 18th October 2014.

The following Medical Subject Headings (MeSH) and key words were used in combination:

cerebrovascular accident, stroke, CVA, CIMT, CIT, forced use, upper limb, upper extremity, arm, shoulder, hand, wrist, fingers. The full search is presented in Figure 3.1.

**Fig 3.1 Systematic review search terms**

1. upper limb\*
2. upper extremity\*
3. arm
4. shoulder
5. hand
6. wrist
7. fingers
8. #1 or #2 or #3 or #4 or #5 or #6 or #7
9. Constraint?induced movement therapy
10. Constraint?induced therapy
11. Forced?use
12. CIT
13. CI therapy
14. CIMT
15. Constraint induced movement therapy
16. Constraint induced therapy
17. #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16
18. Stroke
19. CVA
20. Cerebrovascular
21. Cerebro-vascular
22. #18 or #19 or #20 or #21
23. #8 and #17 and #22

### 3.3.2 Study selection

Selection criteria were developed from the PIOS table. Studies were included if: participants were survivors of ischaemic or haemorrhagic stroke, 18 years or older, and more than 14 days and less than nine months post-stroke on recruitment to the study; CIMT addressed UL function, comprised constraint or reduction of use of the ipsilesional UL and re-training of the contralesional UL; comparison interventions were a control, traditional therapy or an alternative intervention group; outcomes measured UL function or participation; studies were a randomized controlled trial research design. Studies were excluded if: they were not published in or translated into English; the source was a web-site that was no longer active; the source was an abstract of a study that had been published fully in a peer-reviewed journal (to avoid duplication), or where no further information was available; protocols for studies that had not yet been undertaken.

The searches were conducted by one researcher (KJ). The selection criteria were applied independently by two researchers (KJ and EG). Study titles and abstracts were compared to the selection criteria. Where a decision about inclusion could not be made, the full article of the study was retrieved. If there was a difference in opinion, the decision was discussed and an agreement reached. Where a study was excluded, the assessors documented a reason for exclusion by allocating a code from a pre-defined ranked inclusion criteria list (Appendix 3). These codes were also compared and if there was a difference in the allocated code, this was discussed and a decision reached. Reference lists of included studies were hand-searched for further potential studies.

### 3.3.3 Quality assessment

The studies that met the inclusion criteria were assessed for quality by two independent assessors (KJ, EG). The studies were assessed using a checklist developed from the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Moher et al., 2001) (Appendix 4). Many of the recognised quality assessment tools (Downs & Black, 1998; Jadad et al., 1996; Physiotherapy Evidence Database, 2015) use a numerical system to summarise quality. The decision to utilise a CONSORT checklist to assess quality was based on its potential to comprehensively assess all aspects of study design that should be reported, and its narrative rather than numerical approach to describing quality as recommended by the CRD (Centre for Reviews and Dissemination, 2009, p. 44). This recommendation is based on a lack of testing of reliability and validity of many numerically based quality measures, and problems with identifying the direction of bias when using these checklists (Centre for Reviews and Dissemination, 2009, p. 43). This approach has been taken previously utilising the Consolidated Criteria for Reporting Qualitative Studies (COREQ) (Tong et al., 2007) for assessing qualitative studies (Soundy et al., 2014) and the QUORUM for assessing systematic reviews (Intercollegiate Stroke Working Party, 2012, p. 7). In line with other RCT quality assessments (Downs & Black, 1998; Higgins et al., 2011; Jadad et al., 1996; Physiotherapy Evidence Database, 2015), the final rating was based primarily on: 1) clear selection and randomisation procedures, 2) masking of assessors and use of valid outcome measures, 3) clear analysis of baseline data, 4) appropriate analysis of the data including an intention-to-treat analysis, 5) appropriate conclusions based on findings.

Each assessor independently considered the potential biases for each study and made a decision about the overall quality, thereby rating the study. A 'low risk of bias' rating was assigned where no serious sources of bias were identified in the above areas of the study design; a 'moderate risk of bias' rating was allocated where there were one or two areas of concern; and a 'high risk of bias' rating was allocated when three or more potential sources of bias were identified. If there

was a difference in opinion about the quality, agreement was reached through discussion.

Studies were not excluded based on quality assessment rating, but the findings of the poor quality studies were weighted accordingly in the reporting of the review findings.

### **3.3.4 Data extraction**

The data were extracted into a structured, piloted data extraction form (Appendix 5) by two independent assessors, one OT (KJ) and one physiotherapist (SH). The completed data extraction forms were compared. Where there were omissions or queries, the original study was consulted, the data were agreed and summarised in a final data extraction form.

### **3.3.5 Data synthesis**

The data from the agreed data extraction forms were transposed into a narrative results table. The headings in the table focused on the data required to meet the review objectives; study sample, inclusion criteria, CIMT intervention and comparison interventions, outcome measures, and findings. Following the completion of the narrative table, findings that addressed the review objectives were reported. Where papers reported the same study, this was noted and the results were reported once to avoid multiple publication bias.

The scoping search indicated a variety in CIMT protocols and of comparison interventions in the published literature. For this reason it was agreed that a narrative synthesis, recommended when “studies are too diverse (either clinically or methodologically) to combine in a meta-analysis” (Centre for Reviews and Dissemination, 2009, p. 48) was appropriate. A narrative synthesis is potentially subjective in nature (Centre for Reviews and Dissemination, 2009). In order to present a transparent and robust process for synthesis, CRD guidance (2009) recommends the framework

devised by the Economic and Social Research Council (ESRC) Methods Programme (Popay et al., 2006). This framework was applied, and the following four stages were undertaken:

- 1 A preliminary synthesis of the findings from the included CIMT studies. This identified and critically reviewed the CIMT protocols to identify and describe those with evidence to support their use in clinical practice.
- 2 An analysis of the relationships of the findings from the included studies. This element of the analysis focused on the potential influence of study design and quality (risk of bias), population and intervention on the outcome.
- 3 Development of the theory-base underpinning CIMT, including why it works and for whom. This stage included an analysis of beneficial or detrimental effect of CIMT on sub-groups of stroke survivors.
- 4 An assessment of the robustness and trustworthiness of the narrative synthesis by considering the synthesis process, the methodological quality and strength of evidence of the included studies.

In the narrative synthesis reported below, these four stages were used to structure the findings.

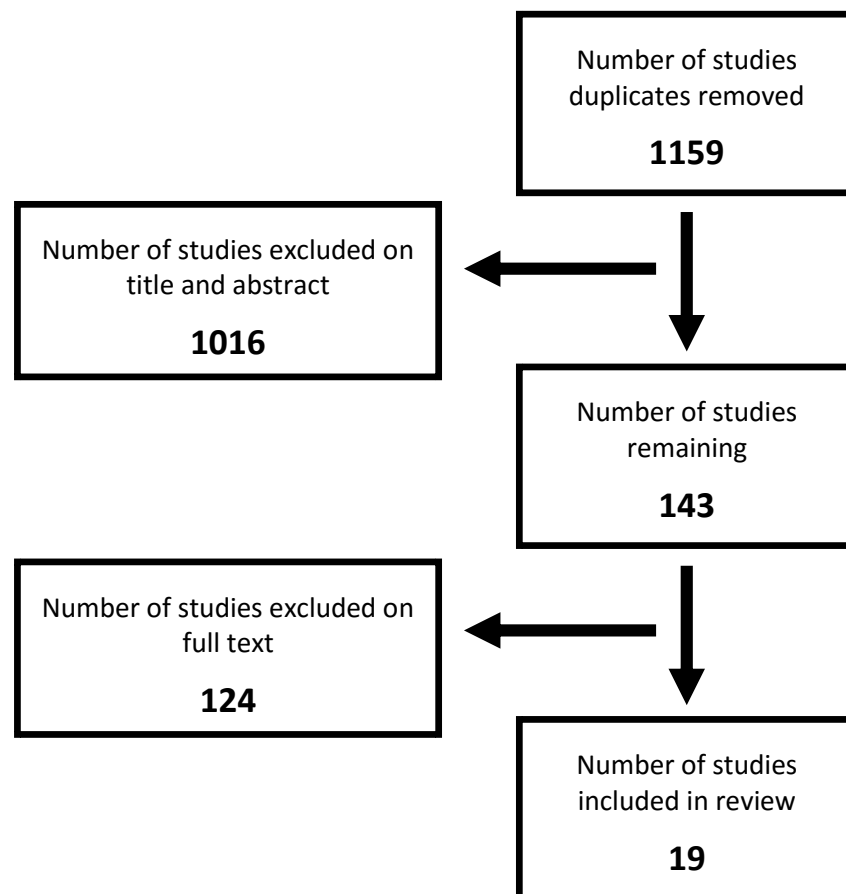
Whilst the fourth stage could justifiably be reported in the 'Discussion' of this chapter, the decision to report this stage under 'Results' recognises the robustness, trustworthiness, and ultimately the credibility of the synthesis, a finding in itself.

### **3.4 Results**

After removal of duplicates, the searches retrieved 1159 titles; 1016 of these were excluded on the title and abstract, and 124 were excluded once the full paper had been retrieved and read. The remaining 19 studies were retained for analysis. No additional studies were found from

searching the reference lists of the included studies. This is summarised in Figure 3.2. Each excluded paper was allocated an exclusion code. The codes are shown in Appendix 3, and the number of papers excluded against each code is reported in Appendix 6.

**Fig 3.2 Flow chart of exclusion process**



A summary of the 19 studies is shown in Table 3.2.

There was evidence of multiple publication of some studies. One trial had been published twice (Hammer & Lindmark, 2009a; Hammer & Lindmark, 2009b) the two publications report different outcome measures. One paper (Hammer & Lindmark, 2009a) reports the upper extremity section

on the Fugl-Meyer test, Modified Ashworth Scale, ARAT, Motor Assessment Scale, 16-hole peg test and grip strength, whilst the additional paper (Hammer & Lindmark, 2009b) reports the MAL. In order to prevent multiple publication bias only Hammer and Lindmark (Hammer & Lindmark, 2009a) is reported, unless specifically considering MAL results.

Five studies report follow-up data or additional analyses of an original study. Four studies (Alberts et al., 2004; Underwood et al., 2006; Wolf et al., 2007; Wolf et al., 2008) report follow-up and additional analyses of the EXCITE trial (Wolf et al., 2006), and a further study, (Brogårdh & Lexell, 2010), reported one year outcomes of an earlier study (Brogårdh et al., 2009) study. These have been reported individually in Table 3.2 due to the variety in sampling methods and outcomes measures utilised, which subsequently led to different quality ratings of the studies. In summary, there were 13 original studies and six supplementary studies. When considering characteristics of the studies, the original study only has been referenced to avoid multiple publication bias. The 13 original papers were the focus of the review with the supplementary six papers being discussed only when the findings provided additional, relevant information. The supplementary studies are differentiated in Table 3.2 by the citation being presented in italics.

Table 3.2 Summary of included studies (quantitative data)

Study Identifier	Design	Sample	Interventions	Outcome Measurement	Quantitative Results	Quality
<b>Alberts JL, Butler AJ, Wolf SL.</b> <i>The effects of constraint-induced therapy on precision grip: a preliminary study.</i> <i>Neurorehabilitation &amp; Neural Repair, 2004;18(4):250-8.</i>	Small RCT within a large RCT (EXCITE trial) Compared CIMT and customary care at post-intervention N=10 CIMT group n=5 Customary care group n=5	Recruited from medical facilities in the US Selection criteria as for EXCITE trial (Wolf et al 2006) stated on p.98 Age range 41-84 Months post stroke 3-8	As for EXCITE Trial (Wolf et al 2006) stated on p.98	Key-turning task Maximum precision grip-squeezing (exert maximum force against a transducer embedded in handle of key). FMA and WMFT reported, but also reported as part of EXCITE trial, so not reported here. Measured at baseline and post-intervention.	Key turning task time (post-test compared to pre-test): Intervention group reduced time by average 47%, control group increased on average by 15%. No significant interaction between groups. Grip strength: Intervention group 11.3N to 19.9N, Control group 14.5N to 15.0N. Significant between group difference in maximum grip force ( $t_{1,4}=2.76; p=0.05$ ).	High risk of bias
<b>Atteya AAA.</b> <i>Effects of modified constraint induced therapy on upper limb function in</i>	Prospective randomised pre-test, post-test controlled trial Compared CIMT, traditional therapy and	Recruited from a medical complex in Saudi Arabia. Mean age (SD) 54.3 (6.9); range 45-67 yrs. 4 weeks - 6 months post ischaemic	CIMT and traditional therapy group: ½ hour PT and ½ hour OT (outpatient) 3 times per week for 10 weeks. 80% time focused on PNF techniques with emphasis on ADL tasks where possible, 20%	FMA-66 point UL motor component ARAT WMFT MAL (patient and caregiver)	FMA and ARAT baseline scores were consistent at pre-intervention (FMA varied by no more than 1 point, ARAT by no more than 2 points). Post-intervention, both CIMT participants increased, FMA $\geq 7$ points and ARAT $\geq 10$ points. In the traditional group one	High risk of bias

<p><b>subacute stroke patients.</b></p> <p><b>Neurosciences, 2004;9(1):24-9.</b></p>	<p>control intervention at post-intervention</p> <p>N=6</p> <p>CIMT group n=2</p> <p>Traditional therapy group n=2</p> <p>Control group n=2</p>	<p>stroke, discharged from rehabilitation, able to actively extend the MCP and IP joints 10°, able to actively extend the wrist 20°</p> <p>Exclusions included: &lt;70 on the Modified Mini Mental Status Examination, ≥2 on Modified Ashworth Spasticity Scale; significant pain in the affected upper limb (≥4 on a pain Visual Analog Scale)</p>	<p>time focused on compensatory techniques</p> <p>CIMT group: In addition to above, CIMT participants chose 2 functional tasks from WMFT and practiced these as part of therapy. Shaping used.</p> <p>Ipsilesional UL constrained with a sling and mitt for 5 hrs each weekday for 10 wks</p> <p>Control group: No therapy over the 10 weeks</p>	<p>Measured at baseline (FMA and ARAT applied twice before intervention) and post-intervention</p>	<p>participant's FMA and ARAT scores decreased and the other participant's FMA score increased by 3 points and ARAT increased by 6 points. In the control group neither participant increased on the FMA and did not gain more than 3 points on the ARAT. Due to small sample statistical significance was not calculated.</p> <p>WMFT functional score: CIMT group mean increased ≥ 1 for both participants; traditional group 0 and 0.3; control group 0.1 and -0.4. WMFT mean time: CIMT group +0.1, -0.8; Traditional group 0, -0.4; Control group -0.1, -1.9. Statistical analysis of between group differences not calculated.</p> <p>MAL: AOU for CIMT group increased by 12 points, Traditional group increased by 4 points and control 0 points. QOU for CIMT group increased by 2.3 points, traditional group by 0.2 points and control by -0.5 points. Statistical analysis of between group differences not calculated.</p>	
<p><b>Brogårdh C, Vestling M, Sjölund BH.</b></p>	<p>Randomized controlled trial</p>	<p>Recruited from a university hospital in Sweden.</p>	<p>Both groups: 3 hrs of training for 2 weeks (12 days) including task practise, fine motor</p>	<p>Modified MAS, Sollerman Hand Function Test,</p>	<p>Sollerman Hand Function Test significant within group median increase in both groups. Mitt group pre-post</p>	<p>Low risk of bias</p>

<b>Shortened constraint-induced movement therapy in subacute stroke - no effect of using a restraint: a randomized controlled study with independent observers.</b>  <b>Journal of Rehabilitation Medicine (Stiftelsen Rehabiliteringsinformation) 2009;41(4):231-6.</b>	Assessor blinded	Mean (SD) age 57.6(8.5)	practice, muscle strength training, muscle stretching, swimming pool training, general activity training. Encouraged to use contralesional hand as much as possible.	2-point discrimination test, MAL	treatment 16.5 points (p<0.05), pre- to 3 month follow up 21.5 points (p<0.05); non-mitt group pre-post treatment 11.5 points (p<0.05), pre- to 3 month follow-up 14.5 points (p<0.001) (Dunn's <i>post-hoc</i> test)	
	N=24  Mitt group n=12  Non-mitt group n=12	Single stroke, between 1 and 3 months post-stroke, mean (SD) 7 weeks (2.7), able to extend the wrist of contralesional hand at least 10° and to extend 2 fingers at least 10° and to abduct the thumb at least 10°, grasping score ≤ 65/80 points on the Sollerman Hand Function Test, able to walk 20 m within 40 secs, no gross language deficits (≥ 4 out of 6 parts on the Token test); no severe cognitive impairments (Mini-Mental State Examination > 24/30).	Mitt group: Encouraged to wear mitt for 90% of waking hrs (Log kept)  Non-mitt group: No wearing of mitt	Measured at baseline, post-intervention and 3 months post intervention	MAS significant within group increase of median pre-test to follow up 4 points in mitt group (p<0.01), 6 points (p<0.01) in non-mitt group (Dunn's <i>post-hoc</i> test)  MAL AOU and QOM - significant within group increase of median pre-test to 3 month follow up in both groups. Mitt group AOU/QOM 1.15/1.15 points (p<0.001); non-mitt group 1.15/1.1 points (p<0.01) (Dunn's <i>post-hoc</i> test)  No significant within group changes in 2 point discrimination.  No significant between group differences in any measures at any time.	
<b>Brogardh C, Lexell J.</b>  <b>A 1-year follow-up after shortened constraint-induced</b>	Randomized controlled trial 1-year follow-up (N=20)  Assessor blinded	As for Brogardh et al. (2009) p.85  Mean age in yrs 58.8 (SD not stated).	As for Brogardh et al (2009) p. 85	Sollerman Hand Function Test  MAS  MAL  Measured and reported 12 months	Both groups had significantly increased within group medians pre- to 12 month follow-up for Sollerman Hand Function Test, MAS and MAL AOU/QOM (p<0.05) (Wilkinson signed-rank test)	Moderate risk of bias

<p><i>movement therapy with and without mitt poststroke.</i></p> <p><i>Archives of Physical Medicine &amp; Rehabilitation 2010; Mar;91(3):460-4.</i></p>	<p>Mitt group n=11</p> <p>Non-mitt group n=9</p>			<p>post-intervention follow up to Brogardh et al (2009).</p>	<p>There were no significant differences between the groups in any measure at any time</p>	
<p><b>Brunner IC, Skouen JS, Strand LI. Is Modified constraint-induced movement therapy more effective than bimanual training in improving arm motor function in the subacute phase post stroke? A randomized controlled trial. Clinical Rehabilitation, 2012; 26(12): 1078-86.</b></p>	<p>Randomised Controlled Trial.</p> <p>Comparing CIMT to bimanual intervention.</p> <p>Blinded assessor</p> <p>N=30</p> <p>CIMT group n=14</p> <p>Bimanual group n=16</p>	<p>Recruited from two hospitals in Norway.</p> <p>Mean (SD) age 63.0 (11.6)</p> <p>Single stroke or former stroke with no residual motor impairment; between 2 and 16 weeks post stroke; upper extremity paresis, but ability to extend wrist and fingers at least 10° but experiencing deficits in dexterity (&lt;52 on ARAT); no severe cognitive impairments (Mini-Mental State Examination &gt; 24/30).</p>	<p>CIMT group: 4 hrs training per week for 4 weeks with a therapist focusing on unilateral activities. Self-training exercises and advice to use arm 2-3 hrs a day in daily life activities. Tasks were planned to ensure a motor challenge (followed 'shaping' principles). Encouraged to wear mitt 4 hrs each day (log kept)</p> <p>Bimanual group: 4 hrs training per week for 4 weeks with a therapist focussing on bilateral activities. Self-training exercises and advice to use arm 2-3 hrs a day in daily life activities. Tasks were planned to ensure a motor</p>	<p>ARAT</p> <p>NHPT</p> <p>MAL AOU and QOU</p> <p>Measured at baseline, post-intervention and 3 months follow-up</p>	<p>Within group differences, ARAT mean change scores were significant for both groups from baseline to post intervention (paired t-tests): CIMT group mean (SD): 13.23 (8.18), p&lt;0.001; bimanual group 15.2(10.7), p&lt;0.001 and baseline to 3 month follow-up: CIMT group 17.77 (14.66), p&lt;0.001; bimanual group 15.47(13.59), p&lt;0.001.</p> <p>Within group differences, NHPT mean change scores were significant for both groups from baseline to post intervention (paired t-tests): CIMT group 0.12 (0.13), p=0.009; bimanual group 0.10 (0.11), p=0.003 and baseline to 3 month follow-up: CIMT group 0.18 (0.21), p=0.01; bimanual group 0.16 (0.17), p=0.002</p> <p>Within group differences, MAL AOU/QOM mean change</p>	<p>Low risk of bias</p>

			challenge (followed 'shaping' principles)		<p>scores were significant for both groups from baseline to post intervention (paired t-test): CIMT group 1.3 (0.66)/ 1.23 (0.67), <math>p&lt;0.001</math>; bimanual group 1.5 (0.99)/1.4 (0.86), <math>p&lt;0.001</math> and baseline to 3 month follow-up CIMT group 1.78 (0.67)/ 1.7 (1.10), <math>p&lt;0.001</math>; bimanual group 1.4 (1.37)/1.31 (1.27) (<math>p\leq 0.001</math>).</p> <p>Between group change score was not significant (ANCOVA) for any measure (<math>p&gt;0.4</math>) for either time interval.</p>	
<p><b>Hammer AM, Lindmark B.</b></p> <p><b>Effects of forced use on arm function in the subacute phase after stroke: a randomized, clinical pilot study</b></p> <p><b>Physical Therapy, 2009; 89(6), 526-545</b></p>	<p>Prospective, randomised, non-blinded clinical pilot trial</p> <p>N=30</p> <p>Standard care with constraint n=15</p> <p>Standard care group n=15</p>	<p>Recruited from a department of rehabilitation medicine, Sweden</p> <p>Age range 31-83 yrs</p> <p>Mean age (SD), Constraint group: 66.3 yrs (10.3); Non-constraint group: 60.4 yrs (11.1).</p> <p>1 to 6 months after stroke; able to perform independent transfers to and from chair, bed, and toilet; able to move the shoulder and elbow voluntarily,</p>	<p>Constraint group: constraint sling worn for a target of 6 hrs on each training day.</p> <p>Both groups: Training for 2 weeks, 5 days each week-customary rehabilitation (task-orientated approach). Encouraged to be active and use contralesional upper limb</p> <p>Motor exercises and task-oriented activities, included facilitation of motor control, exercises of strength/endurance, and ROM, task training-moving objects, putting pegs in a board, writing,</p>	<p>Upper extremity section FMA</p> <p>ARAT</p> <p>MAS</p> <p>16-hole peg test</p> <p>Isometric grip strength</p> <p>Measured at pre-intervention, post-intervention, 1 month post-intervention, 3 months post-intervention</p>	<p>Between group, interaction effects (time x group) were not significant for any measures</p> <p>Within group statistics both reported. Pooled data indicated improvement in both groups:</p> <p>All participants improved over time in 4 of 6 measures.</p> <p>FMA 52 to 57 (ANOVA <math>p&lt;0.001</math>)</p> <p>Motor Assessment Scale 10.1 to 12.4 (ANOVA <math>p=0.009-0.014</math>)</p> <p>16 hole peg test 92 secs to 60 secs (ANOVA <math>p=0.008-0.011</math>)</p> <p>Grip strength ratio 0.40 to 0.55 (ANOVA <math>p&lt;0.001</math>)</p>	Moderate risk of bias

		extend the paretic wrist 20° and the fingers 10°; score of ≤2 of 5 on the Modified Ashworth Scale for muscle spasticity; no complete sensory loss in the arm or hand; no severe perceptual impairments, assessed by drawing a clock and a human figure; score of ≥20 of 30 on the MMSE; able follow instructions	typing and daily tasks. Lower-limb training also completed, balance and gait training and exercises to improve strength and endurance  Practice sessions were 30-45 mins long, several sessions a day			
<b>Hammer A, Lindmark B.</b>  <i>Is forced use of the paretic upper limb beneficial? A randomized pilot study during sub-acute post-stroke recovery.</i>  <i>Clinical Rehabilitation, 2009; 23: 424-33</i>	As for hammer 2009 p.100	As for hammer 2009 p.88	As for hammer 2009 p.88	MAL  Measured at pre-intervention, post-intervention, 1 month post-intervention, 3 months post-intervention	Pre-intervention measures not stable  Within group AOU and QOM increased post-intervention, at 1 and 3 month follow-up, not tested for significance. AOU mean (SD) change scores: Constraint group 0.598(0.411), 0.828(0.543), 1.026(0.778); Non-constraint group 0.287(0.388), 0.369(0.312), 0.689 (0.596) QOM mean (SD) change scores: Constraint group 0.615(0.371), 0.768(0.498), 0.916(0.736); Non-constraint group 0.227(0.325), 0.577(0.535), 0.861 (0.781)	Moderate of risk

					Between groups, a significant difference in change of mean was found only for the constraint group compared to non-constraint group QOM pre- to post-intervention 0.388 (ANOVA after Bonferroni correction, $p=0.021$ ). However change pre-intervention to follow-up was not significant.	
<b>Krawczyk M, Sidaway M, Radwanska A, Zaborska J, Ujma R, Czlonkowska A.</b> <b>Effects of sling and voluntary constraint during constraint-induced movement therapy for the arm after stroke: a randomized, prospective, single-centre, blinded observer rated study. Clinical Rehabilitation, 2012; 26(11): 990-998.</b>	Prospective, randomised, observer blinded, single centre study.  Comparing constraint with a sling to voluntary constraint with no sling.  N=47  Sling group n=24  Voluntary constraint group n=23	Recruited from neurorehabilitation unit in Poland.  Sling constraint group Mean age (SD): 48 yrs (14)  Voluntary constraint group Mean age (SD): 46 yrs (13)  First stroke < 6 weeks prior to study enrolment; motor deficit in arm assessed with RMA-arm scale; able to lift a floppy disc off the table and to release it; score of $\geq 24$ on MMSE; lack of neglect syndrome and self-awareness of stroke (assessed	Both groups: therapy for 3 weeks, 5 days each week. 5hrs a day therapy focused on upper limb -2.5hrs of repetitive task-orientated training- (physio-therapist) and 2.5hr of task practice (OT). Plus 1hr PT-to address motor limitations of trunk and lower limb, also to encourage multi-joint movements-included upper limb (NDT and PNF). Task practice homework given. Participants encouraged to use only affected upper limb in afternoons and evenings.  Sling group: wore sling for 5hrs a day	MAL QOM  RMA-arm scale  Measured at baseline, post-intervention and 12 month follow-up	Significant increases in both groups on MAL QOM and RMA arm scale reported, pre- to post-intervention, although p-values not presented.  Between group, mean differences for MAL QOM scores baseline to post intervention and baseline to 12 month follow-up not significant (t-test, $p=0.687$ and $p=0.211$ respectively)  Difference between groups for RMA-arm scale scores baseline to post intervention and baseline to 12 month follow-up not significant (Wilcoxon signed-rank test, $p=0.211$ and $p=0.289$ respectively)	Moderate risk of bias

		by neuropsychologist); able to walk 10m independently	Non-sling group: instructed not to use ipsilesional UL to perform tasks			
		Excluded if: arm used permanently in life situations or lack of treatment goals by stroke survivor; excessive pain, spasticity or ataxia; bilateral or brainstem stroke				
<b>Myint JMW, Yuen GFC, Yu TKK, Kng CPL, Wong AMY, Chow KKC, Li HCK, Wong CP.</b>  <b>A study of constraint-induced movement therapy in subacute stroke patients in Hong Kong.</b>  <b>Clinical Rehabilitation 2008;22(2):112-24.</b>	Prospective, single-blind randomised controlled trial comparing CIMT and control intervention at post-intervention and 12 weeks follow-up  N=48  CIMT group=28  Conventional therapy group=20	Recruited from regional hospital in Hong Kong.  Mean age yrs (SD), CIMT group: 63.4 yrs (13.6) Conventional therapy group: 63.9 yrs (12.2).  2-16 weeks after stroke; functional level 3 (functional test for hemiparetic upper extremity); $\leq 20^\circ$ wrist extension and $10^\circ$ all digits contralesional UL; cantonese version of MMSE score of 17 or above; able to walk with or without equipment	CIMT Group: 4 hrs training, 5 days per week, 5 days a week for 2 weeks. Training incorporated shaping and provision of error information. Therapist used sets of ADL tasks. Ipsilateral arm restrained in a shoulder sling; contract to wear sling for 90% of waking hrs during 10 day treatment (except, bathing, toileting and if there was risk of falling)  Conventional therapy group: 4 hrs OT and PT, 5 days per week, 2 weeks. Therapy included NDT, bimanual tasks, compensatory techniques for ADLs,	Primary measures:  Functional test for hemiparetic upper extremity (functions based on Brunnstrom's seven levels of recovery  ARAT  MAL AOU and HW  Secondary measures: Modified BI, NHPT  Measured at baseline, post-intervention and 12 week follow-up	Significant between group differences in favour of the CIMT group:  Functional test ,ANCOVA $F=14.08$ , $P=0.001$ .  MAL AOU, ANCOVA $F=12.67$ , $P=0.001$ and HW $F=5.82$ , $P=0.021$  ARAT total $F=7.60$ , $p=0.009$  The ARAT sub-section means were all significantly higher (Kruskal-Wallis test, $p<0.05$ ) in the CIMT compared to the conventional therapy group at post intervention; however only the 'Grip' component (Kruskal-Wallis test, $P=0.019$ ) was significantly greater at follow-up.  Significantly greater number of participants in CIMT compared	Moderate risk of bias

		Exclusion criteria: severe aphasia; high risk of fall; cerebellar stroke; severe shoulder pain	strength and motion, positioning and mobility training		to conventional therapy group able to complete NHPT at post-intervention, 69.6% compared to 45% (chi-square 5.223, p=0.022) and follow-up, 78.3% compared to 50% (chi-square 4.77, p=0.029)  No significant between group differences were found in modified BI score	
<b>Page S, Sisto S, Levine P, Johnston M, Hughes, M.</b>  <b>Modified constraint induced therapy: a randomized feasibility and efficacy study.</b>  <b>Journal of Rehabilitation Research and Development, 2001; 38(5), 583-590.</b>	Multiple baseline, single-blind randomised pre-test, post-test control group design  Comparing CIMT, traditional therapy and control intervention at post-intervention  N=6  CIMT group (n=2)  Traditional therapy (n=2)  No therapy (n=2)	Recruited by letters sent to discharged patients from 4 rehabilitation hospitals in the US  Age range: 44-77  Able to extend $\geq 10^\circ$ at MCP and IP joints and $20^\circ$ at the wrist; single, unilateral stroke 4 weeks-6 months prior to enrolment; $\geq 70$ on the Modified MMSE; no excessive spasticity (< 2 on the Modified Ashworth Spasticity Scale); no excessive pain in the affected upper limb	CIMT and Traditional Groups: $\frac{1}{2}$ hr OT & $\frac{1}{2}$ hr PT 3 times a week for 10 weeks. OT and PT focussed on neuromuscular facilitation (PNF) with emphasis on ADL where possible (80% of time) and compensatory techniques (20% of time)  CIMT Group: in addition to above, ipsilesional arm was restrained 5 days a week for 5 hrs by sling and mitt (wearing log kept). Two tasks from WMFT practiced for at least 5 minutes within therapy sessions with shaping  Control group: No therapy	FMA-66 point UL motor component  ARAT  WMFT  MAL  Measured at baseline (FMA and ARAT applied twice) and post-intervention (10 weeks)	Descriptive stats indicate CIMT participants had improved post-intervention scores on FMA (+7, +9) and ARAT (+10, +8). The traditional therapy participants, one participant had increased post-intervention FMA and ARAT scores whilst the other did not (FMA -6, +4; ARAT -2, +7),. Both participants in no therapy group had small or no post-intervention gains (FMA +2, -1; ARAT +1, 0).  Descriptive statistics report an increase pre- to post-intervention in mean task rating (functional score) of 1.3, 1.0 points in CIMT participants compared to 0.3, 0.0 in traditional therapy participants and 0.1, -0.2 in control participants. With a decrease in mean task time of 0.0, 0.8 seconds in CIMT participants, 0.4, 0.0 in traditional therapy	High risk of bias

					<p>participants and 0.1, 0.8 in control participants.</p> <p>Descriptive statistics indicated greater post-intervention increases in MAL (QOU &amp; AOU) in the CIMT group compared to the other two groups. Mean change score CIMT group AOU: +12, QOU: +2.3, traditional therapy group AOU: +4, QOU +0.2, control group: AOU: 0, QOU: -0.5.</p> <p>The results have not been subject to statistical analysis.</p>	
<p><b>Page S, Sisto S, Johnston M, Levine P.</b></p> <p><b>Modified constraint-induced therapy after subacute stroke: a preliminary study.</b></p> <p><b>Neurorehabilitation and Neural Repair, 2002; 16(3), 290-295.</b></p>	<p>Prospective, single-blind, multiple pre-test, post-test, randomized clinical trial.</p> <p>Comparing CIMT, traditional therapy and control intervention at post-intervention</p> <p>N=14</p> <p>CIMT group n=4</p> <p>Traditional therapy n=5</p>	<p>Recruited by advertisement sent to discharged patients from 4 rehabilitation hospitals in the north-eastern US</p> <p>Age range: 45-83</p> <p>Able to extend <math>\geq 10^\circ</math> at MCP and IP joints and <math>20^\circ</math> at the wrist; single, unilateral stroke 4 weeks-6 months prior to enrolment; <math>\geq 70</math> on the Modified MMSE; 18 – 95 yrs of age; no excessive spasticity (<math>&lt; 2</math> on the Modified Ashworth Spasticity Scale); no</p>	<p>CIMT Group: <math>\frac{1}{2}</math>hr OT &amp; <math>\frac{1}{2}</math>hr PT 3 times a week for 10 weeks. OT mainly focused on functional tasks (eg writing, opening containers, folding clothes) with some wrist/arm strengthening. PT focused on UL stretching, balance and gait training. Ipsilateral arm was restrained 5 days a week for 5 hrs by sling and mitt. Two tasks from WMFT practiced for at least 5 minutes within therapy sessions with shaping</p> <p>Traditional therapy group: <math>\frac{1}{2}</math>hr OT &amp; <math>\frac{1}{2}</math>hr PT</p>	<p>FMA-66 point UL motor component</p> <p>ARAT</p> <p>MAL</p> <p>Measured at baseline (FMA and ARAT applied twice) and post-intervention (1 week after intervention)</p>	<p>Within groups, the CIMT group showed a mean pre- to post-intervention increase of +11.5 points on ARAT and 11.4 points on FMA. In comparison the other groups made small gains or no gains (traditional therapy group: ARAT +1.4; FMA -0.9; control group: ARAT -0.7; FMA +2.6)</p> <p>Between groups, ANCOVA (pre-test covariate, group independent variable and post-test dependent variable found FMA score significantly for CIMT group only, ANCOVA (<math>F[2, 10] = 5.75, P = 0.02</math>). Least square means for CIMT, traditional, and control groups on the FMA were 50.81, 40.76, and 40.99, respectively. CIMT group exhibited significantly</p>	<p>High risk of bias</p>

	No therapy=5	excessive pain in the affected upper limb	3 times a week for 10 weeks. OT and PT focussed on PNF compensatory techniques  Control group: No therapy		greater FMA scores after intervention than traditional ( $t[10] P = 0.02, d = 2.2$ ) and control ( $t[10] P = 0.01, d = 2.12$ ) groups. ARAT ANCOVA not significant.  MAL mean change score between pre- to post-intervention increased in CIMT group AOU: +2.49, QOU: +1.47; traditional group AOU: +0.49 and QOU: -0.26; control group AOU: +0.40, QOU: 0.08. No statistical analysis undertaken.	
<b>Singh P, Pradhan B.</b>  <b>Study to assess the effectiveness of modified constraint-induced therapy in stroke patients: a randomized controlled trial.</b>  <b>Annals of Indian Academy of Neurology, 2013; 16(2), 180-4.</b>	Non-blinded, randomised controlled trial.  N=40  CIMT group n=20  Standard care group n=20	Recruited from Central Referrla Hospital and STNM Hospital in Sikkim, India.  Age mean yrs (SD) CIMT group 55.2 (9.27); standard care group 56.4 (11.4)  First stroke; 2 weeks to 4 weeks after onset; at least 10° of active extension of each MCP and IP and wrist joints; spasticity $\geq 1$ modified Ashworth scale; $\geq 17$ MMSE. Excluded stroke survivors with severe aphasia;	CIMT group-constraint wearing 10 hrs a day for 2 weeks and training for 2 hrs a day for 2 weeks, 5 days a week. Shaping used.  Standard care group-training for 2 hrs a day for 2 weeks, 5 days a week, included compensatory techniques for ADL, strength and positioning work and positioning.	WMFT-performance time  FMA  Measured at pre-intervention and post-intervention	Within groups, WMFT mean time to complete tasks significantly reduced pre- to post-intervention in both groups Mean in seconds (SD) CIMT group: 28.04 (6.58) to 13.59 (2.86) paired t-test $p=0.03$ ; standard care group 29.59(5.84) to 22(4.68) paired t-test $p<0.01$ .  FMA significantly increased pre- to post-intervention in both groups Mean (SD) CIMT group: 31.15(6.37) to 55.7(6.4) $p<0.01$ ; standard care group 29.3(6.1) to 39.1(6.4) $p<0.01$ .  Between group differences: WMFT CIMT group mean reduction of 14.75 (4.83) compared to standard care group 7.21 (2.01). FMA CIMT group mean increase of	High risk of bias

		severe shoulder pain or comorbidity that might impact upper limb function.			24.95(3.74) compared to standard group 9.5 (7.7). No statistical analyses undertaken.	
<b>Tregar I, Aidinof L., Lehrer H, Kalichman, L.</b>  <b>Modified constraint-induced movement therapy improved upper limb function in sub-acute poststroke patients: a small scale study. Topics in Stroke Rehabilitation, 2012; 19(4): 287-93.</b>	Single-blind, randomised controlled trial. Comparing CIMT to group with equal intensity/duration therapy  N=28  CIMT group n=9  Control group n=19	Recruited from admissions to a hospital rehabilitation centre, Israel  Age mean (SD) 61.7 (8.4), range 43-82.  First stroke; active movement in most joints of paretic upper limb (grade $\geq$ 16 of the Manual Function Test); cognitive and lingual ability to communicate with research staff; right hand dominant	Both groups: OT sessions 5 times a week for 2 weeks. 1hr in total (30mins individual and 30mins group). Task-orientated, repetitive training of functional tasks (eg picking up cup/coins, eating, combing hair, writing), used shaping. If required 45mins of PT  CIMT group: hand restrained for the therapy and asked to wear constraint for an additional 4hrs each day during the 2 weeks.  Control group: encouraged to use affected upper limb	Task 1: Transfer pegs from saucer to pegboard for 30 seconds-repetitions recorded  Task 2: Grasp, carry and release a hard rubber ball for 30 second-repetitions recorded  Task 3: Eating using a spoon to remove jelly from a plate, bring towards mouth and place on a different plate for 30 seconds-repetitions recorded  Measured at baseline and post-intervention	Within groups, CIMT group had significantly improved pre- to post-intervention mean score in all three functional tests (independent t-test). Task 1 (t=4.90, p<0.001), task 2 (t=4.25, p<0.001, task 3 (t=4.99, p<0.001). Control group significantly improved pre- to post-intervention mean score only in significantly improved scores in task 3 (t=3.08, p=0.004)  Between groups, the CIMT group showed significantly more change in all three tests than the control group (independent t-test), task 1 (t=3.03, p=0.005), task 2 (t=2.71, p=0.012), task 3 (t=3.46, p=0.002).	Moderate risk of bias
<b>Underwood J, Clark PC, Blanton S, Aycock DM, Wolf SL.</b>  <b>Pain, fatigue, and intensity of practice in</b>	Retrospective analysis of a sub-set of a RCT (EXCITE trial)  To determine changes in pain, fatigue	Sub-set of participants at the Emory University site (US) of EXCITE trial. All had a full EXCITE data set.  22 male, mean age yrs (SD) 63.8 (12.2);	Sub-acute participants (immediate group): mitt worn on less-impaired UL for 90% of waking hrs of 2 week period including 2 weekends (12-14 days). Each weekday participants received shaping	WMFT reported, but also reported as part of EXCITE trial, so not reported here.  Joint pain subscale of FMA for upper extremity. PROM	Within group, Pearson correlation revealed no relationship in the sub-acute group between Joint pain and WMFT, fatigue and WMFT, change in motor function and pain, change in motor function and fatigue, time in therapy and joint pain (FMA), time in	Moderate risk of bias

<p><b>people with stroke who are receiving constraint-induced movement therapy.</b></p> <p><b>Physical Therapy, 2006;86(9):1241-50.</b></p>	<p>and examine relationships with intensity of CIMT</p> <p>N=32</p> <p>Sub-acute (immediate) group n=18</p> <p>Chronic (delayed) group n=14</p>	<p>10 female mean age 56.8(15.4).</p> <p>Randomly allocated to a sub-acute or a chronic group as part of EXCITE trial</p> <p>Selection criteria as for EXCITE trial (Wolf et al 2006)</p> <p>p.98</p>	<p>(adaptive task practice, ATP) and standard task training (repetitive task practice, RTP) of paretic limb for up to 6 hrs per day. RTP less structured than ATP, functional tasks practised for 15-20 mins. Behavioural techniques used to encourage mitt wearing-contracts, mitt compliance device, daily schedules/diary</p> <p>Chronic (delayed group): customary care and CIMT as described above after 1 year post-stroke</p>	<p>through 12 movements of UL.</p> <p>Measures at pre- and post-intervention</p> <p>In addition, during intervention phase fatigue and pain were measured on an analogue scale 1-10, at end of each morning and afternoon session.</p> <p>Time spent engaged in therapy (intensity) was also recorded</p>	<p>therapy and fatigue or pain. In the chronic group, a significant correlation was found between change score for motor function and daily pain score (<math>r=-0.53</math>, <math>p=0.05</math>) and fatigue <math>r=-0.75</math>, <math>p&lt;0.05</math>).</p> <p>Within group, fatigue was significantly greater in the afternoon compared to the morning in both groups sub-acute (<math>t=4.2</math>, <math>df=17</math>, <math>p&lt;0.01</math>); chronic (<math>t=3.4</math>, <math>df=13</math>, <math>p&lt;0.05</math>)</p> <p>There was no significant within group difference in pain between morning and afternoon in either group, or in joint pain scores before and after CIMT</p>	
<p><b>Van Delden AEQ, Peper CE, Nienhuys KN, Zijp NI, Beek PJ, Kwakkel G.</b></p> <p><b>Unilateral versus bilateral upper limb training after stroke: the upper limb training after stroke clinical trial.</b></p>	<p>Randomised control trial</p> <p>To test hypothesis that CIMT and BACTRAC would significantly improve upper limb function when compared with dose-matched conventional</p>	<p>Recruited from Reade Rahabilitation Center, Amsterdam</p> <p>Age Mean yrs (SD): CIMT group 59.8 (13.8); BACTRAC group 62.6 (9.8); DMCT group 56.9 (12.7)</p> <p>First stroke; between 1 and 6 months post-stroke; upper limb paresis with min. 10° active wrist extension and</p>	<p>All groups-60 minute therapy sessions, 3 days a week for 6 weeks. Encouraged to practice outside therapy hrs according to allocated treatment.</p> <p>CIMT group-repetitive task practice and shaping. Emphasis on control of wrist and finger extensors. Also constraint mitt worn for 6 hrs each weekday.</p>	<p>Primary outcome-ARAT</p> <p>Secondary outcomes:</p> <p>Motricity Index</p> <p>FMA</p> <p>NHPT</p> <p>Erasmus modification of NSA</p> <p>MAL QOM and AOU</p> <p>SIS</p>	<p>Within groups, Kruskal-Wallis H tests found significant improvement for all groups on ARAT after intervention that lasted or improved at 6 week follow-up.</p> <p>Between groups, Mann-Whitney U tests with a Bonforroni correction for multiple comparisons found no significant difference in change scores on ARAT or secondary outcomes at post-intervention or follow-up.</p>	<p>Moderate risk of bias</p>

<b>Stroke, 2013; 44(9), 2613-6.</b>	therapy (DMCT)  N=60  3 intervention groups:  CIMT n=22  BATRAC n=19  DMCT n=19	thumb abduction/extension and at least 2 addition digits; less than 53 on ARAT; at least 23 on MMSE; able to communicate.	BATRAC group- apparatus mounted on a chair with arm rests, hands vertically fixated to arm rests. Treatment applied in 3 minute blocks with 5 minute rest periods. Symmetrical and alternating movements to a sound, adjusted in response to improvement.  DMCT group-Exercise based on Dutch guidelines with elements of CIMT and BATRAC were removed.	Measured at pre-intervention, post-intervention and 6 week follow-up		
<b>Wang Q, Zhao J, Zhu Q, Li J, Meng P. Comparison of conventional therapy, intensive therapy and modified constraint-induced movement therapy to improve upper extremity function after stroke. Journal of Rehabilitatov</b>	Randomised clinical trial  To compare the effects of CIMT, conventional rehabilitation and intensive rehabilitation  N=30  CIMT group=10  Intensive conventional rehabilitation (ICR) group=10	Recruited from a university hospital in China  No excessive pain; ability to understand and follow verbal directions (using Chinese aphasic battery; no major cognitive deficit (MMSE of >24; wrist extension $\geq 20^\circ$ ; active extension of MCP and $\geq 10^\circ$ IP joints; able to stand for 2 minutes	CIMT group: 3hrs of OT 5 days a week for 4 weeks. Tasks included reaching, grasping, lifting and placing. Difficulty level was 'shaped' to ensure goal just above participants' level to perform it. Resting hand splint restraint worn for 90% of waking hrs for 20 consecutive weekdays  Conventional rehabilitation (CR): 45mins of OT 5 days a week for 4 weeks. Involved strength,	WMFT  Measured at baseline, 2 weeks post-intervention and 4 weeks post-intervention.	Within groups, WMFT functional score significantly improved from pre-intervention to 2 and 4 week measures in all groups, Friedman's test CR group $X^2=15.84$ , $df=2$ , $p<0.001$ ; ICR group $X^2=18.20$ , $df=2$ , $p<0.001$ ; CIMT group $X^2=20.00$ , $df=2$ , $p<0.001$ . Between groups ANOVA found significant interaction effect between groups and time ( $F_{(4,54)}=2.80$ , $p=0.03$ ) indicating the type of intervention had a different effect on functional ability scores at 2 and 4 weeks post intervention; however, post-hoc analyses (Bonferroni)	High risk of bias

<b>Medicine 2011; 43 (7): 619-25</b>	Conventional rehabilitation (CR) group=10		balance, manual dexterity exercises (eg grasp, release), functional tasks, stretching and weight-bearing of the contra-lesional arm and teaching compensatory methods.  Intensive Conventional rehabilitation: 3hrs of OT 5 days a week for 4 weeks. Content as CR.  Participants focused efforts on contra-lesional UL in all three groups		indicated this effect mainly emerged from differences between CR and CIMT at 2 weeks. All groups were comparable at 4 weeks.  Within groups, WMFT functional time significantly improved from pre-intervention to 2 and 4 week measures in all groups, Friedman's test CR group $X^2=9.50$ , $df=2$ , $p<0.01$ ; ICR group $X^2=17.54$ , $df=2$ , $p<0.001$ ; CIMT group $X^2=18.72$ , $df=2$ , $p<0.001$ . Between groups, a significant interaction effect was found between groups and time ( $(F_{(4,54)}=2.81$ , $p=0.04)$ . Post-hoc analyses indicated this effect was due to a significant difference between CIMT and CR groups at 4 weeks in favour of CIMT and a significant difference from pre-intervention to 2 and 4 week measures in both the CIMT and ICR group (all Bonferroni tests $p<0.05$ ).	
<b>Wolf SL, Winstein C.J, Miller JP, Taub E, Uswatte G, Morris D, Giuliani C, Light KE, Nichols-Larsen D.</b>	Prospective single-blind multicentre (7 sites) RCT  N=222  CIMT group=106	Recruited from 7 medical facilities in the US  Mean age yrs (SD) CIMT group: 61.0 (13.5); Customary care group: 63.3 (12.6)	CIMT group: mitt on ipsilesional UL for 90% of waking hrs over a 2 week period including 2 weekends (14 days). Each weekday participants received shaping (adaptive task practice) and standard	WMFT  MAL  SIS-hand function domain  Measured at pre-intervention, post-	No between group differences for less-impaired arm at any time  Within groups, both showed significant increase all 1° and 2° outcome measures of paretic UL ANOVA ( $p<0.05$ )	Low risk of bias

<p><b>Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial.</b></p> <p><b>JAMA: Journal of the American Medical Association 2006;296(17):2095-104</b></p>	<p>Customary care=116</p>	<p>3 to 9 months post-stroke at enrolment; <math>\geq 18</math> yrs; first stroke; met higher or lower functioning criteria (higher-functioning: <math>\geq 20^\circ</math> wrist extension, <math>\geq 10^\circ</math> extension in each MCP and IP joint; lower-functioning: <math>\geq 10^\circ</math> wrist extension, <math>\geq 10^\circ</math> thumb abduction/extension, <math>\geq 10^\circ</math> extension in at least 2 additional digits); <math>\geq 90^\circ</math> passive shoulder flexion and abduction; adequate balance while wearing the constraint; able to stand from sitting, and stand for <math>\geq 2</math> minutes.</p> <p>Exclusions included: <math>&lt;24</math> on MMSE; medical problems or insufficient stamina that would interfere with participation; excessive pain in contralesional extremity; MAL <math>\geq 2.5</math></p>	<p>task training of contralesional UL for up to 6 hrs per day. Behavioural techniques to encourage mitt wearing-contracts, mitt compliance device, diary. Participants were encouraged to practice 2 to 3 tasks daily at home. Participants encouraged to perform 30 minutes of task practice daily after the 2 week intervention complete</p> <p>Customary care group: Varied eg no treatment, application of mechanical interventions (orthotics), various OT and PT approaches at home, day treatment or out-patient setting. Participants in this group were offered CIMT as described above after 12 months</p>	<p>intervention, 4, 8 and 12 month follow-up</p>	<p>Between groups, post-treatment: CIMT group showed larger improvements than customary care group on all 1° and 2° outcome measures of contralesional UL ANOVA (<math>p &lt; 0.05</math>) except 2 strength items on WMFT. At 4,8,12 month follow up: CIMT showed significantly larger improvements than customary care for WMFT performance time, MAL scales ANOVA (<math>p &lt; 0.01</math>). No significant gains of CIMT group in WMFT functional ability score over customary care at 12 month follow-up</p> <p>Larger gains in CIMT compared to customary care for caregiver MAL and SIS hand function at 12 months ANOVA (<math>p &lt; 0.001</math>)</p>
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<p><b>Wolf SL, Newton H, Maddy D, Blanton S, Zhang Q, Winstein CJ, Morris DM, Light K.</b></p> <p><b><i>The Excite Trial: relationship of intensity of constraint induced movement therapy to improvement in the wolf motor function test.</i></b></p> <p><b><i>Restorative neurology and neuroscience. 2007; 25 (549-626)</i></b></p>	<p>Retropective analysis of RCT (EXCITE)</p> <p>To examine relationship between intensity of CIMT and WMFT</p> <p>Original study: N=222, n=169 with complete data sets were analysed.</p> <p>Immediate group (sub-acute group) n=96; High functioning (HF)=76; low functioning (LF)=20. Delayed group (chronic) n=73; HF=58; LF=15</p>	<p>Recruited from 7 medical facilities in the US</p> <p>Mean age yrs (SD) Immediate group: 63.3 (12.8); Delayed group: 66.1 (11.5)</p> <p>Other inclusion/exclusion criteria as for EXCITE Trial (Wolf et al) p.98</p>	<p>As for EXCITE Trial (Wolf et al 2006) p.98</p>	<p>WMFT-performance time</p> <p>Measured at baseline, post-intervention and every 4 months for 2 yrs</p>	<p>Immediate (sub-acute) group</p> <p>Within group, no relationship found between total intensity of training and ImWMFT (r=0.14, p=0.16).</p> <p>No relationship between time undertaking either training approach and the change in ImWMFT score (ATP r=0.00034, p=0.997 and RTP r=0.17, p=0.10)</p> <p>Delayed (chronic) group</p> <p>Within group, no relationship found between total intensity of training and ImWMFT (r=0.03, p=0.83)</p> <p>No relationship between time undertaking either training approach and the change in ImWMFT score (ATP r=0.04, p=0.71 and RTP r= 0.08, p=0.51)</p>	<p>Moderate risk of bias</p>
<p><b>Wolf SL, Winstein C.J, Miller JP, Thompson PA, Taub E, Uswatte G, Morris D, Blanton S, Nicols-Larsen D, Clark PC.</b></p>	<p>Further assessment of intervention group from EXCITE trial.</p> <p>Study of retention of treatment gains in CIMT</p>	<p>Recruited from 7 medical facilities in the US</p> <p>Mean age yrs (SD) CIMT group: 61.0 (13.5)</p> <p>Other inclusion/exclusion criteria as</p>	<p>As for CIMT group in EXCITE Trial (Wolf et al 2006) p.98</p>	<p>WMFT</p> <p>MAL</p> <p>SIS-hand function domain</p> <p>Measured at pre-intervention, post-intervention, 4, 8, 12, 12.5, 16, 20 and</p>	<p>Within group, comparing means of all post-training scores with pre-training score showed a significant difference in overall WMFT Time, WMFT weight to box task, WMFT grip strength, MAL AOU and How Well (HW), SIS strength, ADL and IADL, social participation</p>	<p>Moderate risk of bias</p>

<b><i>Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: the EXCITE randomised trial.</i></b>  <b><i>Lancet Neurology, 2008; 7(1), 33-40.</i></b>	group in EXCITE trial  Original study: N=222, CIMT group n=106	for EXCITE Trial (Wolf et al) p.98	24 months from randomisation	and physical domain (repeated measures F-test, $p \leq 0.002$ ).  Repeated-measures mixed model ANOVA found overall WMFT Time and MAL AOU and HW change scores from 12 to 24 months were not significant indicating retention of benefits. Significant improvements were found in WMFT weight to box test (-0.63, 95%CI -1.24 to -0.02, $p=0.04$ ), WMFT grip strength (-4.39, 95%CI -6.91 to -1.86, $p<0.0001$ ) and all 5 SIS domains tested (strength, memory and thinking, ADL and IADL, social participation and physical domain) ANOVA ( $P \leq 0.003$ ).
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### Key of Abbreviations

ADL	Activities of daily living	IADL	Instrumental activities of daily living	QOM	Quality of Movement
AOU	Amount of Use	HW	How Well	RCT	Randomised Controlled Trial
ANOVA	Analysis of Variance	MCP	Metacarpophalangeal joint	RMA	Rivermead Motor Assessment
ANCOVA	Analysis of Covariance	MAL	Motor Assessment Log	ROM	Range of motion
ARAT	Action Research Arm Test	MAS	Motor Assessment Scale	RTP	Repetitive task practice
ATP	Adaptive task practice	MFT	Muscle Function Test	SD	Standard deviation
BATRAC	Bilateral arm training with rhythmic auditory cueing	MMSE	Mini-mental State Examination	secs	Seconds
BI	Barthel Index	NDT	Neurodevelopmental techniques	SIS	Stroke Impact Scale
CIMT	Constraint induced movement therapy	NHPT	Nine Hole Peg Test	UL	Upper limb
FMA	Fugl-Meyer Assessment	NSA	Nottingham Sensory Assessment	US	United States of America
hrs	Hours	OT	Occupational therapy	wks	Weeks
IP	Interphalangeal joint	PNF	Proprioceptive Neuromuscular Facilitation	WMFT	Wolf Motor Function Test
lnWMFT	log of WMFT time	PROM	passive range of motion		
m	metres	PT	Physiotherapy		

### 3.4.1 A preliminary synthesis of the findings

#### 3.4.1.1 Country of origin

The 13 original studies originated from 10 countries; three from US (Page et al., 2002b; Page et al., 2001; Wolf et al., 2006), two from Sweden (Brogårdh et al., 2009; Hammer & Lindmark, 2009a), one each from Saudi Arabia (Atteya, 2004), Hong Kong (Myint et al., 2008), Norway (Brunner et al., 2012), Poland (Krawczyk et al., 2012), Israel (Treger et al., 2012), Netherlands (van Delden et al., 2013), India (Singh & Pradhan, 2013) and China (Wang et al., 2011). There were no UK studies.

#### 3.4.1.2 CIMT intervention

Only Wolf et al. (2006) studied the original CIMT protocol of 6hour training and 90% of waking hours constraint over two weeks. All the other protocols were adapted and were usually termed modified CIMT (Atteya, 2004; Brunner et al., 2012; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Treger et al., 2012; Wang et al., 2011) or shortened CIMT (Brogårdh et al., 2009). As there is overlap in these definitions, the term CIMT has been used throughout this chapter. In addition to the original protocol over two weeks there were an additional five protocols based on a two week intervention (Brogårdh et al., 2009; Hammer & Lindmark, 2009a; Myint et al., 2008; Singh & Pradhan, 2013; Treger et al., 2012), one protocol over three weeks (Krawczyk et al., 2012), two protocols over four weeks (Brunner et al., 2012; Wang et al., 2011), one protocol over six weeks (van Delden et al., 2013) and one protocol over 10 weeks (Atteya, 2004; Page et al., 2002b; Page et al., 2001). A summary of the protocols is provided in Table 3.3.

**Table 3.3 Summary of CIMT protocols**

Citation	Training	No. of training days per week	Restraint	No. of restraint days per week	Restraint	Length of protocol	Homework	Behavioural contract	Log restraint / use of UL	Summary of Outcome
Wolf et al (2006)	Up to 6hrs per day <i>Average 4.5hrs (Underwood 2006)</i>	5	90% of waking hours	7	Mitt	2 weeks	Practice 2-3 tasks at home Encouraged to do about 30 mins of task practice daily after completion of intervention	Behavioural contract and caregiver's contract	Home dairy to report mitt wearing	CIMT more effective than usual therapy Strong evidence with a low risk of bias
Krawczyk et al (2012)	5hrs per day	5	5hrs per day	'Each day' not stated if this included weekends	Sling	3 weeks	Task practice homework for a few weeks after treatment	Not reported	Not reported	CIMT with restraint as effective as same training without restraint Moderate risk of bias
Myint et al (2008)	4hrs per day	5	90% of waking hours	5	Sling	2 weeks	Not reported	Contract to wear restraint for 90% of waking hours	Log of sling use	CIMT more effective than equal duration usual rehabilitation Moderate risk of bias
Brogårdh et al(2009)	3hrs	12 consecutive days	90% of waking hours	12 consecutive days	Mitt	2 weeks	Not reported	Not reported	Log of restraint	CIMT with restraint as effective as same training without restraint Low risk of bias
Hammer & Lindmark (2009)	3hr per day	5	6 hrs per day	5	Sling	2 weeks	Not reported	Not reported	Not reported	CIMT as effective as equal duration usual rehab) Moderate risk of bias
Wang et al (2011)	3hrs	5	90% of waking hours	5	Resting splint	4 weeks	Not reported	Not reported	Not reported	CIMT as effective as equal duration conventional rehabilitation CIMT more effective than conventional rehabilitation Moderate risk of bias

Singh & Pradhan 2013	2hrs	5	10hrs per day	5	Mitt	2 weeks	Not reported	Not reported	Not reported	CIMT and standard therapy groups both showed improvement, no statistical comparison undertaken High risk of bias
Atteya (2004) Page (2001) Page (2002)	1hr	3	5hrs per day	5	Sling and mitt	10 weeks	Not reported	Not reported	Not reported	CIMT was more effective than usual therapy CIMT was more effective than no therapy High risk of bias
Van Delden et al	1hr	3	6 hrs per day	5	Mitt	6 weeks	Not reported	Not reported	Not reported	CIMT as effective as BACTRAC (a bilateral UL intervention) Moderate risk of bias
Treger et al (2012)	1 hr	5	4hrs per day	7	Mitt	2 weeks	Not reported	Not reported	Not reported	CIMT with restraint as effective as same training without restraint Moderate risk of bias
Brunner et al (2012)	4hrs per week	Not reported	4hrs per day	7	Mitt	4 weeks	Self-training exercises Use arm 2-3 hrs each day in addition to therapist-led training	Not reported	Log of exercise Log of restraint	CIMT as effective as a bimanual training of equal duration Moderate risk of bias

All studies stated that the CIMT intervention included task practice, although only Wolf et al. (2006) defined the practice into adaptive and repetitive task practice. All but two of the original studies (Brogårdh et al., 2009; Hammer & Lindmark, 2009a) stated that they used shaping in the training element of the CIMT. In three studies (Atteya, 2004; Page et al., 2002b; Page et al., 2001) the participants practiced only two self-selected tasks in addition to standard occupational therapy and physiotherapy; shaping was used during this task practice. In all other studies the task practice was the predominant part of the therapy.

#### **3.4.1.3 Assessment of methodological quality**

Of the 13 original studies, three were found to be at low risk of bias (Brogårdh et al., 2009; Brunner et al., 2012; Wolf et al., 2006), five at moderate risk (Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Myint et al., 2008; Treger et al., 2012; van Delden et al., 2013) and five at high risk of bias (Atteya, 2004; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Wang et al., 2011), whilst for the six supplementary studies, five were considered to be at moderate risk of bias (Brogårdh & Lexell, 2010; Hammer & Lindmark, 2009b; Underwood et al., 2006; Wolf et al., 2007; Wolf et al., 2008) and one at high risk of bias (Alberts et al., 2004). The reasons for these decisions are summarised in Table 3.

It was not possible to blind participants and care-givers in any of the studies, due to the nature of the intervention. Some studies had additional threats to validity such as the lack of a masked assessor (Atteya, 2004; Hammer & Lindmark, 2009a; Singh & Pradhan, 2013; van Delden et al., 2013), unclear randomization procedures (Atteya, 2004; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Wang et al., 2011), small samples (Atteya, 2004; Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Treger et al., 2012; Wang et al., 2011), a lack of detail about selection procedures (Atteya, 2004; Brunner et al., 2012; Myint et al., 2008; Page et al., 2002b; Page et al., 2001; Singh

& Pradhan, 2013; Treger et al., 2012; van Delden et al., 2013; Wang et al., 2011), and no intention-to-treat analysis (Brunner et al., 2012; Krawczyk et al., 2012; Myint et al., 2008; van Delden et al., 2013; Wang et al., 2011) which may have introduced a type I error (ie rejection of a null hypothesis that is true) (Sim & Wright, 2000, p. 205). Details of the quality assessment for the individual studies are given in Table 3.4. This information has been used in the analysis of the strength of the evidence in the sections below.

**Table 3.4 Summary of quality assessment of included studies**

Study	Objective, Sample Size and Selection	Randomisation Procedures	Blinding (Masking)	Outcome Measures Employed	Consideration of Baseline Data	Analysis of Data including reporting: Intention-to-treat Adverse events	Interpretation of Results (including Generalisability)	Decision
Alberts et al (2004)	To determine the effects of a 2 week CIT intervention on the force-producing capabilities of the hemiparetic hand during the performance of a functional dexterous task  N=10 Selected from participants enrolled in EXCITE trial. Not clear how sample was selected	No details given	Assessors blinded for FMA and WMFT. Not clear for grip force and key turning	FMA WMFT Precision grip Grasping force and torque in a key turning task	Demographic information given. Brief baseline data documented, not analysed	Statistical analyses used in comparing improvement between groups for WMFT and FMA. Variability within and between groups at baseline identified, but not convincingly considered. Grasping force and torque in key turning reported case-by-case-descriptions and results indicate some improvement in intervention group. Intention to treat not applicable due to small sample size.  Adverse events not reported	No significant difference in groups for FMA and WMFT. Although paper discusses a 'close to significant' result for WMFT. Poor consideration of between group differences in these outcomes. Consideration of weaknesses of study limited. Need for further research recognised	High risk of bias
Atteya (2004)	To examine the feasibility and efficacy of a CIMT protocol	No details given	No evidence of blinding (masking)	FMA ARAT WMFT MAL	Basic demographic information of participants given. No	Descriptive results indicate improvement in constraint induced therapy group in	Limited consideration of results in light of other research	High risk of bias

	<p>on stroke patients</p> <p>N=6 Sample from a medical unit in Saudi Arabia Not clear how sample was selected</p>				analyses of baseline data	<p>FMA, ARAT and MAL. No clear picture for WMFT.</p> <p>Intention-to-treat not relevant</p> <p>Adverse events not reported</p>	<p>Poor consideration of limitations of study. Need for further research recognised</p>	
Brogardh et al (2009)	<p>To determine whether wearing a mitt enhances a possible improvement in arm and hand function in patients with sub-acute stroke</p> <p>N=24</p> <p>Consecutive patients admitted to Swedish hospital</p>	Randomised from a computer-generated list of consecutive random numbers	Assessor blinded (masked)	Modified MAS Sollerman Hand Function Test 2-point discrimination test MAL	Basic demographic information of participants given and compared statistically	<p>Results analysed. Repeated measures and ANOVAs used to compare differences in mean within groups. Tukey's post-hoc test for 2-pt discrimination (parametric), Friedman test with Dunn's post-hoc test for Sollerman, MAS and MAL</p> <p>Intention-to-treat completed for missing value from 1 participant Between group means were compared with t-test (parametric) and Mann-Whitney (nonparametric)</p> <p>Adverse events not reported</p>	Both groups improved, no benefit of mitt found. Sound discussion reports results, and recognised limitations of study and need for more research	Low risk of bias

Brogardh, Lexell (2010)	To investigate the arm and hand function and self-reported use of more affected had 1 year after participation in the shortened CIMT program with and without using a mitt  N=20  All of 24 participants from 2009 study invited for follow-up	Original study participants randomised from a computer-generated list of consecutive random numbers	Assessor blinded (masked)	Modified MAS Sollerman Hand Function Test MAL	Basic demographic information of participants given and compared statistically in original study	To assess within groups Wilcoxon signed ranked test was used. To assess differences between groups Mann-Whitney U test was used.  No intention to treat analysis at 1 year.  Adverse events not reported	Sound discussion reports results, and recognised limitations of study and need for more research	Moderate risk of bias
Brunner et al (2012)	To compare the effectiveness of CIMT with dose matched bimanual task-related training for patients in the sub-acute phase post stroke  N=30  Participants recruited from 2 hospitals in	Computerised random numbers generator was used to randomise patients in blocks of 4 participants to a CIMT or bimanual group. Opaque sealed envelopes were	Assessor blinded (masked)	ARAT NHPT MAL	Basic demographic information of participants given and compared statistically	Normal distribution assumptions and homogeneity examined for all outcome measures (Kolmogorov-Smirnov) Paired samples t-tests used to analyse change scores within group. Independent samples t-tests to analyse between groups change scores.	No significant difference between the groups on any outcome measure at any time point.  Sound discussion of findings, recognised limitations of study and need for more research	Low risk of bias

	Bergen, Norway. No details given	prepared by a person not involved in the study				ANCOVA used to analyse differences between groups after treatment and at follow-up, using baseline score as covariate. Statistical significance set at $p \leq 0.05$  No intention-to-treat analysis, but low and equal drop-out rate  Adverse events not reported		
Hammer, Lindmark (2009)	To investigate any difference in changes in motor impairment and capacity between a group of patients wearing a restraining sling in addition to receiving rehabilitation training and a group of participants receiving rehabilitation training only  N=30	Block randomisatio n Blocks of 10 (5 mitt, 5 non-mitt)  A member of staff in hospital selected a piece of paper from a box	No blinding (masking)	FMA ARAT MAS (sum of UL scores) 16 hole peg test Grip strength ratio (contra- lesional to ipsilesional hand) Modified Ashworth Scale	Demographic information provided and analysed statistically	Descriptive stats summarised baseline data-compared using Fisher exact test to compare category variables, and other data was compared using t-test or Mann- Whitney. Intention- to-treat analysis completed. Parametric and non- parametric analyses were used to measure effect. This was because not all the assumptions were met for ANOVA (parametric data), non-parametric data measured with	Sound discussion of results, recognised limitations of study and need for more research	Moderate risk of bias

	Convenience sample from Swedish hospital					Mann-Whitney U Test Bonferroni correction was applied in case of significance to avoid type 1 errors. Effect sizes (Cohen d) were calculated  Adverse events not reported		
Hammer, Lindmark (2009)	To investigate the effect of 2 weeks of forced use as a supplement to the rehabilitation programme in the sub-acute phase of stroke  N=30  Convenience sample from Swedish hospital	Block randomisation Blocks of 10 (5 mitt, 5 non-mitt)  A member of staff in hospital selected a piece of paper	No blinding (masking)	MAL	Demographic information provided and analysed statistically	T-test, Mann-Whitney U and Fischer's exact test were used to compare baselines. Intention-to-treat analysis completed. Effect of treatment was measured by 2-way ANOVAs with repeated measures. Also difference in score was compared with t-test. Bonferroni correction was applied in case of significance to avoid type 1 errors. Effect sizes (Cohen d) were calculated  Adverse events not reported	Sound discussion of results, recognised limitations of study and need for more research	Moderate risk of bias
Krawczyk et al (2012)	To determine whether the change of motor deficits and the	Computer program randomly allocated	Assessor blinded (masked)	MAL RMA-arm scale	Not specifically tested-possible differences in	Differences between groups analysed using t-test for MAL and Wilcoxon signed	No significant difference between the two groups	Moderate risk of bias

	<p>amount of functional use of the arm in a sling-constraint group was significantly different from the change in a voluntary-constraint group</p> <p>N=47</p> <p>Sample from consecutive patients admitted to inpatient neuro-rehabilitation unit in Poland</p>	<p>patients to the groups, stratified by age, gender, affected side, time post-stroke, severity of arm motor deficit</p>			<p>motor deficit between groups</p>	<p>rank-test for RMA. Significance level set at <math>p &lt; 0.05</math></p> <p>No intention-to-treat analysis</p> <p>States no adverse events occurred</p>	<p>Sound discussion of results, recognised limitations of study</p>	
Myint, et al (2008)	<p>To investigate the beneficial effect of CIMT in improving the function of hemiplegic upper extremity in early subacute stroke patients</p> <p>(Objective implies bias)</p> <p>N=48</p> <p>Sample from consecutively admitted</p>	<p>Sealed envelopes-no further details</p>	<p>Assessor blinded (masked)</p>	<p>Functional test for hemiparetic upper extremity</p> <p>ARAT</p> <p>MAL</p> <p>BI</p> <p>NHPT</p> <p>Measures used without established validity</p>	<p>Baseline data reported and analysed</p>	<p>Results clearly analysed and tabulated</p> <p>Intention-to-treat analyses not apparent although attrition indicated</p> <p>Adverse events not reported</p>	<p>Results interpreted in light of other studies.</p> <p>Limitations of present study recognised</p>	<p>Moderate risk of bias</p>

	patients from one hospital in Hong Kong. Two other hospitals also referred patients. Selection process unclear							
Page et al (2001)	To determine the feasibility and efficacy of a CIMT protocol  N=6  Recruitment letters sent out to service users discharged from out-patient therapy from four hospitals-no other information	No details given	Assessor blinded (masked)	FMA ARAT WMFT MAL	Basic demographic information presented. No analyses of the differences between participants pre-treatment.	No statistical analyses, descriptive statistics appropriate for the small sample. Intention-to-treat analysis not appropriate  Adverse events not reported	Discussion of key findings in relation to main objective. Some discussion of participant, carer and therapist perceptions of constraint induced therapy, although this does not form part of the objective. Poor consideration of study limitations	High risk of bias
Page et al (2002)	To determine the efficacy of a CIMT protocol administered to patients with subacute stroke  N=14  Recruitment through advertisement-no other information	No details given	Blinding (masking) procedures unclear-only mentioned in Discussion	FMA ARAT MAL	Basic demographic information presented. No analysis of pre-test data	Simple statistical analyses appropriate for the small sample. Intention-to-treat analysis not discussed  Adverse events not reported	Sound interpretation of results with respect to the hypothesis and in context of other studies. Poor consideration of study limitations	High risk of bias

Singh, Pradhan (2013)	<p>To determine the effect of CIMT in improving upper extremity function of stroke subjects</p> <p>N=40</p> <p>Recruited from 2 hospitals in India-no additional details given</p>	Randomised by lottery method-no further details	No blinding (masking)	WMFT-time FMA	<p>Demographic information given. Brief baseline data documented, not analysed</p>	<p>Paired t-test to compare within group differences before and after CIMT</p> <p>Intention-to-treat not relevant</p> <p>States no adverse events occurred</p>	<p>Within group differences only analysed, between group differences not addressed</p> <p>Discussion did not take account of the lack of between group analyses. Conclusions indicate that CIMT is effective, but does not comment on improvements in control group</p>	High risk of bias
Tregar et al (2012)	<p>To evaluate the effect of CIMT during subacute rehabilitation on the improvement of paretic arm function in poststroke patients</p> <p>N=28</p> <p>Sample from 100 consecutive patients admitted to hospital in Israel were asked to participate</p>	<p>Randomisation was performed by computer generated randomised table of numbers created prior to the study. Individual sequentially numbered index cards with the random assignment were prepared, folded and placed in sealed</p>	<p>Assessor blinded (masked) Same assessor completed baseline and follow-up tests</p>	<p>3 functional tasks at baseline and post-intervention.</p> <p>Validity/ reliability not established</p> <p>NIHSS and FIM on admission and discharge</p>	<p>Baseline data presented and analysed. No significant difference in age, chronicity, FIM, NIHSS or MFT on admission</p> <p>Significantly higher proportion of females in CIMT group</p>	<p>Between group differences analysed using t-tests. <math>P &lt; 0.05</math> was considered significant</p> <p>No participants lost to follow-up, no intention-to-treat reported</p> <p>Adverse events not reported</p>	<p>CIMT group showed significantly more change than the control group in each task</p> <p>Sound discussion reports results, and limitations of study recognised</p> <p>Generalisability not discussed</p>	Moderate risk of bias

		opaque envelopes						
Underwood et al (2006)	<p>To examine the changes in pain and fatigue among people receiving CIMT</p> <p>N=41</p> <p>All participants were enrolled in EXCITE trial, however, selection for retrospective analysis in this study is unclear</p>	Not applicable	<p>Assessors of WMFT and FMA were blind (masked) to group allocation</p> <p>Visual analogue scales for fatigue and pain analogue scales were completed by participants</p>	<p>WMFT Joint pain sub-scale of the FMA</p> <p>Intensity of therapy</p> <p>Visual analogue scale for fatigue and pain during CIMT</p> <p>Measures used without established validity</p>	Basic baseline participant characteristics provided	<p>Subacute and chronic data separated in analysis</p> <p>Paired and independent/tests, and repeated-measures analysis of variance (ANOVA) to determine relationships between pain, fatigue, and function. Pearson correlation used to examine relationships between pain, fatigue, and upper-extremity function</p>	<p>Confusion between full EXCITE trial and this study which considered only a sub-set of participants from EXCITE trial</p> <p>Recognises potential participants with pain have been excluded</p> <p>Some consideration of other studies</p> <p>Some consideration of limitations of this study</p>	Moderate risk of bias
Van Delden et al (2013)	<p>To test hypothesis that CIMT and BACTRAC would significantly improve upper limb function when compared with dose-matched conventional therapy</p> <p>N=60</p> <p>Recruited from rehabilitation</p>	Stratifies for higher and lower functioning, then randomised in permuted blocks and allocated to 1 of the 3 intervention groups	No evidence of blinding (masking)	<p>ARAT</p> <p>Motricity Index</p> <p>FMA</p> <p>NHPT</p> <p>Erasmus modification of NSA</p> <p>MAL QOM and AOU</p> <p>SIS</p>	Baseline data presented and analysed. No significant difference in age, chronicity, gender, laterality, concordance, ARAT, MI, FMA, NHPT, NSA, MAL,SIS on admission.	<p>Tested difference between groups, pre-to post-intervention and follow-up and post-intervention to follow-up using Chi-square for nominal outcomes, Kruskal-Wallis H tests for ordinal outcomes and ANOVAs for continuous outcomes. Significant change-score between groups underwent Mann-Whitney U tests with</p>	<p>All 3 groups showed significant improvement in ARAT that was retained at follow-up</p> <p>Sound discussion reports results, and limitations of study recognised</p>	Moderate risk of bias

	centre in Amsterdam. Selection process unclear					<p>a Holm-Bonferroni correction for multiple comparisons post-hoc analyses. Significant change scores post-intervention and follow-up, within groups were subjected to Wilcoxon signed-rank tests. All tests applied with two-tailed significance of <math>p &lt; 0.05</math></p> <p>No intention-to-treat analysis</p> <p>Adverse events not reported</p>		
Wang et al (2011)	To compare the effects of 4 weeks of intervention using conventional rehabilitation (CR), intensive conventional rehabilitation (ICR) and CIMT on the hemiplegic upper extremity in stroke patients	Randomised by a random numbers table. No other details given	Assessor blinded (masked) to group allocation	WMFT	Baseline characteristics provided. No significant differences found between groups	<p>For Functional Ability and Median Time scores:</p> <ul style="list-style-type: none"> <li>-Friedman's test to test differences in treatment across multiple tests within each group</li> <li>-Kruskal-Wallis one-way analysis of variance (ANOVA) by ranks at each time point</li> <li>-Interaction effects using repeated measures ANOVA (log transformation</li> </ul>	<p>No significant differences between CIMT and ICR group. CIMT better therapeutic effects on motor function than CR</p> <p>Some conclusions were not fully supported ie recommended CIMT over ICR even though no statistical reason for doing this</p>	High risk of bias

	<p>N=30</p> <p>Recruited from Chinese hospital between April 2004 and Nov 2007</p>					<p>of non-normally distributed data), pre-treatment, post-treatment and 4 weeks follow-up, with post-hoc analysis (Bonferroni tests) to assess pairwise differences in Functional Ability and Median Time scores</p> <p>-correlation between values for each group at each time point</p> <p>Numbers at follow-up not stated. No intention-to-treat analysis</p> <p>States no adverse events occurred</p>		
Wolf et al (2006)	<p>To compare the effects of a 2 weeks multisite program of CIMT vs customary care on improvement in upper extremity function among patients who had a first stroke within the previous 3 to 9 months</p> <p>N=222</p>	<p>An adaptive randomisation process was employed to maximise the chances of an even distribution of sex, poststroke dominant side, side of stroke and level of</p>	<p>Assessors were blind (masked) to group allocation during each of the 5 measurements</p>	<p>WMFT</p> <p>MAL</p> <p>SIS</p> <p>Training provided for assessors</p>	<p>Substantial baseline participant characteristics provided and analysed</p>	<p>A repeated-measures analysis of variance model was fit with group assignment (CIMT or customary care) and paretic arm motor ability (higher or lower) as between-patient factors and visit as a within-patient factor. Group-by-time interaction tested if time course differed between groups.</p>	<p>Findings discussed in context of other studies</p> <p>Limitations of this study discussed</p>	<p>Low risk of bias</p>

	<p>Numbers recruited from each of the 7 sites stated</p> <p>Description of power calculation provided, but not replicable.</p>	<p>paretic arm function. Centralized system administered by a data management centre</p>				<p>Within patient comparison-assessed significance of change from baseline within each group</p> <p>Sub-group analyses of higher and lower functioning sub groups</p> <p>Clear reporting and analysis of results.</p> <p>Intention-to-treat analysis completed</p> <p>Adverse effects reported</p>		
<p>Wolf et al (2008)</p>	<p>To assess the retention of the effects and further improvements during the 24 month period after CIMT in patients with subacute symptoms</p> <p>N= 105</p> <p>Participants were the intervention group from the EXCITE trial</p>	<p>Not applicable</p>	<p>No evidence of blinding (masking) to study objective</p>	<p>WMFT MAL SIS (lacks full description)</p>	<p>Demographic information not reported</p> <p>Baseline results reported, as appropriate for cohort study</p>	<p>Results analysed. Results for Post-CIMT was a mean of 3 measures (post-CIMT, 12 month and 24 month post-CIMT). This result was compared to baseline for each measure. Retention to 12 months not reported. Retention from 12-24 months.</p> <p>Sub-group analyses of higher/lower functioning participants, concordance and gender</p>	<p>Results discussed in context of other studies.</p> <p>No consideration of study limitations</p>	<p>Moderate risk of bias</p>

						Drop out rate commented on, but intention-to-treat analysis not reported		
						Adverse events not reported		
Wolf et al (2007)	To examine the relationship between change scores on the log mean WMFT and the intensity of supervised CIMT in participants with subacute and chronic stroke  N=169  Paper clearly describes how this 169 participants were selected from the 222 participants in the EXCITE trial	Not applicable	Not applicable	WMFT	No demographic information given	An analysis of variance models were fit to examine the effect of training intensity on the outcome variable (change scores of the pre-post lmWMFT)  The interaction between function level and ratio of training type was included in models to examine the training type impact on function level group	Given the moderate to weak correlations, the discussion indicates the results have more importance than should actually be attributed to the findings  Some sub-group findings are given too much emphasis given the numbers in the sub-groups  Discussed findings in context of other studies, finding and future research.  Poor consideration of study limitations.	Moderate risk of bias
Wolf et al (2012)	To identify and assess the movement components of the tasks that could not be	Not stated in this paper. Selection criteria stated in Wolf (2006)	Not stated in this paper, but assessors in EXCITE trial were blind	Completion and non-completion of tasks in WMFT	Not considered in this paper, but was considered in Wolf (2006)	Completed and non-completed tasks recorded with a binary value. Generalized estimating equation	Link between non-completed tasks and movement analysis unclear. Discussion and objective focussed	Moderate risk of bias

	completed following CIMT  N=222  Included all participants in EXCITE trial		(masked) to group allocation			(GEE) model was used to analyse Visit x group. Analyses were adjusted by controlling for functional level, affected side, dominant side, age and gender as covariates. Also for multiplicity by making a Bonferroni correction, therefore setting p-value at 0.0033	on movement analysis. Objective does not relate directly to the outcomes collected, instead it relates to the discussion	
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**Key of Abbreviations:**

ANOVA	Analysis of Variance	FMA	Fugl-Meyer Assessment	NHPT	Nine Hole Peg Test
ANCOVA	Analysis of Covariance	lnWMFT	Log of WMFT time	NIHSS	National Institutes of Health Stroke Scale
ARAT	Action Research Arm Test	MAL	Motor Assessment Log	RMA	Rivermead Motor Assessment
BI	Barthel Index	MAS	Motor Assessment Scale	SIS	Stroke Impact scale
CIMT	Constraint induced movement therapy	MFT	Muscle Function Test	UL	Upper limb
FIM	Functional Independence Measure	MI	Motricity Index	WMFT	Wolf Motor Function Test

#### 3.4.1.4 Overview of the included studies

The focus of this section is the 13 original studies, with the supplementary six studies only being considered where they report different outcomes than those in the original studies.

Of the 13 original RCTs (Atteya, 2004; Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Myint et al., 2008; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Treger et al., 2012; van Delden et al., 2013; Wang et al., 2011; Wolf et al., 2006), nine compared CIMT to an alternative intervention (Atteya, 2004; Brunner et al., 2012; Myint et al., 2008; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; van Delden et al., 2013; Wang et al., 2011; Wolf et al., 2006). In seven of these studies (Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Myint et al., 2008; van Delden et al., 2013; Wang et al., 2011), there was a comparison intervention training of the same duration as the CIMT intervention. In six studies, the comparison intervention involved a group that gained less training time than the CIMT group (Atteya, 2004; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; Wang et al., 2011; Wolf et al., 2006). Three studies also included a control group which received no intervention (Atteya, 2004; Page et al., 2002b; Page et al., 2001).

A variety of outcomes (n=21) have been measured in the included studies. The ICF framework has been used to organise the findings in this systematic review with UL outcomes being categorised as measuring the constructs of: body structure or function, activity (including the assessment of components of an activity) and participation.

### 3.4.2 An Analysis of the relationships in the included studies

#### 3.4.2.1 Does CIMT increase UL function in sub-acute stroke survivors (14 days to nine months post-stroke)?

There is good quality evidence (Wang et al., 2011; Wolf et al., 2006) that CIMT leads to significantly improved UL activity and participation (WFMT and MAL) outcomes, and evidence from a poor quality study that it increases body function (grip strength) UL outcomes (Alberts et al., 2004) compared to customary care, of unequal duration. Three small studies suggest that CIMT leads to better activity and participation (FMA-66UL component, WMFT and MAL) outcomes than no intervention (Atteya, 2004; Page et al., 2002b; Page et al., 2001), although all three studies were found to be at high risk of bias.

Where studies compared CIMT to an equal duration intervention, the results were more varied. Three studies (Brunner et al., 2012; van Delden et al., 2013; Wang et al., 2011) found no difference in activity and participation UL outcomes (ARAT, 9HPT, MAL, WMFT) between CIMT and interventions (bilateral interventions and conventional rehabilitation) of comparable duration. In contrast, Myint et al. (2008) found CIMT led to significantly improved activity and participation UL outcomes on the majority of measures used (grip component of ARAT, NHPT and MAL), compared to an equal duration intervention (conventional therapy). Although all four studies (Brunner et al., 2012; Myint et al., 2008; van Delden et al., 2013; Wang et al., 2011) were of moderate quality, it is not possible to analyse this discrepancy further as the CIMT protocols in the four studies were all different, as were the comparison interventions and the outcomes measured. This heterogeneity may explain the differences in the outcomes of these studies.

There is evidence from four studies (Brogårdh et al., 2009; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Treger et al., 2012) that there is no significant difference in body function and activity

UL outcomes (good evidence) or participation UL outcomes (moderate evidence) for a CIMT group with constraint compared with a group undertaking the same training without the constraint element. In all four studies both groups had significantly improved UL outcomes post-intervention. Again there was substantial variation in the protocols and assessments (Tables 3.2 and 3.3).

There is evidence that CIMT increases UL function in sub-acute stroke survivors (14 days to nine months post-stroke), but there is significant heterogeneity in the CIMT protocols and comparison interventions in the studies, on which this conclusion is based.

#### **3.4.2.2 Adverse events and reactions**

Eight of the original studies did not report adverse events or reactions (Atteya, 2004; Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Page et al., 2002b; Page et al., 2001; Treger et al., 2012; van Delden et al., 2013). Three studies (Krawczyk et al., 2012; Singh & Pradhan, 2013; Wang et al., 2011) stated there were no adverse events. Myint et al. (2008) reported one exacerbation of a pre-existing shoulder pain, whilst Wolf et al. (2006) reported a total of 14 events in the control group and 21 events in the customary care group that required hospitalization within 12 months of enrolment. Only one event (a stroke) occurred during the intervention period, there was no significant difference between the groups in rate of adverse effect. A further study (Underwood et al., 2006) studied a sub-set (n=18) of the EXCITE trial (Wolf et al., 2006) and considered whether pain and fatigue increased following CIMT. Fatigue was significantly greater in the afternoon, compared to the morning, but pain was not. There was no relationship between either pain or fatigue and change in motor function or with time in therapy in the sub-acute group of participants.

### 3.4.2.3 Long-term outcomes

Three of the original studies reported follow-up assessments at 12 months (Brogårdh et al., 2009; Krawczyk et al., 2012; Wolf et al., 2006). Two published their findings in a supplementary paper (Brogårdh & Lexell, 2010; Wolf et al., 2008). Wolf et al. (2006) found the log of WMFT performance time and MAL (AOU and QOM) to be significantly better for the CIMT group than the customary care group at 12 months. Whilst the WMFT functional ability was significantly better for the CIMT group post-intervention, this was not the case at 12 months. The effects gained at 12 months for the WMFT performance time and MAL were maintained or improved at 24 months follow-up (Wolf et al., 2008).

Activity and participation UL outcomes (Sollerman Hand Function Test, Rivermead Motor Assessment Arm Scale and MAL) were maintained or improved at 12 months compared to post-intervention (Brogårdh et al., 2009; Krawczyk et al., 2012) and three month follow-up (Brogårdh et al., 2009), with no significant differences between a 'constraint' and 'no constraint' group.

### 3.4.2.4 Which of the CIMT protocols are effective in increasing UL function in sub-acute stroke survivors?

Eleven different protocols (Table 3.2) were described in the 13 original studies, with variations in the amount of daily training, the amount of daily constraint and the total number of days of CIMT. Some evidence of effectiveness has been found for all the CIMT protocols. However, for two protocols, one hour therapy, three times a week for 10 weeks with five hours constraint wearing (Atteya, 2004; Page et al., 2002b; Page et al., 2001), and two hours therapy, five days a week for two weeks with 10 hours a day constraint wearing (Singh & Pradhan, 2013) this evidence is considered weak due to the high risk of bias. In addition, in seven studies (Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Treger et al., 2012; van Delden et al., 2013; Wang et al., 2011), the evidence indicates that CIMT is only as

effective as an alternative intervention. No study indicates that CIMT is less effective in increasing UL outcomes than a comparative intervention. Due to the variation in research design and CIMT protocols, the current evidence is not sufficient to identify which protocols are most effective in the sub-acute phase of stroke.

### **3.4.3 Theory-base underpinning CIMT (Who benefits? What are the gaps?)**

#### **3.4.3.1 Is there evidence that CIMT is more effective in increasing UL function for a definable sub-group of sub-acute stroke survivors?**

All of the participants in 13 original studies (N=585) had some active movement in their contralesional hand. Some studies specified the higher functioning level of inclusion of 20° active wrist extension and 10° active extension at the MCP and IP joints (Atteya, 2004; Hammer & Lindmark, 2009a; Myint et al., 2008; Page et al., 2002b; Page et al., 2001; van Delden et al., 2013; Wang et al., 2011) whilst others specified a lower functioning level of 10° active wrist extension and 10° at MCP and IP of thumb and at least two additional fingers (Brogårdh et al., 2009; Brunner et al., 2012; Singh & Pradhan, 2013). Wolf et al. (2006) included participants who met either of these criteria and stratified for pre-intervention functional level in the data analyses. One study used a functional task (Krawczyk et al., 2012) and one the Manual Function Test (Treger et al., 2012) to establish if there was sufficient UL movement to be included in the study. In addition to these stringent inclusion criteria, a number of studies excluded participants if they experienced serious cognitive deficits (Atteya, 2004; Brogårdh et al., 2009; Brunner et al., 2012; Krawczyk et al., 2012; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013; van Delden et al., 2013; Wang et al., 2011; Wolf et al., 2006), excess spasticity (Atteya, 2004; Hammer & Lindmark, 2009a; Page et al., 2002b; Page et al., 2001; Singh & Pradhan, 2013), significant pain (Atteya, 2004; Myint et al., 2008; Page et al., 2002b; Page et al., 2001; Wang et al., 2011; Wolf et al., 2006), limitations in their balance or mobility (Brogårdh et al., 2009; Hammer & Lindmark,

2009a; Myint et al., 2008; Wolf et al., 2006), sensory loss (Hammer & Lindmark, 2009a), or severe language deficit (Brogårdh et al., 2009; Krawczyk et al., 2012; Myint et al., 2008). By considering the selection criteria of the individual studies, it is apparent that the CIMT evidence presented in this review relates to a small group of stroke survivors.

Three original studies provided sub-group analyses of the study participants (Myint et al., 2008; van Delden et al., 2013; Wolf et al., 2006), with two further studies from the EXCITE trial (Wolf et al., 2007; Wolf et al., 2008) providing additional sub-group information. Myint et al. (2008) considered participants with unilateral spatial neglect and sensory loss. Whilst these participants did not respond differently to CIMT than those without, the analyses was based on very small numbers with only one of 23 participants in the CIMT group with unilateral spatial neglect and five participants with sensory loss. In the same study, concordant (contralesional UL is dominant UL) participants did not respond differently to discordant (contralesional UL is non-dominant UL) participants.

Wolf et al. (2006) and van Delden et al. (2013) compared participants with a greater amount of function in the hand with participants with lower hand function; both studies found treatment effects did not significantly differ in response to CIMT. Wolf et al. (2007) further considered data from the EXCITE trial to analyse whether the type of training impacted on outcome. The amount of adaptive task practice (ATP) and repetitive task practice (RTP) was measured for each participant, where RTP was the practicing of a functional task and ATP included breaking a task into components, practicing these components and eventually putting these back together to form the functional task. A moderate correlation was found between a lower log of WMFT performance time change score and increased ATP in the lower functioning group ( $n=20$ ,  $r=0.55$ ,  $p=0.01$ ), and a weak correlation was found between lower log of WMFT performance time change score and increased time in RTP in the higher-functioning sub-acute group ( $n=76$ ,  $r=0.26$ ,

$p=0.02$ ). This indicates that lower hand-functioning stroke survivors may benefit from a greater proportion of task practice, whilst higher hand-functioning stroke survivors may benefit from a greater proportion of functional practice. A moderate correlation was also found between increased training time and increased change of log of WMFT in females ( $n=34$ ,  $r=0.43$ ,  $p=0.01$ ) but not in males (Wolf et al., 2007), indicating a greater training time may benefit female, but not male stroke survivors. These analyses highlight the importance of having the knowledge to be able to match the CIMT protocol to a given stroke survivor to achieve the best outcome.

Wolf et al. (2008) also analysed the retention of effect between 12 months and 24 months for high functioning, low functioning, male, female, concordant and discordant sub-groups. They found in all sub-groups there was retention of WMFT performance time, WMFT weight to box task and MAL (AOU and HW), with significant improvements in all groups for WMFT grip strength ( $p \leq 0.02$ ).

There is a limited amount of evidence about who might benefit most from CIMT; this systematic review identifies some gaps in the current evidence-base. There is good evidence that both higher and lower hand-function groups benefit from CIMT, where the lower functioning group have a minimum of  $10^\circ$  active extension in the contralesional wrist, MCP and IP joints of thumb and two additional fingers. There is some evidence, based on one moderate quality study, that the type of training may impact outcome (Wolf et al., 2007) and that functioning level, gender or concordance does not affect retention of gains from CIMT (Wolf et al., 2008), but there is very limited evidence about the impact of unilateral spatial neglect and sensory loss on those gains.

#### **3.4.4 Robustness of synthesis**

The review retrieved 19 papers, reporting 13 original studies. The use of the scoping search to inform the decision to use a narrative synthesis was a strength of this study. As anticipated, the protocols in the retrieved studies could not be compared directly as they reported 11 different CIMT protocols; however, where possible, the information has been synthesised to draw conclusions as recommended when undertaking a narrative synthesis (Centre for Reviews and Dissemination, 2009).

The majority of the included studies were of moderate or good quality. Whilst there were some potential risks to validity in the included studies, attempts were made to be transparent in the weighting given to each piece of evidence, based on the assessment of potential risk.

The synthesis was completed utilising both an established framework (Popay et al., 2006), and the research questions identified in 3.1.2. Within this synthesis, the findings of the studies have been reported in the context of the quality of the studies to provide an overall summary of the findings and to indicate the level of confidence that can be attributed to these findings.

### **3.5 Discussion**

This systematic review addressed two aspects identified in the PARIHS analysis under the 'Evidence' element. Firstly it critically reviewed the evidence relating to the effectiveness of CIMT in sub-acute stroke, and the range of CIMT protocols reported in these primary studies. Secondly it summarised what is known about different responses to CIMT in sub-acute stroke survivors. Each of these is discussed in more depth below.

### 3.5.1 Effectiveness of CIMT in sub-acute phase of stroke

In line with findings from previous systematic reviews of studies across the phases post-stroke (Peurala et al., 2012; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012), this review found evidence that CIMT protocols (both original and modified) increase UL function in sub-acute (14 days to nine months post-stroke) stroke, with all included studies finding some evidence of benefit, although not all studies found a between group difference. Sub-group analyses in previous systematic reviews were limited by small numbers and therefore conclusions could not be drawn on the effect of CIMT in the sub-acute phase of stroke. This current review suggests that CIMT has a role in sub-acute rehabilitation, but as with the previous systematic reviews (Corbetta et al., 2010; Nijland et al., 2011; Peurala et al., 2012; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012) the included studies were heterogeneous with variations in CIMT protocol, comparison group and outcomes.

Previous reviews (Corbetta et al., 2010; Nijland et al., 2011; Peurala et al., 2012; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012) have used meta-analyses to combine results; however, in this review, a narrative synthesis was selected in order to further explore the findings with respect to the CIMT protocols. The variation of protocols highlighted by the synthesis meant that studies that could not be easily compared or the findings assimilated. None of the included studies compared protocols to establish if one protocol is more effective than another. As identified in Chapter 2, a previous study (Sterr et al., 2002a) compared a three hour and six hour training CIMT protocol in chronic stroke participants, and found both groups attained an improved MAL at post-treatment. A training by time interaction indicated significantly better MAL for the six hour group compared to the three hour group (AOU:  $F_{6,66}=2.8$ ,  $p<0.5$ ; QOM:  $F_{6,66}=2.6$ ,  $p,0.5$ ). High quality studies that compare different doses of CIMT in the sub-acute phase of stroke are required to clarify the most effective protocols in this early phase of recovery.

CIMT is a complex intervention and by definition (Medical Research Council, 2008) this means it has a number of components that may impact on outcome. The founders of the original CIMT protocol made assumptions that all components were required to gain the best results (Taub et al., 1993); however, studies included in this review indicate that all components may not be required in the sub-acute phase of stroke, with several studies (Brogårdh et al., 2009; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Treger et al., 2012) finding CIMT with a mitt constraint did not lead to significantly better outcomes than the same training protocol without a constraint.

CIMT was compared to a protocol of equal dose in eight included studies (Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; Myint et al., 2008; Treger et al., 2012; van Delden et al., 2013; Wang et al., 2011). In five of these studies (Brogårdh et al., 2009; Brunner et al., 2012; Hammer & Lindmark, 2009a; Krawczyk et al., 2012; van Delden et al., 2013), both the intervention and comparison groups improved, and the difference between the groups was not significant. As there was no control group it was not possible to say that this gain was greater than the natural recovery expected in the first months following stroke. Other studies, however, indicate that CIMT is better than customary care (Atteya, 2004; Page et al., 2002b; Page et al., 2001; Wang et al., 2011; Wolf et al., 2006) and no therapy (Atteya, 2004; Page et al., 2002b; Page et al., 2001), so it is likely that, in studies where gains are made in both a CIMT and an equal dose comparison group, these gains are greater than natural recovery.

#### **3.5.1.1 Describing CIMT**

Medical Research Council guidance (Medical Research Council, 2008) recognises that to evaluate complex interventions there is first a need to be able to describe the intervention. As established in Chapter 2, rehabilitation interventions should be described through a number of concepts. Intensity of therapy can be considered the number of hours per day, and frequency, the number

of therapy days per week (Keith, 1997; Pomeroy et al., 2011). Duration is the number of weeks over which the therapy is given (Keith, 1997; Pomeroy et al., 2011). Dose can be considered to encompass intensity, frequency and duration, in this way a daily, weekly or total dose can be described. A three hour therapy session for five days a week over two weeks is a daily dose of three hours, a weekly dose of 15 hours and a total dose of 30 hours. It is important to recognise that CIMT comprises a dose of both the training and constraint components, although the duration is usually the same for both components.

Keith (1997) also identified the concept of ‘purity’ which attempts to describe how well the designated protocol is followed. Purity, or fidelity as it is often termed (Dumas et al., 2001; Medical Research Council, 2008), requires that the components of an intervention are comparable in the manner it is provided for all participants (Dumas et al., 2001). This is important, as without fidelity of an intervention, the internal validity may be compromised (Dumas et al., 2001); significant effects may be due to unknown variables (Dumas et al., 2001), or non-significant effects the result of the intervention being effective in some forms but not others, so that an averaging of the effect occurs. Fidelity of an intervention is also important for replication and dissemination (Dumas et al., 2001; Medical Research Council, 2008). It is not possible to establish if a CIMT protocol has been adhered to unless the protocol can be described and standardised.

Standardising CIMT requires more than a description of the dose; it must also identify the type of training, the type and timing of feedback, the type of constraint, whether a wearing contract will be agreed and the expectations when wearing the constraint, for example undertaking additional practice. There is also evidence that, in addition to the training and constraint components of CIMT, some researchers are starting to consider whether a ‘transfer package’ facilitates better transfer of activity into everyday life (Gauthier et al., 2008; Takebayashi et al., 2013). These

transfer packages are provided as part of the CIMT protocol and include: monitoring the use of the contralesional UL; encouraging the use of the contralesional UL outside therapy; and advice and assistive devices. Takebayashi et al. (2013) found a 'transfer package' group, compared to a 'no transfer package' group, maintained gains at six month follow-up in a sample of 21 chronic stroke survivors. Whilst this small RCT was not sufficiently powered to have confidence in the findings, it does suggest that additional elements may have the potential to increase long-term activity and also merit further investigation.

In addition to the complexity of describing CIMT, there is often also a lack of consistency in comparison intervention. Some studies compared CIMT to customary care, while other studies compared CIMT to a different intervention. To further study the effectiveness of CIMT there needs to be a means to describe the interventions. A number of studies have developed occupational therapy and physiotherapy treatment schedules for this purpose (Donaldson et al., 2009; Hunter et al., 2006; Jarvis et al., 2014c; Pomeroy et al., 2005; Tyson & Selley, 2004). Future studies should utilise these to better describe therapy interventions. Once the CIMT intervention and the comparison interventions can be described, it should be possible to test the different components of CIMT and to establish whether it is the content or intensity of the training that is important.

### **3.5.2 Response to CIMT**

This systematic review suggests that therapists should be utilising CIMT for a small group of stroke survivors with specific motor abilities; however, it is not clear which protocols should be implemented. It is difficult to draw conclusions about which sub-groups benefit most from CIMT. There was a paucity of sub-group analysis within the included studies. Well-designed observational studies are required to develop hypotheses about the sub-groups that might

benefit from this intervention. Whilst this review found no evidence that sensory loss, unilateral spatial neglect or concordance impacted outcome, this conclusion is based on small numbers and requires further study. The indication that the type of training may be important for different ability groups (Wolf et al., 2007), alongside the finding from a previous systematic review (Nijland et al., 2011) that low intensity protocols (constraint of less than 90% and less than 3hrs training per day) may be more beneficial than high intensity protocols in early stroke, suggests that further exploration of sub-groups' response to CIMT is warranted.

It is worthy of note that none of studies included in this systematic review were based in the UK. Studies completed outside the UK in the context of a different healthcare service, may not be generalisable to UK stroke services and may potentially impact on response to the intervention. Research into CIMT must be undertaken within the UK; this is particularly important when considering implementation, as the context is recognised as an important influence on any implementation process (Rycroft-Malone, 2004).

### **3.5.3 Context**

This systematic review found no RCTs originating in the UK that compared CIMT to an alternative intervention. This supports the initial PARIHS analysis (Table 2.3) and strengthens the need for UK based studies to inform implementation of CIMT into practice. The context in which an intervention is undertaken may impact on the outcome (Skubik-Peplaski et al., 2015). The health care service may impact on the effectiveness of CIMT, and there may be cultural variations in expectations or approaches to CIMT from either therapists or stroke survivors that may affect the outcome. Any one of these may have an impact on the implementation of CIMT into practice; therefore, for the context of CIMT implementation in a UK stroke service to be understood, studies originating from the UK are essential.

### 3.5.4 Strengths and limitations

This systematic review followed established guidelines and advice was sought from a specialist librarian to develop the search strategy. Independent assessors selected studies, extracted data and assessed quality. The narrative synthesis was underpinned by guidelines (Popay et al., 2006) which provided a structure that increased transparency in reporting the findings in this systematic review. It is, however, possible that additional studies could have been retrieved if the review had not been limited by language, and that bias could have been further reduced by blinding the reviewers to the origins of the studies. The review was also limited by the quality tool used which was adapted from the CONSORT guidelines. Whilst this provided a narrative on quality that was congruent with the study methodology, it may be that this impacted on the reliability of the quality decisions and that a standardised tool may have led to different quality ratings of the individual studies. The narrative analysis was an informative tool for the systematic review questions; however, it is recognised that a meta-analysis may have provided an alternative analysis.

## 3.6 Conclusion

Although the long-term benefits of CIMT are unclear, this systematic review supports previous systematic reviews (Corbetta et al., 2010; Nijland et al., 2011; Peurala et al., 2012; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012) in finding that research evidence indicates that therapists should be utilising CIMT as part of their practice for the group of sub-acute stroke survivors who have some active movement in their hand and wrist. As established in Chapter 1, few stroke therapists have implemented the intervention into their practice. The reasons for this have not been explored, with implementation of this intensive intervention receiving little attention.

The systematic review reported in this chapter identified that there has been limited exploration of the response of sub-groups to CIMT, and that it is not possible to identify which protocols are most effective in sub-acute stroke. Both of these issues need addressing to support the implementation of CIMT

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# Chapter 4

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## Acceptability and Feasibility of CIMT in Sub-acute Stroke: a Systematic Review

Chapter 2 identified the importance of exploring the acceptability and feasibility when evaluating and implementing complex interventions. The purpose of this chapter is to report a systematic review of qualitative evidence, to establish what is known about the acceptability and feasibility of CIMT in sub-acute stroke. The findings from this study will provide the foundations for three implementation studies included within this thesis and additional post-doctoral studies.

### 4.1 Background

Previous systematic reviews of quantitative data indicate that, for a sub-group of stroke survivors, constraint induced movement therapy (CIMT) is effective in increasing function in the contralesional upper limb (Peurala et al., 2012; Sirtori et al., 2009; Stevenson et al., 2012). The previous chapter supplemented this evidence by reporting a systematic review of effectiveness in sub-acute stroke and concluded that, whilst there is evidence that CIMT can improve UL activity and participation, there remain problems with defining the dose of CIMT. Although there is evidence of its effectiveness, CIMT is not routinely provided (McHugh et al., 2013; Pedlow et al., 2014). As identified in Chapter 1, the reasons for this are unknown.

The implementation analysis using the PARIHS, in Chapter 2, identifies there are questions that have not been answered about the use of CIMT use in practice. The PARIHS analysis (2.4), clearly indicates a need to understand stroke survivors' and therapists' qualitative experiences of CIMT, and to identify facilitators and barriers to its implementation into practice. Whilst quantitative data helps understand the effectiveness of an intervention, not all knowledge can be gained through this type of data (Walshe, 2007). As established in Chapter 2, questions about acceptability and feasibility of an intervention require a different approach; the collection of qualitative data is more suited to this purpose. For a complex intervention such as CIMT, these approaches can be complementary and help gain a broader perspective (Taylor, 2007, pp. 88-9). It is important to understand the effectiveness, but if an intervention is not acceptable or feasible it is unlikely to be implemented (Dopson et al., 2002). As no previous systematic review has synthesised qualitative data of CIMT in the sub-acute phase of stroke, the purpose of this study was to address the gap through the question, 'What is known about the acceptability and feasibility of CIMT in the sub-acute phase of stroke?' The research objectives were:

- To critically review the reported experiences of therapists providing CIMT and stroke survivors undertaking CIMT in the sub-acute phase of stroke, through the retrieval and synthesis of published evidence.
- To explore, utilising the critical review of the reported qualitative experiences, therapist and stroke survivor reported facilitators of and barriers to undertaking CIMT in sub-acute stroke.

## 4.2 Methodology

As identified in the previous chapter, systematic reviews "identify, evaluate and summarise the findings of all relevant individual studies" (Centre for Reviews and Dissemination, 2009, p. v) to

allow easy access to the information and to enable consumers to make decisions (Centre for Reviews and Dissemination, 2009; Khan et al., 2011). Systematic reviews have historically analysed quantitative, often RCT evidence (Dixon-Woods et al., 2006, p. 28), but, more recently there has been growing interest in systematic reviews of qualitative findings (Dixon-Woods et al., 2006; Dixon-Woods et al., 2007; Lloyd Jones, 2007a; Lloyd Jones, 2007b). Whilst quantitative meta-analysis aims to bring together studies that address the same research question and then combine the data to increase the statistical power (Lloyd Jones, 2007a; Sim & Wright, 2000, p. 284), a qualitative meta-synthesis of studies usually aims to analyse the findings from the included studies to further develop the concepts or theory of the area of interest (Lloyd Jones, 2007a).

As qualitative systematic reviews are a more recent methodology than the traditional quantitative systematic review, the process is less established, with a number of approaches being adopted (Dixon-Woods et al., 2006; Lloyd Jones, 2007a). The methodology underpinning this work was been guided by established guidelines (Centre for Reviews and Dissemination, 2009), which informed the searching, study selection, quality assessment and data extraction in this review. Whilst reflecting a traditional systematic review methodology, these guidelines recognise that the inclusion of qualitative research may be required where the remit of a review goes beyond effectiveness. As the data was qualitative, a meta-synthesis methodology (Ritchie & Spencer, 1994) was utilised in the interpretation of the data. This methodology was selected as it aligned with a primary qualitative data synthesis methodology recommended by (Dixon-Woods et al., 2006, p.32). It was anticipated that this would give some consistency between the primary synthesis of the included studies through to the meta-synthesis in the studies in the review. The details of these methods are described further in 'Data Extraction' and 'Data Synthesis' (below).

### **4.2.1 Theoretical perspective**

This systematic review maintains the constructivist epistemology described in Chapter 1.

Supported by the work of Meyers et al. (2012), the review assumes that, in order to successfully implement an innovation, it is important to gather evidence about the constructed perceptions of the users of the intervention. By taking this stance in this systematic review, there is an assumption that there will be a variety of perceptions and beliefs about CIMT and that understanding these will assist in the implementation of CIMT into a stroke service.

## **4.3 Methods**

As in the systematic review described in Chapter 3, the process started by summarising the research question in a Population, Intervention, Outcome and Study Design (PIOS) format (Table 4.1). This step is recommended (Khan et al., 2011, p. 10) to assist in refining the research question and developing search terms. Although this review aimed to answer a different question than the systematic review reported in the previous chapter, the search terms were similar. The search strategy in the previous systematic review (Chapter 3) aimed for a high yield (comprehensiveness of the search), accepting that this led to low precision (a high number of studies that would not be relevant); this, alongside the complexity of searching for qualitative data (Cooke et al., 2012) meant that it was appropriate to use the same search for this systematic review that had been used in the review reported in Chapter 3. Only this element of the method was shared with the previous systematic review; all other aspects of the method are specific to this systematic review.

**Table 4.1 PIOS Table for Systematic Review of Qualitative studies**

<b>Research Question: Population, Intervention, Outcomes and Study Design</b>	
<b>Population</b>	<p>Studies with stroke survivor participants who have experienced ischaemic or haemorrhagic stroke</p> <p>Studies whose participants are 18 years or older</p> <p>Studies where the participants are in the sub-acute phase of stroke, defined as more than 14 days and not more than 9 months post-stroke on recruitment to the study</p> <p>Studies of mixed diagnoses, where the outcomes are reported separately for stroke</p> <p>Studies of mixed ages, where the outcomes are reported separately for participants of 18 years or more</p> <p>Studies where participants are mixed phases post-stroke, where the outcomes for the sub-acute phase (as defined above) are reported separately</p>
<b>Intervention</b>	<p>Intervention must include constraint or reduction in use of less affected upper limb and re-training of the more affected upper limb</p> <p>CIMT</p> <p>Modified CIMT or shortened CIMT</p> <p>forced use if it included a training aspect</p>
<b>Outcome</b>	<p>Service-user or caregiver reported acceptability of CIMT</p> <p>Service-user or caregiver experiences of CIMT</p> <p>Therapist experiences in providing CIMT</p> <p>Stroke survivor, caregiver or therapists reported barriers to CIMT</p> <p>Stroke survivor, caregiver or therapists reported facilitators of CIMT</p>
<b>Study Design</b>	<p>Primary research study designs, where qualitative findings have been reported</p>

### **4.3.1 Search strategy**

The search was reported in full in Chapter 3. The computer assisted search and the MeSH and key words are described in Section 3.3.1. The full search is presented in Figure 3.1. The final search was completed on 18th October 2014. The reference list of any included papers were searched for further relevant studies.

### **4.3.2 Study selection**

Primary research studies were included if: participants were stroke survivors of ischaemic or haemorrhagic stroke, 18 years or older, more than 14 days and less than nine months post-stroke on recruitment to the study; CIMT addressed upper limb function, comprised constraint or reduction of use of the ipsilesional UL and re-training of the contralesional UL; qualitative findings reported stroke survivor perspective of experience of receiving CIMT, therapist perspectives of providing CIMT or barriers or facilitators of CIMT; they were published in English language. Studies were excluded if the qualitative findings were only reported as time wearing constraint, time undertaking practice, or a list of activities undertaken, as these were not felt to offer any insights into the experience of undertaking or providing CIMT.

The scoping search found no studies using a purely qualitative methodology, so all study designs were included in this review. This approach was taken to capture any qualitative data, whether from a qualitative study or a predominantly quantitative study with an embedded qualitative element.

The searches were conducted by one researcher (KJ). The retrieved studies were reviewed by two independent reviewers (KJ, EG), who considered the titles, abstracts and, where necessary, the full articles of the retrieved studies to identify those that met the selection criteria. Differences in

opinion were resolved through discussion. Assessors documented a reason for exclusion by allocating a code from a pre-determined ranked exclusion criteria list (Appendix 7).

### **4.3.3 Quality assessment**

Each of the studies that met the inclusion criteria were assessed for quality by two independent assessors (KJ, EG).

A scoping search had indicated that the studies included in this review were likely to comprise a variety of research designs. As this systematic review was concerned with the qualitative data in the studies, the McMaster Critical Review Form for Qualitative Studies (Letts et al., 2007a; Letts et al., 2007b) was used to assess the quality of the findings. This tool was designed specifically for use with qualitative studies and had an advantage over other qualitative study review tools (Long & Godfrey, 2004; Popay et al., 1998; Spencer et al., 2003) in that it was designed by OTs, and reflected the professional perspective outlined in Chapter 1. This tool provided a framework to assess the credibility of any qualitative findings.

For each study, the assessors independently considered the rigour and overall trustworthiness of the research (Letts et al., 2007a; Lincoln & Guba, 1985); this included assessing the credibility (steps taken to ensure the findings described reflect the phenomenon under investigation), transferability (steps taken to enable the assessor to make a judgement about whether the findings can be transferred to another setting), confirmability (steps taken to be open about, and responsive to, influences that might impact on the findings) and dependability (steps taken to ensure consistency between the data and the findings) (Lincoln & Guba, 1985). Supported by an established quality tool and guidelines (Letts et al., 2007a; Letts et al., 2007b), five main aspects of quality were considered: clarity and appropriateness of sampling process; clarity of theoretical

perspective; congruency of study design and data collection methods with the theoretical stance; analytical rigour; overall trustworthiness. Based on the reported quality narrative, the assessors made a decision about the overall quality of the study, rating the study as poor, moderate or good quality. A 'good quality' rating was assigned where there were no concerns or minimal concerns in the above areas of the study design; a 'moderate quality' rating was allocated where there were concerns in no more than two of the above areas of study design and a 'poor quality' rating was allocated when there were concerns in three or more areas. Where there was a difference in opinion about the quality, the decision was discussed with reference to these aspects of quality and an agreement reached.

Studies were not excluded based on quality assessment rating, but the findings of the poor quality studies were weighted accordingly in the reporting of the review findings (Centre for Reviews and Dissemination, 2009, p. 53; Dixon-Woods et al., 2006, p. 35).

#### **4.3.4 Data extraction**

The data were extracted into a piloted, structured data extraction form (Appendix 5). Two independent assessors (KJ, SH), extracted both quantitative and qualitative data into the form. The completed data extraction forms were compared. The assessors met to discuss the data extraction forms. Where there were omissions or queries, the original study was consulted, the data were agreed and summarised in a final data extraction form.

#### **4.3.5 Data synthesis**

There was an underlying assumption that there are factors that impact the acceptability or experience of using CIMT and that it is possible to identify these along with the facilitators and barriers that impact the implementation of CIMT. The aim of the synthesis was to explore these

facilitators and barriers from both therapists and stroke-survivors and to identify any patterns in the data.

A scoping search had indicated a paucity of qualitative methodologies in the CIMT evidence; therefore, a decision was made to select a method of synthesis that would enable the researchers to explore qualitative findings, even if these were embedded in a predominantly quantitative study.

The synthesis reflected the methods developed by Ritchie and Spencer (1994). This four-stage structure facilitated an analysis that was clear and methodical and could be used even where data was limited. As there had been only minimal study of this area previously, '*a priori*' themes were not set. In the first stage of synthesis, there was a process of familiarisation of the data. During this stage, the extracted data, the findings and the quality assessment were summarised in narrative tables. In the second stage, a thematic content analysis (Dixon-Woods et al., 2005) was undertaken; using an iterative process, a preliminary thematic framework was developed. Due to the small amount of qualitative data, an aggregative synthesis, a synthesis that summarises the data (Dixon-Woods et al., 2006), rather than an interpretative synthesis, in which concepts and theories are developed from the data (Dixon-Woods et al., 2006), was undertaken. It is recognised that where data are limited, an aggregative synthesis may be simply an ordered description of the findings (Dixon-Woods et al., 2006).

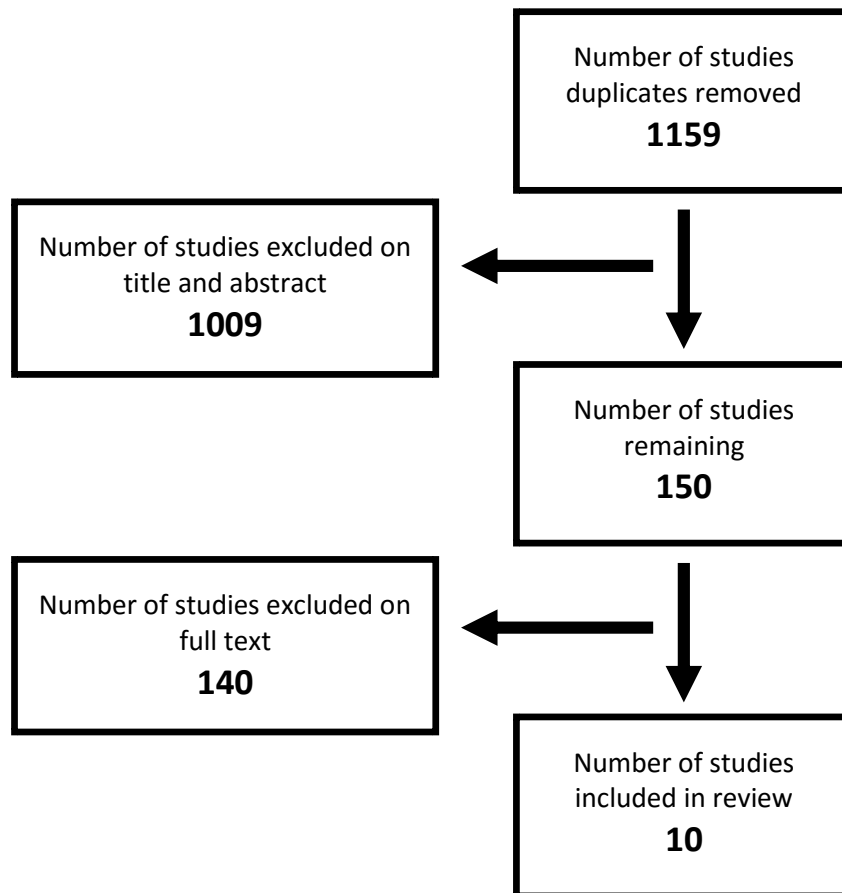
The third stage of this synthesis was a process of indexing, which entailed ensuring all relevant data were represented within the thematic framework. In the fourth stage, charting, the data were reconsidered to ensure they reflected the theme in which they were placed; where this was not the case, the data were moved in the thematic framework. Finally, mapping and interpretation was undertaken in an attempt to understand the experiences of participating in

CIMT and the barriers and facilitators that impact on its use. It was only at this final stage that the emergent thematic framework was considered in respect to the original research objectives and to the PARIHS.

## **4.4 Findings**

After removal of duplicates, the searches retrieved 1159 titles, 1009 of which were excluded on the title and abstract, and 140 were excluded once the full paper had been retrieved and read (Figure 4.1).

The remaining 10 studies were retained for analysis. No additional studies were retrieved from the reference list search. Each excluded paper was allocated an exclusion code for tracking purposes. The number of papers excluded against each code is reported in Appendix 8.

**Fig 4.1 Flow chart of selection process**

A summary of the included studies is shown in Table 4.2. Where a study was included in both this review and the review reported in Chapter 3 the details describing the study appear in both narrative tables for clarity.

Five studies originated from the US (Blanton & Wolf, 1999; Page et al., 2002b; Page et al., 2002c; Page et al., 2001; Thorne, 2009), three from Canada (McCall et al., 2011; Stevenson & Thalman, 2007; Tremblay & Trembley, 2002), one from Hong Kong (Myint et al., 2008) and one from Saudia Arabia (Atteya, 2004). All included studies were quantitative in design; there were four RCTs (Atteya, 2004; Myint et al., 2008; Page et al., 2002b; Page et al., 2001) and six case study designs

(Blanton & Wolf, 1999; McCall et al., 2011; Page et al., 2002c; Stevenson & Thalman, 2007; Thorne, 2009; Tremblay & Trembley, 2002).

Table 4.2 Summary of included studies (qualitative data)

Study Identifier	Design	Sample	Intervention & Control (where appropriate)	Qualitative Data Collection Method	Qualitative Findings
<b>Atteya AAA.</b> <b>Effects of modified constraint induced therapy on upper limb function in subacute stroke patients.</b> <b>Neurosciences, 2004;9(1):24-9.</b>	Prospective randomised pre-test, post-test controlled trial comparing CIMT, traditional therapy and control intervention at post-intervention N=6 n=2 CIMT group n=2 traditional therapy group n=2 control group	Ischaemic stroke 4 weeks - 6 months ago, 18 - 75 yrs, discharged from rehabilitation, able to actively extend the metacarpophalangeal (MCP) and interphalangeal (IP) joints 10°, able to actively extend the wrist 20° Exclusions included: significant cognitive impairment <70 on the Modified Mini Mental Status Examination, significant spasticity ≥2 on Modified Ashworth Spasticity Scale, significant pain in the affected upper limb ≥4 on a Visual Analog Scale	CIMT: ½ hour PT and ½ hour OT (outpatient) 3 times per week for 10 weeks. In addition, CIMT participants chose 2 functional tasks from WMFT and practiced these as part of therapy. Shaping used. Ipsilesional UL restrained with a sling and mitt for 5 hours each weekday Traditional Therapy: ½ hour PT and ½ hour OT (outpatient) 3 times per week for 10 weeks. Control: No therapy over the 10 weeks	In-clinic interview every 2 weeks and informal interviews at home with participants (by researcher). No additional detail given.	In-clinic interview indicated high satisfaction with protocol, no formal reporting of this finding. Therapists reported that protocol was easy to administer, no formal reporting of this finding.
<b>Blanton S, Wolf SL.</b> <b>An application of upper-extremity constraint-induced</b>	Case report N=1	3 to 7 months since stroke; ≥18 yrs; able to actively extend the contralesional wrist greater than 10°, actively extend the metacarpophalangeal (MCP) and interphalangeal (IP) joints	Mitt on ipsilesional hand for all waking hours except water-based activities for 14 day treatment period. Each weekday (10 days) 6 hours of supervised activities (selected with participant). Kept a log	No details given	Reported tiring of wearing the mitt, difficulty with full adherence at home Fatigue after being in clinic and tempted to 'cheat'

<p><b>movement therapy in a patient with subacute stroke.</b></p> <p><b>Physical Therapy 1999;79(9):847-53.</b></p>	<p>of the thumb and at least 2 additional digits 10°, passive range of motion of at least 90° shoulder flexion and abduction, 45° shoulder lateral (external) rotation, no more than 230° elbow extension, 45° of forearm supination and pronation, wrist extension to neutral, and finger extension (all digits) with no greater than 30° of flexion contracture at the MCP and IP joints; at least 24/30 on the Folstein Mini-Mental State Examination; able to independently and safely transfer to and from the toilet, stand from a sitting position, and maintain standing balance for 2 minutes</p>	<p>of activities when away from the rehab facility. Behaviour contract</p>		<p>Caregiver reported 'like a different woman' more attention to appearance, interacting socially and driving again.</p>
<p><b>McCall M, McEwen S, Colantonio A, Steiner D, Dawson, DR. Modified constraint-induced movement therapy for elderly clients with sub-acute stroke. The American</b></p>	<p>Interrupted time series, at least 4 before and after measurements for each participant.</p> <p>Non-blinded</p> <p>N=4</p>	<p>Inclusion criteria: ≥65 yrs old, ischaemic or haemorrhagic stroke confirmed by CT or MRI, able to complete at least one UL task at stage 3 on the Chedoke-McMaster Stroke Assessment Impairment Inventory</p> <p>Exclusion criteria: rapidly improving motor function, hemispatial neglect as &gt;10 errors on Bells Test, successful completion of CMII (stage 7)</p>	<p>10 days of UL training. Massed practice sessions of 2 hrs, 5 days per week for 2 weeks. Participants wore a mitt on ipsilesional UL during these 2 hours and an additional 4 hrs. Totalling 6hrs of mitt wearing. Training mainly shaping, task selection depended on participants functional goals identified on COPM. Each training session consisted of three elements motor tasks related to goal, goals specific functional tasks, other functional tasks. Therapists tried to motivate</p>	<p>No details given</p> <p>None of the participants wore the mitt outside of the treatment period. They reported that it was too difficult to manage around the home when wearing the mitt or that they were frustrated wearing the mitt to complete tasks.</p>

<b>Journal of Occupational Therapy 2011; 65(4): 409-418.</b>		4 participants 2 female; 43-81 days post-stroke Age range: 71-91	participants to improve performance, provided feedback (eg time taken to complete task, or repetitions). Each task repeated 6-10 times. Bimanual tasks, sometimes modified with researcher becoming second hand.		
<b>Myint JMW, Yuen GFC, Yu TKK, Kng CPL, Wong AMY, Chow KKC, Li HCK, Wong CP.</b>  <b>A study of constraint-induced movement therapy in subacute stroke patients in Hong Kong.</b>  <b>Clinical Rehabilitation 2008;22(2):112-24.</b>	Prospective, single-blind randomised controlled trial Comparing CIMT and control intervention at post-intervention and 12 weeks follow-up N=48 Intervention group=28 Control group=20	2-16 weeks after stroke, functional level 3 (functional test for hemiparetic upper extremity), minimal movement of 20° wrist ext and 10° all digits, cantonese version of MMSE score of 17 or above, able to walk with or without equipment  Exclusion criteria: severe aphasia, high risk of fall, cerebellar stroke, severe shoulder pain	CIMT: 10 days of UL training by OT, 4 hours training, 5 days per week, 2 weeks. ipsilesional arm restrained in a shoulder sling. Contract to wear sling for 90% of waking hours during 10 day treatment (except, bathing, toileting or if a was risk of falling). Training incorporated shaping and provision of error information. Therapist used sets of tasks relating to participants ADLs  Conventional therapy (OT and PT): 4 hours therapy, 5 days per week, 2 weeks. Therapy included neurodevelopmental techniques, bimanual tasks, compensatory techniques for ADLs, strength and motion, positioning and mobility training.	No details given	One incidence of exacerbation of shoulder pain 4 weeks after CIMT in one participant who reported shoulder pain prior to commencing CIMT
<b>Page, S., Sisto, S., Levine, P., Johnston, M., &amp; Hughes, M.</b>  <b>Modified constraint induced therapy: a</b>	Multiple baseline, single-blind randomised pretest, posttest control group design, comparing CIMT, traditional therapy and	Able to extend $\geq 10^\circ$ at the metacarpophalangeal and interphalangeal joints and $20^\circ$ at the wrist (the focal criterion), stroke 4 weeks-6 months prior to enrolment, $\geq 70$ on the Modified Mini Mental Status Examination, no hemorrhagic or bilateral	CIMT and traditional therapy groups: $\frac{1}{2}$ hr OT & $\frac{1}{2}$ hr PT 3 times a week for 10 weeks. OT and PT focussed on neuromuscular facilitation (PNF) with emphasis on ADL where possible, this comprised 80% of time (24 mins) and compensatory techniques (tasks with ipsilesional arm, including	In-clinic interviews every 2-3 weeks and weekly telephone calls to participant's home.  Informal interviews with participating therapists	Adherence to the sling wear schedule by patients in the CIT group was supported by interviews and weekly telephone calls.

<b>randomized feasibility and efficacy study.</b>  <b>Journal of Rehabilitation Research and Development, 2001, 38(5), 583-590.</b>	control intervention at post-intervention  N=6  CIMT group (n=2)  Traditional therapy (n=2)  No therapy (n=2)	lesions, 18 – 95 yrs, no excessive spasticity (defined as $\geq 2$ on the Modified Ashworth Spasticity Scale), no excessive pain in the affected upper limb (defined as $\geq 4$ or higher on a Visual Analogue Scale)	helping contralesional arm when required) 20% of time (6 mins)  CIMT group: During the 10 weeks ipsilesional arm was restrained 5 days a week for 5 hours identified as frequent use. Using cotton sling supporting elbow and forearm. Hand in a mesh polystyrene filled mitt (Sammons-Preston). Also identified 2 tasks from WMFT. Both tasks practiced for at least 5 minutes within therapy sessions with shaping. Not clear if this is in addition to $\frac{1}{2}$ hour or part of $\frac{1}{2}$ hour  Control group: No therapy	No further details given	Informal interviews revealed high satisfaction with the protocol  Informal interviews with CIMT participants revealed a positive transfer of skills learned in rehabilitation to ADLs, eg enrolment in driver rehabilitation program, cooking playing grandchildren, return to work. Also improvements in relationship with family.  Therapists found protocol easy to administer.
<b>Page, S., Sisto, S., Johnston, M., Levine, P., &amp; Hughes, M.</b>  <b>Modified constraint-induced therapy in subacute stroke: a case report.</b>  <b>Archives of Physical Medicine and Rehabilitation, 2002, 83(2), 286-290.</b>	Case report with blinded assessor  Comparing at effect of CIMT on one person from baseline to post-intervention  N=1	Able to actively extend $\geq 10^\circ$ at the metacarpophalangeal and interphalangeal joint of thumb and 2 other digits and $10^\circ$ at the wrist, stroke 4 weeks-6 months prior to enrolment, $\geq 70$ on the Modified Mini Mental Status Examination, no haemorrhagic or bilateral lesions, 18 – 95 yrs, no excessive spasticity (defined as $\geq 2$ on the Modified Ashworth Spasticity Scale), no excessive pain in the affected upper limb (defined as $\geq 4$ or higher on a Visual Analogue Scale)	$\frac{1}{2}$ hr OT & $\frac{1}{2}$ hr PT 3 times a week for 10 weeks. OT and PT focussed on neuromuscular facilitation (PNF) with emphasis on ADL where possible (80%) and compensatory techniques ie tasks with ipsilesional arm, including helping affected arm when required (20%). OT PNF mainly focused on functional tasks (eg writing, opening containers, folding clothes, hanging a coat) with some wrist and arm strengthening. PT PNF mainly focused on UL strengthening, dynamic stand and balance activities and gait training. Participant also identified 2 tasks from WMFT. Both tasks practiced for at least 5 minutes within therapy sessions with shaping. Not clear if this is in addition to $\frac{1}{2}$ hour or part of $\frac{1}{2}$ hour. During the 10	In-clinic interviews every 2-3 weeks and weekly telephone calls to participant's home. No further details given	Participant reported performing ADLs that were not previously possible including meal preparation with min assistance, telephone use, grooming, eating with minimal assistance and dressing with minimal assistance.  Interviews and telephone calls indicated adherence to sling wearing schedule.

			weeks uninvolved arm was restrained 5 days a week for 5 hours identified as frequent use. Using cotton sling supporting elbow and forearm. Hand in a mesh polystyrene filled mitt (Sammons-Preston)		
<b>Page, S., Sisto, S., Johnston, M., &amp; Levine, P.</b>  <b>Modified constraint-induced therapy after subacute stroke: a preliminary study.</b>  <b>Neurorehabilitation and Neural Repair, 2002, 16(3), 290-295.</b>	Prospective, single-blind, multiple pre-test, post-test, randomized clinical trial  Comparing CIMT, traditional therapy and control intervention at post-intervention  N=14 mCIT group =4  Traditional therapy=5  No therapy=5	Able to extend $\geq 10^\circ$ at the metacarpophalangeal and interphalangeal joints and $20^\circ$ at the wrist, stroke 4 weeks-6 months prior to enrolment, $\geq 70$ on the Modified Mini Mental Status Examination, no haemorrhagic or bilateral lesions, 18 – 95 yrs, no excessive spasticity (defined as $\geq 2$ on the Modified Ashworth Spasticity Scale), no excessive pain in the affected upper limb (defined as $\geq 4$ or higher on a Visual Analogue Scale)	CIMT group: $\frac{1}{2}$ hr OT & $\frac{1}{2}$ hr PT 3 times a week for 10 weeks. OT mainly focused on functional tasks (eg writing, opening containers, folding clothes) with some wrist and arm strengthening. PT mainly focused on UL stretching, dynamic stand and balance activities and gait training. During the 10 weeks the ipsilesional arm was restrained 5 days a week for 5 hours identified as frequent use. Using cotton sling supporting elbow and forearm. Hand in a mesh polystyrene filled mitt (Sammons-Preston). Also identified 2 tasks from WMFT. Both tasks practiced for at least 5 minutes during OT sessions with shaping. Not clear if this is in addition to $\frac{1}{2}$ hour or part of $\frac{1}{2}$ hour.  Traditional therapy: $\frac{1}{2}$ hr OT & $\frac{1}{2}$ hr PT 3 times a week for 10 weeks. OT and PT focussed on neuromuscular facilitation (PNF 25 mins) and compensatory techniques taught (5 mins)  Control group: No therapy	Informal in-clinic interviews	Informal interviews indicated high satisfaction with protocol  CIMT participants reported transfer to of abilities to tasks eg opening cans, loading laundry, pouring liquids, assembling puzzles, and playing the piano.

<b>Stevenson T, Thalman L.</b>  <b>A modified constraint-induced movement therapy regimen for individuals with upper extremity hemiplegia.</b>  <b>Canadian Journal of Occupational Therapy 2007;74(2):115-24.</b>	<p>Two single case studies</p> <p>Exploration of modified CIMT in 2 individuals</p> <p>Two N=1 studies</p>	<p>Residual deficits in upper limb function from stroke or traumatic brain injury, living in the community, willing to comply with the programme, sensorimotor ability must be sufficient to allow the more involved limb to pick up an empty water glass at waist height, raise it to a table positioned approximately 20 cm higher towards the more involved side, and then release it.</p>	<p>Intervention took place in groups of 2-3 in workshop in hospital. 4 hours a day, for 5 days a week for 2 weeks. Two types of tasks were performed: 1. circuit tasks-tasks selected based on relevance to person and demands of task. Each task performed for 10 minutes with 10 minute rest each hour. 2. goal specific tasks. Clinician modified tasks to provide challenge, also may provide verbal and tactile input</p> <p>4 hours included 30 mins talking as a group about previous session and 30 mins for lunch, although this was seen as a training opportunity. Mitt worn for 90% of waking hours. Could remove if felt at risk of injury, or for toileting, washing, and eating, Homework given and log of wearing time and performance of homework is recorded by participant.</p>	<p>No details given</p>	<p>Both participants reported fatigue.</p> <p>Impact on a pre-existing back pain discussed, tasks adapted, so that they could be performed in sitting or standing to prevent long periods in one position, and with hot packs, participant reported pain got no worse.</p> <p>Both reported increased use of UL and improved ability to perform tasks with contralesional UL</p> <p>Participant 2 did not wear restraint for required no. of hours due to responsibilities at home</p> <p>Participant 2 required a splint on contralesional UL to allow successful attempts in tasks</p>
<b>Thorne AJ.</b>  <b>Early use of constraint induced therapy (CIT) following a CVA: a case study examining this</b>	<p>Case study to examine the use of CIMT in an acute rehabilitation setting</p> <p>N=1</p>	<p>Inclusion criteria: admitted to rehab unit for therapy, medically stable, orientated to time, place &amp; person, able to follow commands of 3 components, manual muscle test score of 2/5 in wrist extension on hemiparetic</p>	<p>CIMT commenced 3 weeks post-stroke.</p> <p>First week (at hospital). Ipsilesional arm restrained in lace-up mitt for at least 80% of waking hours (not used when walking and for some tasks such as eating where task was considered too frustrating with mitt applied). Daily therapy for 4 hrs each</p>	<p>No details given</p>	<p>Reported less reliance on less affected limb by participant, family and therapist</p>

<p><b>treatment during the acute rehabilitation phase of recovery.</b></p> <p><b>Acute Care Perspectives 2009;18(1):12-8.</b></p>		<p>side, ability to understand, accept, decline CIMT</p> <p>Participant:</p> <p>69yr old male, multiple lacunar infarcts in left basal ganglia, right-sided hemiparesis and dysarthria, decreased proprioception and touch sensation on right side, mobilized with stick and ankle orthosis with assistance from therapist. Motivated to gain functional recovery.</p>	<p>day (not clear if this is 5 or 7 days)</p> <p>Comprised intensive physical, occupational and speech therapy. Therapy included eating, weight-bearing and electrical stimulation.</p> <p>Second week (at home following discharge). Participant and spouse trained to continue CIMT.</p>		
<p><b>Tremblay F, Tremblay LE.</b></p> <p><b>Constraint-induced movement therapy: evidence for its applicability in the context of a home rehabilitation intervention for sub-acute stroke.</b></p> <p><b>Physiotherapy Canada 2002; 54(2):116.</b></p>	<p>Two single case studies to explore a CIMT home-based intervention in 2 participants</p> <p>Two N=1 studies</p>	<p>Selected from a case load in out-patient department</p>	<p>Home intervention programme over 2 weeks. Morning and afternoon sessions of 2 hours each. Partial restriction of movement of less affected arm with a mitt for the 14 days (excluding time for personal hygiene). Functional tasks and ROM exercises.</p> <p>Participant 1 worked on tasks which involved reach and grasp and functional tasks, where participant 2 worked mainly on tasks focused on proximal joints including strength and ROM, included practice grasping balls of different sizes</p>	<p>Both participants were visited every 2 days during intervention to review compliance and treatment programme. No further details given</p>	<p>Good compliance reported.</p> <p>Participant 1 reported some discomfort in affected shoulder after a few days, but this was reduced by 'correcting posture to perform tasks'</p>

None of the qualitative findings were underpinned with an appropriate theoretical perspective or study design. The procedures for the collection and analysis of data in the included studies were not transparent; this lack of rigour negatively impacted on the credibility of the findings. For these reasons all studies were rated as of poor quality. The details are summarised in Table 4.3.

The extracted data did not provide a comprehensive picture of the experience of providing and receiving CIMT in the sub-acute phase of stroke. The limited amount of information presented in the 'Qualitative Findings' column in Table 4.2 reflects the detail provided in the included studies.

All 10 included studies reported some qualitative findings from at least one stroke survivor. In some instances, it was not possible to identify the number of stroke survivors to which the statements referred (Atteya, 2004; Myint et al., 2008; Page et al., 2002b; Page et al., 2001). Only two studies reported therapist experience (Atteya, 2004; Page et al., 2001).

Although the analytical process stated in the Method was undertaken, due to the lack of data, the third stage was a simple checking process and the fourth stage did not involve any movement between the themes. These analyses led to three very sparsely populated themes: satisfaction, benefits and potential risks. These themes are summarised in Figure 4.2.

Table 4.3 Summary of quality assessment

Study	Study Design and Study Objective	Sampling Procedures	Theoretical Perspective	Collection of Qualitative Data	Analytical Rigour	Overall Trustworthiness of Qualitative Findings	Overall Quality of Qualitative Findings
Atteya (2004) Effects of modified constraint induced therapy on upper limb function in subacute patients	Prospective RCT  To examine the feasibility and efficacy of a modified constraint induced therapy protocol on stroke patients	N=6 Sample from a medical unit in Saudi Arabia Not clear how sample was selected.  Selection criteria provided.	No details given	In-clinic interviews every 2 weeks and informal interview (home visit) by researcher	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
Blanton, Wolf (1999) An application of upper-extremity CIMT in a patient with sub-acute stroke	Case study  To demonstrate the application of CIMT with an individual with upper-extremity hemiparesis 4 months after stroke.  Objective implies bias	N=1 Not clear how participant was selected  Selection criteria provided	No details given	Not stated	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
McCall, McEwen, Colantonio, Streiner, Dawson (2011)	Interrupted time series-before and after measurements To determine whether CIMT had an	N=4  Sample from 2 rehabilitation units in Toronto. Not	No details given	Not clearly stated, but appeared to be participant	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability,	Poor

Modified constraint-induced movement therapy for elderly clients with subacute stroke	effect greater than that of natural recovery on the participation, activity and impairment of the hemiplegic arm and hand in elderly people after a stroke.	clear how participant was selected		reflections on activity log		dependability or transferability	
Myint, Yuen, Yu, Kng, Wong, Chow, Li, Wong (2008) A study of constraint induced movement therapy in subacute patients in Hong Kong	Prospective RCT  To investigate the beneficial effect of CIMT in improving the function of hemiplegic upper extremity in early subacute stroke patients.  Objective implies bias	N=48  Sample from consecutively admitted patients from one hospital in Hong Kong. Two other hospitals also referred patients. Selection unclear.  Selection criteria provided.	No details given	Not stated	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
Page, Sisto, Levine, Johnston, Hughes (2001) Modified constraint induced therapy: a randomized feasibility and efficacy study.	Multiple baseline randomised controlled case series  To determine the feasibility and efficacy of a modified Constraint induced therapy protocol.	N=6  Recruitment letters sent out to service users discharged from out-patient therapy from four hospitals-no other information Selection criteria provided.	No details given	Informal interviews every 2-3 weeks and weekly telephone calls. Information corroborated with each participant's caregiver. Informal interviews with	Qualitative data analysis not described	No evidence of actions to address confirmability, dependability or transferability. Credibility addressed by gaining corroboration of data collected from caregiver	Poor

				participating therapists			
Page, Sisto, Johnston, Levine, Hughes (2002) Modified CIT in sub-acute stroke: a case report	Multiple baseline, before-after case report.  To determine the efficacy of a modified CIT protocol administered to a patient with subacute stroke	N=1 Recruitment letters sent out to service users discharged from out-patient therapy. Participant was one of two respondents  Inclusion/exclusion criteria provided.	No details given	Informal interviews every 2-3 weeks and weekly telephone calls	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
Page, Sisto, Johnston, Levine (2002) Modified CIT after subacute stroke: a preliminary study.	Prospective multiple baseline, before-after randomised clinical trial.  To determine the efficacy of a modified CIT protocol administered to patients with subacute stroke.	N=14 Recruitment through advertisement-no other information  Selection criteria provided.	No details given	Informal in-clinic interviews	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
Stevenson, Thalman (2007) A modified CIMT regimen for individuals with upper extremity hemiplegia	Case study design  To describe a modified version of CIMT	N=2  Not clear how participants were selected, although inclusion/exclusion criteria were provided.  Two different case studies presented	No details given	Not stated	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor

		which supports a qualitative methodology					
Thorne (2009) Early use of constraint induced therapy (CIT) following a CVA: a case study examining this treatment during the acute rehabilitation phase of recovery	Case study  Objective not clearly stated.  Examines a patient who has experienced CIMT and offers a discussion of the challenges faced in clinic	N=1  Not clear how participant were selected. No inclusion/exclusion criteria	No details given	Not stated	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor
Tremblay, Tremblay (2002) Constraint-induced movement therapy: evidence for its applicability in the context of a home rehabilitation intervention for sub-acute stroke	Case study design  To describe observations on two patients in the sub-acute phase after stroke, in whom CI therapy was applied in the context of a home rehabilitation intervention.	N=2  participants were selected, but not clear how participants were selected	No details given	Not stated	Qualitative data analysis not described	No evidence of actions to address credibility, confirmability, dependability or transferability	Poor

**Fig 4.2 Emergent themes and corresponding evidence****Satisfaction with the CIMT Protocol**

- Three studies indicated high participant satisfaction with a 10 week CIMT protocol (Atteya, 2004; Page et al., 2002b; Page et al., 2001)
- One study reported that therapists found the 10 week protocol easy to administer (Atteya, 2004)
- Studies found participants complied with five hour constraint (Page et al., 2001) and four hours training and partial constraint for time excluding personal care (Tremblay & Trembley, 2002)

**Benefits of CIMT**

- Five studies encompassing a variety of protocols reported qualitative descriptions of participants' increased ability to undertake valued activities of daily living, four of these reports were from the stroke survivor (Page et al., 2002b; Page et al., 2002c; Page et al., 2001; Stevenson & Thalman, 2007) and one was from a caregiver (Blanton & Wolf, 1999)
- One study reported less reliance on the ipsilesional UL following four hour training combined with constraint of at least 80% of waking hours (Thorne, 2009)
- Two studies described psychosocial benefits through increased social interaction (Blanton) and improved relationship with family (Page et al., 2001)

**Potential Risks and Barriers**

- Studies found participants fatigued after a six hour training protocol (Blanton & Wolf, 1999) and a four hour training protocol (Stevenson & Thalman, 2007)
- One participant found the fatigue they experienced in wearing mitt impacted on full adherence to protocol at home (Blanton & Wolf, 1999)
- Studies found a potential for protocols to increase back (Stevenson & Thalman, 2007) and shoulder (Myint et al., 2008; Tremblay & Trembley, 2002) pain. Although there was evidence that the pain might be controlled through adapting the training (Stevenson & Thalman, 2007; Tremblay & Trembley, 2002) and pain relief measures (Stevenson & Thalman, 2007).
- One study indicated participants reduced the four hour constraint wearing time to undertake bimanual tasks at home (McCall et al., 2011) and one participant did not wear constraint for the required 90% of waking hours due to responsibilities at home (Stevenson & Thalman, 2007)
- One study reported an initial inability to undertake the training with the contralesional hand which was resolved with additional support in the form of a splint to hold the contralesional hand in a position that facilitated function (Stevenson & Thalman, 2007)

Evidence to address the first review objective, to critically review the reported experiences of therapists providing CIMT and stroke survivors undertaking CIMT in the sub-acute phase of stroke, crossed all three themes: satisfaction with the CIMT protocol; benefits in CIMT; and potential risks and barriers. Evidence indicated that some participants could adhere to the protocol, whilst others found this difficult. There was not enough detail in the studies to identify the reasons for non-adherence. A number of findings indicated stroke survivor satisfaction with the protocol, although some potential risks, fatigue and pain, were also identified. As in-depth data were not available, and the quality of the findings was poor, it was not possible to draw conclusions about which stroke survivors are likely to encounter difficulties with a CIMT protocol, and those who are not. Therapist evaluation was present only in the 'satisfaction with CIMT protocol' theme. Findings from the two studies (Atteya, 2004; Page et al., 2001), indicated that the 10 week protocol was easy to administer, but no further findings or additional detail were available to address the first review objective.

In order to address the second objective, to explore therapist and stroke survivor reported facilitators of and barriers to undertaking CIMT, a few barriers were identified in the 'potential risks and barriers' theme: pain, fatigue, additional support required for the contralesional UL to undertake training, inability to undertake full constraint wearing schedule due to responsibilities at home, and challenges in undertaking bimanual tasks. Facilitators of CIMT could not be easily identified from the data, although the successful outcomes documented in the Benefits of CIMT theme may be a facilitator. Due to the methodological flaws in the included study designs, it is unlikely that this is a definitive list of barriers and facilitators.

## 4.5 Discussion

The PARIHS analysis (section 2.4) identified some definable gaps in the CIMT knowledge (see Table 2.3). The aim of this systematic review was to address some of these gaps by synthesising previously reported experiences of receiving and providing CIMT in the sub-acute phase of stroke. The findings from this systematic review have revealed a paucity of good quality evidence; therefore, the resultant synthesis was insufficient to gain a good understanding of the acceptability of CIMT to stroke survivors in the sub-acute phase of stroke or the feasibility of providing CIMT. Furthermore, quality of the included studies did not allow for the confident identification of the barriers to or the facilitators of CIMT.

The study did, however, identify a few areas that require further investigation in order to facilitate the implementation of CIMT. These include the potential of CIMT to increase fatigue and pain, and the challenges of wearing a constraint.

As reported in the previous chapter, fatigue and pain have also been studied in a sub-set of the EXCITE trial (Underwood et al., 2006). Underwood et al. (2006) studied these constructs with quantitative measures. They found no difference in pain between a CIMT group (21 participants) and a traditional therapy group (20 participants) at pre-intervention or post-intervention. Fatigue was found to be significantly greater in the afternoon than in the morning for both groups. Whilst these quantitative measures indicate that pain and fatigue should not be greater for participants undertaking CIMT compared to traditional therapy, these findings were based on small participant numbers. Given findings from the systematic review reported in this chapter, albeit based on research with limited qualitative rigour, indicating that pain and fatigue do occur during CIMT, there is a need to further study the relationship of these constructs to CIMT.

Ploughman and Corbett (2004) and Burns et al. (2007) provide insights into constraint use through their forced-use studies in chronic and sub-acute stroke survivors respectively; as established in Chapter 2, this intervention involves wearing a constraint, but without additional training. Ploughman and Corbett (2004) reported the informal finding that participants were neither frustrated nor uncomfortable while wearing the mitt constraint. Burns (2007) provided further detail through a closed question, subjective evaluation questionnaire completed by 10 participants: nine felt the mitt constraint made them use their hand more, but five were relieved to stop wearing the mitt; six participants found it hard to do things while wearing the mitt, whereas three did not. These forced-use studies support the findings of this systematic review indicating that some stroke survivors seem able to tolerate the constraint wearing schedule, whilst some experience challenges. To date, the factors influencing response to the constraint have not been investigated. It is not clear whether either the level of tolerance or the acceptability is related to the type of constraint, the protocol or other environmental factors such as support at home or personal responsibilities.

The potential barriers identified from this qualitative systematic review can only be a starting point for future research, due to the limited trustworthiness of the qualitative data. The challenge of how to assess quality is well recognised (Centre for Reviews and Dissemination, 2009; Dixon-Woods et al., 2006; Dixon-Woods et al., 2007). It is important to choose an appropriate quality assessment tool that will enable credible and transparent judgements (Centre for Reviews and Dissemination, 2009), and allow opportunities during the review process to discuss and address issues that arise (Dixon-Woods et al., 2006). The assessment of quality was particularly challenging in this study. As the focus of the review was the collection of qualitative data, a qualitative assessment tool was selected; however, all the included studies were quantitative in design with only a small embedded qualitative element. It may be that a quantitative quality assessment tool could be seen as more appropriate; however, the research

team agreed that the decision to use a qualitative assessment tool appropriately reflected the aim and methodology of this systematic review.

It is worthy of note that some studies were included in both this and the previous systematic review (Chapter 3), and have received a different overall quality rating in the two reviews. This is appropriate because in this systematic review the assessment of quality takes into account whether the study uses an appropriate methodology to support the qualitative data presented. The study of qualitative data requires a different study design and methodology than quantitative data. The outcomes of the quality assessment are, therefore, dependent on how well each study meets the criteria of the two differing assessment tools.

Whilst studies were not excluded based on quality, it is worth noting that if Finfgeld's (2003) quality criteria had been adopted, namely that the study must utilise accepted qualitative methods and the findings must be supported by the data, none of the 10 studies would have been included. The decision to include studies that did not meet these criteria was taken during the initial development of the systematic review protocol as no synthesis of this area had previously been undertaken, and it was important to establish the extent of the qualitative evidence.

The selection criteria in this review reflected the study aim by including only studies where the participants had reported experience of CIMT. As discussed in Chapter 2, a previous study (Page et al., 2002a) collected stroke survivor perceptions of CIMT where participants had not participated in CIMT. Of the 208 stroke survivor participants, 68% (n=141) did not think they would participate in CIMT; this was mainly due to length of time wearing constraint and number of hours in therapy. Perceptions of undertaking CIMT may be very different to actually experiencing the intervention; the perceptions themselves may be a barrier to CIMT. It is

important that the experience of undertaking CIMT is understood; only in this way will therapists be able to articulate and address the potential challenges, thereby assisting stroke survivors to make an informed choice about CIMT as an upper limb intervention.

CIMT emerged from the discipline of neuropsychology which has a long and strong tradition in quantitative measurement (Todd et al., 2004, p. 4). The research pathway for CIMT reflects this with very limited qualitative exploration of CIMT. Whilst this review took a constructivist stance, the evidence collected did not give the depth required to fully address the study objectives. All the studies were quantitative in design. None presented a theoretical perspective, nor utilised qualitative data collection or analytical methods. This limited the amount of possible analysis. It is evident that there are gaps in the knowledge base. Building on the PARIHS analysis in Chapter 2, the evidence from the systematic reviews was integrated into the PARIHS framework to provide an up-dated summary and to plan for future studies to further the implementation of CIMT. This summary is presented in the following sections.

## **4.5.1 Summary of evidence using PARIHS**

### **4.5.1.1 Evidence**

There is a substantial amount of quantitative research that has been undertaken, and yet CIMT is not part of routine practice. The current quantitative evidence is well conceived, designed and conducted; however, therapists' views about the use of CIMT and the current evidence are not known. It is, therefore, not possible to establish if these impact on the provision of and engagement with CIMT. Neither therapists' experiences of providing CIMT, nor stroke survivors' experiences of receiving CIMT, have been studied. There has, therefore, been no opportunity to fully explore therapist and stroke survivor views to see if these are congruent. Future qualitative studies need to express the theoretical assumptions on which they are based, and should employ

study designs that are congruent with the theoretical stance, thereby enabling consumers of the evidence to understand what was investigated, and the potential influences on the findings (Creswell, 1998; Grix, 2004).

#### **4.5.1.2 Context**

The studies included in this systematic review all originated outside the UK; the already limited evidence is further limited for UK therapists by the lack of studies based within UK stroke services. When introducing an intervention into practice, the context needs assessing at a local level (Greenhalgh et al., 2005; Rycroft-Malone, 2004). Studies to address the gaps identified in the 'Evidence' section should, therefore, be undertaken in UK stroke services where CIMT may be utilised. It is important to note that, although evidence from one service may be specific to that setting and not directly transferable to another setting, sharing this information may inform implementation at other sites.

#### **4.5.1.3 Facilitation**

There is very limited information about facilitators of this complex and intensive intervention. Previous qualitative studies have successfully identified the facilitators and barriers in other health-related areas (Jaarsma et al., 2015; Kaminsky et al., 2014; Wagstaff, 2005). The phenomenological approach underpinning these studies aimed to understand the lived experience of the area of interest (Creswell, 2009, p. 13) and offered a useful theoretical perspective for future CIMT research. If the evidence indicates CIMT is a desirable intervention, implementation needs to be facilitated and the identified support and advancement of CIMT within the target stroke service must be planned and undertaken.

### 4.5.2 Strengths and limitations

There are a number of strengths to this study. The use of recognised and established guidelines (Centre for Reviews and Dissemination, 2009) directed the systematic review process, and an established method was used to guide the synthesis of the data, which supported the constructivist theoretical stance, underpinning the study. The use of a quality assessment tool designed by therapists for critical appraisal in their practice, promoted both a rigorous process and a professional perspective.

Searching in a qualitative review is more difficult than the traditional systematic review of RCTs, due to the many study designs that comprise qualitative research (Cooke et al., 2012). This review utilised a PIOS based search (Khan et al., 2011), but may have been enhanced by using a search tool designed specifically to retrieve the wide range of qualitative studies such as SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) (Cooke et al., 2012). There is evidence that SPIDER retrieves more qualitative studies than using PIOS (Cooke et al., 2012); however, as the PIOS search strategy was planned to ensure sensitivity (comprehensiveness) was high, it is likely that this will have offset some of the limitations of using PIOS.

The decision to select CRD guidance to underpin the review in order to align it with the systematic review reported in Chapter 3 may also have undermined the review of qualitative data. There is debate about how qualitative data should be reviewed and recognition that reviews of qualitative data cannot simply be transposed into a traditional quantitative systematic review process (Dixon-Woods et al., 2006; Lloyd Jones, 2007a). In this review, a qualitative synthesis was utilised within a mainly quantitative review process; however, given the decision to aim for high sensitivity during the search for studies and the subsequent lack of qualitative data

retrieved, it is unlikely that an alternative approach, with more emphasis on the qualitative aspects of the data throughout the review would have substantively affected the findings.

Qualitative data were difficult to pick out of the predominantly quantitative studies. On a number of occasions a 'sling log', a record of when the constraint was worn, was documented as a data collection method. A decision was made to exclude sling logs, as there was no indication that these were more than a list of when the constraint was worn and the activities undertaken during this time. It is possible that, had these also been included, they may have given a feel as to whether a stroke survivor was able to adhere to the constraint wearing schedule; however, it is unlikely that this would have given any qualitative insights into the barriers to adhering to the protocol.

Finally, in undertaking the search, only studies that related to sub-acute stroke survivors were included as this was the group of interest. It could be argued that it may not matter at what phase of stroke the evidence is collected, as it is the experience of the intervention that is important. If the review inclusion criteria had been broader to encompass all phases of stroke, further data may have been collected that would have offered additional insights, for example it would have led to the inclusion of qualitative data from the mixed methods study of two participants in the chronic phase of stroke (Gillot et al., 2003) (described in Chapter 2). The threat, however, was that by broadening the scope of the review, the specificity (precision) would have decreased. As implementation has been identified (Chapter 2) as context specific, and time post-stroke may be an important part of the context, including chronic stroke survivors experiences of CIMT may not ultimately facilitate implementation in the sub-acute phase of stroke. Until it is known whether the experience of CIMT for sub-acute stroke survivors is similar to that of chronic phase stroke survivors, the decision to undertake the search with the smaller scope is supported.

The decision to undertake two separate systematic reviews (reported in Chapter 3 and 4) recognised that each systematic review was pursuing a different line of enquiry. If the aim had been to address two perspectives on one line of enquiry it would have been possible to undertake one systematic review incorporating both qualitative and quantitative data. However, leading on from the background literature review, there were two markedly different primary research questions. In order to answer these sufficiently, a different approach was required for each line of enquiry. Whilst it was appropriate to use one search, as the data came from the same body of evidence, the selection criteria and most importantly the means of analysing the extracted data were individual to each systematic review. This ensured that the systematic reviews were methodologically appropriate to answer the research questions. A potential risk of this approach was the fragmentation of the underpinning evidence. This has been addressed by using the PARIHS framework throughout the thesis to draw together these separate, but intertwined aspects of CIMT research.

Conclusions could not be drawn about the acceptability and feasibility of CIMT in the sub-acute phase of stroke due to the poor methodological quality, and the limited amount of qualitative evidence. The objectives: a) to critically review the reported experiences of therapists providing CIMT and stroke survivors undertaking CIMT in the sub-acute phase of stroke; and b) to explore therapist and stroke survivor reported facilitators of and barriers to undertaking CIMT in sub-acute stroke; were met, but the lack of evidence indicates a need for further exploration of these aspects of CIMT implementation through primary research. Future research needs to establish whether CIMT is acceptable to stroke survivors and whether it is feasible to provide this intervention in a UK stroke service. There remains a need to capture stroke survivor and therapist experience of CIMT, including adequately identifying barriers to and facilitators of this intervention, so that implementation of CIMT into practice can be appropriately supported. To

address these gaps in the evidence-base, good quality, well designed qualitative studies with a clear theoretical stance are required.

# Chapter 5

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## Therapists' Perceptions of Implementing CIMT into a Stroke service

This chapter aims to explore therapist perceptions of CIMT as a means to better understand the implementation process of this intervention. Converging evidence from the PARIHS analysis presented in Chapter 2 and the findings from the systematic review presented in Chapter 4 indicate a paucity of evidence regarding therapists' perceptions of CIMT. As therapists are the potential adopters of CIMT, it is essential to understand their perceptions if CIMT implementation is to be furthered.

This chapter reports a study to: explore which evidence-based CIMT protocols therapists perceive could feasibly be provided within a UK NHS stroke service; explore therapists' perceptions of the optimum time, location and population for the range of evidence-based CIMT protocols; explore therapists' perceived facilitators and barriers to implementing the identified CIMT protocols.

### 5.1 Background

Previous studies (McHugh et al., 2013; Pedlow et al., 2014) have found that CIMT has not been implemented into practice by therapists working in stroke services in the UK. In a recent

qualitative study (Jarvis et al., 2014c), which aimed to describe all UL interventions used by OTs following stroke, only four out of eight occupational therapy participants identified CIMT as part of their practice; three of these participants worked for a Hospital Trust, whilst the fourth was employed by a community-based Trust. Each of the four participants had used interventions that reduced the use of the ipsilesional UL while practising tasks with the contralesional UL during therapy treatment sessions. The participants did not appear to utilise a specific CIMT protocol nor have a comprehensive understanding of the evidence-base. Two participants did not refer to the evidence-base in their interview; one participant indicated an awareness of the original six hour a day protocol, while one participant indicated uncertainty about who, based on the evidence, might be appropriate for CIMT.

*“I’d say higher level patients. I can’t remember ... is it that you need 10% movement distally? 10 or 30% - so you’d have to judge ...”*

There was, however, evidence that therapists would consider cognitive skills, neglect of the UL, movement of the UL, balance and available family or carer support when deciding with whom they might choose to use CIMT. As CIMT was not the focus of this study, these aspects were not explored in detail.

In summary, there was evidence that some OTs were incorporating elements of CIMT into their practice, but the findings supported previous evidence (McHugh et al., 2013; Pedlow et al., 2014) that the protocols used by the OTs were not evidence-based and the therapists did not appear to be confident about the current CIMT evidence-base.

Practice development is defined as:

“a continuous process of improvement towards increased effectiveness in patient centred care. This is brought about by enabling health care teams to develop their knowledge and skills and to transform the culture and context of care. It is enabled and supported by facilitators committed to systematic, rigorous continuous processes of emancipatory change that reflect the perspectives of both service users and service providers” (McCormack et al., 2004, p. 316).

This definition clearly identifies the importance of the service user and service providers in developing practice such as the implementation of CIMT. The PARIHS analysis undertaken in Chapter 2 indicates the scarcity of evidence across the three PARIHS components for both stroke survivors (the service users) and the therapists (the service providers). In addition, Chapter 4 has identified that, little is known about the experience of receiving or providing CIMT.

The systematic review reported in the previous chapter, identified a small number of potential facilitators and barriers that might impact the implementation of CIMT for stroke survivors in the sub-acute phase of stroke. In spite of evidence that therapist circumstances and the environmental context are important in developing practice (Melton et al., 2010), of the 10 studies included in the review, only two studies explored the facilitators and barriers from the perspective of the therapist (Atteya, 2004; Page et al., 2001), with the other nine studies concentrating solely on stroke survivors perceptions. Atteya (2004) and Page et al. (2001) reported that, when interviewed informally, therapists who provided a 10 week CIMT protocol found the protocol easy to administer. It was unclear how this information was collected and analysed as this was not documented as part of the methods.

Whilst limited by its questionnaire data collection method, a further study (Page et al., 2002a), reviewed as part of the literature review in Chapter 2 but not meeting the inclusion criteria for the systematic review, studied therapists' perceptions to CIMT comprising six hours training for two weeks and constraint wearing for 90% of waking hours. A number of potential barriers were identified including length of therapy time, participant fatigue, decreased safety as a result of wearing a constraint, transport to therapy and insufficient resources within the service to administer CIMT.

The studies by Atteya (2004) and Page et al. (2001) were undertaken outside the UK more than 10 years ago; they each considered only one CIMT protocol, and did not address therapist perceptions about when, where, or with whom the protocol might be used. In addition, the systematic review reported in the previous chapter concluded that there was an overall shortage of qualitative evidence, and that the included studies were of poor methodological quality. Recent developments have resulted in a range of evidence-based CIMT protocols; the systematic review described in Chapter 3 found 11 different CIMT protocols with evidence of efficacy in a sub-acute stroke population. This increase in CIMT protocols, along with evidence that some therapists are now using elements of CIMT in their practice in the UK (Jarvis et al., 2014c; McHugh et al., 2013; Pedlow et al., 2014), may impact on the previously identified (Page et al., 2002a) perceived facilitators of and barriers to implementing CIMT. Further study of this area is, therefore, warranted. To address this gap, this study aims to explore therapist perceptions of implementing evidence-based CIMT protocols in a UK stroke service.

The need for high quality research to further implementation was identified in Chapter 2. In contrast to previous studies, this study will take a qualitative approach with the aim of collecting rich data in order to gain a detailed understanding of the factors impacting on implementation in one NHS Trust. Chapter 1 identified evidence-based practice as comprising research evidence,

clinical expertise and patient preference; this is supported by Rycroft-Malone et al. (2004b) who propose evidence is stronger when it emerges from a number of sources. It has been suggested that a broader base of evidence for implementation should include the three elements identified for evidence-based practice, along with local data (Rycroft-Malone, 2004). The latter should include how the evidence is perceived in the local environment (Rycroft-Malone, 2004). The systematic reviews reported in Chapters 3 and 4 have summarised the research evidence to date. The focus of the study reported in this chapter is therapist (clinical) experience and perceptions of CIMT. To address the research question 'what are therapists' experiences and perceptions of providing CIMT in a UK stroke service?', it will address the following research objectives:

- To explore which evidence-based CIMT protocols therapists perceive could feasibly be provided within a UK NHS stroke service.
- To explore therapists' perceptions of the optimum time, location and population for the range of evidence-based CIMT protocols.
- To explore therapists' perceived facilitators of and barriers to implementing the identified CIMT protocols.

## 5.2 Methodology

As indicated in Chapter 1, this study was underpinned by a constructivist epistemological stance which assumed that knowledge is constructed from human experience. A social constructionist theoretical approach accepts that beliefs and views are made (constructed) in the context of external influence and are shaped by interactions with others (Andrews, 2012). The impact of this is that there is an underlying belief that the knowledge is likely to be dependent on the context in which it was developed (Creswell, 2009, p. 8). This epistemological stance and approach underpinned the study design, data collection and analysis. The study utilised qualitative

methods to explore therapists' perceptions and attitudes in a focus group. A focus group provides opportunity to collect detailed information about a subject (Sim, 1998, p. 346; Winship & Repper, 2007, p. 127). This data collection method was congruent with the underlying theoretical beliefs of this programme of work, enabling exploration of the construction and development of knowledge (Sim & Wright, 2000, p. 57). Participants bring with them views that have been developed in a social environment (e.g. in a practice setting); these views may be developed further in the focus group as a result of the discussion and are dependent on the context in which they are collected (Finlay, 2006, pp. 16-7).

The study was approved by Keele University Faculty of Humanities and Social sciences Ethics Review Panel (Appendix 9).

## **5.3 Methods**

### **5.3.1 Recruitment**

The PARIHS framework recognises context as an important factor in the implementation of new innovations into clinical practice (Chapter 2); the focus for this programme of work was the implementation of CIMT in one Hospital Trust. The decision was, therefore, taken to recruit therapists from this one Trust. Whilst this may have limited the data collected, it was anticipated that this approach would facilitate articulation of the perceptions of CIMT, including the facilitators and barriers specific to this context.

OTs and physiotherapists in one Hospital Trust, meeting the following inclusion criteria: Agenda for Change (The NHS Staff Council, 2013) job band 5, 6, 7 or 8; providing upper limb interventions to stroke survivors; working with stroke survivors two weeks to six months post-stroke; were

approached initially by a therapy service manager at the Hospital Trust. All therapists meeting the inclusion criteria were asked if they would be willing to participate in the study. Therapists indicating an initial interest in participating were asked to contact the Chief Investigator directly. These therapists were provided with additional information about the study in written (Participant Information Sheet, Appendix 10) and verbal format by the Chief Investigator.

A purposive sampling strategy was selected to ensure a range of participants across both professions with a broad range of job bands. In line with focus group recommendations (Krueger & Casey, 2000; Morgan, 1998), to ensure that all participants have sufficient time to express their views in response to all focus group questions, the aim was to recruit between six and eight participants. Allowing for drop-out, the protocol stated that if more than 10 therapists were interested in participating, the Chief Investigator would consider the therapists' professional background and experience and would select a group of 10 therapists that provided the broadest range of experience and diversity in professional role. Where a therapist was not selected for participation they were contacted by the Chief Investigator to thank them for their interest and to explain why they had not been selected.

All participating therapists provided written consent before entering the study (Appendix 11). Participants were advised that they were free to withdraw from the study at any time without giving a reason. A second consent was completed by each participant following the focus group. In the second consent, participants were able to decide how the data they had generated could be used during the reporting of the findings, a copy of the second stage consent form is presented in Appendix 12.

The Chief Investigator had no previous relationship with the Therapy Service Manager, but did have a previous professional relationship with two participants. Participant 1/0 and the Chief

Investigator had worked on a number of small, therapy projects together, and participant 1/2 had been a student at the University where the Chief Investigator had taught seven years prior to the study.

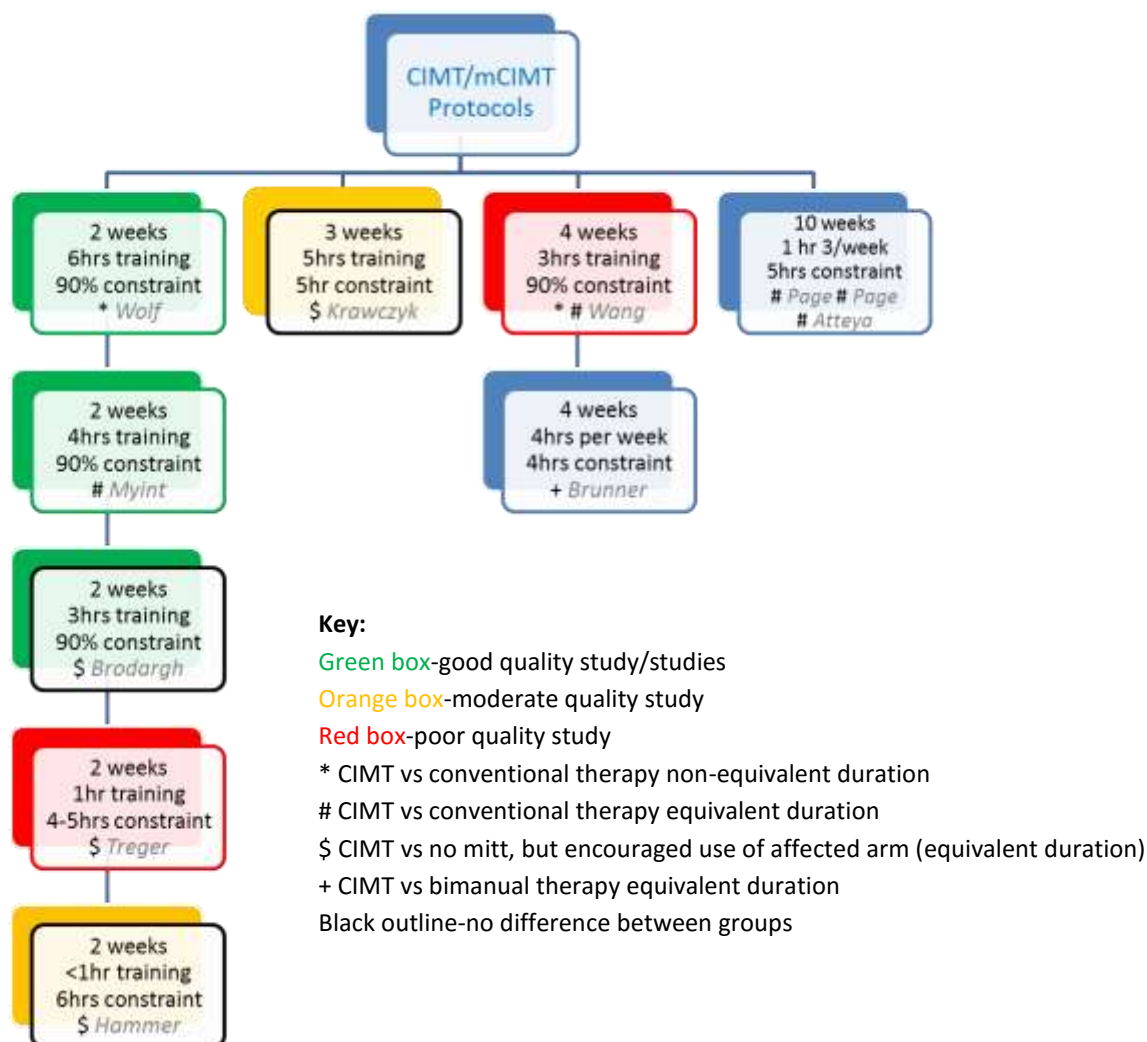
### **5.3.2 Procedures**

Participants completed a questionnaire to provide details of their professional background, current professional grade and length of time working with stroke survivors. They then participated in one focus group of 90 minutes, which took place on the 10th June 2013 in a Hospital Trust Education Centre.

Ground rules were discussed and agreed prior to the focus group. This included participants agreeing to keep confidential the individual contributions made during and in the context of the focus group.

During the focus group participants were asked to consider their own needs and those of the organisation in implementing CIMT, the focus group schedule is shown in Appendix 13. The facilitator presented all the protocols, identified through the systematic review reported in Chapter 3, which had been shown to increase UL function in the sub-acute phase of stroke. The document summarising the protocols is shown in Figure 5.1. The facilitator used this document to present each of the protocols in a written and verbal format. The participants were asked to consider each of the protocols with respect to the research questions. The focus group was led by a facilitator with previous clinical and research experience in facilitating groups (KJ); a co-facilitator (GR) observed the group processes, took field notes and identified any additional areas for discussion as the group progressed.

Fig 5.1 Summary of protocols for group discussion



### 5.3.3 Ethical issues

The first ethical issue was the loss of clinical time due to attending the focus group, which may have impacted on the service the stroke survivors received; this was particularly pertinent as all the therapists were employed by one Hospital Trust. This issue was addressed by considering the timing of the focus group to minimise the disruption to clinical practice. In addition, the time the therapists were engaged in the focus group was considered a part of the therapists' allocated continued professional development time; thereby participation did not take time from clinical tasks.

A second ethical issue was the risk that a participating therapist might disclose a practice that did not meet professional standards or that was unethical. The facilitator had a professional responsibility to report any such practice to the therapist's line manager (College of Occupational Therapists, 2010). This was addressed by making this responsibility clear in the Patient Information Sheet (Appendix 10); the Chief Investigator also discussed this with each participant verbally. Whilst this did not remove the risk, it ensured that the participants were aware of the risk and could make an informed decision about participating.

#### **5.3.4 Data collection**

Prior to the focus group, the participants completed a questionnaire which collected the following data about the participant: their profession, their job 'band'; how long they had been working with stroke survivors; and whether UL interventions were part of their clinical practice.

The focus group was audio-recorded to ensure an accurate recording of the verbal content of the group discussion. This was transcribed verbatim. Field notes were made during the focus group by the co-facilitator. The facilitator reflected on the discussion and the interactions once the group was complete.

#### **5.3.5 Data analysis**

The analysis was underpinned by the constructivist stance and aimed to understand individual perspectives alongside the sociocultural contexts that influence the data as recommended by Braun and Clarke (2006). This process commenced with a thematic content analysis based on the phases described by Braun and Clarke (2006). Thematic content analysis is often poorly described (Attride-Stirling, 2001); the method articulated by Braun and Clarke (2006) was selected for this study as it clearly outlines the phases of the analysis. These phases comprise: familiarising

yourself with the data, generating initial codes, searching for themes, reviewing the themes, defining and naming the themes, and finally producing a report; guidance for undertaking each step (Braun & Clarke, 2006) was utilised. This clear description of thematic content analysis supported transparency during the analysis.

#### **5.3.5.1 Familiarisation of the data**

Two researchers independently analysed the data. One researcher (KJ) had facilitated the group discussion, so had some knowledge of the content prior to formally starting the analysis. The researchers (KJ, SH) read the verbatim transcripts multiple times, and then identified codes at a semantic level (Braun & Clarke, 2006). One researcher (KJ) also used the audio-recording to help interpret meaning by listening to the emphasis given to the spoken words.

The analysis was supported by the use of NVivo 10 (QSR International, 2015).

#### **5.3.5.2 Generating initial codes**

The initial codes were derived from the raw data content of the audio recording and the transcript, rather than from selecting codes based purely on the barriers to and facilitators of CIMT. One researcher (KJ) used NVivo 10 to record the codes, whilst the second researcher used a similar paper-based system.

#### **5.3.5.3 Searching for themes**

These codes were independently considered by the researchers, who looked for patterns between the codes that could offer some structure to the data. This process led to the development of themes. The NVivo 10 modelling tool was used to present these themes in diagrammatic form. The researchers compared their themes and, where there were differences, these were discussed and a definition and name agreed for each theme.

#### **5.3.5.4 Reviewing the themes**

The data and the context of the data (i.e. the discussion around each coded quote) were reviewed again to ensure the themes represented that data. The researchers aimed to be reflexive and to be aware of situations where their views may have influenced the development of the theme, rather than the data informing the theme. During this process there was a review to ensure all relevant codes were included within each theme.

#### **5.3.5.5 Defining and naming the themes and reporting the findings**

A narrative, including participant quotations, was produced to support each theme; these narratives formed the basis of the findings section reported in this chapter. The final step of the analysis was to consider the themes and associated narratives, in terms of the original research questions. The themes were re-visited looking for evidence to develop knowledge with respect to the research questions. The findings were reported in respect to the original research questions.

### **5.3.6 Reflexive processes**

In this study, the focus was on methodological reflexivity, which endeavoured to recognise the researcher's relationship to the data, and attempted to put in place systems and processes that enabled a professional distance (Johnson & Duberley, 2003). Processes have been built into the methodology of the study, to establish the researcher's theoretical perspectives and relationship to the topic, the participants, and the data.

The group discussion was facilitated by an OT with experience of working with stroke survivors. The group schedule was adhered to, field notes were made during the group discussion by the co-facilitator, and the interviewer reflected, post-interview, on times during the group where questions may have been leading and the subsequent impact of this on the data collected. In the

post-interview reflections, there was also consideration of the potential for the facilitator to be perceived, by the participants, as in a position of power due to her interest and knowledge of CIMT.

It would have been difficult for a facilitator with no knowledge of CIMT to facilitate the discussions due to the complexities of the intervention and a need to understand the terminology used by the therapists. The researcher was seen as a part of the process and there was an acknowledged recognition that her presence influenced the data collected. Reflexivity provides a means to explore and understand this influence, rather than attempting to remove it. The reflections made during this process were taken into account in the reporting of the data, for example, where there was evidence of the facilitator using leading questions, this was identified and the influence of this considered in the analysis of the data.

In addition to the field notes and post-group reflections, made respectively by the co-facilitator and the facilitator, a reflexive log was kept throughout the analysis phase. This log was held within NVivo 10 and documented decisions made during the analysis to ensure the reasons for these decisions were transparent. It provided an audit trail and justification for the decisions made.

## **5.4 Findings**

Eight therapists took part in the focus group; a summary of their professions and Agenda for Change (The NHS Staff Council, 2013) job band is provided and length of time working with stroke survivors is reported in Table 5.1.

**Table 5.1: Summary of focus group participants**

<b>Participant Identification Number (PIN)</b>	<b>PT/OT</b>	<b>Band</b>	<b>Time working with stroke survivors</b>
10	OT	7	6-10 yrs
12	OT	6	3-5 yrs
13	OT	6	Less than 3 yrs
14	PT	6	Less than 3 yrs
15	PT	7	11-15 yrs
16	PT	6	3-5 yrs
17	PT	5	Less than 3 yrs
18	PT	8a	16-20 yrs

During the group discussion, all participants indicated that they were aware of CIMT as a post-stroke UL intervention. Four participants reported encouraging some stroke survivors to use a constraint such as an oven glove, a pillowcase, or a pocket to prevent use of the ipsilesional hand whilst undertaking tasks; none used an evidenced-based CIMT protocol. All participants reported encouraging the use of the contralesional UL and discouraging the use of the ipsilesional UL in tasks during some sessions when working for UL function.

Following familiarisation of the data, the second phase of the analysis generated 52 codes. These are listed in Appendix 14.

In the third phase of the analysis, these codes were organised into four themes: the CIMT intervention; personal characteristics; setting and support; how 'to do' CIMT. The NVivo 10 models of these initial themes and the associated codes are shown in Appendix 15.

Following discussion between the researchers in the fourth phase of analysis, one theme originally named 'How to do CIMT' was felt to contain 3 distinct concepts. This theme was split accordingly and the three new themes emerged: Ethical considerations, Education and Training, and Practicalities. Three other themes remained unchanged, resulting in the final six themes:

- The CIMT Intervention
- Personal Characteristics
- Setting and Support
- Ethical considerations
- Education and Training
- Practicalities

The final six themes and the codes associated to each are shown in Figures 5.2 to 5.7.

Fig 5.2 Final theme: the CIMT intervention

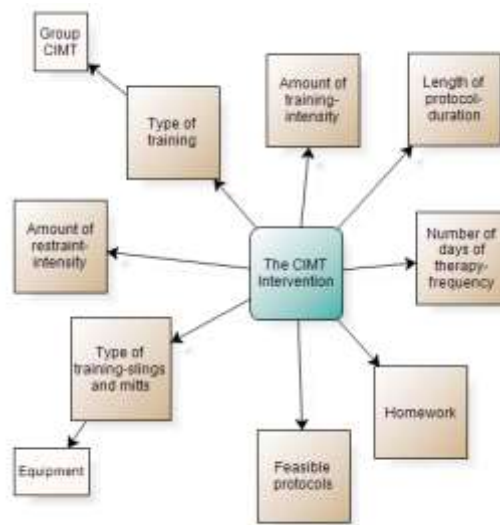
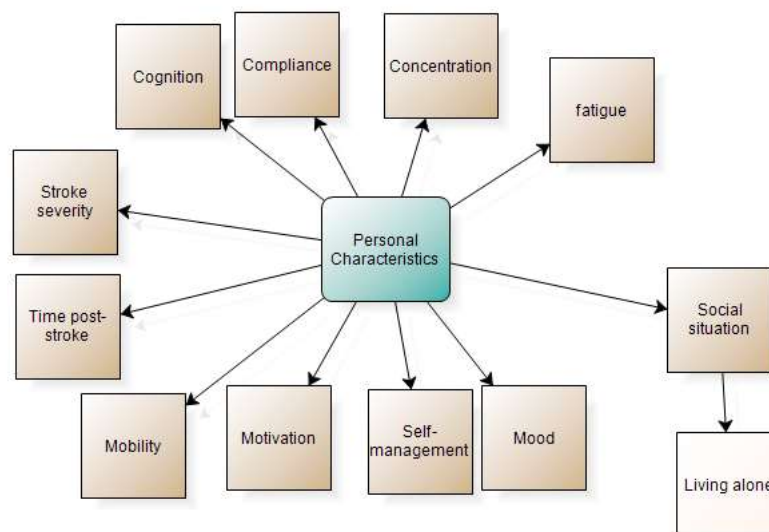
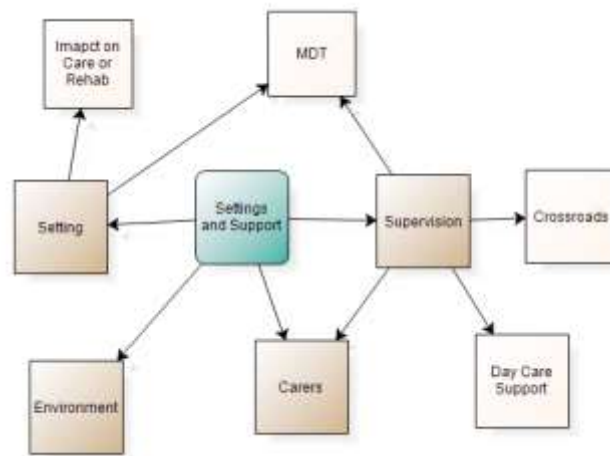


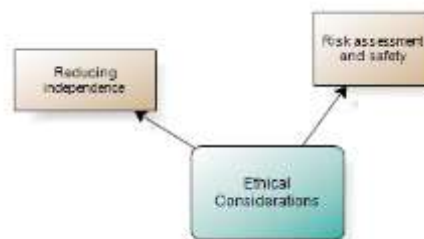
Fig 5.3 Final theme: personal characteristics



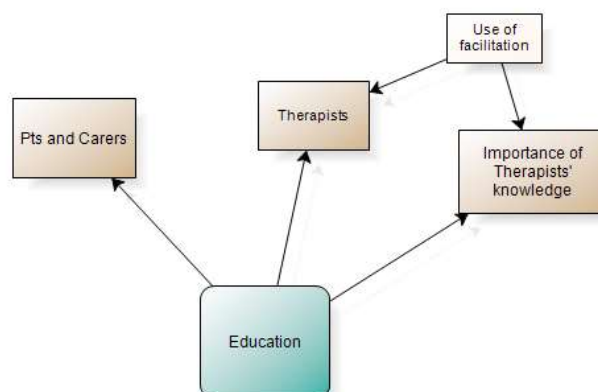
**Fig 5.4 Final theme: setting and support**

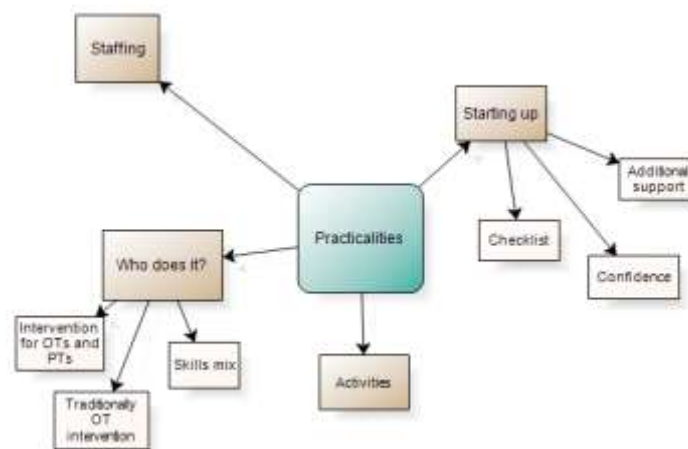


**Fig 5.5 Final theme: ethical considerations**



**Fig 5.6 Final theme: education and training**



**Fig 5.7 Final theme: practicalities**

The codes and supporting quotations were collated to present a narrative for each theme. This document with the embedded themes and codes were examined in order to answer the original research questions. As the analysis was ultimately used to address the study research questions, the findings have been reported using the research questions as sub-headings. The themes that were used to answer each question are clearly stated, indicating the relationship between the themes and the findings, thereby evidencing dependability (Letts et al., 2007a).

#### **5.4.1 Research question 1: which of the evidence-based CIMT protocols do therapists perceive could be provided within a UK stroke service?**

This first research question was answered from data contained within 'The CIMT Intervention' theme. Therapists identified a number of key issues when selecting an evidence-based CIMT protocol.

##### **5.4.1.1 Amount of training**

The amount of training was felt to be the most important aspect when making a decision about which protocols might be feasible; this appeared to be based on the time the therapists had

available to offer the intervention and what they felt they would be able to offer within service constraints:

*“We can keep our patients on for the 10 weeks within the service that we provide. So I guess that's not the length, the duration of the period isn't it as big an issue, because if they were inpatient, it could be carried over to outpatient for 10 weeks, we can provide that. It's more the daily time...”* **Participant 1/0**

The longer daily training sessions were considered too long for the current in-patient and Early Supported Discharge service (ESD):

*“The six hours would go over a morning and into an afternoon ... taking up most of your day. We're here seven and a half hours, some of us more, but six hours is a big chunk of your day to sustain over two weeks. Whereas some of the others, like say three hours, gives you ... your afternoon to do other clinical work.”* **Participant 1/0**

One of the protocols considered was the provision of four hours training per week. This protocol was discussed at length as it was representative of the amount of therapy currently offered by the stroke services:

*“...most of our patients will get four hours a week if they need that four hours. So they're do-able. I think the difficult part would be making sure we look at their [service-users] lives and how we get the five hours, the extra constraint time in...”* **Participant 1/0**

Whilst the therapists could see how they could fit four hours per week training into their current workload, they also agreed that it might be possible to offer a slightly more intensive training over a short period:

*“...but say two hours [daily training] potentially could be [possible] for like a short-ish period of time, like two weeks, and it might be something that you could have similar level patients doing activities, two supervised by one assistant, and you can keep an eye on both at the same time.”* **Participant 1/6**

#### **5.4.1.2 The constraint element**

The therapists reported that they felt constraint of 90% of the waking hours was not feasible:

*“But then with 90% of their time restrained per day...it just seems a tad unrealistic.”*

**Participant 1/0**

*“That won't happen in any of our areas.”* **Participant 1/8**

The therapists seemed to think that the break-even point was around 4-5 hours of constraint, with recognition that the constraint time had to be considered as part of planning a day:

*“...because I was just looking at the five hours, that's hard to squash into a patient's day, thinking about community patients. Whereas the four, you can almost do breakfast, lunch, evening meal, bedtime...it's easier to fit in the four hours than the five...because the five goes into more than half a day of your patient's time. Because at least you can say you're restrained this amount, you can be free in the afternoon.”* **Participant 1/0**

Whilst concerns were expressed about the five hours constraint, it was recognised that it might be possible if the circumstances supported this:

*“...the five hours restraint might be something that the patient can do themselves with supervision at home, or if they are motivated and compliant, they could do that themselves...”* **Participant 1/6**

#### **5.4.1.3 Feasible protocols**

Following presentation of the evidence-based CIMT protocols, the therapists felt that the protocol comprising training for four hours a week, with four hours daily constraint, for a duration of four weeks, and the protocol comprising one hour training, three times a week, with five hours daily constraint, for a duration of 10 weeks, might be feasible within the current service provision:

**1/2:** *“The one that's standing out for me is the four...over four hours; four hours a week and four hours restraint. Like that is pretty much... going on between the OT and the assistant [in the community]...and doing functional tasks and making the restraint working when you're there ... that one's probably the one that's standing out for me.”*

**1/8:** *“It's probably the easiest one to do, isn't it?”*

Whilst a community physiotherapist had some concerns about the duration of the longer protocol, she stated:

*“In a community setting, the one hour three times a week is something that could be feasible with early supported discharge...because that's something we aim for as a*

*minimum for certain patients...So I know that's [it's] over 10 weeks, um, but it could be that, that could be a bit long"* **Participant 1/6**

Group members focused mainly on the amount of training time, rather than the length of the protocol. There were very few comments on the length of protocol, with discussion touching briefly on whether a protocol over 10 weeks would be feasible. Some therapists questioned whether this was too long in duration to be integrated into the current service, while some staff in ESD reported that they could 'keep' people for 10 weeks making this protocol feasible.

#### **5.4.2 Research question 2: when, where and with whom would therapists choose to use these identified CIMT protocols?**

This second research question was answered from data captured in the 'Personal Characteristics' and 'Setting and Support' themes.

##### **5.4.2.1 With whom would therapists choose to use a CIMT protocol?**

The findings reported to answer this question were from the 'Personal Characteristics' theme.

There was agreement that motivation was an essential characteristic in undertaking a CIMT protocol:

*"...[service users are] keen to get on and motivated, but as soon as we go, they don't pick up their home exercise programme, they do very little in between our sessions ...to get them to follow one of these protocols for four or five hours every single day is a big ask to get them motivated and involved with it."* **Participant 1/5**

There was recognition that support might be required to facilitate CIMT:

*“... our patients are often low in mood and motivation, so getting them to do stuff for that amount of time without a supervising body would be difficult. So it’s not really successful without a supervising body...”* **Participant 1/0**

The therapists questioned whether a stroke survivor with cognitive impairment would be able to undertake CIMT and there was discussion about how this would be judged:

*“...I think it's about [the service user] understanding the task isn't it, and having the ability to follow the programme. You know, and them being able to tell you what the programme is, or...repeat back what the programme is...it's having that checking mechanism.”* **Participant 1/0**

There was a discussion about the possibility of having set questions to check to a person’s ability to understand and follow the programme.

Therapists appeared agreed that CIMT requires a high level of concentration, and that attention and fatigue would impact on a person’s ability to concentrate. There was also some discussion about the challenges of providing the intervention:

*“... if you are repeating a task and they're not really seeing it as meaningful...they'll lose concentration very quickly”* **Participant 1/6**

with some reflection about the potential for CIMT to have a positive impact on inattention:

*“... somebody... who's just a bit inattentive but does have good activity, I think it is actually ideal, because it's just making them think, right, well, I can't use this one [ipsilesional hand] so I know...I see why I've got to do it.” Participant 1/6*

The therapists indicated that they would only offer CIMT to stroke survivors with some activity in their contralesional hand, described by one participant as:

*“-unfunctional function-I know it's not a functional hand, but they've got activity.”*

**Participant 1/8**

Overall the therapists seemed to be in agreement that CIMT would be appropriate for only a small proportion of stroke survivors:

*“...you might start off with a huge group of patients that you think would be potential, but then you'd probably narrow it down quite quickly...I think it would be quite a small group of patients you'd be able to do it with.” Participant 1/8*

#### **5.4.2.2 When would therapists choose to use a CIMT protocol?**

The findings reported to answer this question were from the ‘time post-stroke’ code, a sub-theme in the ‘Personal Characteristics’ theme (see Figure 5.3).

The therapists indicated that using a CIMT intervention would be based more on the potential benefit for a given person, rather than the time post stroke. However, there was evidence that it might be utilised in the early stages post-stroke:

*“It might be best to start as early as possible in terms of compliance and in terms of becoming habitual in their daily routine to build it in, rather than spend say two weeks, a month in an inpatient setting and then for it to start. And I don't know a great deal about it, but in terms of like neuroplasticity, starting from day one after the stroke when the swelling's reduced, would you want to try and tap into changing everything in a more positive way...”* **Participant 1/6**

There were also indications that it may also be appropriate after in-patient stroke rehabilitation:

*“It just depends, doesn't it, because the walking wounded that we get in...we refer straight from the acute setting to ESD, they're the type of people who could be using it, or...later on, after a few weeks, on stroke rehab...”* **Participant 1/2**

#### **5.4.2.3 Where therapists choose to use a CIMT protocol?**

The findings reported to answer this question were from the ‘Setting and Support’ theme.

##### **In-patient setting**

There was recognition that, within an in-patient setting, the success of CIMT may be influenced by other members of multi-disciplinary team (MDT) and that there are likely to be barriers to other members of the MDT supporting CIMT:

*“And it is just because they [nursing staff] are so under pressure with time and things, they haven't got the sort of time to sit there with them [the service users] and let them practice that whatever function it is. So I think from a ward point of view, it will be quite difficult to leave them [the stroke survivor] to do their activity on their own, encourage*

*them, leave them, go away and come back, and see how they've improved, without people sort of butting in and going, oh, I'll do this for you."* **Participant 1/4**

The feasibility of CIMT in an institutional setting may depend on the role and personalities of the staff and the relationship between the therapists and the rest of the team.

*"... I do think, in terms of individual personalities of carers, some would be more willing to want to do that [support CIMT]...if it comes, you know, with a training...session for them and lots of reinforcement, this is how we're doing it...because we are there every day...we can have like a good, close relationship...and that could help."* **Participant 1/6**

### **Community setting**

It was agreed that it was most likely that the majority of CIMT would take place once the stroke-survivor was in a community dwelling. There was also agreement that formal carers working in the community would not be able to support CIMT due to shortage of time:

*"...you do hear so many people saying they [formal carers] are just in and out, they didn't give me chance to try and do that, they just did it for me and then they're off to the next job; which is true because they're under a lot of time constraints."* **Participant 1/6**

It was recognised that there may be some environments, such as an Intermediate Care Unit with a re-ablement remit, where formal carers may be able to offer short-term support in the transition from the Unit to home. There was also agreement that informal carers may also be able to offer support:

*“...but I think we'd have more chance of getting family carers on board to help their stroke-affected relative than formal carers. Could it be something we could link in with [informal] carers, for example, like the OTs with washing and dressing in the morning, to show how it could still be done in a timeframe, you know.” Participant 1/6*

This might be particularly important if a stroke survivor had cognitive impairment:

*“If somebody had...cognitive impairments, then it might be okay if we had someone there to prompt them, like a carer, so then it wouldn't really matter if they needed prompting because of attention or memory, or things like that.” Participant 1/3*

### **5.4.3 Research question 3: what are therapists' perceived facilitators and barriers to implementing the identified CIMT protocols?**

This final research question bridged all six themes. A summary of all the facilitators and barriers extracted is given in Table 5.2.

**Table 5.2: Summary of facilitators and barriers to therapists implementing CIMT**

	<b>Facilitators</b>	<b>Barriers</b>
<b>Personal Characteristics</b>	<ul style="list-style-type: none"> <li>• Activity in contralesional hand</li> <li>• Motivation to undertake</li> <li>• Therapists' ability to influence/judge ability to participate:               <ul style="list-style-type: none"> <li>○ questions to check ability to follow instructions</li> <li>○ awareness of CIMT evidence base to be able to inform</li> <li>○ plan tasks that are manageable, but challenging</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Low mood</li> <li>• Low motivation and its impact on compliance</li> <li>• Cognition-not being able to follow task</li> <li>• Decreased concentration</li> <li>• Living alone</li> </ul>
<b>Setting/support</b>	<ul style="list-style-type: none"> <li>• Training for staff on the ward</li> <li>• In-patient staff prompting a referral for CIMT on discharge</li> <li>• Less rapid turn-over of staff in services</li> <li>• Re-ablement services</li> <li>• Informal carers (link to cognition)</li> <li>• Enthusiasm from staff (in-patient setting)</li> <li>• Strong relationship between ward staff and therapists</li> </ul>	<ul style="list-style-type: none"> <li>• On ward - no time for nursing staff to leave people to be independent</li> <li>• Impact on transfers and ADL tasks on ward</li> <li>• Formal carers in the community would not be able to offer support</li> </ul>
<b>Practicalities</b>	<ul style="list-style-type: none"> <li>• Checklist to follow protocol</li> <li>• Consideration of staff mix</li> <li>• List of activities available as a resource</li> <li>• Decreased caseload when first implementing</li> <li>• Ethos that encourages independence (in-patient/rehabilitation setting)</li> <li>• Specialist equipment such as the BTE</li> <li>• Changing environments to increase the use of unilateral activities</li> </ul>	<ul style="list-style-type: none"> <li>• Decreased staff numbers, eg through sickness and attrition</li> </ul>

<b>Education and training</b>	<ul style="list-style-type: none"> <li>• Training for therapy staff: <ul style="list-style-type: none"> <li>○ formal training</li> <li>○ joint practical sessions with a senior therapist</li> </ul> </li> <li>• CIMT mentor available to ask for support and assistance with problem solving</li> <li>• Training for staff on the ward</li> <li>• In-patient staff prompting a referral for CIMT on discharge</li> <li>• Less rapid turnover of staff</li> <li>• Re-ablement services</li> <li>• Informal carers</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of knowledge</li> <li>• Lack of confidence using CIMT</li> <li>• Junior staff want support from senior staff, who may not have knowledge/skills</li> </ul>
<b>Ethical considerations</b>	<ul style="list-style-type: none"> <li>• Risk assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Decreased safety</li> <li>• Risk of falls</li> <li>• Decreased independence</li> <li>• Increased assistance required</li> </ul>
<b>CIMT intervention</b>	<ul style="list-style-type: none"> <li>• Shorter training sessions more feasible</li> <li>• 1hr x 3 per week over 10 weeks or 4hrs once a week over 4 weeks might be possible</li> <li>• 4-5hrs constraint might be reasonable</li> <li>• Constraint might be easier on ward as there would be greater supervision</li> <li>• Protocol over 5 days</li> <li>• Use functional tasks and repetition</li> <li>• Splitting large blocks of training into shorter training sessions</li> <li>• Involvement of team</li> <li>• Group CIMT could help offer CIMT intervention to a greater number of people</li> </ul>	<ul style="list-style-type: none"> <li>• Longer training protocols not feasible in current service</li> <li>• Big blocks of training difficult to provide</li> <li>• Being with a stroke survivor for a long time to provide training session - difficult to fill time</li> <li>• &gt;5hrs constraint too long, 90% constraint not possible</li> <li>• Slings with stroke survivors with mobility problems</li> <li>• Protocols over 7 days</li> <li>• Compliance for homework</li> <li>• Specialist equipment required (mitts)</li> <li>• 10 week duration may be difficult</li> </ul>

Therapists expressed strongly a need to be confident in the evidence-base and their knowledge, and discussed the need for their own training:

*"I think just for me - and I might be speaking for some of the others as well - it's just if we were gonna implement this...I would feel like I would need quite a bit of training. It's not a negative, it's just if I'm gonna implement this with patients and be very positive to improve compliance, I'd want a lot more...training."* **Participant 1/7**

When asked about the type of training required, therapists reported that they would probably need a variety of training to increase their knowledge and confidence in using CIMT:

*"...so probably a formal training session and then a double up with a senior therapist, to know how to [use CIMT] practically...so you can have the theory and then the practical."*

**Participant 1/7**

It was also proposed that a 'CIMT mentor' would be valuable:

*"I feel like it would be useful to have maybe like one member of the team, so somebody ... more senior ... or someone we can take any potential problems to, like a trouble-shooter."*

**Participant 1/6**

There was also a suggestion that a short-term reduction in a therapists caseload might help in implementing CIMT:

*"... maybe then would it be ... that we have a slightly reduced caseload, to allow us more time [for CIMT]? And I know that depends on caseload demands and therapy demands in general ... [it] would just help us to not feel like it's insurmountable because we've got all these other patients to see in the time."* **Participant 1/6**

Every effort has been made to portray the key findings in this section, with additional facilitators and barriers documented in Table 5.2.

## 5.5 Discussion

This study aimed to explore which of the evidence-based CIMT protocols therapists perceived could be provided within a UK stroke service, considering when, where, and with whom therapists would choose to use these protocols. It also explored the therapists' perceived facilitators and barriers to implementation of this intervention. The six emergent themes provided foundations to this work.

### 5.5.1 Therapist perceptions of the evidence-based CIMT protocols

Whilst there has been previous work considering the efficacy of a variety of CIMT protocols (Nijland et al., 2011; Shi et al., 2011; Sirtori et al., 2009; Stevenson et al., 2012), there has been no previous formal exploration of therapists' perceptions of the range of protocols and their feasibility in a stroke service. In this study, therapists appeared to make decisions about the feasibility of CIMT based on the constraints of their service. Whilst it might have been informative to encourage the therapists to undertake some 'blue sky thinking' during the focus group, the decisions regarding the feasibility of a given protocol seemed to be mainly driven by the therapists' perceptions of a stroke survivor's ability to undertake a protocol. The protocols that may have been possible with changes to service structure or with additional funding were still not seen as feasible for the service users. There was consensus that the protocols with the shorter daily training time and shorter constraint times were more feasible. An indication of the strength of evidence for each protocol (shown on protocol summary, Figure 5.1) was provided in the focus group, although there was little evidence that this was considered during the group discussion. This may have been due to the large amount of information that had to be processed

during the group or a perceived lack of value of the evidence by the therapists. The fast pace and complexity of the group discussion indicated that, at least in part, the former was likely.

### **5.5.2 When, where and with whom would therapists choose to use CIMT protocols?**

Previous CIMT studies have established UL motor control inclusion criteria (Brunner et al., 2011). These were based on observations by Wolf and Binder-MacLeod (1983) during studies of electromyographic biofeedback which suggested that chronic stroke survivors with a level of voluntary finger extension and with greater range of motion (ROM) at the shoulder, elbow and wrist, had a greater potential for recovery of hand function (Taub & Wolf, 1997).

The study reported in this chapter aimed to collect therapist views about which stroke survivors might benefit from CIMT. Based on their clinical experience and expertise, the therapists supported previous inclusion criteria by indicating that they would only offer CIMT to people with activity in the contralesional UL. They also identified motivation, concentration, and sufficient cognitive ability to be able to follow CIMT tasks, as important personal characteristics that would influence their clinical decision to use CIMT. Given that CIMT is based on the existence of learned non-use (Taub et al., 1993), and that, following stroke, people with unilateral spatial neglect do not respond fully to their contralesional side (Parton et al., 2004), thereby not fully using the contralesional limb, it has been suggested that people with unilateral spatial neglect may benefit preferentially from CIMT compared to those without unilateral spatial neglect (van der Lee et al., 1999). This has not yet been tested experimentally, with sufficient numbers, to draw any conclusions. Overall the therapist participants thought it would be a very small group who were appropriate for CIMT; this supports the evidence presented in Chapter 2 that only between 3% and 20% of stroke survivors in the sub-acute phase of stroke are likely to be offered CIMT.

The therapists felt that most CIMT would take place in the community, but that some may start within an in-patient or reablement setting if the support was available. The discussion about the importance of team work and relationships is supported by Bayley et al. (2012) who found team functioning and communication as to be important when implementing stroke rehabilitation evidence.

### **5.5.3 Therapists' perceived facilitators of and barriers to implementing CIMT protocols**

Walker and Pink (2009) proposed that therapists may be reluctant to use CIMT due to a lack of guidance in transferring CIMT into practice, insufficient understanding of CIMT, insufficient research skills to assess the evidence, and a lack of confidence in its effectiveness. A lack of knowledge and confidence in using CIMT was supported by our study; the participants clearly articulated training needs. There were a number of suggestions for training, including formal sessions, individual sessions with a senior therapist, and a CIMT mentor. The senior staff also indicated the need for training, recognising the importance of ensuring senior staff have opportunity to develop their own knowledge and skills in order that they can support the learning of other team members. Whilst the initial training may be provided in the form of external formal training, there may still be a need for support and mentoring whilst an intervention is implemented. The role of a mentor in this context, sometimes described as a champion, advocate or clinical leader, has been recognised as a potentially valuable resource in enabling effective practice development and implementation of an innovation (Greenhalgh et al., 2005, p. 129; Manley et al., 2013, p. 156). Whilst an advocate or champion may operate in a number of ways (Greenhalgh et al., 2005, p. 126), in this study the therapists described the need for the mentor to provide support, facilitation and problem-solving; champions providing these

roles have been found to be beneficial in previous implementation studies in health services (Greenhalgh et al., 2005).

In support of findings by Page et al. (2002a), but in contrast to Atteya (2004) and Page et al. (2001), participants indicated substantial challenges therapists might face in offering a CIMT protocol in practice. The concerns expressed included service user acceptability of the six hour protocol, the challenges to the therapist of spending this period with one service user, and the impact of this on a therapist's caseload. Concerns were also expressed about safety including the impact of the constraint on balance, and the facilities and support required, including the need for carer support. It may be that therapist perceptions are not borne out when CIMT is actually undertaken, or that CIMT is more feasible or appropriate in some settings or with some stroke survivors, thereby explaining the difference between the findings from this study and those of Atteya (2004) and Page et al. (2001).

The systematic review, reported in Chapter 4, identified that a CIMT protocol might cause pain or fatigue to a stroke survivor. Whilst participants, in our study, expressed concern about stroke survivor tolerance in undertaking CIMT, and several potential risks did emerge, none of those identified in the systematic review featured strongly in the focus group discussions. This study collected detailed data on therapists' perceptions of CIMT, rather than reflections after the event; this may have led to some of these differences.

Little attention has been given to the need for carer support to facilitate implementation; however, in their review of CIMT evidence, Blanton et al. (2008), did note the need of carer support for both emotional and physical needs due to the intensity of CIMT. This was clearly supported by the substantial discussion in the focus group indicating that the participants felt

that support from a carer was likely to be required and that, due to service constraints, this support would have to be from informal rather than formal carers.

This study used a qualitative design to collect rich data and produce a detailed analysis, giving a broad picture of therapist perceptions of CIMT. Context is an important factor when considering implementation of an intervention (Rycroft-Malone, 2004); therefore, recruitment of participants from one Hospital Trust, one context, was appropriate; however, this recruitment strategy limits the transferability of these findings to other settings. It is anticipated that, whilst the findings may not be directly transferable to a different setting, they will inform questions that should be asked before implementation of CIMT into a stroke service in the NHS.

This study has furthered knowledge in each of the elements of the PARIHS. This is summarised in Table 5.3

Table 5.3 Summary of findings using PARIHS framework

Core element	Summary of CIMT implementation Based on original analysis (reported in Chapter 2) and subsequent studies reported in Chapter 3 and 4	What has this study added?
<b>Evidence</b>	<ul style="list-style-type: none"> <li>• A quantitative systematic review (Chapter 4) found that CIMT is effective in increasing UL function in sub-acute stroke survivors. However, a variety of CIMT protocols have been used in the published literature; it is not known which CIMT protocols are most effective in sub-acute stroke. It remains unclear whether stroke survivors experiencing sensory loss, unilateral spatial neglect, or other impairments benefit more than those who do not in the sub-acute phase of stroke.</li> <li>• A systematic review of qualitative evidence (Chapter 5) identified a lack of qualitative study of the patient's (stroke survivor) and clinician's experience of CIMT in the sub-acute phase of stroke. This means that factors such as facilitators and barriers to implementing CIMT have not been summarised.</li> <li>• A need for well-designed qualitative research, to enable a greater understanding of factors that may impact implementation of CIMT, from both a stroke survivor and therapist perspective, was identified.</li> <li>• There have been very few studies of CIMT in the UK. It is unclear how the current evidence-base relates to UK stroke services. It is not clear whether local data/information has been a part of the implementation process in UK stroke services to date.</li> </ul>	<p>This study has collected therapist perceptions and opinions. Therapists in one Hospital Trust identified some key areas for the implementation of CIMT, (reported above).</p> <p>The study had a clear theoretical perspective and utilised a design congruent with qualitative research.</p> <p>The evidence from this study has provided insights that can be used to support implementation of CIMT, including:</p> <ul style="list-style-type: none"> <li>• the evidence-based CIMT protocols therapists perceive could feasibly be provided within a UK NHS stroke service</li> <li>• therapists' perceived facilitators and barriers to implementing the identified CIMT protocols.</li> </ul>
<b>Context</b>	<p>Analysis based on the evidence reviewed and evaluated in this chapter:</p> <ul style="list-style-type: none"> <li>• Evaluation of effectiveness of the intervention has taken place in a number of settings; however little CIMT research has taken place in the UK.</li> </ul>	<p>This study was undertaken in the UK and in a sub-acute stroke service. All therapist participants worked for the same Hospital Trust; the organisational culture and environment was similar for all participants. The findings give an insight into this context, but may not be transferable to other sub-acute services.</p>

	<ul style="list-style-type: none"> <li>The majority of stroke rehabilitation occurs in the sub-acute phase of stroke, there is a need to evaluate implementation of CIMT in this context.</li> </ul> <p>As the 'Evidence' element above indicates, there is a need to establish factors that may impact implementation:</p> <ul style="list-style-type: none"> <li>The impact of culture and environment on stroke survivor and therapist beliefs about CIMT are unclear.</li> <li>It is not clear what type of leadership might be required and available to implement CIMT.</li> <li>The aspects of teamwork required to implement CIMT have not been explored.</li> </ul> <p>There has been some recognition that CIMT is likely to require some changes to current rehab environment (Blanton et al., 2008; Sterr &amp; Conforto, 2012); this information has been collected informally and is not necessarily transferable to all locations/settings. Further study is required to understand the impact of context on the implementation of CIMT.</p>	<p>There was evidence that the therapists considered the current context when considering implementation of CIMT. This included perceptions that: it would not be possible to provide CIMT over 7 days due to a reduced weekend service; ward staff and formal carers would not be able to offer the necessary support due to pressures on their time; services known to have a low staff turnover may be more able to offer CIMT.</p> <p>Only protocols with training that could be undertaken in the current service context were seen as feasible.</p>
<b>Facilitation</b>	<p>Although two studies (Gillot et al., 2003; Page et al., 2002a) undertook some exploration of the perceptions of stroke survivors and therapists, the actual barriers to CIMT, have not been fully explored. Facilitation would need to overcome these barriers:</p> <ul style="list-style-type: none"> <li>It is not known what form facilitation should take to further the implementation of CIMT into practice.</li> <li>The support therapists might need in order to gain the necessary knowledge and skills to implement CIMT are not known.</li> </ul>	<p>This study identified some specific areas that need addressing to facilitate the implementation of CIMT:</p> <ul style="list-style-type: none"> <li>Formal training for therapy staff, including joint practical sessions with a senior therapist. With a recognition that senior staff may also require training and may not be confident using CIMT.</li> <li>A CIMT mentor (from the therapy staff) available to ask for support and assistance with problem solving.</li> <li>Training for the wider team including carers as CIMT has implications for others working in the team.</li> <li>Smaller caseload for therapists in the early stages of implementing CIMT.</li> <li>Practical prompts such as checklists and ideas for tasks.</li> </ul>

### 5.5.4 Recommendations for implementation

The following are recommendations to facilitate implementation, based on the findings from this study and their interpretation via the PARIHS framework.

- 1 Provide sufficient training to therapy staff prior to implementation. This training should ensure that senior therapists have opportunity to gain skills and be confident in using them, as they are likely to be a source of support for more junior staff.
- 2 Ensure that there is at least one identified CIMT mentor or champion to support therapists problem-solve during the implementation process.
- 3 Provide checklists to ensure that selected protocol is being followed, and ideas for training tasks that can be used as a resource by therapists.
- 4 Ensure that each stroke survivor undertaking CIMT has first undergone a risk assessment to assess putting on and taking off the constraint, walking with constraint and provide specific guidance about when and where to wear the constraint.
- 5 Ensure that any additional support is identified and is available for each stroke survivor undertaking CIMT.
- 6 Aim to identify ways that a reduced caseload could be achieved whilst CIMT is being implemented, this may involve local short-term flexible working in the early stages of implementation; however, this may have an impact on overall therapy provision.
- 7 Monitor therapist and stroke survivor response to spending an extended length of time in therapy sessions.
- 8 Ensure communication, and if appropriate training, with the wider team including formal and informal carers.

A number of processes supported the overall rigour of this study. Field notes were taken by the focus group facilitator and the co-facilitator; these were compared and considered as part of the analysis. A reflective log was used throughout the analysis to document the process clearly, and record all decisions thereby forming an audit trail. The analysis was undertaken independently by two researchers, and as the analysis developed, the focus group co-facilitator considered whether the analysis reflected the discussions and interactions within the group. The data analyses were embedded in the theoretical approach with quotations used in the analyses, and the context in which they were spoken being compared to the original transcript (Asbury, 1995, p. 418) to ensure the social interactions supported the analyses. Although the research questions were not explicitly considered during the development of codes and themes, there was a clear link between the themes and the research questions throughout the analytical process.

There are some aspects of the study that may negatively impact on rigour. Firstly, conformity or censoring (Asbury, 1995, p. 418; Sim & Wright, 2000, p. 58) may have occurred during the focus group interactions as the participants were of differing seniority and some members may have been perceived as having more 'power'. The facilitator endeavoured to encourage all participants to offer views, but conformity and censoring may have impacted the data collected. Additionally, only one focus group was possible due to the limited number of potential participants. Whilst it was not possible to be confident that there was a saturation of the reported facilitators and barriers to implementing CIMT, it was possible to reflect on the diversity of the group and to recognise that both OTs and physiotherapists, working over the range of stroke services and covering all Agenda for Change (The NHS Staff Council, 2013) job bands, were represented in the group. Whilst this does not ensure data saturation, it provides a level of confidence that the discussion was comprehensive in its scope.

## 5.6 Summary

This study reports the barriers and facilitators of CIMT as perceived by therapists working with stroke survivors in one Hospital Trust. The findings may not be directly transferable to a different setting; however, the study does provide a foundation to inform questions that should be addressed in a service implementing CIMT. Future research should address stroke survivor perceptions of the barriers to and the facilitators of undertaking a CIMT protocol.

# Chapter 6

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## **An Exploration of CIMT through Three Case Studies**

The study of complex interventions requires the collection of both qualitative and quantitative data (Campbell et al., 2000; Medical Research Council, 2008). The purpose of this chapter is to report a mixed methods, pilot study which: explored the feasibility of providing selected CIMT protocols in a UK NHS sub-acute stroke service; explored the appropriateness and practicability of qualitative and quantitative data collection and methods of analysis as a means to explore stroke survivors' perceptions and experiences of and response to CIMT; explored sub-acute stroke survivors' initial perceptions of the barriers to and facilitators of receiving CIMT; explored sub-acute stroke survivors' experiences of undertaking CIMT. This work was undertaken to address an identified gap in knowledge about the acceptability of CIMT, including the facilitators of and the barriers to undertaking a CIMT protocol. The findings from this study provide valuable information about the factors impacting implementation and provide a basis on which to build future studies to further the implementation of CIMT into practice.

## 6.1 Background

Complex rehabilitation interventions, pose specific challenges to the development of evidence and the translation of this to practice. Huang et al. (2010) noted differences between the testing of drugs and rehabilitation interventions. Huang et al. (2010) observed that animal models do not predict the functional outcomes of rehabilitation interventions which are often individualised to a participant's lifestyle; furthermore rehabilitation interventions are not 'administered'; therefore, adverse effects are more difficult to identify. In addition, blinding a therapeutic intervention in an RCT, where the intervention is evident to both therapist and participant, is not possible (Sim & Wright, 2000, p. 97). All these aspects make the translation of rehabilitation research and the subsequent implementation of innovative interventions a difficult and often a slow process (Huang et al., 2010).

OTs acknowledge the importance of a hierarchy of evidence (Ilott, 2012) but recognise that, to understand the importance and meaning of an intervention, other methods are required (Borell et al., 2012; Ilott, 2012). Borell et al. (2012) observed that the focus of OT practice, namely human occupation, cannot easily be simplified which makes its measurement challenging. Cherulnik (1983) in Sim & Wright (2000) observes that if only true experiments, in this case, RCTs are used "we stand to lose many rich opportunities to study behavior as it is influenced by real and powerful events that are scheduled and shaped by forces we cannot control" (p.35). Whilst high level quantitative methods such as RCTs afford a level of confidence in the findings (Ilott, 2012), not all knowledge can, or should be, collected in this way. Different types of research questions require different types of evidence (Seers, 2007; Tonelli, 2010). Indeed, there are some who question whether RCT can be an appropriate study design for evaluation of complex interventions, given that the outcome may be affected by variation in context or application (Seers, 2007; Walshe, 2007). The MRC (2008, p. 10) notes the importance of understanding the

acceptability of a complex intervention. The systematic review in Chapter 4 found a notable lack of evidence of both the experience of participating in a CIMT protocol, and the factors that may present barriers or act as facilitators to CIMT. The review identified a small number of potential barriers, namely: fatigue, pain, and the challenges to wearing a constraint. However, the limited scope of these qualitative findings indicated that these are unlikely to be the only barriers.

Acceptability must be addressed as part of CIMT feasibility testing. Whilst work was undertaken to understand barriers to and facilitators of CIMT from a therapist perspective in Chapter 5, further study is required to explore participants' responses to CIMT (Page et al., 2004), and to gain a detailed picture of which protocols may be feasible and acceptable (Walker & Pink, 2009), and under what circumstances.

The development-evaluation-implementation process (Medical Research Council, 2008) described in Chapter 1 proposes that evaluation and implementation of complex interventions has a number of stages: developing, piloting and feasibility testing, evaluating, and implementing. These stages are not necessarily unidirectional.

CIMT in the sub-acute phase of stroke has been evaluated through a number of high quality RCTs (Brogårdh et al., 2009; Myint et al., 2008; Wolf et al., 2006) and the systematic review, reported in Chapter 3, indicating effectiveness in increasing UL function for a specific group of stroke survivors; however, there are a number of aspects of development and feasibility that have not been explored.

The systematic review reported in Chapter 3 indicates the wide variety of protocols being used, with each aspect of dose, namely intensity, frequency and duration, being a potential variant. The most appropriate dose for any given stroke survivor (Dobkin, 2007) needs to be established.

This may be based on effectiveness, but also, as outlined by the PARIHS model, on the acceptability of the protocol.

Individual variables may also impact response to CIMT. National stroke guidance (Intercollegiate Stroke Working Party, 2012) currently recommend CIMT for stroke survivors with 10° active finger flexion and good cognitive skills. Dobkin (2007) suggests age, impairments, spared function, comorbidity, optimal time after injury, and natural history of change over time may influence outcome following stroke; however, there is some evidence that in the chronic phase of stroke the efficacy of CIMT does not appear to be related to time since stroke, side of stroke, hand dominance or gender (Fritz et al., 2006). It has been suggested that stroke survivors with unilateral spatial neglect, or sensory impairment may benefit more from CIMT than those without (Freeman, 2001; van der Lee et al., 1999). There is also evidence that cognitive ability (Freed & Wainapel, 1983; Wagle et al., 2011), mood disturbance (Ostir et al., 2008), motivation (Barker & Brauer, 2005; Bright et al., 2011; Jurkiewicz et al., 2011) and sensory impairment (Freed & Wainapel, 1983) including visual impairment (Freed & Wainapel, 1983) may have an effect on recovery. To date there has been only a limited attempt to explore these links in CIMT studies. Whilst the MRC (Medical Research Council, 2008, p. 12) advocates sub-group analysis to identify variation in outcomes and to identify those most likely to respond to the intervention, qualitative studies provide a means to gain detailed data about response to an intervention (Merlo et al., 2013) and to enable development of theory (Charmaz, 2003) that may be subsequently tested.

A number of gaps in the evidence base have been discussed. It is proposed that, by facilitating exploration of the experience and response to CIMT, qualitative studies may open a door to better understanding CIMT. Findings from qualitative studies may facilitate theory development in relation to the optimal CIMT protocol and the stroke survivors most likely to benefit most from CIMT.

This study is underpinned by the PARIHS analysis reported in Chapter 2, which was further developed in Chapter 5. These analyses identified that:

1. Little is known about the experience of receiving CIMT as this area remains relatively unexplored; there is a need for qualitative exploration of CIMT.
2. Implementation is context specific and different services might experience different challenges to providing CIMT; this needs to be addressed in future research.
3. To date there has been a limited exploration of the potential barriers to and facilitators of CIMT.

Studies need be undertaken to address these in order that implementation of CIMT can be furthered.

### **6.1.1 Rehabilitation and early supported discharge (ESD)**

UK national guidelines and strategy documents state that services should: offer high-quality stroke rehabilitation as soon as possible after a stroke and that this should continue for as long as it is required (Department of Health, 2007); and that stroke survivors should receive at least 45 minutes therapy, five days a week for as long as they are gaining benefit (National Institute for Health and Clinical Excellence, 2010). In addition, there has been a move to transfer care to the community, with the National Audit Office stating that "Community-based stroke-specialist rehabilitation teams, such as Early Supported Discharge teams, can provide better and potentially more cost-effective outcomes than exclusively hospital-based rehabilitation for stroke patients with moderate disabilities" (National Audit Office, 2010, p. 8).

ESD is a service that "allows transfer of care from an inpatient environment to a primary care setting to continue rehabilitation, at the same level of intensity and expertise that they would have received in the inpatient setting" (National Institute for Health and Clinical Excellence,

2013). ESD services, provided by a specialist multi-disciplinary team with a similar intensity of rehabilitation to a stroke unit, can reduce length of stay (National Audit Office, 2010), help stroke survivors adapt to life at home (Department of Health, 2007; National Audit Office, 2005; Winkel et al., 2008), reduce long-term mortality (Department of Health, 2007), reduce bed days (Hunter et al., 2009), reduce long-term dependency and admission to institutional care (National Audit Office, 2010), and cut costs (Department of Health, 2007). There is an aim that all stroke units should have an ESD service by 2020 for up to 43% of stroke survivors (National Audit Office, 2010). A growing number of stroke survivors will, therefore, receive at least part of their rehabilitation in an ESD service and the majority of stroke survivors using ESD will be in the sub-acute phase of stroke. As established in Chapter 5, implementation of an innovation is dependent on context and setting. Facilitators or barriers may be personal to individuals or may be organisational in nature (Rycroft-Malone et al., 2004b) and therefore may vary across settings (Greenhalgh et al., 2005). Studies of complex interventions should take account of this and be undertaken in the settings in which they are most likely to be used (Campbell et al., 2000). It is for these reasons that this study of CIMT was embedded in an ESD service.

### **6.1.2 Research aims**

The primary aims of this pilot work were to investigate the feasibility of providing CIMT protocols to individuals in the sub-acute phase of stroke as part of a UK NHS stroke service, and to test the data collection methods and the data analysis to explore stroke survivors' perceptions and experiences of CIMT. It is anticipated that the findings of this study will inform a future, post-doctoral study which will ultimately aim to evaluate the effects of a CIMT protocol and generate hypotheses about the characteristics of stroke survivors who might benefit most from the CIMT intervention. The overarching research question for this study, 'what are stroke survivors' expectations, experiences and responses to receiving CIMT in a UK NHS stroke service?' was addressed through the following research objectives:

1. To explore the feasibility of providing selected CIMT protocols in a UK NHS sub-acute stroke service.
2. To pilot the appropriateness and practicability of qualitative and quantitative data collection and methods of analysis as a means to explore stroke survivors' perceptions and experiences of CIMT.
3. To explore sub-acute stroke survivors' initial perceptions of the barriers to and facilitators of receiving CIMT.
4. To explore sub-acute stroke survivors' experiences of and response to undertaking CIMT.
5. To make recommendations to further the implementation of CIMT into practice.

## 6.2 Methodology

With the bounded realist, anti-foundationalist ontological stance and the constructivist epistemological stance discussed in Chapter 1, two approaches to this study were considered. A constructivist grounded theory approach or a pragmatic phenomenological approach.

In a grounded theory study, the researcher aims to analyse the data to generate new theory about a given subject or situation (Creswell, 1998, p. 33; Robson, 2011, p. 146), there exists "systematic inductive guidelines for collecting and analysing data to build ... theoretical frameworks that explain the collected data" (Charmaz, 2003, p. 249). Grounded theory originally evolved from an objectivist epistemology and was described by Glaser and Strauss in their seminal text in 1967 (Charmaz, 2003, p. 252; Denscombe, 2007, p. 88). It was developed to challenge the belief that only quantitative data could provide answers to social science questions and to provide a systematic approach to the development of theory (Charmaz, 2003). The proponents of this perspective recognised an external reality, with neutral observers who aimed to discover unbiased data, which was verified to 'test' the emerging theory (Charmaz, 2003).

Over time, the concepts in grounded theory have developed; some researchers favour the traditional or classic grounded theory based on a realist ontology, whilst others have founded a constructivist grounded theory paradigm which accepts the assumption of multiple realities favoured by constructivists (Charmaz, 2003; Charmaz, 2006). Processes that are corner stones of grounded theory methodology, such as undertaking data collection and data analysis in tangent, the use of theoretical sampling (the purposeful sampling of participants to facilitate the development of the theory (Robson, 2011, p.148) and the detailed use of memos to develop theory (Charmaz, 2003; Charmaz, 2006) remain constant; however, in a constructivist grounded theory paradigm, the principles and methods are used to address meaning and understanding, whilst recognising that the context in which this knowledge is gained may impact on the outcome (Charmaz, 2006). Researchers must, therefore, recognise varying views about a given construct. Grounded theory studies often deal with qualitative data; however, it is well recognised that it can be appropriate to augment qualitative data collection with quantitative data (Denscombe, 2007, p. 92; Robson, 2011, p. 147).

Developing grounded theory requires specialist skills. A novice researcher may find that without the necessary support, they find themselves moving away from a grounded theory methodology; novice researchers may be tempted to use purposive rather than theoretical sampling and rely on only one data collection method (El Hussein et al., 2014). Undertaking grounded theory requires an infrastructure and sufficient specialist expertise to ensure rigour of the process and credibility of the findings.

A pragmatic phenomenological approach was the alternative theoretical perspective considered. In contrast to grounded theory, this approach does not aim to develop a theoretical understanding of a construct but, as described in Chapter 1, aims to gain insights into the lived experience of a situation. In order to identify a given person's experience, it is usual to undertake

a small number of in-depth interviews that are either semi-structured or focused (Hoffman et al., 2010) (p.224) to gain rich data. Within the interview, the participant should have control over what is important and the direction of the interview (Hoffman et al., 2010). There is a recognition that each person's experience of a phenomenon is individual and may depend on many factors. It is not anticipated that the findings from a phenomenological study could be generalised to a population; instead, qualitative researchers consider the relevance or transferability of their findings (Hoffman et al., 2010; Lincoln & Guba, 1985).

As established in Chapter 1, the constructivist epistemological stance assumes that knowledge and understanding is constructed and dependent on a human's interactions with the environment (Crotty, 1998; Gray, 2009). The phenomenological theoretical perspective is interpretive and recognises the double hermeneutic in the construction of knowledge, where a simple hermeneutic is a person's subjective interpretation of their own reality, and a double hermeneutic is a researcher's interpretation of a participant's subjective reality (Alvesson & Skoldberg, 2009).

The phenomenological perspective, ultimately selected to underpin this study, provided the opportunity to gain insights into the lived experience of undertaking CIMT in the context of an ESD service, recognising that each participant's experience would be different, but also looked for findings that were shared.

### **6.2.1 Mixed methods case study design**

A number of unaddressed feasibility and piloting issues have been identified that may impact on the implementation of CIMT. This final study utilised mixed methods in a series of case studies to

pilot data collection methods that might ultimately address some of the identified gaps in the evidence base.

Case study methodology is an established means of evaluating practice (Bloom et al., 2009; Domholdt, 2005) with the use of mixed methods recognised as a means to understand the experience following stroke (Donnellan et al., 2013). Both qualitative (Kaminsky et al., 2014; Nicholson et al., 2014) and mixed methods designs (Freene et al., 2014; Jaarsma et al., 2015) have been successfully employed in the study of barriers and facilitators. In this study, detailed qualitative and quantitative data were collected from a small sample of stroke survivors before and after experiencing CIMT. Qualitative methods were used to explore stroke survivor's perceptions and attitudes towards CIMT through individual semi-structured interviews, utilising a phenomenological approach to establish individual stroke survivors' experiences and views of CIMT. The quantitative data collection methods and subsequent analyses were used to record stroke survivors' responses to the introduction and subsequent withdrawal of a selected CIMT protocol. The resultant quantitative data were used to help understand and triangulate the qualitative findings.

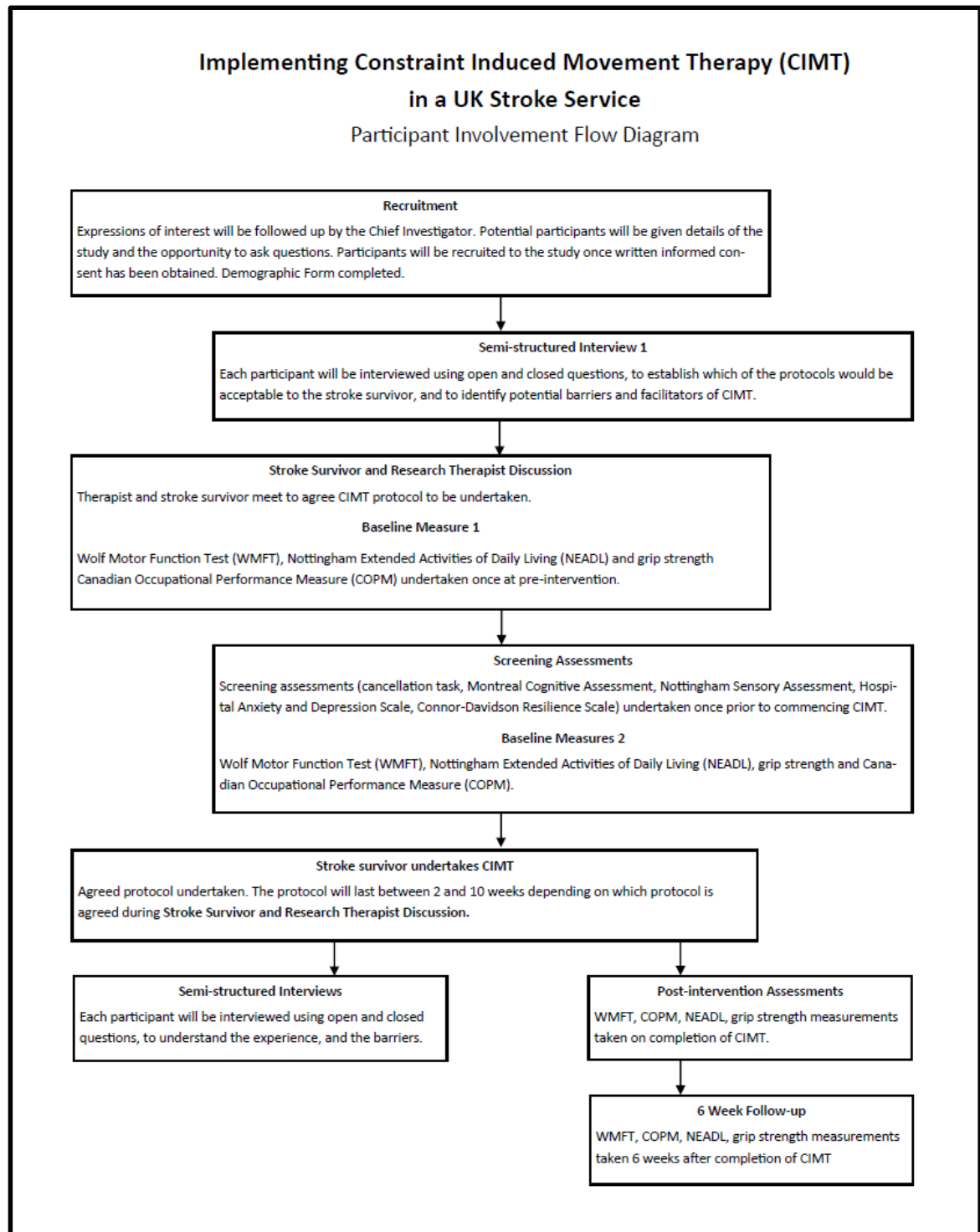
## **6.3 Methods**

### **6.3.1 Study setting**

The therapeutic context for this study was an ESD service. In the collaborating Hospital Trust, the ESD service reflected current stroke pathways (NHS Improvement, 2008) by providing UL rehabilitation following discharge from hospital in a community-based setting. This study aimed to explore implementation of CIMT in this setting.

A flow diagram of the full study is shown below (Figure 6.1).

**Fig 6.1 Flow diagram of CIMT mixed method study**



The study received favourable ethical opinion from NRES (13/NW/0309) (Appendix 16) and R&D Trust approval (Appendix 17).

### **6.3.2 Inclusion criteria**

Stroke Survivors were included if they were: more than two weeks and less than nine months post-stroke on recruitment to study; had experienced a single, first stroke; had reduced upper limb function due to paresis of the upper limb as a result of stroke; had at least 10° active extension in the more affected wrist and metacarpophalangeal joints; were able to balance safely whilst wearing the restraint (assessed through clinical observation); had been discharged from all occupational therapy and physiotherapy; and discharging therapists reported upper limb function had plateaued.

### **6.3.3 Exclusion criteria**

Stroke survivors were excluded if they: declined to participate; were still receiving occupational therapy or physiotherapy; had other neurological conditions; were unable to follow one-step instructions due to changes in cognition or communication; had changes in cognition or communication following their stroke which meant that they were not able to provide a valid consent to participate in the study. The latter was assessed using the four questions required for assessment of capacity (Department for Constitutional Affairs, 2007):

1. Can the individual understand the information provided?
2. Can the individual retain the information for sufficient time to make a decision?
3. Has the individual got the capacity to make a reasoned decision?
4. Can the individual express him/herself?

### 6.3.4 Recruitment

This study aimed to recruit four participants. Stroke survivors discharged from the ESD service were invited to volunteer for this study. This ensured baseline measures could be taken without co-interventions impacting on the findings. Potentially eligible stroke survivor participants were identified by therapy staff based in the ESD team.

Participants were initially approached by a therapist working within the ESD team. If a stroke survivor was interested in participating, a meeting with the Chief Investigator was arranged to provide further information and answer any questions. The Chief Investigator provided a verbal explanation of the study and a written Participant Information Sheet (Appendix 18). Each participant provided a written consent (Appendix 19). The Chief Investigator obtained this consent from each participant. Witnessed consent was obtained in circumstances where a participant was able to understand the patient information and could gesture their consent, but were unable to sign the consent form themselves. All participants were advised verbally and in writing (in the Participant Information Sheet and Consent Form, Appendix 18 and 19) that they were free to withdraw from the study at any time without giving a reason.

#### 6.3.4.1 Amendments to recruitment

Two amendments were made to the recruitment procedures of this study. The initial application aimed to recruit participants up to six months post-stroke. As participants were not being discharged from the ESD within this timeframe, this was amended to nine months with approval from NRES on 22<sup>nd</sup> April 2014 (Appendix 20). In the original application it was proposed that as people with unilateral spatial neglect may gain additional benefit from CIMT (Freeman, 2001; van der Lee et al., 1999), purposive sampling was to be used to ensure that at least two of the four participants had a measurable unilateral spatial neglect, identified using Albert's Test (Canadian

Stroke Network; Fullerton et al., 1986); however, as the study progressed, these initial assumptions were considered and the research team agreed that, if appropriateness for CIMT was to be considered, all eligible participants should be included irrespective of unilateral spatial neglect. This change gained approval on 9<sup>th</sup> May 2014 (see Appendix 21)

### **6.3.5 Procedures**

Each participant was offered CIMT which included the movement of the ipsilesional upper limb being constrained for a portion of time each day with a mitt specifically designed for this purpose (C-MIT® Odstock Medical Limited). In accordance with the selected protocol, the mitt covered the ipsilesional hand, thereby reducing use of this hand. During the same time period, participants also undertook activities with their contralesional upper limb on a pre-agreed schedule.

The findings from the systematic review in Chapter 3 informed the choice of protocols. As it had not previously been established which protocols were most effective, participants were offered the full range of protocols that had been found to have some evidence of effectiveness in the systematic review (based on searches complete by 7<sup>th</sup> March 2013). This practice enabled participants to express a preference for one or more protocols thereby offering additional insights into perceived acceptability and feasibility of the protocols. The most intense protocol that a participant could select required the wearing of the constraint for 90% of their waking hours and practice activities for six hours for 10 days over two weeks. The least intensive protocol required the participant to wear the constraint for five hours each day, and practice activities in therapy for one hour for three days each week for 10 weeks.

Prior to commencement of the study, discussion took place, between the Chief Investigator and the research therapists, about the type of training that would be offered during the CIMT. It was

agreed that both functional and task based activities should be used and that all activities should be selected to provide a challenge to each participant and must, therefore, be dependent on the participant's ability. The activities undertaken were documented using the Occupational Therapy Stroke Arm and Hand Treatment Record (OT-STAR) (Jarvis et al., 2014a; Jarvis et al., 2014b; Jarvis et al., 2014c). The OT-STAR was developed through consensus development to provide a means to accurately and comprehensively record OT UL stroke interventions (Jarvis et al., 2014c). Interventions are categorised using the ICF: body structure and function, activity and participation. The OT-STAR and the accompanying instruction booklet are shown respectively in Appendix 22 and 23.

Previous work has identified shaping as a potentially important element of the training component of CIMT; however, as identified in Chapter 2, shaping in CIMT has been called into question because of the ambiguity of its definition. The research therapists, in this study, were asked to describe the techniques they used to increase UL function. The research therapists described these on the OT-STAR recording forms as: the use of verbal prompts; the use of facilitation (definition from OT-STAR); and the use of assistance (definition from OT-STAR). During the discussions, the term 'grading' was generally used to describe the process of making a task more challenging. In this way the ambiguous term 'shaping' was avoided and the specific techniques were described.

#### **6.3.5.1 Assessment of risk**

The literature indicates that the intense activity involved in CIMT may cause shoulder pain in the paretic shoulder (Myint et al., 2008; Ploughman & Corbett, 2004; Tremblay & Tremblay, 2002) and fatigue (Blanton & Wolf, 1999). Although a large RCT study (N=222) (Underwood et al., 2006) did not find evidence of an increase in either shoulder pain or fatigue, these aspects were measured during the CIMT. Pain and fatigue were measured using a visual analogue scale (0-10).

The scales were completed at the start and end of each therapy session. Where there was an increase in fatigue level, from one therapy session to another, of three points or more at either the start or end of the day, or between the start and end of a day, the therapist discussed the change in fatigue level with the participant, discussed possible strategies to reduce fatigue, and checked that the participant was prepared to continue with the CIMT. If the participant did not want to continue, the protocol was terminated. If the participant reported an increase in pain of two points or more on the visual analogue scale, the therapist informed the Chief Investigator. The participant, therapist and Chief Investigator met and agreed an action plan which might involve: adaptation of the activities or the CIMT protocol; referral to have pain assessed or treated; or termination of the protocol. All discussions and decisions were recorded.

As the non-paretic upper limb was constrained during the CIMT, this might have compromised a participant's balance and increase the risk of falling. To minimize this risk, the constraint mitt only prevented movement in the hand, the participant still being able to use their upper limb to steady him/herself to balance. All aspects of the intervention were discussed with, and the constraint shown to, the participants before they were required to decide if they wanted to participate. The risks were fully explained and an assessment of safety was undertaken and documented before the CIMT was commenced; any actions taken to reduce risks were documented.

### **6.3.6 Data collection**

#### **6.3.6.1 Initial data collection and screening assessments**

Where a stroke survivor consented to participate, demographic information was collected from the participant medical notes to complete a participant Demographic Form (Appendix 24).

It had been suggested that chronicity of stroke, hand dominance and side of hemiplegia should also be investigated for prognostic influence (Stevenson & Thalman, 2007). Information was therefore collected about each of these through the Demographic Form.

Prior to undertaking CIMT, the participants undertook the following assessments: Albert's Test (Canadian Stroke Network; Fullerton et al., 1986) to assess for unilateral spatial neglect; Nottingham Sensory Assessment (NSA) (Lincoln et al., 1998) to test upper limb sensation; Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) to assess mood disturbance; Montreal Cognitive Assessment (MOCA) (Nasreddine et al., 2005) to screen for cognitive abilities; an abbreviated Connor-Davidson Resilience Scale (CD-RISC) (Campbell-Sills & Stein, 2007) to measure resilience. The data collected from these assessments were used to explore potential patterns emerging between stroke survivor profile and their response to CIMT. Where there were validated forms available in the above references, these were used to record the outcomes (NSA, HADS, MOCA). Data collection forms were designed to record the Connor-Davidson Resilience Scale and the Albert's Test, these are shown in Appendix 25.

#### **6.3.6.2 Qualitative data collection**

Each participant was interviewed prior to and following participation in an agreed CIMT protocol.

The pre-CIMT semi-structured interview lasted for up to 60 minutes. During the interview participants were asked to consider and discuss their perceptions of, and their attitudes towards CIMT. The interview questions were structured with respect to the research questions (see Appendix 26 for interview schedule). The nine CIMT protocols were presented in written format, summarised in a table (Table 6.1), and supported by a verbal explanation, to enable the participant to consider the feasibility and acceptability of the individual protocols. If a participant consented and participated in an interview, but as part of this process decided that they did not

want to, or were unable to undertake a CIMT protocol, with the participant's consent, the data from the interview was analysed, and included in the study findings. Where a participant's speech had been affected by the stroke, strategies were used to facilitate communication throughout the research process, using specialist guidance from Connect (The Communication Disability Network) (Connect, 2007).

Following this pre-CIMT interview, the participants were invited to undertake a CIMT protocol. A discussion took place between the stroke survivor, the Research Therapist who would be providing the CIMT and the Chief Investigator. The purpose of the discussion was to agree the CIMT protocol and to agree the details of when and where the protocol would be provided. This discussion utilised the findings from the stroke survivor's pre-CIMT interview. Each participant was asked to consider the evidence-based CIMT protocols, (identified in Chapter 3, summarised in Table 6.1), and identify the protocols they would be prepared to undertake. The final selection of the protocol was led by participant preference. The discussion reflected a therapist-patient discussion and collaborative decision-making process used in clinical practice. If no agreement could be reached the reasons for non-agreement were documented, and the CIMT protocol was not undertaken.

Following participation in a CIMT protocol, participants were invited to take part in a second semi-structured interview, which lasted up to 60 minutes. During these post-CIMT interviews, participants were asked to discuss their experience and to describe any barriers and facilitators in undertaking the CIMT protocol; the interview schedule is presented in Appendix 27.

Both interviews were audio-recorded. Following each interview a second consent was completed to ensure that the participant had control over how the data were reported (Appendix 28)

Table 6.1 Summary of CIMT protocols for discussion

Length of protocol	No. of training days per week	Training	Restraint	No. of restraint days per week	Restraint	Homework	Behavioural contract	Log restraint/ use of UL	Citation	Summary of Outcome
2 weeks	5	Up to 6hrs per day <i>Average 4.5hrs (Underwood 2006)</i>	90% of waking hours	7	Mitt	Practice 2-3 tasks at home Encouraged to do about 30 mins of task practice daily after completion of intervention	Behavioural contract and caregiver's contract	Home dairy to report mitt wearing	Wolf et al (2006)	CIMT more effective than usual therapy Strong evidence with a low risk of bias
2 weeks	5	4hrs per day	90% of waking hours	5	Sling	Not reported	Contract to wear restraint for 90% of waking hours	Log of sling use	Myint et al (2008)	CIMT more effective than equal duration usual rehabilitation Moderate risk of bias
2 weeks	12 consecutive days	3hrs	90% of waking hours	12 consecutive days	Mitt	Not reported	Not reported	Log of restraint	Brogårdh et al(2009)	CIMT with restraint as effective as same training without restraint Low risk of bias
2 weeks	5	1 hr	4hrs per day	7	Mitt	Not reported	Not reported	Not reported	Treger et al (2012)	CIMT with restraint as effective as same training without restraint Moderate risk of bias
2 weeks	5	3hr per day	6 hrs per day	5	Sling	Not reported	Not reported	Not reported	Hammer & Lindmark (2009)	CIMT as effective as equal duration usual rehab) Moderate risk of bias

Length of protocol	No. of training days per week	Training	Restraint	No. of restraint days per week	Restraint	Homework	Behavioural contract	Log restraint/ use of UL	Citation	Summary of Outcome
3 weeks	5	5hrs per day	5hrs per day	'Each day' not stated if this included weekends	Sling	Task practice homework for a few weeks after treatment	Not reported	Not reported	Krawczyk et al (2012)	CIMT with restraint as effective as same training without restraint Moderate risk of bias
4 weeks	Not reported	4hrs per week	4hrs per day	7	Mitt	Self-training exercises Use arm 2-3 hrs each day in addition to therapist-led training	Not reported	Log of exercise Log of restraint	Brunner et al (2012)	CIMT as effective as a bimanual training of equal duration Moderate risk of bias
4 weeks	5	3hrs	90% of waking hours	5	Resting splint	Not reported	Not reported	Not reported	Wang et al (2011)	CIMT as effective as equal duration conventional rehabilitation CIMT more effective than conventional rehabilitation Moderate risk of bias
10 weeks	3	1hr	5hrs per day	5	Sling and mitt	Not reported	Not reported	Not reported	Atteya (2004) Page (2001) Page (2002)	CIMT was more effective than usual therapy CIMT was more effective than no therapy High risk of bias

### 6.3.6.3 Quantitative outcome measures

This quantitative element of the study was observational in nature to explore the effects of CIMT on upper limb function in each of the participants. The outcomes measured in this study were selected to cover three domains in the ICF (World Health Organization, 2002): body function (grip strength); activity (WMFT); and participation (Canadian Occupational Performance Measure and Nottingham Extended Activities of Daily Living Scale).

#### 6.3.6.3.1 Primary outcome

The WMFT is a detailed measure of upper limb activity, developed for CIMT research (Taub et al., 1993; Wolf et al., 1989), used extensively in stroke research (Hsieh et al., 2009), with established test-retest and inter-rater reliability (Lin et al., 2009a; Morris et al., 2001; Wolf et al., 2001), concurrent (Lin et al., 2009a; Nijland et al., 2010; Wolf et al., 2001) and criterion validity (Wolf et al., 2001). The WMFT comprises 15 items, each is timed (performance time) with a maximum time of 120 seconds and allocated a functional ability score (0-5). The scoring scheme and the tasks comprising the WMFT are shown in Appendix 29.

Two studies have calculated the minimal clinically important difference (MCID) for the WMFT. Both have used a mean functional ability score and performance time as the basis for this calculation. Lang et al. (2008) calculated the MCID for WMFT function ability score in the acute phase of stroke as 1.0 points for the dominant hand and 1.2 points for non-dominant hand. These were anchored against participant perception of the change. It was not possible to calculate a WMFT time MCID for the non-dominant hand, as this hand did not show a relationship with perceived change; however, the MCID for the dominant hand was estimated as -19 seconds.

A further study of participants in the later stage of stroke found the minimum detectable change (MDC) for WMFT performance time to be 4.36 seconds and WMFT function ability score to be 0.37 (Lin et al., 2009b). Lin et al. (2009b) found MCID range to be between 1.5 and 2 seconds for time and between 0.2 and 0.4 for functional score. As the MCID for the WMFT performance time is lower than the MDC, the MDC of 4.36 seconds for performance time and 0.37 for functional ability score were taken as the MCIDs in this study.

In an amendment to the original protocol, permission was sought and gained (Appendix 30) from the NRES panel to video-record one of the baseline and the post-CIMT WMFT measures, to provide a visual record of any changes.

#### **6.3.6.3.2 Secondary outcomes**

It has been recognised that there is a need to include a measure of participation in CIMT studies (Dobkin, 2007; Peurala et al., 2012). The Canadian Occupational Performance Measure (COPM) (Law et al., 2000; The Canadian Occupational Performance Measure, 2015) enables a participant to select and rate activities of most importance to them (Law et al., 2000). It is an individualised measure, but has been shown to have good test-retest reliability and discriminant validity (Cup et al., 2003). Respondents are interviewed about their occupations and a list of up to five occupations that are currently causing difficulty are identified. The respondent then allocates a score from 0-10 for importance, performance and satisfaction for each identified occupation. The mean for performance and satisfaction are calculated, giving a score between zero and 10 for both. The validated scoring form (The Canadian Occupational Performance Measure, 2015) was used to record the COPM outcomes. Although an MCID has not been formally established, the authors of the COPM (Law et al., 2000) propose that, based on studies across a range of populations and interventions, an increase of 2 points can be considered as an important change for the COPM.

The Nottingham Extended Activities of Daily Living Scale (NEADL) (Nouri & Lincoln, 1987) is a questionnaire of activities of daily living, and has been found to be responsive and valid with stroke participants (Wu et al., 2011) with established reliability in non-stroke groups (Harwood & Ebrahim, 2002; Nicholl et al., 2002). It presents 22 occupations and requires the respondent to state if they have completed the activity within the last few weeks. Each item is scored 0 or 1, producing a total score of 0-22. The MCID has been calculated by two different measures (Wu et al., 2011). It was calculated as 2.4 points by distribution and 6.1 points when calculated through anchoring with an alternative ADL scale (Stroke Impact Scale, ADL domain). As the 2.4 point calculation is lower than the minimal detectable change (MDC), calculated at 4.9 points, the MCID cannot separate potential change from differences in the measure that has occurred by error (Lin et al., 2009b). Therefore the 6.1 anchored MCID was used in this study.

Grip strength was measured using a Jamar® hydraulic hand dynamometer. Dynamometers have been shown to produce a valid measure of this construct with a good inter-rater and test-retest reliability (Hamilton et al., 1994; Mathiowetz et al., 1984). Lang et al. (2008) calculated the MCID for grip strength as 5 kg for the dominant hand and 6.2kg for the non-dominant hand in acute stroke participants. Although the authors propose that these MCIDs may be higher than would be expected in the later stages of stroke, due to high expectations for recovery, these provide a reasonable estimate of the grip strength MCID for sub-acute stroke.

The WMFT (Taub et al., 1993; Wolf et al., 1989), NEADL (Nouri & Lincoln, 1987) and grip strength (Hamilton et al., 1994; Mathiowetz et al., 1984) were completed at two baseline measurement sessions (pre-intervention) not more than fourteen days apart, post-intervention, and at six week post-intervention follow-up. The baselines were completed twice to explore the stability of the participants' UL function prior to commencing the CIMT. The initial COPM assessment takes the form of an interview, whilst the re-assessments do not (Law et al., 2000). It would be

inappropriate to undertake this interview twice at baseline; therefore, the COPM (Law et al., 2000) was administered once pre-intervention (baseline), then at post-intervention and six weeks post intervention follow-up.

### **6.3.7 Data analysis**

#### **6.3.7.1 Analysis of qualitative data**

The audio-recordings from the interviews were transcribed verbatim.

Analysis was undertaken following guidelines for interpretative phenomenological analysis (IPA) described by Willig (2001). In the first phase, the researchers (KJ and SH) independently aimed to become familiar with the text. The text was read and re-read, to gain an overview of the content. The same researchers developed 'a feel' for the interview and the broad concepts encompassed within. In the second phase, the researchers (KJ and SH) worked through the text line by line (for one of the researchers (KJ) this was completed in conjunction with listening to the audio-recording where it was available), and open coding was used to extract data and capture the meaning of what was articulated; these strings of text were allocated an initial label or code. In the third stage these codes were analysed using an inductive approach (Silverman, 2000) for shared 'reference points' (Willig, 2001). Where there was a perceived sharing of meaning, these codes were clustered to develop themes. The researchers worked independently, and then met to compare the initial codes and themes. The emergent codes were compared and, where differences arose, the original data were considered and agreement reached. Once agreed, the initial themes were also considered. Themes were also discussed and agreed. This process included the development of sub-themes where the data indicated this would assist the theme structure. The data continued to be identifiable as pre-CIMT or post-CIMT. This enabled a comparison of the facilitators and barriers at different time points. Although Willig (2001)

advocates development of a table to summarise the emergent themes and the primary data that constitutes each theme, in this study, the use of the modelling feature in NVivo 10 served the same purpose. This feature was used to develop a diagrammatic representation of the themes. It also enabled cross-referencing between the themes and the original codes that made up that theme. As the findings were developed, all the primary data recorded within a theme were reviewed to ensure they supported that theme. An example of how IPA was used is provided in Appendix 31.

#### **6.3.7.2 Reflexive processes**

A number of strategies were employed to increase self-awareness, and address the impact of the researcher on the collection of qualitative data, its analyses and the ultimately the findings. Self-reflection was undertaken individually, as part of supervision and during conversations with a 'critical friend'. These reflections were supported by field notes during data collection and a reflective log throughout the process. The reflective log was particularly valuable during analyses, enabling reflection on the impact of the interactions and the researcher's experience and beliefs on the interpretation of the data. Decisions made during the data analyses process were documented, thereby producing an audit trail.

Each case study was analysed separately. Once this stage was complete, a comparison across the case studies was undertaken to look for patterns that may have been present in the findings. The aim of this was to provide evidence to answer the research questions.

It was not possible to pilot the interview schedule as it relied on the respondent having undertaken a CIMT protocol; therefore, the interview schedules and qualitative data analysis were reviewed following each case study. Changes were made where this was indicated to gain a

better understanding of the participants' experiences of undertaking a CIMT protocol. All changes were recorded.

#### **6.3.7.3 Analysis of quantitative data**

Analysis of the quantitative data from the case studies (WMFT, COPM, NEADL and grip strength) was descriptive in nature. Visual and descriptive analyses were examined for the differences between the baseline, pre- and post-CIMT data. Where there was variation in baseline scores, the 'best' score was used. This was the higher score for all measures except for WMFT performance time where a lower score indicated better performance. Changes were compared against the relevant MCID. In this pilot study, the quantitative outcomes were analysed to explore whether changes in quantitative measures supported the qualitative findings.

## **6.4 Findings**

Recruitment to the study was slower than anticipated with therapists identifying only three potential participants from the start of December 2013 to the start of November 2014. Each of the three stroke survivors, approached to consider participation in the study, consented and subsequently participated in the study. The findings are reported below; a pseudonym has been used for each participant to ensure anonymity.

### 6.4.1 Case study 1: Janet

#### 6.4.1.1 Background information

Janet was 58 years of age on recruitment to the study. She lived with her daughter, but her daughter was out of the house for large parts of the day. Janet experienced a right-sided ischaemic stroke, resulting in a left-sided hemiparesis, six months before being recruited to the study. Prior to the stroke Janet worked and drove a car. She was right hand dominant. Janet selected the two week protocol with three hours training each weekday and six hours constraint per day.

##### 6.4.1.1.1 Findings from screening

Table 6.2 summarises the findings from the screening assessments.

**Table 6.2 Janet's screening assessments results**

Assessment	Score	Outcome
HADS (anxiety)	11	Indicated a potential issue
HADS (depression)	15	Indicated a potential issue
CD-RISC (resilience)	64	Lower than general population
MOCA (cognition)	27	Normal
Line crossing	36	Normal
Light touch (Left/Right)	6/12	Left UL impaired
Temperature (Left/Right)	6/12	Left UL impaired
Pinprick (Left/Right)	8/12	Left UL impaired
Pressure (Left/Right)	12/12	Normal
Tactile localisation (Left/Right)	6/12	Left UL impaired
Bilateral simultaneous touch	12	Normal
Proprioception (Left)	10	Left UL slightly impaired
Stereognosis	19	Normal

### 6.4.1.2 Qualitative findings

#### Pre-CIMT interview

The initial analysis led to the development of six themes; these are shown in Appendix 32.

Following discussion, 'practicalities of CIMT' was re-named 'undertaking CIMT' to indicate a broader remit to encompass the impact of wearing mitt and understanding CIMT protocol. It was also agreed that the 'benefits' theme would be more precise if it was re-named 'impact of CIMT'.

The researchers agreed that this theme encompassed codes such as fatigue/sleep, pain and response to CIMT. This theme was separated into 5 sub-themes to describe the impact, namely: physical, psychological, behavioural, functional and external. The initial themes 'the future' and 'potential barriers' and 'what was important?' were retained. This analysis resulted in five themes: impact of CIMT, undertaking CIMT, 'what was important?', the future, and potential barriers. The themes and sub-themes are shown diagrammatically in Figures 6.2a to 6.2e.

**Fig 6.2 Janet's themes and sub-themes**

**Fig 6.2a Theme 1: impact of CIMT**

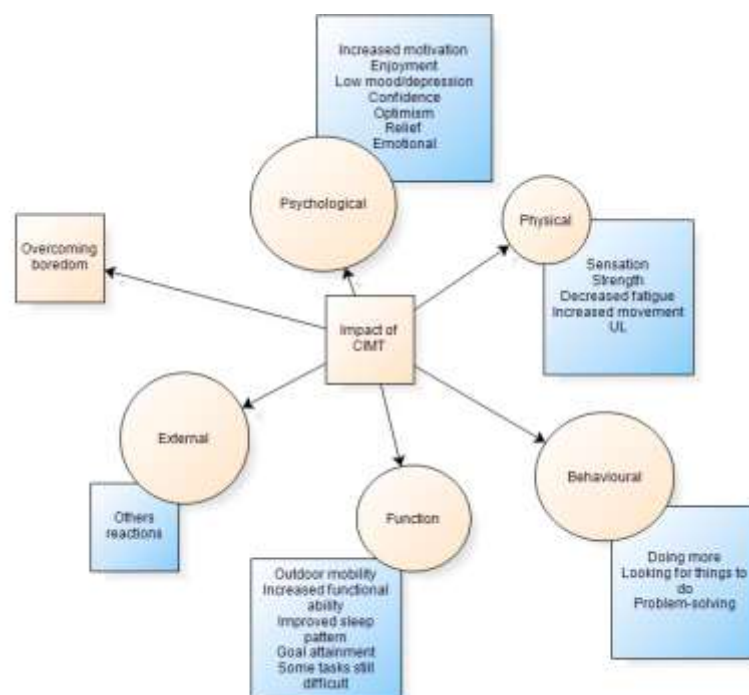


Fig 6.2b Theme 2: undertaking CIMT

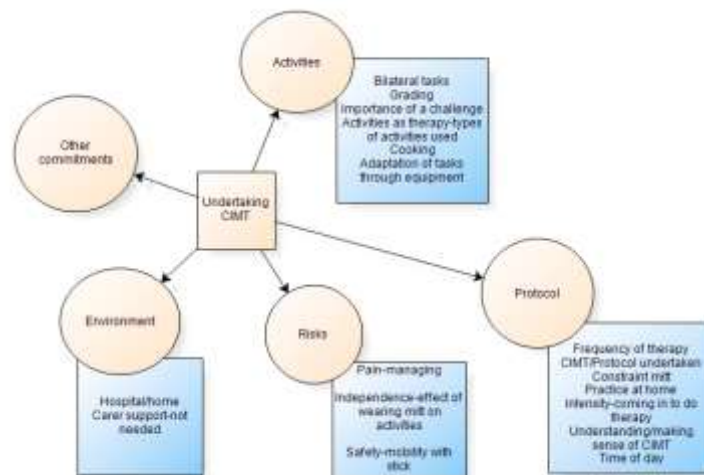


Fig 6.2c Theme 3: what was important?

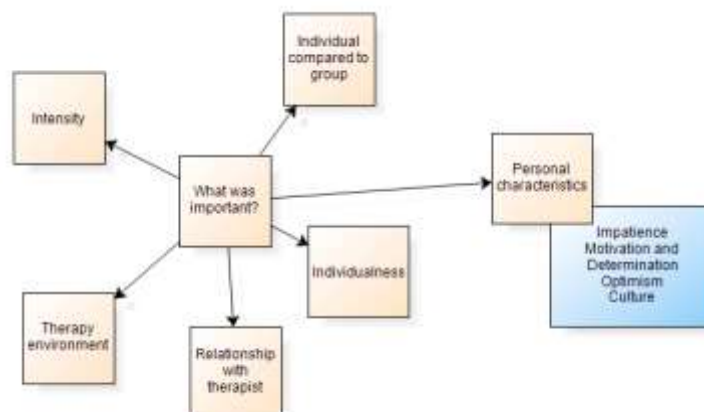
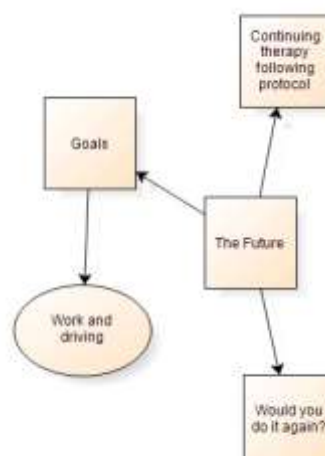
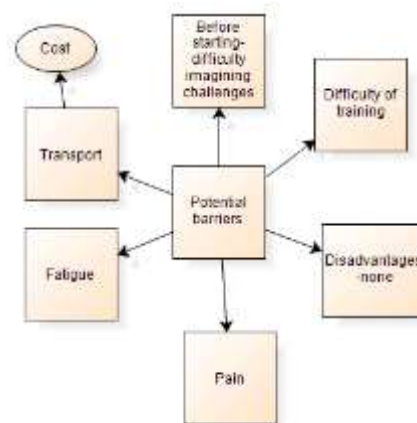


Fig 6.2d Theme 4: the future



**Fig 6.2e Theme 5: potential barriers**

These themes are described in more detail below.

#### **6.4.1.2.1 Impact of CIMT**

This theme encompassed most data. There were a number of sub-themes that emerged strongly when the data were interpreted. The first focused on Janet’s sleeping pattern. Prior to the CIMT, Janet reported a disrupted sleeping pattern:

*“...I can stay up until three or four o'clock in the morning, I can stay up all night and not go to bed because I'm awake, but then other times, like, I'll fall asleep on the couch.”*

She also stated:

*“...if my brain stops working, I go to sleep...If I sit down and relax, I just conk out.”*

Looking back after experiencing CIMT, Janet reflects on the reasons that her sleep pattern was disrupted:

*“Because you're bored, you'll sleep all the time”*

Additionally she stated:

*“...half the time, I usually just stay on the couch and have fits [of sleep] and dozes all through the night, because I wasn't tired enough to sleep properly.”*

This gives a picture of Janet's occupational deprivation prior to the CIMT and her subsequent dozing during the day. Janet perceived the impact of this to be a disrupted overnight sleep as she was not sufficiently tired. Following the CIMT, Janet's sleep routine appeared to have changed and there was evidence of occupational benefits:

*“I'm sleeping better, I feel livelier, you know, because I'm not just going home, sitting down and going to sleep, I'm doing things, playing in the garden with the ball with the dogs, you know.”*

In addition, there was evidence the CIMT impacted on Janet's well-being:

*“Well, just a job, like, it's [the CIMT] made me get up more. Like, I'd most probably stay in bed 'til about three o'clock otherwise. I think that's why I'm brighter because I'm doing more, not only is my brain but my body is using more energy, isn't it? So I'm sleeping better than what I was because I sleep right through with no problems at all when in bed ...But I have got back into a sleeping pattern now...I was up an hour earlier than what I normally would have been today...I've been up and sat around, and read my emails and*

*things this morning because I do feel livelier and I'm not, like, sitting constantly falling asleep out of boredom as well."*

Janet indicates an occupational change when she comments in the pre-CIMT interview that she dozes off while watching the television, whilst in the post-CIMT interview she comments that she is now seeing all her programmes.

The impact of the stroke on mood was another sub-theme that emerged. During the post-CIMT interview, Janet was tearful; amidst this emotional response she stated:

*"...I was getting to the point where it was depressing me because I couldn't do things [crying]."*

She also stated:

*"It just overwhelms you [crying] Like, I've always been very independent, I've lived most of my adult life on my own and done things for myself, like decorating and everything. And knowing I couldn't do that anymore frustrates."*

There were further indicators of Janet's low mood in the following post-CIMT exchange:

Janet: *"...Because, like, you get to the point where you go stale and you get lazy."*

Interviewer: *"And you think you got to that stage before [the CIMT]?"*

Janet: *"Oh, God, definitely, you know. Couldn't be bothered washing my hair, getting dressed or nothing."*

This evidence of low mood was supported by Janet's pre-CIMT HADS score which indicated a potential issue with both depression and anxiety at the start of the study (see Table 6.2). As the HADS was a screening tool, there was no HADS data available post-CIMT. There was, however, evidence that following the CIMT Janet's outlook had changed:

*"It gives me the will to want to get out and do the work now, whereas I wasn't really bothered. But I've enjoyed coming back out."*

Furthermore, she was more confident to undertake occupations:

*"... I'm getting to the point now where I'm trying more stuff because I feel more confident this week."*

There were other indicators of changes in confidence; pre-CIMT, Janet stated:

*"...when I'm out, I mainly use my right arm for my stick anyway, because I don't feel confident enough to give the stick up yet."*

The following interaction, post-CIMT, seems to indicate a change in confidence that related, at least in part, to Janet's increased ability to use her contralesional UL to maintain safety:

Janet: *"... I think it's because I'm occupied, I feel more confident in myself...when I went out last night, I left the stick at home..."*

Interviewer: *"So what do you think's made you more confident?"*

Janet: *“Coming out every day, meeting more people, being able to use my hand more. Because I know if anything happens, I can stop myself falling with my hand. Because that's how I fell originally, I couldn't get hold of the ambulance with that hand, because I didn't have the movement. But I have now.”*

Interviewer: *“So when have you gained that? Have you gained that in the last few weeks or did you gain it before that?”*

Janet: *“No, I think more in the last two weeks because I'm doing it every day.”*

There were numerous examples of Janet attempting more occupations following the CIMT. Some of these were in the therapy sessions:

*“I even put the scones in the oven yesterday, which I hadn't done before because I didn't have the strength in my wrist to hold the thing.”*

Most changes however, were in Janet's everyday environment whilst participating in her own occupations. She reported changes in personal activities of daily living (PADL):

*“Even the likes of putting my socks on and drying myself, washing myself, I'm doing it more each day with my hand. Like, when I had a shower, [my daughter] would come in and do under this arm for me because I couldn't reach. But now I am attempting it because I have got more movement in it, as you can see.”*

Post-CIMT Janet's motivation and determination is apparent in undertaking domestic activities of daily living (DADL):

*“Like, the shopping the other day, she [daughter] mentioned she needed water. I was already getting cat food, which I've learnt to take that bag with me because I can fit six tins of cat food in that...And then I thought she wanted water, I can't carry that as well, I'll push the trolley up the street. So I pushed the trolley up the street, rather than go back and get it...and it's not an easy task because there's a speed bump halfway up, I've got to get it over the bump. Like, I wouldn't have thought that before, I would have just left it or she would have got her water herself.”*

And also with household occupations:

*“Oh, yeah, I've done a lot more than what I would have done. Like, [daughter] was made up when she come home and found all the towels all folded for a change, instead of it all just left, and all the pyjamas all piled up neat, instead of just left. I went through all the wardrobe, I got all the stuff out that I hadn't worn for a bit, all the pyjamas and put away for the winter. And I did all them. And usually, like, it would be a big stack of washing for her to sort out.”*

There were also indications of changes in leisure occupations:

*“Now that the weather's nicer, I thought, well, play with the ball, because I've been bowling in here [rehabilitation unit] and my aim wasn't very good. So we [Janet and her dog] played with the ball in the garden the day before yesterday.”*

Whilst talking about changes in her ability to fasten a seatbelt, Janet described how she felt the CIMT had impacted on the occupation she was undertaking:

*“...it does teach you to think more of how you can do it to a) not hurt your arm, and b) make sure you're safe...Like, sometimes I just sit and hold it [the seatbelt], rather than try. But last night, our [brother] said, are you alright there? I said, I've done it myself.”*

In addition to the above examples, Janet reported removing weeds and dead-heading plants in the garden, shopping on her own every day where previously she had only gone with her daughter. She described a new found ability to open crisp packets using both hands rather than her teeth and the Research Therapist and her daughter commented on her increased use of her UL when communicating. Janet was also considering how to start using buses in the post-CIMT interview; this goal was achieved six weeks later when she travelled independently by bus to her final measures appointment.

#### **6.4.1.2.2 Undertaking CIMT**

Janet had previously experienced group therapy prior to the CIMT, and felt that the individual CIMT sessions had been preferable to a group:

*“Because I think doing the things we've done in the group once a week, obviously there's people worse off than me anyway, so they get priority and it gets a bit boring. Whereas [with CIMT] you're looking for something new to do all the time every day and it's one to one and you're, sort of, not left on your own, are you? Whereas sometimes in the group, you're just left reaching and grasping, and that bores me.”*

On a practical level Janet was able to put on and take off the constraint mitt independently; she would remove it at times during the constraint time, but felt that it had a role in the therapy:

*“It was strange at first, but...and I was still tending to use my hand, but it did get easier. It gets a bit warm. I got days where I took it off and I just put my hand away somewhere. But it does teach you to use your other hand, you know, and not be dependent on the unaffected hand, as they call it. And you try and do more, it does work.”*

There was evidence of Janet continuing to practice activities at home:

*“Grooming the dog was fun...I felt so...it felt so weird trying to brush him with my left hand. And my big dog, he tends to get over excited because he likes it. Even the cats, I try to do the cats every day with the little comb. And I'm doing that, you know, as much as I can, whenever they come near me, I get the comb out. The kitten's even getting to the point where, if I take the comb out and tap it, she'll come and get combed. She's getting used to getting it done, as well as me getting used to doing it.”*

#### **6.4.1.2.3 What was important?**

As previously identified, Janet felt the individual sessions were important. When asked what was important about the one to one sessions, Janet stated:

*“...you're learning, you learn more to adapt more, and I think you can talk more about what's happened with you.”*

She also indicated that intensity of the therapy and a focus on her UL was important. Prior to the CIMT, Janet reported:

*“Well, I did find that because, like, I was only getting a couple of hours [of therapy] here and there. When I was in the home, I found they would concentrate longer on my walking before anything else. So they didn't do a lot with my hands, to start with. So when I started coming here [rehabilitation unit], I felt as though, when I went on the machine thing, I felt as though it was doing more for my hand.”*

Following the CIMT, the importance of intensity and individualised treatment was articulated:

*“I think one to one therapy is a lot more useful, constant therapy is a lot more useful than once a week. Because you tend to get lazy and don't do it, whereas I want to do it.”*

In terms of fitting the protocol into her week, Janet indicated she was prepared to stop her usual activities, such as going to the gym for a short period to allow for the CIMT protocol.

In terms of fitting the CIMT into her life, Janet compared to it being like a job it was “Just like going to work, wasn't it?”

Janet chose to have her therapy at the rehabilitation unit as she thought that her dogs would be too noisy at her home. She indicated that the rehabilitation unit worked well as an environment for therapy as it was not too “bustly”. There was also a recognition that CIMT would be hard to do unless you got on with the therapist.

It seemed that Janet's response to CIMT was important to her; she was tearful through the post-CIMT interview, expressed relief at the change that had been noticed by both herself and those around her.

*"I think a lot of it is relief as well that something's happening, that it's doing something now, because it wasn't working before."*

#### **6.4.1.2.4 The future**

Janet seemed to have optimism for the future, expressing determination through plans to continue to use her left UL at home:

*"...I intend to every day try and do a bit more. Like, washing the dishes, I try and do it all the time with it [left UL]. It's the pans and things I can't deal with but, like, eventually I'll get there."*

Janet maintained her goal to drive throughout the time of the study. Following the CIMT, Janet was also expressing a wish to undertake voluntary work, and had applied for three jobs in the week prior to the post-CIMT interview. She stated:

*"... I think it does give you the confidence to be more motivated, you know. Because now I'm thinking I can go back to work, whereas I didn't think I ever would."*

#### **6.4.1.2.5 Potential barriers**

This theme contained only a small amount of data. Fatigue and pain did occur (the quantitative measures are reported in section 8.4.1.3.2). Janet did experience some pain:

*"that was the first day we made scones and I said, oh, I can't do it, it's absolutely killing me."*

However this did not appear to present an actual barrier, as Janet managed her pain during the remainder of the protocol with analgesics.

Transport may have been a barrier had it not been possible to provide a taxi, although Janet indicated that she would have overcome this barrier:

*“I'd need to get the bus, wouldn't I? It's that simple because I can't afford taxis all my life. Even if I go back to work, I can't afford taxis here, there and everywhere.”*

There appeared to be few barriers, and a number of important changes for Janet following the CIMT. Her enthusiasm to attempt tasks and her optimism for the future was apparent through her words and her emotional response during the post-CIMT interview.

#### **6.4.1.3 Quantitative outcomes**

##### **6.4.1.3.1 Fatigue and pain**

Janet's fatigue score varied considerably during protocol ranging from 0-8 on a 0-10 Likert scale. There was an increase of three or more points on three occasions. These were discussed and this was carefully monitored. On days two to four fatigue was high, but this had reduced by day five of the protocol.

Pain score ranged from 0-8 on a 0-10 Likert scale. The pain score increased by two points three times during the protocol; this shoulder pain was managed with analgesics.

### 6.4.1.3.2 UL function

The improvements after CIMT reported in the post-CIMT interview were supported by some of the quantitative findings. A summary of the findings is provided in Table 6.3.

**Table 6.3: Summary of Janet's contralesional UL quantitative outcomes**

Assessment	Baseline 1	Baseline 2	Mean of Baselines	Post-CIMT	6 week follow-up	Pre-CIMT to post-CIMT change score	Pre-CIMT to 6 week follow-up change score
Total WMFT FAS	42	41	41.5	55	48		
Mean WMFT FAS	2.8	2.73	2.77	3.24	2.82	0.44*	0.02
Total WMFT Time (seconds)	202.75	212.78	207.77	35.01	37.24		
Mean WMFT Time (seconds)	13.52	14.19	13.86	2.05	2.19	-11.47*	-11.33*
Mean grip (kg)	2.33	2.00	2.17	5.00	2.50	2.67	0.17
NEADL	12	11	11.5	17	20	5.0	8.0*
COPM - performance	2.4	Not assessed	2.4	4	4	1.6	1.6
COPM - satisfaction	2.2	Not assessed	2.2	4.2	4.2	2.0*	2.0*

\* indicates the change score exceeds the MCID

WMFT-Wolf Motor Function Test

NEADL-Nottingham Extended Activities of Daily Living Scale

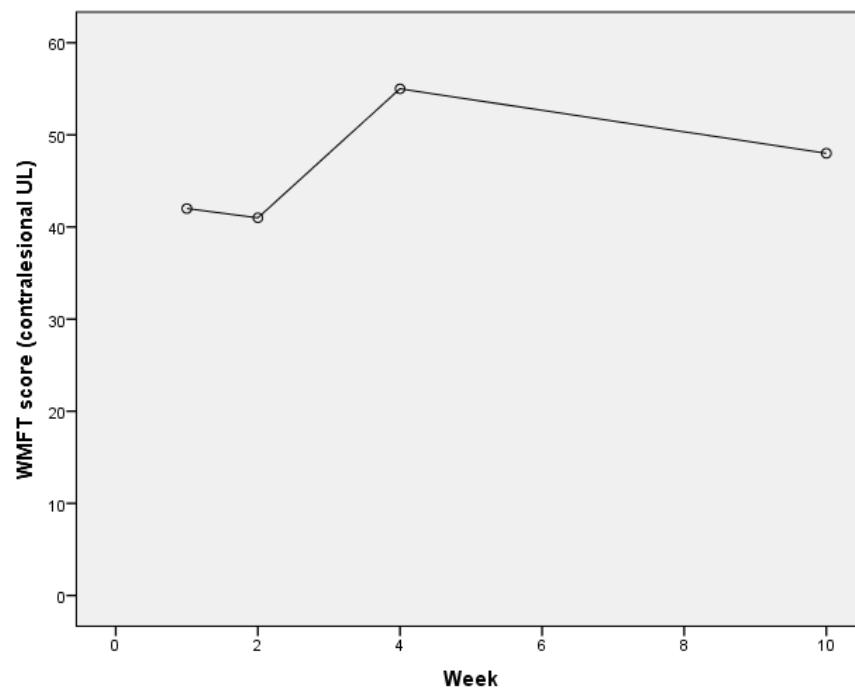
COPM-Canadian Occupational Performance Measure

At week 4 (post-intervention), the functional improvements reported in the interview corresponded with a small improvement in WMFT functional ability score (Figure 6.3) and reduction in WMFT performance time (Figure 6.4) that were greater than the MCID (change score as a mean WMFT functional ability score 0.79, and of mean WMFT performance time 10.17 seconds). Whilst the performance time change score was maintained at the six week follow-up there was a reduction in WMFT functional ability score; the pre-intervention to follow-up change

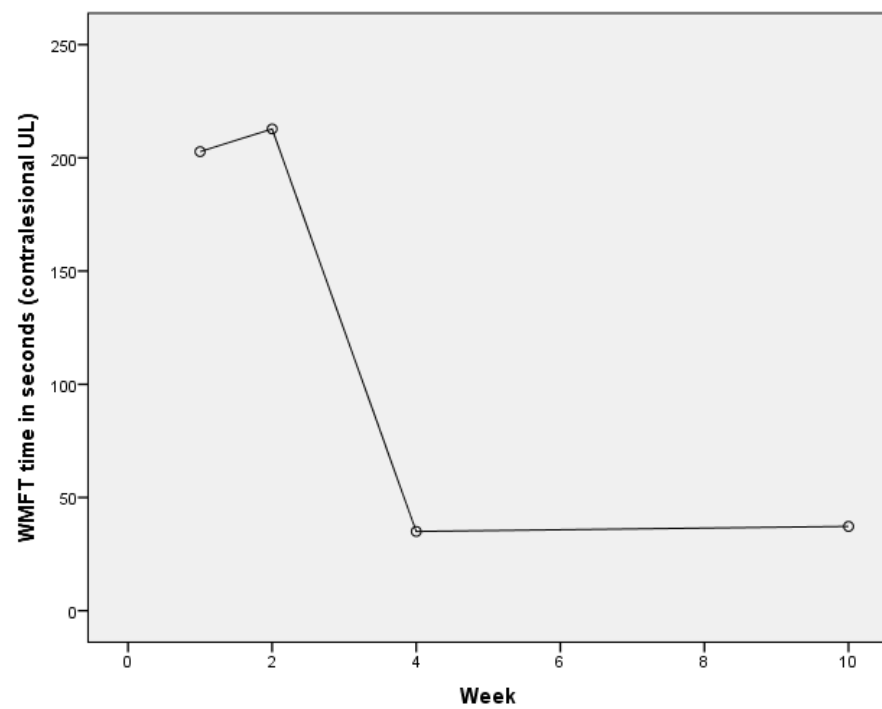
score did not exceed the MCID. With no interview at this stage, it is not possible to consider whether this is reflected in Janet's perception of her functional ability.

Janet's grip strength also increased at post intervention, but this improvement was lost at follow-up (Figure 6.5). However, neither of the grip change scores exceeded the MCID.

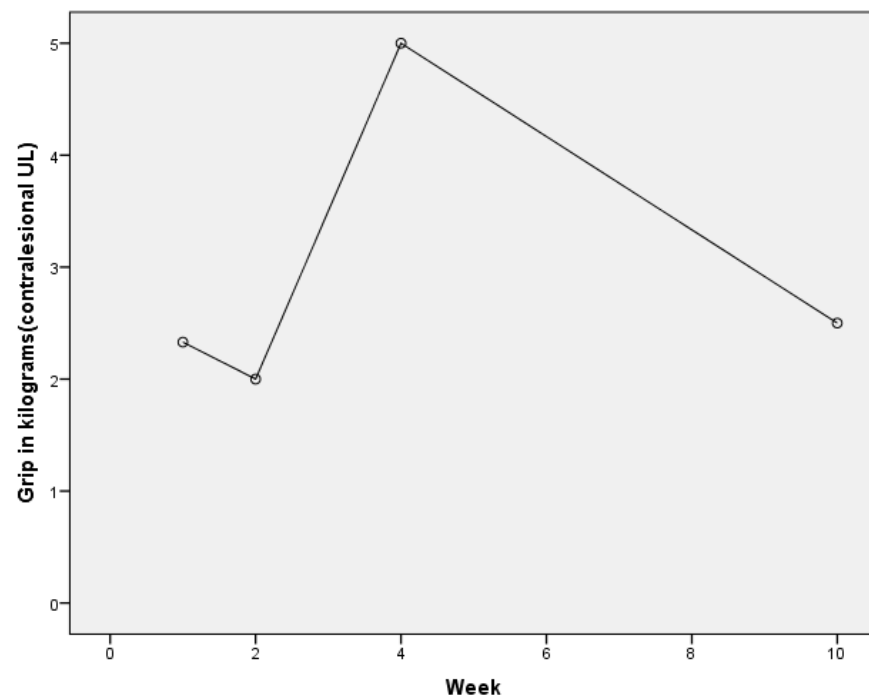
**Fig 6.3 Janet's Contralesional UL WMFT Functional Ability Scores** (two baselines, post-CIMT and six week follow-up)



**Fig 6.4 Janet's Contralesional UL WMFT Performance Times** (two baselines, post-CIMT and six week follow-up)

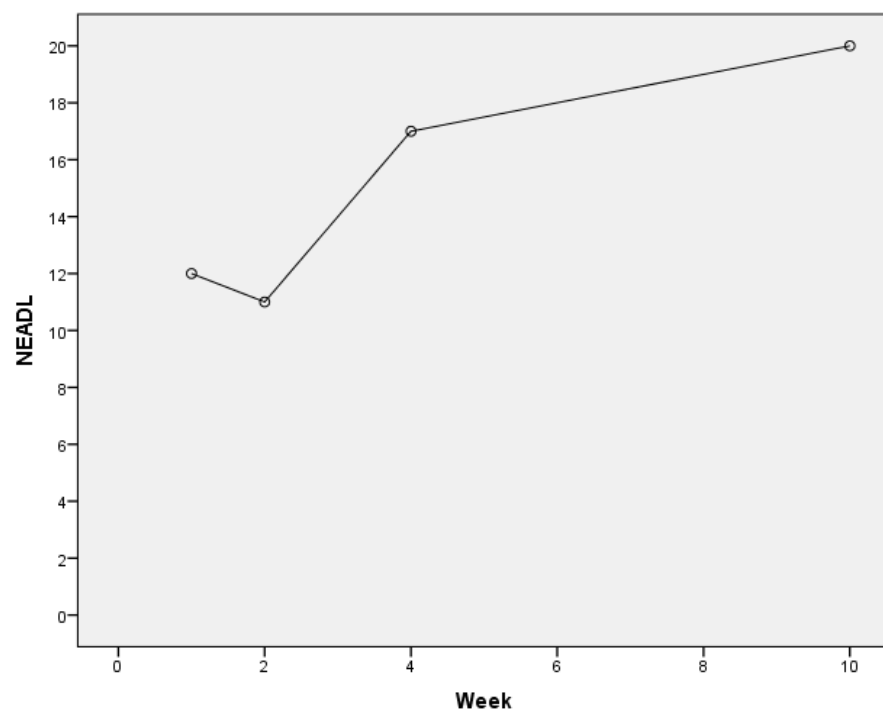


**Fig 6.5 Janet's Contralesional UL Grip** (two baselines, post-CIMT and six week follow-up)



The NEADL score showed a different pattern with an improved score at post-CIMT that had improved further at six week follow-up, exceeding the MCID (Figure 6.6). The COPM performance and satisfaction scores increased from 2.4 and 2.2 respectively at pre-intervention to 4 and 4.2 respectively at post-intervention and six week follow-up. The change scores for satisfaction in performing the occupations exceeded the MCID, although those for performance did not.

**Fig 6.6 Janet's NEADL** (two baselines, post-CIMT and six week follow-up)



#### 6.4.1.4 Summary of Janet's experience of CIMT

Qualitatively, Janet identified the importance of the intense, one-to-one aspects of CIMT and described benefits of the CIMT on her sleep pattern and her participation in activities. These findings were supported by an increase in NEADL and a reduced WMFT performance time at both post-intervention and follow-up compared to baseline. However, improvements in WMFT functional ability score and grip strength were not maintained at six week follow-up.

## 6.4.2 Case study 2: Tina

### 6.4.2.1 Background information

Tina was 37 years of age on recruitment to the study; she lived alone although she spent time with her siblings during the week. Tina experienced a left sided haemorrhagic transformation of an ischaemic stroke, resulting in a right-sided hemiparesis, seven months prior to being recruited to the study. Tina experienced some expressive dysphasia. She was right hand dominant. Tina also selected the two week protocol with three hours training each weekday and six hours constraint per day; however, apart from stating that she did not want to wear the restraint or have therapy at weekends, Tina did not initially indicate a preference for a specific protocol. The final agreement was made after the Chief Investigator and the Research Therapist, encouraged Tina to imagine what it might be like to undertake different lengths of training.

#### 6.4.2.1.1 Findings from screening

Table 6.4 summarises the findings from the screening assessments.

**Table 6.4 Tina's screening assessments results**

<b>Assessment</b>	<b>Score</b>	<b>Outcome</b>
HADS (anxiety)	12	Indicated a potential issue
HADS (depression)	15	Indicated a potential issue
CD-RISC (resilience)	68	Lower than general population
MOCA (cognition)	22	Indicated a potential issue
Line crossing	36	Normal
Light touch (Left/Right)	12/12	Normal
Temperature (Left/Right)	12/11	Normal
Pinprick (Left/Right)	12/11	Right UL slightly impaired
Pressure (Left/Right)	12/12	Normal
Tactile localisation (Left/Right)	12/10	Right UL impaired
Bilateral simultaneous touch	12	Normal
Proprioception (Right)	12	Normal
Stereognosis	3	Impaired

#### **6.4.2.2 Qualitative findings**

There was notably less primary data available for Tina compared to the other participants due to Tina's communication difficulties. Following discussion with Tina, the interview was documented as key points on paper rather than via an audio-recording. Tina was able to check what had been written 'in the moment', and validate what had been documented.

Initial coding led to five themes: impact of CIMT, undertaking the protocol, emotional response, personal attributes and impact on structure of the day. Following discussion the researchers agreed that 'personal characteristics' did not warrant a theme due to the paucity of data. This data was, however, utilised during the analysis of possible facilitators of CIMT. In addition, 'impact on the structure of the day' was felt to be better described through the 'undertaking the protocol' in a sub-theme, where it was re-named 'other commitments' to reflect that commitments encompass more than just their impact on the structure of a day. This ultimately resulted in three themes: emotional response, impact of CIMT, undertaking the protocol. The themes are shown diagrammatically in Figures 6.7a to 6.7c and are explored further below.

Fig 6.7 Tina's themes and sub-themes

Fig 6.7a Theme 1: emotional response

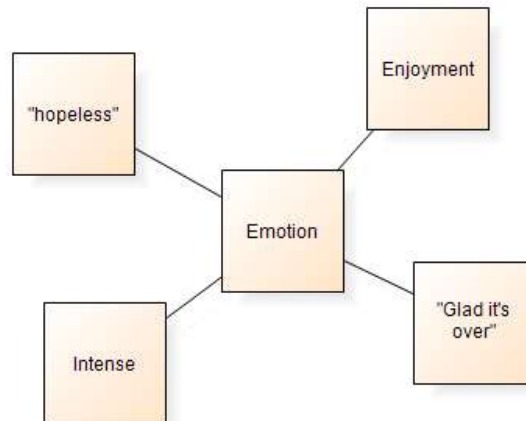


Fig 6.7b Theme 2: impact of CIMT

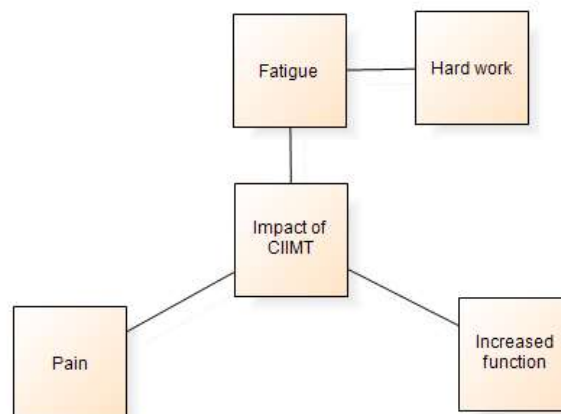
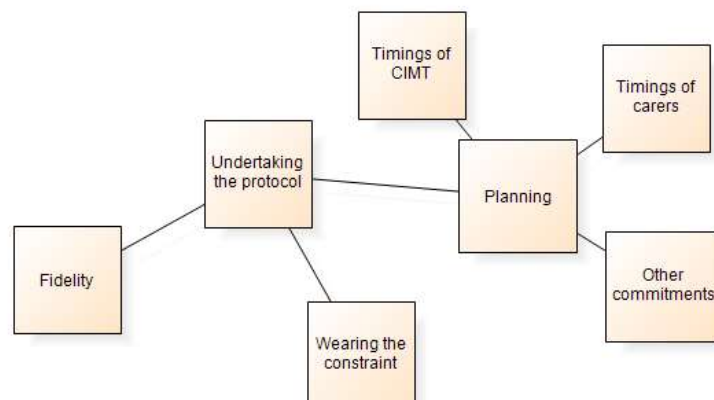


Fig 6.7c Theme 3: undertaking the protocol



#### **6.4.2.2.1 *Emotional response***

This theme contained a range of expressions of emotion attached to the experience. Tina described the initial experience of wearing the mitt as “hopeless”, which seemed to be mainly related to the difficulty undertaking the activities with one hand. This was expressed with feeling during the interview; however, Tina also reported that she got used to it and thought she had managed to complete six hours of constraint each day.

Tina also reported she had enjoyed participating in the activities, but expressed relief that the two weeks were over as it had been very intensive. This intensity appeared to be related to the amount of therapy, the frequency of the sessions and wearing the mitt.

#### **6.4.2.2.2 *The impact of CIMT***

Prior to the CIMT, Tina stated that she “feels tired all the time”; she would usually get a one hour sleep during the day and that she did not sleep well at night. During the CIMT, Tina was sleeping for three hours each afternoon which she attributed to the travel to the rehabilitation unit and the CIMT being tiring. No difference was noted in overnight sleep pattern after the CIMT. Tina did experience some pain in her joints due to other underlying conditions; in addition, Tina indicated she experienced a dull ache in her shoulder that started a few days after CIMT commenced and remained at a similar level until the end of the CIMT. The ache remained during rest periods built into the CIMT, and “a bit” of the ache was still present when interviewed post-intervention.

When asked if she felt the ability to use her arm and hand had changed with the CIMT, Tina stated “Yes...so much more”, but she found it difficult to articulate functional changes, although she did note that the kettle was easier to use. During the interview the interviewer noted in her field notes that Tina placed her hands behind her head as she thought about an answer to a question; when Tina realised what she had done she expressed surprise. Tina indicated that she

did not think she had been doing this since her stroke, which implied that she was using her UL more naturally in conversation.

When asked whether there were benefits in undertaking CIMT, Tina stated “Yes!”. She indicated that she felt her right hand was improved, that her index and middle finger used to stick together, but now separate and that her little finger feels more normal. She demonstrated opposition of thumb to little finger and ring finger to indicate how it had improved.

#### **6.4.2.2.3 Undertaking the protocol**

Whilst discussing protocols prior to CIMT, Tina indicated she was not concerned about the length of the protocol, amount of constraint wearing or amount of therapy, but was clear that she wanted a protocol that left her weekends free (i.e. without therapy or mitt wearing) as she liked to go to visit her Sister at weekends. Tina felt she had undertaken the protocol as planned. She reported completing tasks and exercises while wearing constraint when not with the therapist. The three hour sessions took place on weekdays, always in the morning. However, the final Friday was swapped to the following Wednesday, after a bank holiday weekend due to Tina having a commitment on the Friday.

During the interview there was a discussion about transport. Tina indicated she would need a taxi or ambulance to attend the rehabilitation unit; she got short of breath and experienced difficulty with walking due to other underlying conditions; therefore, using a bus would not have been possible.

### **6.4.2.3 Quantitative outcomes**

#### **6.4.2.3.1 *Fatigue and pain***

Fatigue score varied considerably during protocol ranging from 1-7 on a 0-10 Likert scale. There was an increase of three or more points on one occasion. This was monitored, but no additional action was felt necessary. The fatigue level dropped again after one day.

Pain score reflected the pain Tina described at interview; it ranged from 0-8 on a 0-10 Likert scale. The pain score increased by 2 points twice during the protocol; this pain was managed with analgesics.

#### **6.4.2.3.2 *UL function***

The baselines for Tina for the WMFT functional score (Figure 6.8), WMFT time (Figure 6.9) and grip strength (Figure 6.10) were not stable, with Tina performing considerably less well on each measure at the second baseline. As inclusion criteria specified therapist reported plateauing of UL ability, this may have been as a result of Tina's other underlying conditions. There was no improvement in WMFT functional score. There was an improvement in WMFT performance time at post-CIMT that exceeded the MCID; however, this was not retained at six week follow-up. (Figure 6.9) Given the lack of stability in the baselines, it would not be possible to attribute the change in performance time to functional gains. The small gains in grip strength (Figure 6.10) did not reach the MCID. The quantitative findings are summarised in Table 6.5.

**Table 6.5: Summary of Tina's contralesional UL quantitative outcomes**

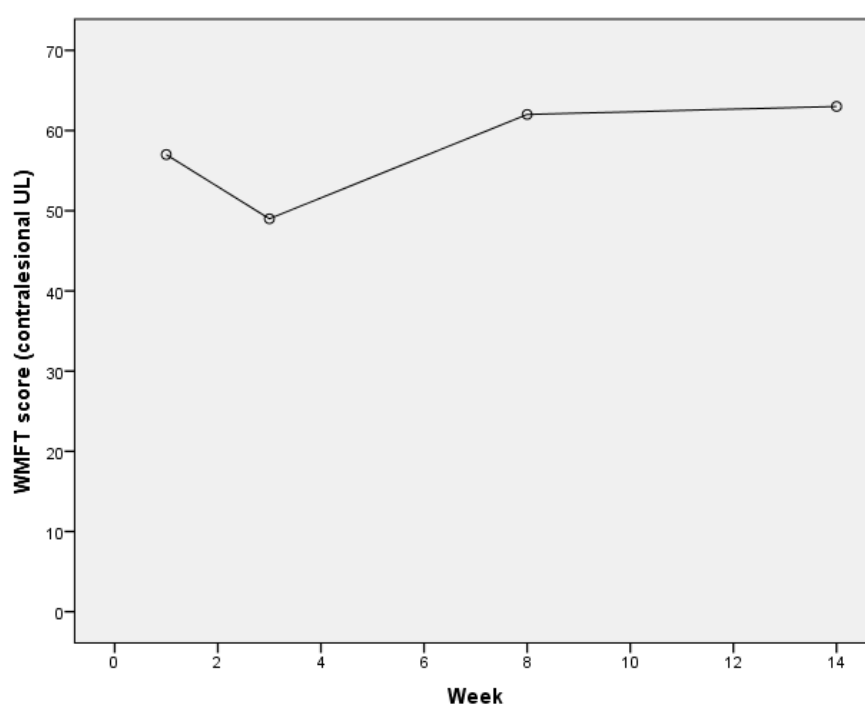
Assessment	Baseline 1	Baseline 2	Mean of Baselines	Post-CIMT	6 week follow-up	Pre-CIMT to post-CIMT change score	Pre-CIMT to 6 week follow-up change score
Total WMFT FAS	57	49	53	62	63		
Mean WMFT FAS	3.8	3.27	3.54	3.64	3.71	-0.16	-0.09
Total WMFT Time (seconds)	218.17	409.79	313.98	97.06	203.47		
Mean WMFT Time (seconds)	14.54	27.32	20.93	5.71	11.97	8.83*	2.57
Mean grip (kg)	9.83	8.83	9.33	10.33	10.50	0.50	0.67
NEADL	13	12	12.5	17	14	4.0	1.0
COPM - performance	3.0	Not assessed	3	5.2	5.2	2.2*	2.2*
COPM - satisfaction	2.4	Not assessed	2.4	3.8	4	1.4	1.6

\* indicates the change score exceeds the MCID

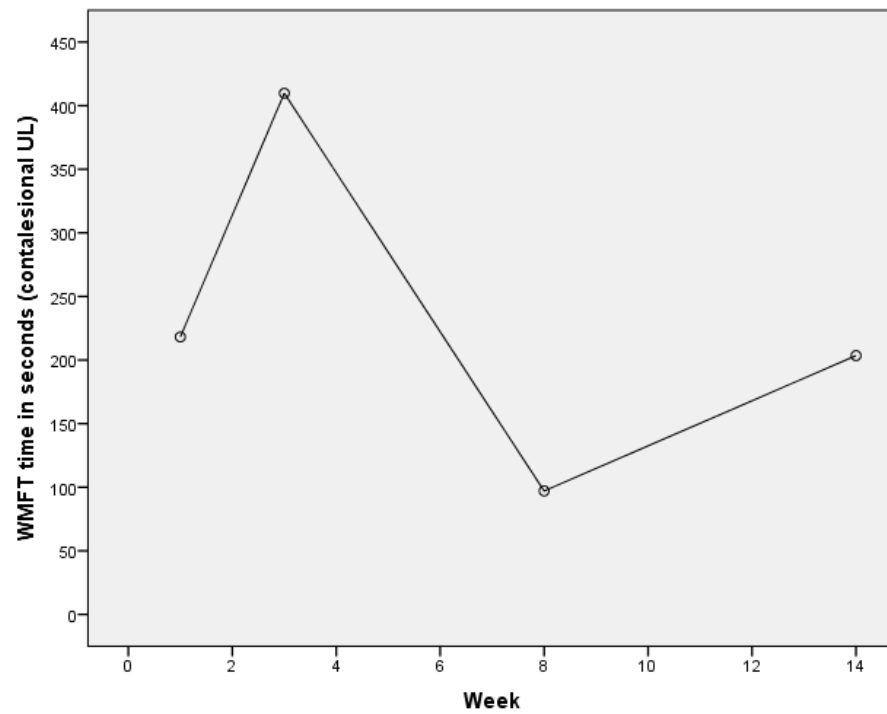
WMFT-Wolf Motor Function Test

NEADL-Nottingham Extended Activities of Daily Living Scale

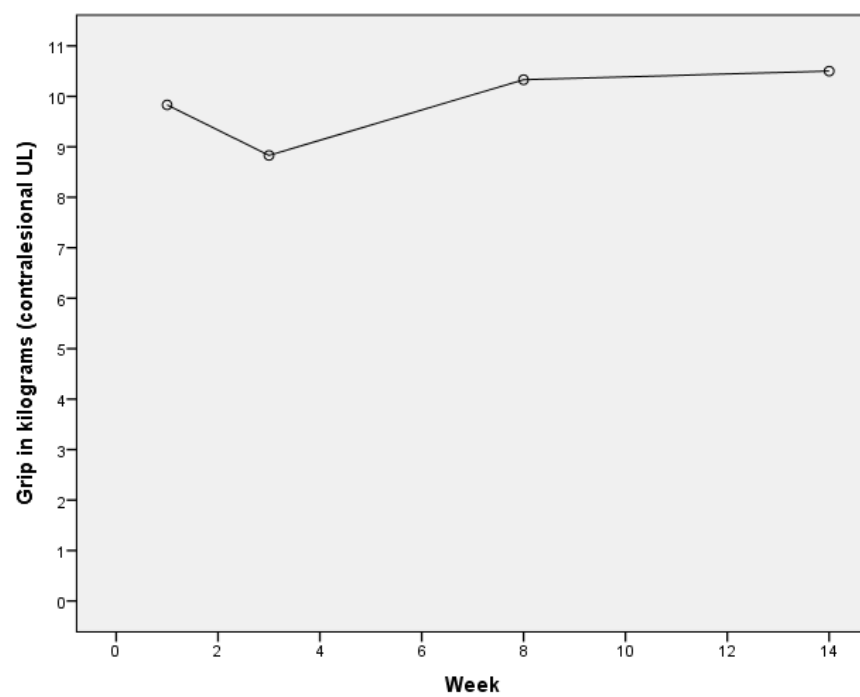
COPM-Canadian Occupational Performance Measure

**Fig 6.8 Tina's contralesional UL WMFT functional ability scores (two baselines, post-CIMT and six week follow-up)**

**Fig 6.9 Tina's contralesional UL WMFT performance time** (two baselines, post-CIMT and six week follow-up)

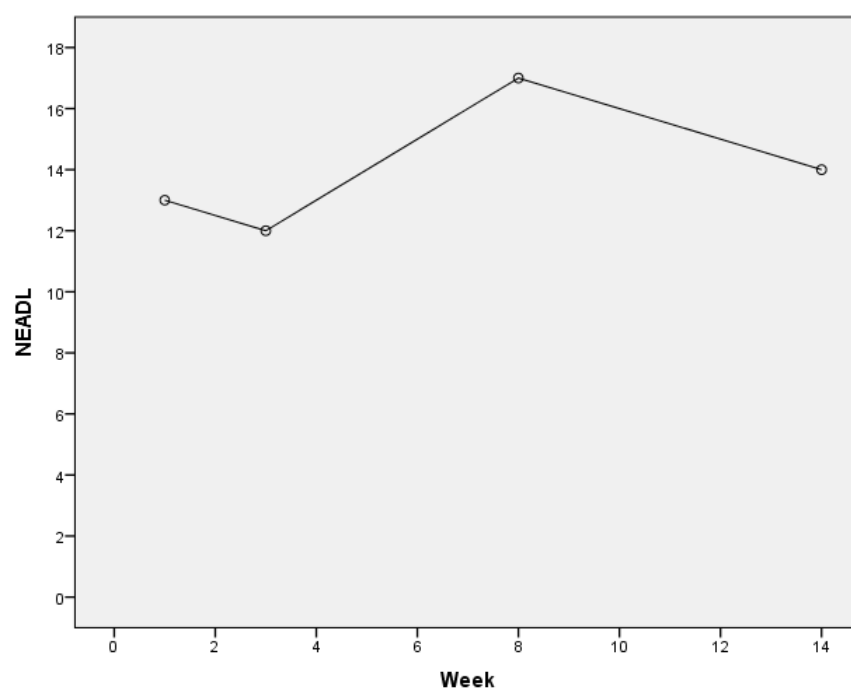


**Fig 6.10 Tina's contralesional UL grip** (two baselines, post-CIMT and six week follow-up)



The NEADL baselines were more stable than for the other measures (Figure 6.11); this may be because the assessment requires the respondent to consider what they have been able to do over the last few weeks. The NEADL seemed to reflect an improvement in ADLs undertaken independently at post-CIMT, although the change score was 4.0, therefore not reaching the MCID. The NEADL score went back to the baseline level at six weeks (Figure 6.11). The COPM performance and satisfaction scores increased from 3 and 2.4 respectively at pre-intervention to 5.2 and 3.8 respectively at post-intervention and were 5.2 and 4 respectively at six week follow-up. The change scores for performance exceeded the MCID, but those for satisfaction did not.

**Fig 6.11 Tina's NEADL (two baselines, post-CIMT and six week follow-up)**



#### 6.4.2.4 Summary of Tina's experience of CIMT

Qualitatively, Tina reported some benefits from the CIMT protocol. The lack of stability in the baseline measures made interpretation of the quantitative findings difficult, but there seemed to

be some support from the WMFT performance time and the COPM that aspects of Tina's UL function may have changed. Although Tina found the protocol tiring, she was able to complete it and it was possible to fit it around her family commitments.

### 6.4.3 Case Study 3: Margaret

#### 6.4.3.1 Background information

Margaret was 69 years of age on recruitment to the study, and she lived with her husband.

Margaret experienced a right sided ischaemic stroke, resulting in a left-sided hemiparesis six months prior to being recruited to the study. She was right hand dominant, and was experiencing an increase in tone of her left index finger. Margaret selected the two week protocol with four hours training each weekday along with wearing a constraint for 90% of waking hours per day.

##### 6.4.3.1.1 Findings from Screenings

Table 6.6 summarises the findings from the screening assessments.

**Table 6.6 Margaret's screening assessments results**

Assessment	Score	Outcome
HADS (anxiety)	1	Normal
HADS (depression)	4	Normal
CD-RISC (resilience)	75	Similar to general population
MOCA (cognition)	28	Normal
Line crossing	36	Normal
Light touch (Left/Right)	12/12	Normal
Temperature (Left/Right)	12/12	Normal
Pinprick (Left/Right)	8/11	Left UL impaired
Pressure (Left/Right)	9/12	Left UL impaired
Tactile localisation (Left/Right)	9/12	Left UL impaired
Bilateral simultaneous touch	11	Slightly impaired
Proprioception (Right)	10	Right UL slightly impaired
Stereognosis	10	Normal

#### 6.4.3.2 Qualitative findings

Initial coding and theme development identified seven themes: the experience of CIMT, the impact of therapy, undertaking the therapy, safety, support systems, setting, and personal

attributes. These themes were further developed through discussion between the researchers.

This led to three larger themes being agreed: 1) a 'personal attributes' theme was felt to encompass 'personal characteristics'; 2) 'undertaking the therapy' encompassed two of the smaller themes ('safety' and 'support systems'); 3) 'experience of CIMT', included emotional, physical, cognitive and social experiences, and encompassed the initial 'impact of CIMT' and 'setting' themes. This development of themes is shown diagrammatically in Figure 6.12a to 6.12c.

The themes are then described in more detail below.

**Fig 6.12 Margaret's themes and sub-themes**

**Fig 6.12a Theme 1: personal attributes**

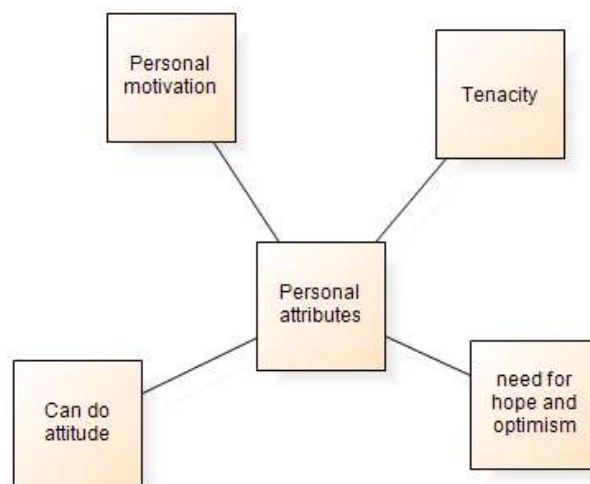


Fig 6.12b Theme 2: undertaking the therapy

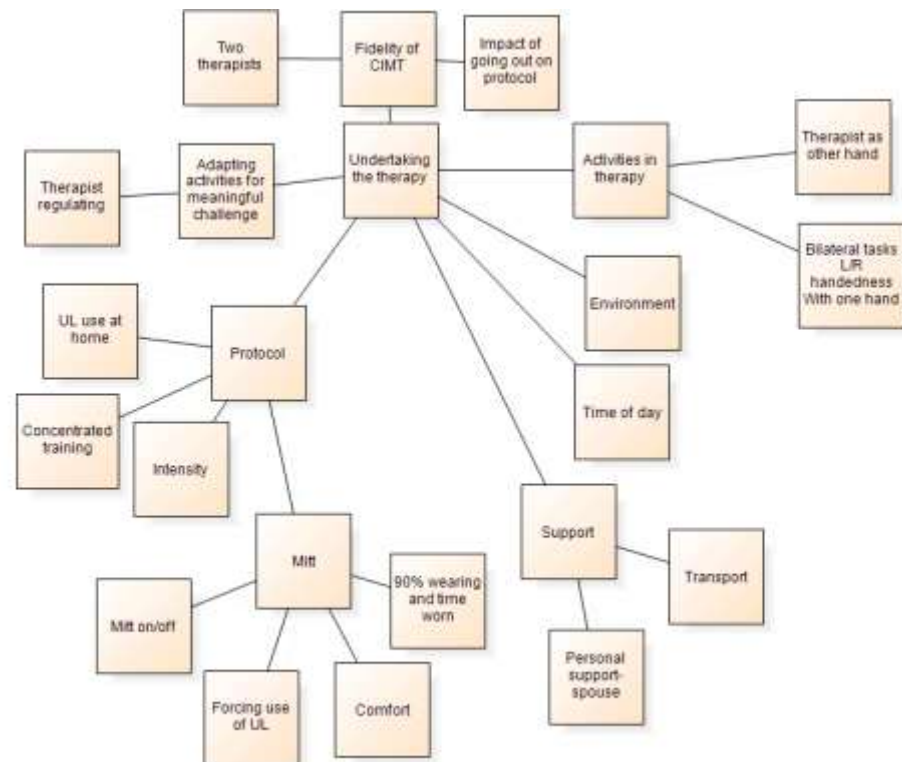
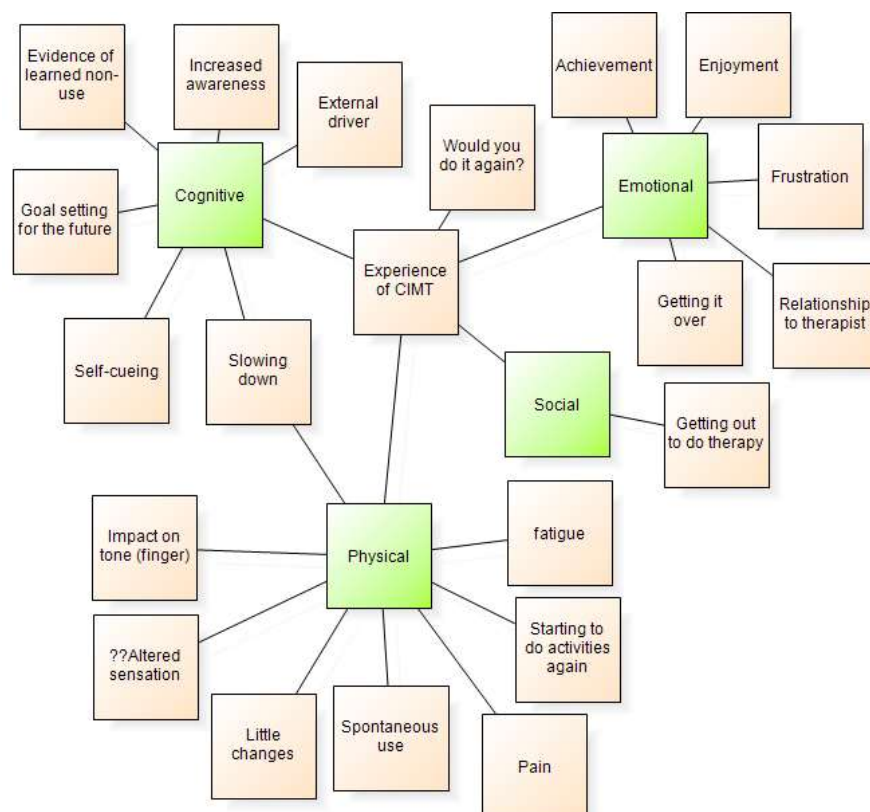


Fig 6.12c Theme 3: experience of CIMT



#### 6.4.3.2.1 *Personal attributes*

There was evidence that Margaret had a number of personal attributes that may have helped in undertaking CIMT. There were indicators of personal motivation being facilitated by perceived recovery post-CIMT.

Margaret: *“Well, I'm just going to have to try and do more things, you know.”*

Interviewer: *“Do you think you will?”*

Margaret: *“Oh yes, I will. I will, because it's frustrating me not to. And I feel as though I'm getting somewhere with it now because as I say, it's not a claw like it was, because it just wouldn't move at all. I mean, this is pretty near perfect to what it was.”*

There was also evidence of determination during the CIMT, with Margaret describing herself as tenacious:

*“As I say, steam was coming out of my ears a couple of times...But I won't give up. Somebody once said of me, you're like a tenacious little terrier, you won't let go. I said, no, I won't let the buggie beat me. You know, I'll give it a few tries before I'll say, well, I can't do it. I'll give it a good go [laugh].”*

Margaret seemed to have a hope or optimism for recovery:

*“Yeah. So the more I do with it, I'm reckoning the easier it'll get. I mean, it may not get...even the surgeon who did my neck said...it may never come back, but it could. He said, but it could. He said, it could but it could take 12 months. He said, you can't rush it.”*

#### 6.4.3.2.2 Undertaking the protocol

Due to some staffing challenges, the CIMT was undertaken by two therapists, and on two of the days the CIMT was provided as a part of an on-going UL group, rather than the individual therapy that was originally planned. This variation was noted during the post-CIMT interview, but not discussed in detail. Whilst the CIMT provision may have led to variation in the CIMT provided and may ultimately have impacted on the findings, there was evidence, from the OT-STAR record forms, and informal discussions between the therapists and the Chief Investigator, that the therapists used similar activities and methods to adapt the activities to ensure they provided a meaningful challenge. Margaret experienced frustration when trying to complete activities using her non-dominant UL:

*“...it's things I wouldn't do with my left hand. So just having to do them was more frustrating, I think, than anything, you know, that I couldn't help this hand [left hand] with this hand [right hand].”*

Margaret stated that she did not wear the constraint for the planned 90% of waking hours:

*“Well, I'd say at home I'd wear it for, say, about three or four hours. But I wasn't doing anything, do you know what I mean, I wasn't, sort of, trying to cook or do anything with my left hand. So I just had it on and it sat there, you know.”*

The decision to wear the constraint for a reduced time was related to a lack of activities undertaken outside therapy.

#### 6.4.3.2.3 Experience of CIMT

There were perceived physical benefits to CIMT. Margaret described “little changes” such as being able to wring out a cloth, and being able to pick up counters more easily. Also the interviewer noted spontaneous use of Margaret’s UL when she was talking, although it was unclear whether this had changed with the CIMT.

In terms of fatigue, Margaret described being able to go out with her husband even after therapy, but noted that there was one day she felt more fatigued after doing a lot in the therapy session, combined with a poor night’s sleep. Margaret described a decrease in pain in fingers following CIMT, she also stated that CIMT didn’t cause any additional pain. Following CIMT, Margaret described a perceived increase in control over unwanted tone in her second digit “it has worked, you know ... it's not clawing”. The increase in tone was still apparent; however, Margaret appeared to feel that she had a greater control. It was unclear whether this was due to a change in control, an increased awareness of the tone, or strategies to overcome the increased tone.

Margaret also appeared to be expressing a sense of achievement and pride about the functional activities:

*“Well, we made cakes. The lemon drizzle cake was fantastic. We got there in the end. [Research Therapist] and I, we did that. And then been shopping, picking up things and putting things in bags, which was good. Then [Therapy Assistant] and I went last week and shopped, and we made a plate mince pie. Well, if you'd seen the state of it, you wouldn't have soled your shoes with it, but we got there in the end...they took it over to the office and they all had a slice of mince pie. And they're still walking round, so it must have been alright [laugh].”*

There was some evidence post-CIMT of an increased awareness:

*“it's made me more aware that I've got a left hand, whereas before it was just there.”*

There was also some evidence that there may have been some learned non-use prior to the CIMT:

*“...I am trying to use it more than I was before...I thought...the attitude was, I can't do anything with it, so I didn't. But I am now.”*

Following CIMT, Margaret seemed to be setting goals for the future, reporting that her next goal was to be able to eat using her left hand. The CIMT did appear to have encouraged Margaret to keep working to improve the function in her UL:

*“... because...doing things, well, especially in here, you know, with the baking and that, I thought, well, I'm using a wooden spoon which I wouldn't do anyway and I'm trying. And if I don't try, I'll never know if I can do it or not, so I just keep on trying. And if I can't do something, well, at least I've tried.”*

Although Margaret chose to have her CIMT at the rehabilitation unit for practical reasons, she also indicated that getting out of the house, and the social element of the therapy was beneficial:

*“To be honest, I enjoyed it, because I don't really go anywhere to socialise. We don't go out anywhere. So as I say, it was nice to come and, you know, have company and that, it was good.”*

### 6.4.3.3 Quantitative outcomes

#### 6.4.3.3.1 *Fatigue and pain*

Fatigue and pain scores remained low throughout the protocol, fatigue ranging from 0-2 and pain from 0-1 on a 0-10 Likert scale.

#### 6.4.3.3.2 *UL Function*

Margaret's baselines for WMFT functional ability score (Figure 6.13) were stable, with an improvement at post-CIMT (change score from pre-intervention to post-intervention of 0.42) exceeding the MCID; however, this was lost at six week follow-up (change score from pre-intervention to follow-up of 0.08). In contrast, the baselines for WMFT performance time (Figure 6.14) and grip strength (Figure 6.15) were not stable, so any changes need to be treated with caution. Margaret's WMFT performance time appeared to reduce (representing an improvement) at post-CIMT exceeding the MCID (change scores pre- to post- intervention of 7.44 seconds) and this seems to be maintained at six week follow-up (change score pre- intervention to follow-up of 7.54 seconds). Both post-intervention and follow-up times reach the MCID (Figure 6.14). Grip strength improved at post-intervention but the change did not reach the MCID and any improvement appears to have been lost at follow-up (Figure 6.15). These findings are summarised in Table 6.7.

**Table 6.7: Summary of Margaret's contralesional UL quantitative outcomes**

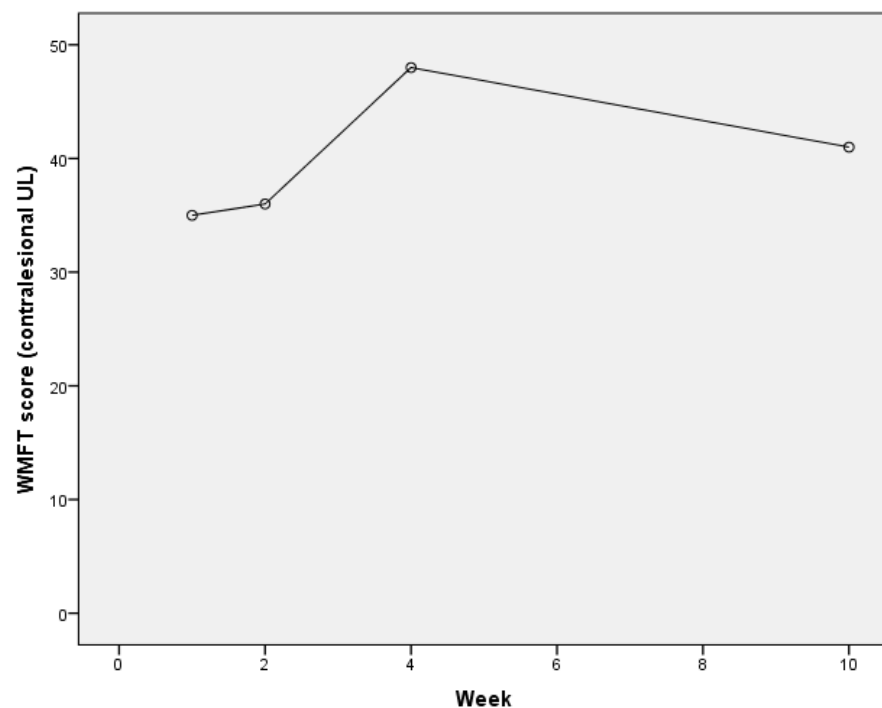
Assessment	Baseline 1	Baseline 2	Mean of Baselines	Post-CIMT	6 week follow-up	Pre-CIMT to post-CIMT change score	Pre-CIMT to 6 week follow-up change score
Total WMFT FAS	35	36	35.5	48	41		
Mean WMFT FAS	2.33	2.4	2.37	2.82	2.41	0.42*	0.08
Total WMFT Time (seconds)	340.46	455.9	398.18	259.41	257.66		
Mean WMFT Time (seconds)	22.70	30.39	26.55	15.26	15.16	-7.44*	7.54*
Mean grip (kg)	3.17	3.83	3.5	4.5	3.5	0.67	-0.33
NEADL	11	11	11	11	16	0	5
COPM - performance	1.0	Not assessed	1.0	1.0	1.0	0	0
COPM - satisfaction	1.0	Not assessed	1.0	1.0	1.0	0	0

\* indicates the change score exceeds the MCID

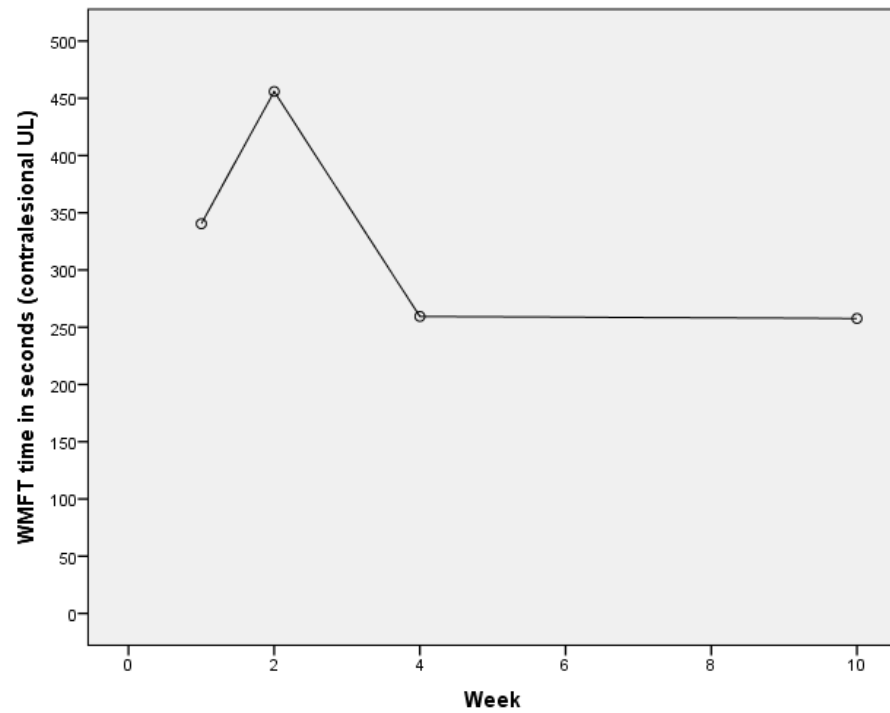
WMFT-Wolf Motor Function Test

NEADL-Nottingham Extended Activities of Daily Living Scale

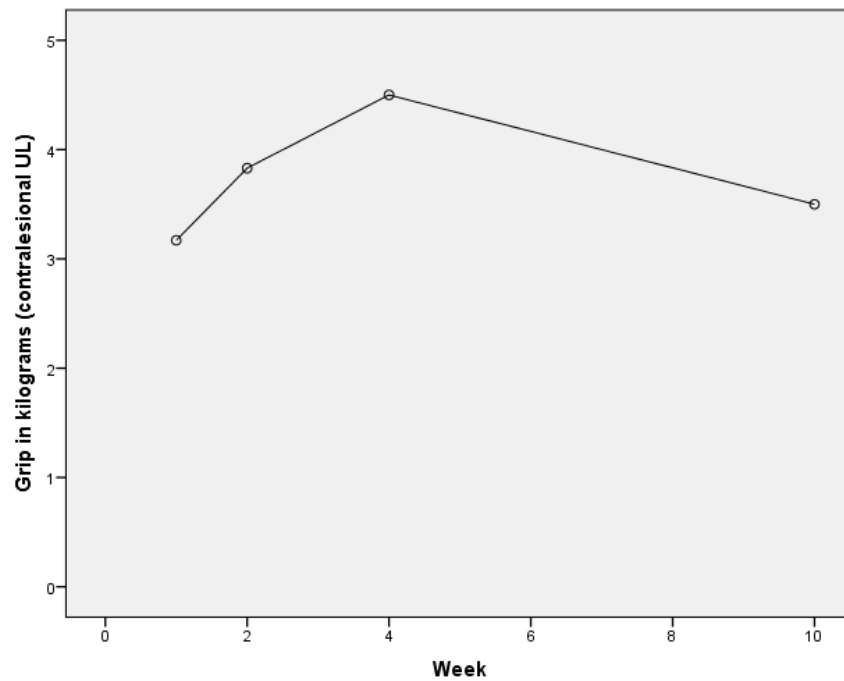
COPM-Canadian Occupational Performance Measure

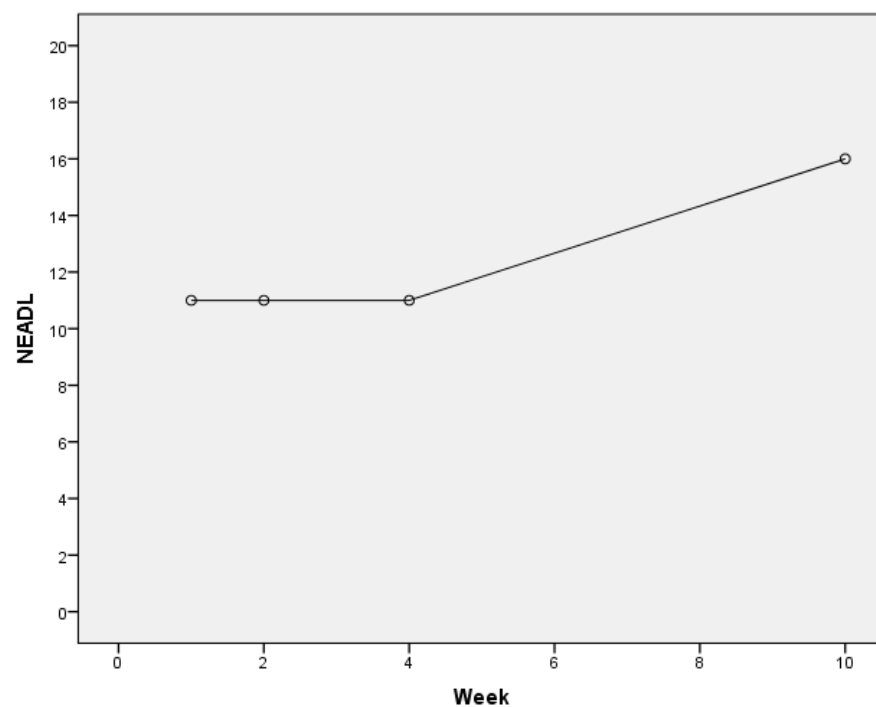
**Fig 6.13 Margaret's contralesional UL WMFT functional ability scores (two baselines post-CIMT and six week follow-up)**

**Fig 6.14 Margaret's contralesional UL WMFT performance time (two baselines, post-CIMT and six week follow-up)**



**Fig 6.15 Margaret's contralesional UL grip (two baselines, post-CIMT and six week follow-up)**



**Fig 6.16 Margaret's NEADL** (two baselines, post-CIMT and six week follow-up)

The NEADL baselines were stable and at post-CIMT there appeared to be no change in NEADL score; however, by the six week follow-up measure this had increased by five points (Figure 6.16). Whilst this is greater than the MDC indicating that an improvement had probably occurred, it did not exceed the MCID.

The COPM performance and satisfaction scores were 1 at pre-intervention and remained at 1 at post-intervention and six week follow-up.

#### **6.4.3.4 Summary of Margaret's experience of CIMT**

Qualitatively, Margaret indicated she had some personal attributes that might be beneficial in undertaking a CIMT protocol. She reported some functional improvements and was able to express UL goals for the future at the post-CIMT interview. She also appeared to be experiencing an increased awareness of her contralesional hand. Margaret did not wear the constraint for the required 90% of her waking hours, which she attributed to not undertaking activities at home in

the evening. Only the WMFT performance time exceeds the MCID at post-CIMT and six week follow-up. The NEADL did appear to have improved at six week follow-up, but this score still did not exceed the MCID.

#### **6.4.4 Overall Summary of case study findings**

All participants reported some functional benefits and stated that, given the opportunity, they would undertake a CIMT protocol again if it were offered. There was some support of these functional benefits from the quantitative findings. All participants exceeded the MCID on the WMFT performance time at post-intervention, the scores of both Janet and Margaret exceeded the MCID at follow-up. Janet and Margaret exceeded the MCID on the WMFT functional score at post-intervention, but this was not maintained at follow-up. Janet and Tina both experienced increased NEADL scores at post-intervention compared to baseline, but neither increase exceeded to MCID. Whilst Tina lost this benefit by the six week follow-up, Janet and Margaret's NEADL indicated increased participation in activities of daily living, from baseline to follow-up, and from post-intervention to follow-up; however, the change in NEADL score only reached MCID for Janet from baseline to six week follow-up. Janet and Tina experienced increases in COPM score at post-intervention, which were maintained at follow-up. Janet's satisfaction score at both post-intervention and follow-up exceeded the MCID, whilst Tina's performance score exceeded the MCID at both post-CIMT measures. (see Tables 6.3 and 6.5). The disparity in NEADL and COPM scores indicates that these outcomes measure different aspects of participation.

### **6.5 Discussion**

The Discussion has been structured through the four questions developed from the research objectives.

### **6.5.1 Is it feasible to provide evidence-based CIMT protocols to sub-acute stroke survivors with a paretic upper limb in a UK stroke service?**

All participants selected a protocol that they felt able to undertake. All three participants chose a two week protocol “to get it over with” (Margaret). Each participant chose a similar amount of training in therapy with two participants selecting to undertake three hours training per day and one participant selecting four hours. The constraint varied, but Margaret who chose 90% constraint reported that she did not wear it for the full time; indeed, she wore it for a similar time to the other two participants (approximately three to four hours).

All three participants completed the protocol; data from the interviews indicated that Janet and Margaret enjoyed the intensive CIMT protocol that they selected (section 6.4.1 and 6.4.3), whilst one participant, Tina, found the intensity challenging (section 6.4.2), but was able to complete the protocol.

Participants were given choice about where the training element of the CIMT should take place: at home, in the rehabilitation unit or a mix of both. Two of the participants indicated that their homes were not suitable for undertaking therapy; for Janet this was due to the presence of her dogs, whilst for Margaret it was a belief that there was not sufficient space. Both Janet and Margaret attended the rehabilitation unit for their therapy, whilst Tina undertook some training at the rehabilitation unit and some at home. In informal reflections (summarised in Appendix 33) the Research Therapist noted benefits of undertaking some of the training in the rehabilitation unit as this made available a wider range of equipment and activities.

Although the content of the training was not formally analysed, evidence from the interviews, therapist reflections (Appendix 33) and completed OT-STAR forms indicated that an

approximately equal amount of functional and task-based training were used. Interviews and treatment schedules reported that functional activities included cooking, baking, hot drink and meal preparation, typing, cleaning the kitchen, ironing, dusting, brushing up, writing a shopping list and shopping, washing and drying up, completing games, drinking and eating, gift wrapping, juicing, brushing teeth, using a remote control, using a phone, writing and filing nails. Task-based training included: PrimusRS® rehabilitation workstation (Baltimore Therapeutic Equipment, 2015), lifting cups, moving cards, using scissors, finger exercises, fastening and unfastening screws and nuts, moving pegs, exercises with putty, reach and grasp, cutting with adapted cutlery, sensory search, opening bottles, turning pages, picking up and releasing objects. Functional activities and task-based training have been termed whole-task practice and part-task practice in the motor learning literature (Gilmore & Spaulding, 2001; Hodges, 2007) and repetitive and adaptive practice in some CIMT studies (Wolf et al., 2007; Wolf et al., 2006). Chapter 2 indicated that the balance of these two types of training may be important, with indications that stroke survivors with lower hand-function may benefit from a greater proportion of adaptive (part-task) practice, whilst those with higher hand-function may benefit from a greater proportion of functional (whole-task) practice. The participants in this study met the higher functioning criteria in the studies by Wolf et al. (2007; 2006), but in the absence of clarity about the most effective proportion of functional (whole-task) and task-based (part-task) training, an equal amount of each type of training provided variety and versatility within the protocol.

There was evidence of activities being adapted to try to ensure a meaningful challenge by using adaptation or alternative equipment, for example insulated mugs, a travel iron, small bottles of milk and a smaller pan. There was also evidence of grading, for example using larger then smaller scissors and different types of counters for games. Reflections from the Research Therapist indicated that she also graded occasionally by using and reducing facilitated movements and,

more frequently, verbal prompts. These strategies ensured that the requirements of the task provided a challenge, whilst reducing likelihood of failure as recommended by Taub et al. (1994). Where it was necessary to complete a bilateral task, the therapist acted as the participant's ipsilesional hand to ensure a successful outcome.

Informed by the literature and the collaborating Trust's current service provision, this study was embedded in an ESD service. Funding was obtained from two research funding bodies (Vreeburg Bursary and Constance Owens Trust). Due to the sporadic nature of recruitment, evidence-based CIMT protocols could not be incorporated into the ESD service as part of the current service. The Research Therapist was released from her usual duties by other therapy staff undertaking additional hours, back-filled from the research funding. The three and four hours training over two weeks, favoured by the participants, was equivalent to the current recommendation of 45 minutes daily therapy (National Institute for Health and Clinical Excellence, 2010) over eight to 11 weeks; this is more therapy time than the ESD service currently offers. In addition, without the funding, the current service could not commit one member of staff to provide the block of three or four hours of training required to make the CIMT protocol feasible. The Chief Investigator and the Clinical Occupational Therapy Lead met with the Therapy Manager on several occasions to plan the release of therapists to provide the CIMT.

A CIMT protocol that comprised three or four hour training and an additional three to four hours constraint was both feasible and acceptable to stroke survivors; however, if CIMT was to be provided by the ESD service on a regular basis, substantial re-organisation or additional funding would be required. This would need to be resolved during a commissioning process.

### 6.5.2 Does the qualitative data analysis facilitate an understanding of the experience of undertaking a CIMT protocol?

Following the final pre-CIMT interview, it was noted that it had seemed difficult for each participant to imagine what CIMT intervention would be like. When asked whether there might be things to make undertaking the protocol easier Margaret stated:

*“I don't know, because until the challenges are there, you don't know, do you?...You know, if you put a thing in front of me and said, do that with your left hand, well, I'd try it. Whether I could succeed in it, I don't know, but you don't know until it's in front of you...because you can't think of things you do every day in life, can you, it's things that are going to come up.”*

This may have been because the process of imagining an experience is a complex cognitive skill (Kosslyn & Ganis, 2001; Liu et al., 2004) and the ability to complete this cognitive task may be detrimentally affected by the stroke (Department of Health, 2007; Intercollegiate Stroke Working Party, 2012). Participation in the pre-intervention interview did not report a lived experience; however, it did provide a few insights into some of the potential perceived barriers to CIMT. Concerns included not being able to undertake tasks successfully with constraint on (Janet), and CIMT causing pain (Janet). On reflection, the amount of data gained from these interviews was relatively limited compared to the post-intervention interviews; therefore, it is proposed that, for future studies, the pre-intervention interview could be removed with little detriment to the findings.

In contrast, the data collected and subsequently analysed in the post-CIMT interview was detailed and explored the experience of undertaking a CIMT protocol. Where a participant

indicated improvements in function at the post-CIMT interview, this was supported by the quantitative outcomes, providing some triangulation of the qualitative findings. It was also possible to triangulate the data from the interview with the twice daily pain and fatigue Likert scale measurements.

During the interview, the interviewer aimed to present questions that facilitated the articulation of the experience of undertaking CIMT. It is evident from the themes above that each participant articulated different experiences of CIMT, supporting the view that the interview followed the participant's lead. The interviewer's reflective log indicated a number of occasions when a question was posed in a manner that may have led the participant in their response. Where this was felt to have occurred, it was taken into account in the analyses.

It was possible to adapt the interview for Tina who had some communication difficulties, by the interviewer writing down the response and reading it back so that Tina could check the data collected. Tina's response gave the interviewer a level of confidence that what was written was an accurate reflection of the original response. Observations documented in the field notes were also used as an additional source of information during the interview. Whilst individual strategies would have to be developed for each participant, it is important to include participants with communication difficulties to ensure that stroke survivors with communication difficulties are not marginalised (Connect, 2007).

The data collection and IPA analyses allowed the identification of concepts that were not articulated, but were felt to be integrated in the participants' responses. An example of this was the presence of optimism for the future following CIMT that seemed strong for both Janet and Margaret. This hope and optimism was evident in goal-setting for the future and an enthusiasm to keep trying to do more after the CIMT had finished. Whilst hope has been identified as a

motivator following stroke (Barker & Brauer, 2005; Bright et al., 2011; Pilkington, 1999) and linked to positive outcomes (Bright et al., 2011), these qualitative concepts have not been explored in the predominantly quantitative CIMT research. The qualitative approach raised potentially important questions that would not be identified from quantitative methods such as: Does CIMT impact on the how the future is perceived, and if so, why? Does a change in hope and optimism have an impact on participation in occupations following CIMT?

The strategy to analyse each case study independently before looking for patterns across the case studies, allowed identification of potentially important findings that may have affected only one participant. An example of this was Janet's articulation of her change in mood. It is known that post stroke depression occurs frequently following stroke (Intercollegiate Stroke Working Party, 2012; White et al., 2014) and that its onset and course are associated with higher disability (Eriksen et al., 2015; White et al., 2014) and low community participation (White et al., 2014); however, the data analysis in this study challenges researchers to consider the impact of CIMT on mood.

The findings of this pilot study indicate that the pre-intervention interview did not provide sufficient data to warrant its inclusion in a future larger study. In contrast, the post-intervention interview and the analysis methods were found to provide a rich account of the experience of undertaking CIMT. It is recommended that the post-intervention interview should continue to be a part of future research.

### **6.5.3 Do the outcome measures record changes in functional use of a sub-acute stroke survivor's paretic upper limb following CIMT?**

As stated in the previous section, where the participants reported a change in functional ability at post-CIMT interview, this appeared to be supported by the quantitative outcomes where the baselines were stable. Where baselines were not stable, the reliability of the quantitative outcomes must be called into question. In spite of some unstable baselines, the quantitative outcomes were valuable tools in triangulating and understanding qualitative data and provided additional information about the direction of change in functional ability. The strategy in this study to use a range of outcomes across the ICF resulted in different responses. Whilst there was some support for a picture of recovery for Janet and Margaret with the WMFT score, WMFT time and grip indicating an improvement at post-CIMT, there was a loss of some of that gain at six week follow-up. This decrement of WMFT functional ability score has been noted in a previous CIMT study (Wolf 2006). The NEADL (measuring ADL) for these two participants, however, indicated a different pattern whereby improvements continued to the six week post-CIMT follow-up measurement. Where a range of outcomes and findings are collected, it is possible that they may not corroborate each other (Denscombe, 2007, p. 120) and the reasons for this should be considered. In this case, the outcomes are measuring different constructs, where the NEADL scores indicate continued increase in participation in daily activities following withdrawal of CIMT, the measures of body function and activity did not. This may indicate participants' willingness to re-try and subsequently continue activities that had been neglected following the stroke.

The COPM identified goals that were important to each participant. As a measure of participation it provided valuable information about whether the CIMT protocol had an effect on an individual's valued occupations. Although the COPM is not a useful tool for comparing

participants' responses to CIMT (Law et al., 2000), it does provide information about the impact of CIMT for an individual; for this reason it should be included in future studies. Measures that identify standardised functions, such as the NEADL and MAL, are valuable if comparisons across participants are to be made. They are less useful as an expression of individual participation. The inclusion of both the NEADL and COPM was a useful strategy; the COPM gave an indication of a participant's goals and their progress towards achieving them, whilst the NEADL gave a standardised outcome. The differences in scores indicate differences in constructs measured.

The screening assessments took substantial time to complete at a time when the participants were keen to start the CIMT protocol; however, they were considered valuable in the endeavour to understand the impact of CIMT. None of the participants were experiencing unilateral spatial neglect, but this is still an area that requires investigation so it is recommended that this screening is included in future studies. Findings from the post-intervention interview indicated a number of potential hypotheses about the impact of CIMT on mood, and hope. These will be further explored in Chapter 7. In future studies it would be useful to repeat the HADS post-intervention and to include measures of hope pre- and post-intervention. Previous research has observed a relationship between increased HADS score and lower resilience (Runkewitz et al., 2006); however this relationship remains unclear in stroke survivors, therefore, both measures should continue to be included in future studies.

The Nottingham Sensory Assessment gathered a broad overview of sensation in this study; however, there is evidence that Semmes-Weinstein monofilaments (Bell-Krotoski, 1990) provide a repeatable method of measuring touch-pressure threshold (Bell-Krotoski & Tomancik, 1987; Bell-Krotoski et al., 1995) and may offer benefits in expediency during the screening process. Apart from these small suggestions for change, the range of screening assessments and outcome measures met the needs of the pilot study and should be utilised in future studies.

This pilot study was not designed to draw conclusions from the quantitative data, nor was it anticipated that patterns would emerge from the small number of participants to inform conclusions about which stroke survivors benefit most from CIMT. Janet appeared to respond most positively to the CIMT, she had the greatest UL sensory impairment, but she also shared a low resilience and a risk of depression and anxiety with Tina. It is anticipated that a larger study would enable further exploration of patterns of recovery. It is recommended that in the future study, additional information is collected. This should include the location of the stroke and the type of stroke, using the Oxford Stroke Classification (Bamford et al., 1991), as these have been found to have a role in predicting outcome (Baer & Smith, 2001; Di Carlo et al., 2006).

#### **6.5.4 Is it possible to identify barriers to and facilitators of CIMT for sub-acute stroke survivors using these data collection and analysis methods?**

##### **6.5.4.1 Barriers**

Barriers were identified from both the pre-intervention and post-intervention interviews. Not being able to undertake activities whilst wearing the mitt (Janet) and concern as to whether the CIMT would cause pain (Janet and Tina) were both articulated in the pre-CIMT interviews. Whilst neither were subsequently reported as issues in the post-intervention interviews, they may deter stroke survivors from initially agreeing to undertake CIMT.

In planning for CIMT, there was some indication that each participant needed to make adjustments to fit the protocol into their lives; this included changes to her own occupations and to other's (for example carer's) routines. Although these did not cause substantial barriers, negotiations were required to reorganise the timings of the formal carers' visits to Tina during

the protocol. It is likely that changes to usual commitments and plans would be required before commencing a CIMT protocol.

During the pre-intervention interviews, both Janet and Tina indicated that they had a disrupted sleep pattern, often sleeping during the day. The qualitative systematic review reported in Chapter 4 led to an expectancy that fatigue might be a barrier; however, evidence from this study indicated that, whilst the protocol did take effort and caused fatigue, this had positive effects on Janet. Tina accommodated the fatigue with extra sleep and Margaret managed to continue usual activities on most days, indicating a relatively small impact of fatigue on her occupations.

There was also evidence from the interviews and the pain Likert scale scores that CIMT did have the potential to increase pain. Where this had occurred, however, the pain had been assessed as due to the result of increased activity of the muscles in the contralesional UL. In each case it was possible to manage the pain with analgesics.

As funding had been obtained for this study, it was possible to arrange taxis to transport the participants to the rehabilitation unit. All three participants used this service and stated that, without it, getting to the rehabilitation unit would have been difficult or costly. By the end of the post-CIMT follow-up, Janet was able to use public transport, which she attributed to an increase in confidence. However, Margaret did not feel ready to tackle independent travel and Tina did not travel independently due to speech and limited mobility. Transport arrangements must be considered in the planning for any CIMT service based in ESD.

Frustration when trying to undertake tasks with one hand was apparent for each participant; however, all participants did complete the protocol and indicated that they would take up the

offer of further CIMT if it was offered. It would seem reasonable to assume that the frustration was acceptable and that this did not cause a barrier to any of the participants in this study.

#### **6.5.4.2 Facilitators**

There was evidence that motivation and determination were facilitators to undertaking CIMT, supporting previous qualitative studies that identify optimism and determination as supporters of participation (Bright et al., 2011; Robison et al., 2009). Janet and Margaret described points during the process where they called upon these personal attributes. As identified in previous sections, being able to or trying to undertake more activities also seemed to motivate Janet. The role of motivation is less clear for Tina, but she appeared to express a level of determination in the post-CIMT where the interview notes state she “got on with it because it’s the correct thing to do-want my arm working but felt like hard work”.

Gate-keeping is the process by which access to research recruitment is restricted by healthcare providers, thereby denying eligible individuals the opportunity to participate (Hudson et al., 2005). In this study, this process may have occurred. Although there were established inclusion criteria, the recruiting therapist may have taken decisions about who would tolerate CIMT beyond these criteria. This may have led to a reduced variation in the participants recruited (Sharkey et al., 2010). One implication is that the response of participants less motivated to participate in CIMT remains unclear. For future studies it is important that there is adherence to inclusion criteria to address this issue.

There were some indicators that CIMT might have acted as an external driver for change. Margaret appeared to see CIMT as a process she was undertaking separate to her husband’s support, while Janet described the CIMT as giving structure to her day. Although evidence in Chapter 3 indicated that there may be no role for the mitt in terms of the quantitative findings,

the wearing of the constraint mitt appeared to be viewed as an external driver. Janet reported that, even when the constraint was removed, she reported that she continued to 'think mitt' and tried to use her left hand. Pre-intervention, mitt wearing may have been seen as a potential barrier to Janet, but it seems that once the CIMT commenced it became a facilitator to undertaking the CIMT.

Each participant chose a protocol that involved either three or four hours training, which could be accommodated in half a day (usually in the morning). Two participants (Janet and Tina) chose a protocol where the constraint was worn for three additional hours per day, whilst one participant (Margaret) chose a protocol with a 90% wearing schedule, although she reported that she actually only wore it for three to four hours. Although the intensity of the protocol has been regarded as a potential barrier in some literature (Page et al., 2002a; Viana & Teasell, 2012), this did not appear to be the case for the three participants, who all reported they were prepared to have a short course of two weeks of therapy. The short intensive protocol appeared to be well received, with each participant completing the protocol.

The setting for the CIMT may be important. OTs assess environmental factors to facilitate participation (Kielhofner, 2011; Law et al., 1996), and should assess intervention settings to maximise engagement and promote participation (Cohn & Lew, 2010). A collaborative approach should be adopted when planning the location of the CIMT training to ensure sufficient access to activities. There were also indications that the social aspect of attending the rehabilitation unit made the CIMT enjoyable, and that this too could be a facilitator.

### 6.5.5 Strengths

There were a number of strengths to this study. Overall rigour was addressed through consideration of credibility, dependability and confirmability (Lincoln & Guba, 1985). Steps were taken to address each of these.

There were a number of processes in place to improve credibility (defined in Chapter 4 as steps taken to ensure the findings described reflect the phenomenon under investigation). A variety of methods were used to collect the data, which enabled triangulation of the data by methods (Letts et al., 2007a), and the selection of quantitative outcome measures enabled assessment of change across the ICF domains. In addition, a reflexive approach was adopted. This included the use of reflective journals and reflection throughout to address potential biases and preconceptions and to ensure transparency of decisions.

Dependability (defined in Chapter 4 as steps taken to ensure consistency between the data and the findings) was addressed through transparency in the collection and analysis of the data. An audit trail of decisions throughout analysis was recorded in the log book, along with the main decisions taken during the development of themes. The main decisions have been reported in the relevant sections of this chapter. The themes have been presented along with examples of the primary data, so that these findings can be subjected to scrutiny.

Neutrality of the researcher could be called into question due to her closeness to the subject, so measures were taken to enhance confirmability (defined in Chapter 4 as steps taken to be open about and responsive to influences that might impact on the findings). A reflexive approach was utilised. Reflections on interactions and analyses were considered to assess the impact of the researcher's previous experience and beliefs on the findings. The data were coded independently

by two researchers and both codes and themes were agreed through discussion. In addition, the processes and analyses were discussed within research supervision meetings, where one supervisor was not directly involved in any aspect of the data collection or analysis.

The decision to ask participants to select their preferred CIMT protocol was seen as a strength in this study. The most effective CIMT protocol had not been established, therefore as indicated in the PARIHS framework (Rycroft-Malone, 2004) stroke survivor preference, in this case the intervention felt to be most feasible and acceptable, was an important part of establishing qualitative information about undertaking CIMT. A potential limitation of this approach was that the participants may have chosen disparate protocols, therefore making comparisons more difficult; however, it was felt that if there was variation in the protocols selected this in itself was an important finding.

It is recognised that ESD services are varied in the services they provide and the time-frame of the provision (Care Quality Commission, 2011). This study gives an overview of the provision of CIMT and the barriers to and facilitators of CIMT in one service. The findings may not be directly transferable to another service, but may provide a platform for implementation research in other ESD services.

### **6.5.6 Limitations**

Therapist views were sought prior to implementation of CIMT; however, their views were not formally sought again after the intervention. Interviewing therapists after the provision of the CIMT would have been useful to identify their experience of the barriers and facilitators of the intervention. The focus group, reported in Chapter 5, comprised both OTs and physiotherapists, recognising that both may utilise CIMT in their practice; however, the research therapists

providing the CIMT in the case studies were both OTs. It is not possible to say if the experience for the participants would have been similar if the CIMT has been provided by a physiotherapist. The professions have some shared values and but also some philosophical differences (Chartered Society of Physiotherapy, 2013; College of Occupational Therapists, no date). It is also noteworthy that the Chief Investigator was an OT, and whilst this may have impacted the analysis, the fact that the other researcher involved in the analysis was a physiotherapist may have negated this effect.

Three participants were recruited from 302 stroke-survivors that were referred to the ESD during a period of 11 months, which equates to approximated 1%. Recruitment difficulties have been reported in previous studies (Blanton et al., 2006; Brunner et al., 2012) and have implications for future studies. Given the recruitment rate of this pilot and low recruitment rates of previous studies (reported in Chapter 2), the recruitment rate in future studies in this ESD setting is unlikely to be higher than 6%. It was unclear if gate-keeping was taking place by the therapists; this needs addressing in future studies through collaboration (Sharkey et al., 2010) to ensure a robust means of checking selection criteria.

Finally, vision was identified as having an impact on stroke recovery, but no screening of vision was included in this study. All three of the participants could read written material, so any visual disturbances were likely to be small; however, there should be consideration of a visual screening tool in future studies.

## 6.6 Conclusion

All three participants selected a two week CIMT protocol with a three or four hour training component, and all wore the mitt for between three and four hours a day. It was feasible for a

Research Therapist to provide a CIMT protocol in a UK NHS stroke service that included a three of four hour daily training component; however, if CIMT was to be a routine part of this ESD stroke service there would need to be re-organisation of the service or additional funding; a commissioning process is likely to be required.

With a few minor alterations, the quantitative and qualitative data collection and analysis methods were found to be suitable for a larger study to continue the process of exploring barriers to and facilitators of CIMT, and to investigate which stroke survivors benefit most from CIMT.

# Chapter 7

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## Grand Discussion

The purpose of this chapter is to draw together the four studies contained within this thesis. The chapter summarises the work undertaken and then explores key findings that have emerged from this original research. It discusses the importance of these findings in relation to the future implementation of CIMT into practice.

Chapter 1 compared the process of describing therapeutic interventions to a Russian doll (Whyte & Hart, 2003) in which many layers of knowledge must be explored to enable a comprehensive description and understanding of the intervention. The work in this thesis has unpacked several layers of the CIMT Russian doll. The systematic review of quantitative studies (Chapter 3) found evidence to support the use of CIMT as part of therapeutic practice in the sub-acute phase of stroke. It resulted in a summary of the evidence-based CIMT protocols, although, there was recognition that it was not possible to identify which protocols were most effective in sub-acute stroke. The systematic review also identified that there had been limited exploration of the response of sub-groups to CIMT.

The systematic review of qualitative evidence (Chapter 4) found a lack of good quality evidence relating to the experience of providing and undertaking CIMT. Some of these gaps were

addressed in two subsequent studies. Firstly, a study to explore therapist perceptions of CIMT (Chapter 5), led to a number of recommendations to support the implementation of CIMT. These recommendations included training for therapists, support from CIMT mentors or champions, checklists and risk assessments to support the CIMT, ensuring good communication throughout the team and monitoring therapist and stroke survivor response to the extended therapy sessions. Secondly, a pilot mixed method study (Chapter 6) tested data collection and analysis from stroke survivors before and after CIMT. This second study found the quantitative and qualitative data collection and analysis methods to be suitable for a larger, post-doctoral study, to continue the process of exploring the barriers to and facilitators of CIMT, and to investigate which stroke survivors benefit most from CIMT. There appeared to be a preference by stroke survivors for a training component that could be completed in a morning or afternoon session. There was also a preference for additional constraint of three to four hours. It was feasible for a research therapist to provide a CIMT protocol in a UK NHS stroke service that met these criteria. However, the study indicated that if CIMT was to be a routine part of this ESD stroke service there would need to be re-organisation of the service or additional funding.

The findings from each of the four studies have been discussed in the relevant chapter. This penultimate chapter aims to widen the discussion and consider the broader findings and implications of the five original studies comprising this thesis. The discussion has been organised into four sections: 1) a summary of how this programme of work has furthered understanding of CIMT implementation through the use of the PARIHS framework; 2) a discussion of ‘participation’ and its possible importance in CIMT; 3) an exploration of the differences and similarities between therapist and stroke survivor perceptions of CIMT; 4) a summary of the issues that surround the fidelity of a CIMT intervention. The chapter concludes with a discussion of the strengths and limitations of the programme of work.

The PARIHS framework provided a structure with which to analyse the implementation of CIMT and to plan research to address identified implementation issues. Although the use of a framework has not been commonly used in previous studies of therapeutic interventions, this systematic approach supported previous recommendations (Campbell et al., 2000; Medical Research Council, 2008) emphasising the need for feasibility and qualitative studies in addition to effectiveness studies for the implementation of a complex intervention.

The PARIHS framework recognises three core elements in the implementation process: evidence, context and facilitation. A number of gaps in each element were identified during the implementation analysis reported in Chapter 2. Findings from subsequent studies, reported in Chapters 3, 4, 5, and 6 have been mapped onto the PARIHS framework in Table 7.1 which indicates how this programme of work has developed new knowledge to address the gaps in the CIMT research.

**Table 7.1 Study findings mapped onto the PARIHS framework**

Core Element	Summary of Findings
<b>Evidence</b>	<p>A systematic review of qualitative evidence was undertaken to explore the patient experience and clinical experience of CIMT in the sub-acute phase of stroke. This process identified a lack of qualitative evidence, although it did identify a number of potential risks and barriers to CIMT such as pain and fatigue. It also identified a few benefits of CIMT including increased ability to use contralesional UL in valued activities and psychosocial benefits.</p> <p>In response to this systematic review, a qualitative study was undertaken with therapists to explore their perspective of undertaking CIMT protocols; a mixed methods pilot study was undertaken to test the processes required to collect good quality qualitative evidence from stroke survivors. These studies were embedded in an ESD service, so that local issues could be identified and transferability of the evidence be considered.</p>

	<p><b>Therapists</b></p> <p>Therapists indicated a lack of knowledge and experience in using CIMT which they felt needed addressing before CIMT could be undertaken.</p> <p>There is strong, good quality evidence that CIMT is effective in increasing UL function in sub-acute phase of stroke; this was summarised and presented to therapists to explore their perceptions about the evidence-based CIMT protocols. Therapists identified that shorter training sessions were more feasible, and that the duration of the overall protocol was less important than the daily training duration in terms of provision. The therapists favoured 1 hour of training over 10 weeks or 4 hours once a week over 4 weeks. They also identified that 4-5 hours of restraint might be feasible. The therapists thought offering CIMT as a group intervention might mean it could be offered to a greater number of people.</p> <p><b>Stroke Survivor</b></p> <p>Stroke survivors also identified some potential facilitators of and barriers to the implementation of CIMT. Barriers included concerns about the CIMT prior to starting, such as increased pain and struggling with activities when wearing a constraint. Transport and fitting the CIMT protocol into life were also barriers. Increased fatigue and pain did occur as a result of the CIMT, but were not perceived as barriers.</p> <p>Facilitators included personal attributes such as motivation and determination, the perception of CIMT as an external driver for recovery, the social aspect of undertaking CIMT at a rehabilitation unit. The participants seemed to value the individual sessions, with one participant indicating that she would be less motivated in a group where there was less direct contact time with the therapist.</p> <p>Protocols including 3 or 4 hours training and 3-4 hours of additional restraint wearing were found to be feasible by three participants.</p> <p>The three stroke survivors found some potential benefits in activity and participation. The benefits were not consistent across the three participants and require further exploration. Some potential psychosocial benefits were also identified from the qualitative data; these too require further exploration.</p>
<b>Context</b>	<p>Evidence from therapists and stroke survivors in Chapters 7 and 8 offered insights into aspects of culture and environment that might impact on the implementation of CIMT.</p> <p>Therapists identified informal carers as an important part of the environment; however, all three stroke survivors were able to undertake the CIMT without additional support from informal carers.</p> <p>Therapists perceived that implementation of CIMT was most likely to occur in an ESD setting, and that it would only be successfully implemented in an in-patient setting where the multi-disciplinary team were prepared to support the intervention, for example, by encouraging use of the contralesional UL during periods of constraint. It was identified that the in-patient setting was unlikely to be a</p>

	<p>suitable environment due to restrictions on staff time and that formal carers were unlikely to be able to provide the support necessary for CIMT. Good team relationships and training for all staff involved were identified as important whatever the setting.</p> <p>There was no previous culture of offering evidence-based CIMT in the ESD service and the study indicated substantial re-organisation or additional funding would be required to implement evidence-based CIMT protocols into the service. A transport strategy would be required to ensure stroke survivors are able to access the service. These issues presented barriers that would need to be addressed during the commissioning process.</p>
<b>Facilitation</b>	<p>Insights into the type of facilitation required and the support therapists might need to gain the necessary knowledge and skills to implement CIMT were gained from qualitative evidence from therapists. The therapists indicated that there was a need for training in the use of CIMT, both formal training and practical sessions with a senior therapist. They also felt it would be helpful to have a CIMT mentor on site for support and assistance with problem solving.</p>

The remainder of this chapter will reflect on the findings from these studies, discussing overarching themes, implications for practice and future research, and concluding with the strengths and limitations of the work.

## 7.1 Participation

Participation can be defined as “a person’s involvement in a life situation” (World Health Organization, 2002, p. 10) and has been a recurring theme throughout this programme of work. The importance of participation was evident in the findings of both systematic reviews, wherein quantitative and limited qualitative evidence of improved participation following CIMT was identified. In the final study, there was qualitative evidence of the importance of increased participation to one of the participants (Janet), with indicators that there had also been positive changes in participation for another participant (Margaret). The NEADL scores for Janet and Margaret supported the qualitative findings, indicating an increase in ability to undertake

activities of daily living even after CIMT had been withdrawn, although this did not reach the MCID for Margaret. For both Janet and Margaret, there were improvements in activity outcomes at post-intervention, but there was some decrement in these outcomes at six week follow-up. This difference in pattern at follow-up may indicate that Janet and Margaret have been attempting occupations that had been lost post-stroke; this may be the result of improved UL function, or an improved ability to compensate for lost movement. There was less qualitative data collected from Tina, but whilst there were some indicators of increased use of arm in activities, there was no qualitative evidence of increased participation outside therapy. Whilst this was supported by the NEADL, where the increases at post-intervention and follow-up did not reach the MDC, Tina did report an increase in occupational performance on the COPM that did exceed the MCID indicating an improvement in her performance in her individualised goals. This increase reflected Tina's regained ability to use a key to open her front door, and undertake specific dressing tasks.

### **7.1.1 Importance of participation to OTs**

There is evidence that participation in valued occupations: 1) has a positive benefit on identity and roles (Bambrick & Bonder, 2005); 2) is linked to increased quality of life (Kniepmann, 2012); and 3) is important in a healthy ageing process (Levasseur et al., 2010), whereas a loss of participation has been found to increase psychological distress (Horowitz & Chang, 2004). Reduced physical activity (Nicholson et al., 2014; Paul et al., 2015; Rand et al., 2009) and reduced participation often occur following stroke (Robison et al., 2009; Walsh et al., 2015b). This may include the loss of valued occupations such as employment, domestic and social roles (including driving and household chores) and social occupations (including sports and hobbies) (Robison et al., 2009; Walsh et al., 2015b), with participation at 12 months post-stroke being influenced by a variety of factors including physical and cognitive disability, environmental factors and the adaptability of the stroke survivor (Robison et al., 2009).

Occupational participation is a fundamental concept to OTs (American Occupational Therapy Association, 2010) and has been defined as “engaging in work, play or activities of daily living that are part of one’s socio-cultural context and that are desired and/or necessary to one’s well-being” (Kielhofner, 2011, p. 101). OTs are encouraged to assess and understand the factors that influence occupational participation (Law, 2013) and, as discussed in Chapter 1, consider the impact of the environment on occupational participation. To facilitate this there are a number of profession-specific models to guide practice. One such model is the Model of Human Occupation (MOHO), a client-centred, conceptual model which was first published in 1980 (Kielhofner, 1980a; Kielhofner, 1980b; Kielhofner & Burke, 1980; Kielhofner et al., 1980). This model offers a framework for analysing occupational participation (Kielhofner, 2011, p. 116). It proposes that the dynamics of human behaviour are complex and that participation in occupation is can be conceptualised by four interacting components (Kielhofner, 2011):

1. Volition - the motivation for undertaking occupations and includes aspects such as the amount of interest a person has for an occupation, the values a person attributes to it, and the perceived likelihood of success (Kielhofner, 2011).
2. Habituation - the routines and roles performed by a person in their lives and across their lifespan (Kielhofner, 2011). Some of these roles and routines may be enjoyable in themselves, whilst some may be perceived as a means to end, depending on a person’s perception of the occupation.
3. Performance capacity - the physical, cognitive, communication and emotional skills and attributes that a person possesses that can be utilised to undertake an occupation (Kielhofner, 2011).
4. Environment - the broad environment and context in which a person performs their occupations. This includes the physical environment, but also a person’s

social and economic environment, it may also include the political or institutional environments (Kielhofner, 2011; Law et al., 1996).

In this model, occupational participation can be viewed as non-linear and multi-faceted. It recognises the impact of the components on each other and on occupational participation.

### **7.1.2 A MOHO perspective of CIMT**

The CIMT research to date has focussed on increasing performance capacity components such as range of motion, grip strength, ability to use UL to complete tasks (Nijland et al., 2011; Shi et al., 2011; Sirtori et al., 2009); however, using MOHO to guide reflection of the final study findings, there are a number of indicators that some of the benefit of CIMT may be its impact on habituation and volition. There was evidence that the intensity of the CIMT protocol led to a more structured and extensive routine (habituation) for all participants; indeed one participant noted that she had dealt with the protocol as if it was a job. For Janet it seemed that the change to her post-stroke routine (habituation) was one of the important components of CIMT. It may be that the intensity of the CIMT protocol provided a structure that had been lost following stroke.

Lack of motivation has been found to be a barrier to physical activity in stroke survivors (Damush et al., 2007; Rimmer et al., 2008). There is also evidence that stroke often effects mood (Pilkington, 1999; Taule & Raheim, 2014), hope and self esteem (Pilkington, 1999; Rochette et al., 2007; Taule & Raheim, 2014). It may be that the intensive nature of CIMT positively influences one or more of these which may in turn have a beneficial effect on motivation (volition) and ultimately participation.

If the impact of CIMT was due to a change of routine or the intensity of the intervention alone, then similar improvements would be observed with other intensive therapies. The systematic

review reported in Chapter 3 found that, in sub-acute phase of stroke, where CIMT was compared to an intervention of equal dose, the benefit of CIMT over the comparison intervention was not clear, with a number of studies reporting conflicting findings. Systematic reviews with a broader remit have addressed this issue across all phases of stroke. Stevenson et al. (2012) found CIMT to be more effective than a range of dose-matched alternative interventions in increasing UL capacity (FMA), UL ability (WMFT and ARAT), FIM and MAL, whilst Van Delden (van Delden et al., 2012) found a significant benefit of unilateral (CIMT) over dose-matched bilateral UL therapy for the MAL. Given these findings, the change of routine and intensity are unlikely to be responsible for all the changes reported following CIMT; however, they may be an important part of the intervention.

It may also be the engagement in CIMT activities that is important. There is evidence that stroke survivors in an in-patient setting benefit from enriched environment (communal areas with puzzles, reading material, board and computer games and dining facilities, and family members being encouraged to bring in activities) (White et al., 2015). Due to the study design, the researchers were not able to compare an enriched environment to one that was not, but the qualitative analysis indicated that the enriched environment provided opportunities for social interaction, an alternative to boredom and a feeling of personal control (White et al., 2015). Janssen et al. (2013) found that an enriched environment led to stroke survivors being more likely to engage in social activities, less likely to be inactive and alone or asleep. Taule and Raheim (2014) identified that stroke impacts negatively on social participation (participation in social occupations) six to eight months post-stroke even where good recovery had occurred. It was, therefore, interesting to note that the two participants commenting positively on the social aspect of CIMT also showed signs of improved participation on the NEADL, supporting previous evidence that socialising and interacting with others may be important in promoting participation (Pieris & Craik, 2004; Satink et al., 2004).

To date, CIMT studies have assumed that benefits are the result of overcoming learned non-use. This may be the case; however, the findings from this study indicate a number of other possible processes. The impact of CIMT on Janet's volition was evident. It was not clear whether the change in motivation was due to a change of routine, an increased hope for recovery, engagement in activities, an improved social environment or an increased performance capacity as a result of the CIMT. Janet clearly described changes in mood as a result of the CIMT protocol. Future research should seek to explore whether there is an interaction following CIMT between mood, UL function and participation.

### **7.1.3 Assessment of participation in CIMT research**

The systematic review reported in Chapter 3 provides evidence that CIMT increases both activity and participation outcomes with some decrement of WMFT functional ability score over time (Wolf et al., 2006; Wolf et al., 2008). Whilst only three case studies were reported in this thesis, and these did not aim to test effectiveness of CIMT, there was support of the systematic review findings with increases in activity and participation for all participants post-intervention and some decrement in WMFT functional score at six week follow-up for two participants (Janet and Margaret). It was notable that the activity and participation response patterns varied, supporting previous evidence (Atler, 2015) that body function, activity and participation are different constructs and that these outcomes may not correlate.

Converging evidence from this body of work indicates OTs should be collecting participation outcomes. The majority of the studies included in the systematic review in Chapter 3 used MAL, a measure of the use of the UL in real world activities (Taub et al., 2011), as an estimate of participation. The MAL asks the participant in a structured interview to make a judgement about the amount of use and the quality of use of their UL in predetermined everyday activities. As the

MAL requires the participant to judge the response of the UL within set activities, this could be considered a measure of activity, rather than participation. For this reason it was not selected for use in this work, and instead, the NEADL and COPM were selected. It has been identified previously (Chapter 6) that these tools measure different aspects of participation. The NEADL measures predetermined occupations whilst COPM allows a participant to set their own goals (Law et al., 2000). By its nature, participation cannot be objectively measured in a laboratory, unlike body function, or activity. In addition, the occupations in which people participate vary considerably. The findings from the pilot study support the use of at least two participation measures in future research to gain an understanding of the different aspects and range within this construct.

## **7.2 Therapist perceptions and stroke survivor experiences of**

### **CIMT**

The studies reported in Chapter 5 and Chapter 6 enabled comparison of therapist perceptions and stroke survivor experiences of CIMT. When compared, there were examples of both incongruence (non-agreement) and congruence (agreement) of the therapist and stroke survivor views.

#### **7.2.1 Areas of incongruence**

Findings from therapists and stroke survivor studies offered some interesting insights. The therapists thought that the most feasible protocols from both a stroke survivor and service point of view were those that included less intensive training. They focussed on two protocols; the first involved one hour training, three days a week over 10 weeks; and the second comprised four hours training once a week. They indicated that they felt that the stroke survivors with which they worked would not be able to tolerate the larger training or mitt wearing protocols. In

contrast, the stroke survivors all chose a protocol of either three or four hours a day over two weeks. There were indications that they perceived the short protocol duration as easier to accommodate in their lives. The three hours of training could be planned into a half day, giving time in the other part of the day for other activities or rest. If change of routine is an important part of CIMT, this intensity is likely to be important and should be an aspect of future studies and service planning.

Two participants chose a protocol that involved wearing the mitt for six hours a day, whilst the third person chose a protocol with a longer wearing schedule (90% of waking hours). The shorter mitt wearing regimes did appear to be better tolerated, but it is hard to draw conclusions from this study. There was evidence from the systematic review that the mitt was not an important component of CIMT in terms of effectiveness, but the participants in this study indicated that the mitt helped them to focus on their contralesional UL. This needs further study.

The therapists identified a number of potential barriers to the implementation of CIMT, namely: a lack of therapist knowledge and confidence using CIMT; concerns about the acceptability of the six hour protocol to stroke survivors; the challenges to the therapist of spending a long period with one service-user; concerns about safety including the impact of the constraint on balance; the facilities and support required, including the need for carer support. In the three case studies, these potential barriers did not present as tangible barriers. Risk was identified as an area of concern by therapists. A thorough risk assessment was completed for each participant prior to starting the protocol. Apart from the previously reported increased fatigue and pain, no adverse effects were experienced whilst undertaking the protocols. These CIMT risk assessments were an important part of the intervention planning and should continue to be part of CIMT in clinical practice and research.

The therapists also identified the importance of carers in supporting the CIMT protocol; however, for each of the three stroke survivor participants, carer support was not required. This was in part due to the thorough risk assessment which aimed to identify risk and put in place a plan to overcome these within the structure of the protocol. In choosing a smaller constraint protocol, the two participants who spent large portions of the day alone reduced the need for support. Margaret who did usually spend time with her husband seemed to see therapy as something she did without her spouse and did not report needing any additional support at home from her husband. It is possible that the participants reduced the need for additional support by choosing a protocol they felt able to undertake independently. Offering a range of protocols may enable participants to choose a protocol that they feel they can fit into their lives.

Therapists suggested that low mood might lead to less engagement in CIMT, but for Janet and Tina, this was not found to be that case. Although Janet's mood was low, she participated readily and, qualitatively, the CIMT appeared to have a positive outcome on her mood. Tina also participated in the full protocol, although there was no evidence of a change in mood following CIMT. The systematic review of qualitative evidence (Chapter 4) indicated the possibility of a psychosocial impact of CIMT through increased social interaction (Blanton & Wolf, 1999) and improved relationship with family (Page et al., 2001), Janet's increased mood indicates a possible mechanism by which these psychosocial changes might have occurred.

### **7.2.2 Areas of congruence**

There were also a number of potential barriers to CIMT that emerged as actual barriers. The therapists voiced that spending a large block of time with one person each day over two weeks or more could be challenging and substantially different compared to the therapy sessions offered in the current NHS service provision. In her reflections following the CIMT interventions, the

Research Therapist noted that, whilst it was a luxury to spend a large block of time with one person, it was difficult for both herself and the participant to remain focussed throughout. Although this was not identified as a concern by the stroke survivors, each participant did indicate that the therapist was an important part of the therapy, and Janet stated that had she not 'got on' with the therapist the experience might have been 'harder'. Alternating therapists during the protocol, or providing the CIMT in a group format, are possible strategies for this potential barrier. The potential benefits of group CIMT were discussed in the therapist focus group; there is also evidence from previous studies that CIMT groups are both possible and effective (Brogårdh & Sjolund, 2006; Henderson & Manns, 2012; Suputtitada et al., 2004; van der Lee et al., 1999). However, the participants in this study valued the one-to-one relationship with the therapist and indicated that this helped them undertake the CIMT. The individual attention appeared to be a motivator to maintain the intensity. The possibility of CIMT groups needs exploring, but it is likely that keeping the intensity of practice and the relationship with the therapist will remain important.

This is further complicated by a practical issue raised by the therapists who indicated that only a small number of users of their services would be appropriate for CIMT. The recruitment rate for this study bore out this, with 302 stroke survivors going through the ESD service during the 11 months of the study, but only 3 people being identified as appropriate for CIMT by the therapists. In the focus group, therapists identified that stroke survivors who were not compliant with treatment, or those experiencing severe cognitive deficits, would probably have difficulties undertaking CIMT. Informal discussions indicated that, when applying the selection criteria, therapists did gate-keep on recruitment to the study: they made decisions about whether some stroke survivors would be appropriate for CIMT based on their cognition or ability to undertake the intensive protocol, which potentially reduced the numbers considered to be eligible. Professional gate-keepers hold power at this key stage of the research process (Lee, 2005). Steps

must be taken in future studies to reduce gate-keeping to ensure equal access to all people who meet the inclusion criteria; in this way potential participants can reclaim autonomy in decisions of beneficence (Sharkey et al., 2010).

This gate-keeping may have led to an artificially low number of potential participants being approached during the recruitment stage of the case studies. Steps must be taken in future research to ensure that there is adherence to the inclusion criteria. If the numbers remain as low as the study indicated then it is unlikely that there would be enough stroke survivors appropriate for CIMT at any one time to run a group. It may be possible to wait until a few people are ready to receive CIMT, but this runs the risk of missing neuroplastic opportunities for those who have to wait. This issue remains unresolved and will need to be considered for clinical practice and future research.

Travel costs were funded in the case studies; this would not be the case if the service was integrated into the current service. Stroke survivors would have to cover their own travel costs, which may be considerable if the rehabilitation unit continued to be the favoured option; transport may become a barrier for some (Nicholson et al., 2014). Evidence-based CIMT protocols could not be integrated without changes to the current service. As identified by the focus group therapists, these environmental issues remained a barrier outside the research context and would need to be considered if a CIMT service was to be commissioned.

### **7.3 Fidelity of CIMT**

An important role of an OT is to address motivation for occupation (Kielhofner, 2011); OTs aim to choose activities that will both challenge and motivate. One way to support this would be to draw up a manual of standardised activities, but this is unlikely to be sufficient, as there will

always be a need for the training programme to be individual to meet the participant's needs. A list of suggested training activities would address the need articulated by the therapists in the focus group (reported in Chapter 5); it would enable the therapist to select activities that provide a challenge; however, activities that are pre-defined may not be considered to be meaningful by the stroke survivor. Even with pre-defined training activities, there is likely to be variation in their execution, so it is unlikely that an intervention can be truly replicable. Whilst a list may provide ideas for CIMT training, it may be more appropriate to accept some variability and ensure that there is thorough documentation of the training offered. In this way some comparisons can be made, but the meaningfulness and relevance of the intervention can be maintained for the participants.

There are aspects of CIMT that can be better defined. The dose of CIMT can and should be clearly described, including the intensity, frequency and duration of both the training and the mitt wearing components. There must be a clear description of the type of training, including the proportion of whole-task, functional activities and the repetitive, task components (part-tasks) practiced, as advocated by Wolf et al. (2007).

In the case studies, the OT-STAR was used to report the activities undertaken, along with the type of assistance provided (facilitation, assistance, verbal prompts). Supported by the critical evaluation of shaping in CIMT in Chapter 2, it is proposed that the term 'shaping' lacks definition and is not sufficient to describe CIMT training. The Research Therapist's CIMT documentation and reflections use language such as facilitation, verbal prompts, assistance, challenge and grading to describe the training. These are terms that were understood by therapists in the development of the OT-STAR (Jarvis et al., 2014c). It is recommended that, as part of translating evidence from bench to bedside (Huang et al., 2010), therapists need to translate the intervention into their

own language in a consistent manner to describe the training. The use of a tool such as OT-STAR provides a common language to facilitate this process.

## 7.4 Overall strengths

Rycroft-Malone (2004) stated "patient experience is high when patient preferences are used as part of the decision making process and when patient narratives and experiences are seen as a valid source of evidence" (p. 298). This is supported by Kristensen et al. (2011) who identified the importance of stroke survivor preference in occupational therapy practice to ensure client-centred stroke services. Stroke survivor preferences, research evidence and clinical expertise have all formed a part of the work undertaken in this thesis. The qualitative systematic review, reported in Chapter 4, along with the primary research in Chapter 6 collected stroke survivor preferences. Both systematic reviews (Chapters 3 and 4) collected previously established research evidence, with the primary studies reported in Chapters 5 and 6 adding new research evidence. Clinical experience was addressed in Chapters 5 and 6. This approach has provided a broad picture of CIMT in the sub-acute phase of stroke, furthering knowledge about CIMT and its implementation into a UK NHS stroke service. It has been shown that therapist and stroke survivor preferences are not analogous, supporting the use of mixed methods to gain data from a variety of sources.

Attempts have been made throughout to state the theoretical underpinnings for this work, enabling consumers to draw conclusions about the trustworthiness (Lincoln & Guba, 1985) of the work. An additional strength was the use of the PARIHS framework to organise and plan the programme of work. The PARIHS analyses, presented initially in Chapter 2, provided the foundations for the studies, affording a clear progression from gap analysis to research question development.

The mixed methods approach ensured that both qualitative and quantitative data shaped the findings, thereby addressing the often neglected aspects of feasibility and acceptability testing and piloting when developing a complex therapeutic intervention (Medical Research Council, 2008). Whilst CIMT has been the focus of this work, the strengths of the process indicate that this methodology may be a valuable resource for exploring other therapeutic interventions.

This programme of work has given the researcher the opportunity to gain skills in establishing an evidence base using systematic review, qualitative enquiry through interviews and focus groups, and quantitative data collection. The stringent requirements in applying for NHS ethical opinion ensured the ethical considerations and the implications of these were fully understood and appropriately addressed within the research. Skills and knowledge were also acquired in seeking and gaining funding to support research, five successful funding applications were made resulting in financial support for transcription services, acquisition of equipment, funding for a therapist to collect data and to provide the CIMT therapy in the case studies.

Undertaking each aspect of this programme of work has enabled the researcher to gain a deeper knowledge and understanding of the research process. Particularly, the importance of articulating the theoretical basis for research, the development of skills in using reflexivity, and an increased confidence in analysing qualitative data. In addition, the researcher has gained a healthy respect for mixed methods as a means to gain a more complete answer to research questions.

## **7.5 Overall limitations**

There are a number of areas that have not yet been addressed. One of the original questions that underpinned this work was ‘Who benefits from CIMT?’; whilst the case studies were a first step

to answering this question, the pilot study was mainly concerned with testing data collection and analysis methods. It has, however, provided some initial ideas that may develop into future hypotheses. Future hypotheses may include:

- The change in routine imposed by CIMT has a positive impact on UL function in sub-acute stroke.
- Stroke survivors experiencing low mood have significantly greater gains in UL function from CIMT than stroke survivors who are not experiencing low mood.
- The social aspect of CIMT is an 'active ingredient' of a CIMT protocol

This thesis has focussed on CIMT, an intervention used by both OTs and physiotherapists.

Physiotherapists were represented in the focus group, discussing perceptions of feasibility, acceptability, barriers and facilitators; however, in the final study an OT was recruited into the role of Research Therapist. If a physiotherapist had been recruited to this role, it is unknown if they would have brought a different emphasis to CIMT which may have altered the outcome. This should be considered when reflecting on the transferability of the findings and in future studies.

## 7.6 Conclusion

This chapter has provided an overview of the key findings from this programme of work. These have been identified as: the relationship between participation and CIMT; the areas of agreement and disagreement between therapist perceptions and stroke survivor perceptions and experiences of CIMT; and the fidelity of CIMT. The importance of each of these key findings for implementation of CIMT into practice, and for future research, have been discussed. The latter part of the chapter provides reflections on the overall strengths and limitations of the work, summarising both the personal learning opportunities and areas that require further investigation.

# Chapter 8

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## Conclusions

The purpose of this thesis was to explore the issues impacting the implementation of CIMT into a sub-acute UK NHS stroke service through the following research questions:

- 1 What is the evidence underpinning CIMT as a complex intervention to increase UL function in sub-acute stroke? (**evidence, Chapter 3**)
- 2 What is known about the acceptability and feasibility of CIMT in the sub-acute phase of stroke? (**evidence, Chapter 4**)
- 3 What are therapists' experiences and perceptions of providing CIMT in a UK NHS stroke service? (**context and facilitation, Chapter 5**)
- 4 What are stroke survivors' expectations, experiences and responses to receiving CIMT in a UK NHS stroke service? (**context and facilitation, Chapter 6**)

The PARIHS framework (Kitson et al., 1998; Rycroft-Malone, 2004) was used to understand and structure this programme of work. The above aims have been met through two primary and two secondary research studies which have addressed the three elements of the PARIHS framework: evidence, context and facilitation.

The first aim was met through two systematic reviews (reported in Chapter 3 and 4).

These two studies and a PARIHS analysis provided foundations for the final two primary studies; Chapters 5 and 6, report therapist and stroke survivor perceptions and experiences of implementing CIMT, thereby addressing both the second and third aims.

The key findings from this programme of work and implications are summarised below.

Recommendations for the implementation of CIMT into practice and future CIMT research are summarised at the end of this Chapter.

## **8.1 Impact of the Research**

A systematic review of CIMT in the sub-acute phase of stroke identified that there were 11 evidence based CIMT protocols from 13 studies of varying quality. There was evidence that CIMT has beneficial effects on activity and participation compared to usual care or no intervention. The evidence was equivocal where the comparison intervention was of a similar duration. Where gains were made, most of these gains were maintained at 12 months with the exception of the WMFT functional ability score. There was also evidence that wearing a constraint did not have a measureable effect on body function, activity or participation measures. It was not possible to identify which of the CIMT protocols were most effective. Apart from recognising that all participants in the RCTs had some active movement, it was not possible to establish which stroke survivors might benefit most from CIMT due to the limited sub-group analyses. None of the included RCTs had been undertaken in the UK, therefore the generalisability of these findings to a UK stroke service still needs to be established.

As a result of this systematic review a document was produced summarising the evidence-based CIMT protocols for CIMT in the sub-acute phase of stroke (shown in Table 6.1). This document described the ‘dose’ of the various CIMT protocols incorporating a description of frequency,

intensity and duration as recommended when describing a complex intervention (Keith, 1997; Pomeroy et al., 2011). It also includes an assessment of the quality of each study. This summary of CIMT protocols was a valuable tool in subsequent studies and is available as a resource for clinicians and researchers.

Whilst there was evidence from this systematic review, that CIMT is effective in increasing UL function in the sub-acute phase of stroke, it was established that evidence-based CIMT protocols are not currently part of the clinical practice of therapists in the UK.

A systematic review of qualitative aspects of the intervention found a lack of published studies exploring stroke survivor experiences of undertaking CIMT and therapist perceptions of providing CIMT. This work revealed that the facilitators of and barriers to implementing CIMT had not previously been explored. To address the gap, two studies within a local context were undertaken. Therapist and stroke survivor perceptions and experiences were explored which resulted in an improved understanding of delivering and receiving CIMT. The findings from these studies spanned all three components of the PARIHS framework, these findings are summarised in the following sections (8.2-8.4).

## **8.2 Key Findings-Evidence**

There were indicators that the perceptions of therapists do not always match the preferences and experiences of stroke survivors undertaking a CIMT protocol. There were differences in a number of key areas such as CIMT protocol preference, length of time a constraint might be worn, risks of CIMT, need for carer involvement and the negative impact of low mood on engagement with CIMT. The incongruence between the therapist and stroke survivor views

supported previous proposals (Kristensen et al., 2011; Rycroft-Malone, 2004) for a culture of involving all stakeholders in an implementation process.

In contrast, a number of potential barriers identified by therapists were realised. These included the small number of stroke survivors appropriate for CIMT, the difficulty in releasing a therapist's time to allow the increased hours of training, and the challenges of working with one person for an extended length of time each day.

Stroke survivor perceived barriers, such as occupations being hindered by the wearing of the constraint, and the fear of pain, did not materialise into actual barriers, but this perception may discourage some stroke survivors from undertaking CIMT. Fatigue, pain and frustration during the CIMT did occur, but they did not appear to be barriers to undertaking the CIMT, with each participant indicating that they would undertake a CIMT protocol again if it was offered.

Potential facilitators of CIMT were also identified. Personal attributes of motivation and determination were evident in the case studies; however, it was unclear whether these attributes were essential to complete a CIMT protocol, and may have been the result of gate-keeping at the recruitment stage. Although previous quantitative findings indicated no benefit to the wearing of a mitt in addition to intensive task-orientated training, with shaping (Krawczyk et al., 2012; Treger et al., 2012) or without shaping (Brogårdh et al., 2009; Hammer & Lindmark, 2009a), the stroke survivor participants reported mitt wearing as an important external driver that encouraged a focus on the contralesional UL. In contrast to the literature (Page et al., 2002a) and primary data from the North-West OT participants, the concept of an intensive programme of treatment seemed to be well received by stroke survivors. The social aspect of the CIMT also seemed to be a facilitator during the intervention.

The participants reported improvements in UL function following the CIMT and, in line with previous studies, some improvement was found in the quantitative outcome measures; however, gains in grip and WMFT functional ability score were not retained at six week follow-up for two participants (Janet and Margaret). Improvements in participation were mainly retained or improved at six week follow-up.

### **8.3 Key Findings-Context**

The CIMT pilot study indicated that the rehabilitation unit was the favoured environment from both a therapist and stroke survivor perspective. It provided an environment that was perceived as suitable for therapy and with a good range of versatile activities. A collaborative approach to deciding the venue for therapy appeared to maximise the opportunity for engagement in meaningful and challenging activities. As much of the CIMT occurred at the rehabilitation unit, transport was highlighted as a potential barrier. All three participants were dependent on hospital arranged transport at the start of the CIMT. If a CIMT service is being developed a transport strategy must be in place to enable inclusive access.

Therapist time for the pilot CIMT was provided through overtime of therapy staff. If the protocols favoured by the stroke survivors in the pilot study were to become part of current practice, re-organisation of services, additional resources, or commissioning of additional services would be required to provide the longer training sessions. Group therapy may be a way to address both the longer training times and the challenges expressed by the therapists of spending concentrated time with one person; however, stroke survivor participants identified the intensity in the one-to-one setting as an important part of the therapy experience. If a group format is being considered, the impact of the group on the intensity of the intervention needs addressing.

In order to accommodate the CIMT protocol into their lives, each stroke survivor needed to reorganise their usual routine. This must form part of the planning for the intervention, highlighting the importance of a collaborative and individualised approach to arranging CIMT.

Whilst it was feasible to provide evidence-based CIMT protocols to sub-acute stroke survivors in a UK stroke service with additional research funding, the 'context' component of the PARIHS indicates a number of issues that need addressing before CIMT could be fully implemented into the ESD service.

## **8.4 Key Findings-Facilitation**

The OT participants identified a lack of knowledge about CIMT. They suggested that training would be necessary both for the OTs and the wider team if this intervention were to become part of their clinical practice. The OTs proposed that a CIMT mentor to help with problem-solving, and a reduced caseload would be beneficial during the early stages of implementing CIMT.

In summary, this work has improved understanding of therapist facilitators and barriers to providing CIMT and has begun to provide some insights into stroke survivor facilitators and barriers. It has made inroads into understanding qualitative experiences of undertaking CIMT and how these findings link with quantitative changes.

## **8.5 Recommendations for Practice**

There are a number of aspects of CIMT that remain unknown or unclear; it is not yet possible to provide comprehensive recommendations for practice. Whilst there may be interventions that are as equally effective as CIMT, this has not yet been established and, given the evidence of benefit of CIMT in the sub-acute phase of stroke, CIMT should be available to those who meet

the criteria recommended (Intercollegiate Stroke Working Party, 2012; Scottish Intercollegiate Guidelines Network, 2010) in national guidelines.

It remains unclear which protocols are most effective. The pilot study indicated that stroke survivor participants may prefer three or four hour training protocols. When developing a service there should be consideration of which CIMT protocols can be offered. Care should be taken to avoid therapists making assumptions about what is feasible, ideally the choice of protocol should be negotiated with each person until it is known which protocols are most effective in a given situation. If only one protocol can be incorporated into a service, the pilot study indicates that a two week protocol incorporating three hours of training each weekday may be feasible and acceptable to some stroke survivors. Whilst the benefit of the constraint remains unclear, qualitative evidence indicates it is useful as a prompt to encourage use of the contralesional UL. It would appear that three to four hours of mitt wearing is feasible and acceptable to stroke survivors; however, it is not yet possible to make a recommendation about the length of time a constraint should be worn.

If implementing CIMT interventions in a current service, it is likely that there will be training needs and practical issues that need resolving such as provision of transport and a means of providing the longer training sessions. It is likely to require re-organisation of the service or additional funding.

## 8.6 Future Research

It is not sufficient to only study the effectiveness of therapeutic interventions; implementation must also be explored (Medical Research Council, 2008). The use of an implementation framework, the PARIHS, facilitated cogent analysis of the gaps in the evidence as a basis for the

work undertaken. The use of an implementation framework is recommended in the future study and implementation of evidence-based complex therapeutic interventions. Whilst the use of an implementation framework has been beneficial in developing knowledge in this area, there remain a number of areas where further work is required.

This programme of work identified potential ‘active ingredients’ of CIMT that had not previously been considered. Whilst there has been previous discussion about the respective roles of the constraint, and the intensive training components, this thesis has proposed the need to also consider the role of a change of routine, increased opportunity for participation in occupations, and the social aspect of CIMT, as possible active ingredients and facilitators. The role of the constraint in CIMT and the most effective training to increase UL recovery require further exploration.

The challenges of developing fidelity for a CIMT protocol have been explored, identifying specific concerns about the definitions of shaping, and the content of the training. Future studies should recognise the shared understanding of therapists by describing training in established and defined therapeutic terms.

This programme of work has started to explore the practicalities of providing CIMT in clinical practice. As part of this process, data collection and analysis methods were tested. The qualitative data analyses were found to facilitate an understanding of the experience of undertaking a CIMT protocol; however, two recommendations are made. Firstly, the analysis of the case study data in the pilot study indicated it may be important to additionally study the effect of routine, motivation and environment (social and physical) when considering which stroke survivors benefit from CIMT; the MOHO framework and assessment tools may provide a means to do this. Secondly, a change to the interview schedule was proposed so that participants

are interviewed post-CIMT and at six week follow-up to explore the longer-term impact of CIMT on participation. The quantitative outcome measures were found to record changes in functional use of a sub-acute stroke survivor's contralesional upper limb following CIMT and these outcomes were found to be helpful in understanding qualitative findings. The proposed changes to the data collection methods will be addressed prior to ethical approval being sought for a larger study. This subsequent study will aim to build on the findings from the pilot study reported in Chapter 8, and develop hypotheses as to which stroke survivors may benefit most from CIMT. The work to date has been supported by two funding bodies, the Vreeburg Bursary and the Constance Owens Trust. Additional funding will be sought to support this further study.

This mixed methods approach to exploring implementation of CIMT into UK practice has deepened the knowledge of CIMT, firstly through a qualitative exploration of therapist perceptions, and subsequently from qualitative and quantitative study of stroke survivors' experiences of CIMT. Both these approaches have contributed to an improved understanding of barriers to and facilitators of CIMT. It is proposed that the study designs used in the latter two studies may be transferable to the study of other therapeutic interventions, thereby opening avenues to explore the feasibility and acceptability of many other complex therapeutic interventions.

## **8.7 Final Conclusion**

This programme of original work has explored the issues impacting the implementation of CIMT into a sub-acute UK NHS stroke service. The research contained within this thesis has led to a number of important developments. Systematic review findings have clarified the gaps in the evidence that remain for CIMT in the sub-acute phase of stroke. Clinicians need this information to inform their clinical reasoning; for researchers of CIMT these findings offer insights that should

be the foundations of future research. The table reporting the summary of CIMT protocols (Table 3.3) developed from the systematic review reported in Chapter 3 provides a valuable synthesis of CIMT protocols that should be valuable to clinicians and stroke survivors as decisions are made about the most appropriate CIMT intervention. It is anticipated that this documents will also be used by researchers when considering which protocols will be utilised in future research.

The therapist and stroke survivor primary research studies have also provided valuable new insights. Of particular importance is the differences between the therapist and stroke survivors perceptions of CIMT; it is crucial that therapists do not make assumptions about the barriers and facilitators to CIMT or which protocol a stroke survivor will find feasible and acceptable. Discussing the range of protocols may open new, more successful avenues for therapy provision. The stroke survivor case studies reported within this thesis indicate important areas for further investigation. The link between CIMT and increased participation in occupation explored through MOHO offers a novel, alternative means of viewing the impact of CIMT, offering new insights into the possible impact of CIMT on hope and motivation. The use of PARIHS has provided a strong framework to consider implementation of CIMT. The implementation of complex therapy interventions require creative and elegant research solutions. The design of this programme of work, both the use of PARIHS and the mixed method research design, offers a means for addressing implementation, not only of CIMT but also of other therapy interventions.

The recommendations, made in this thesis, should be considered to further the implementation of CIMT into practice. Analysis using the PARIHS framework has identified that further study is required of this important aspect of stroke rehabilitation. It is hoped that this thesis helps therapists strive for this knowledge by providing one block in the foundations of future research.

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**Appendix 1****Questions from the CASP Systematic Review Checklist**

1. Did the review address a clearly focused question?
2. Did the authors look for the right type of papers?
3. Do you think all important, relevant studies were included?
4. Did the review's authors do enough to assess the quality of the included studies?
5. If the results have been combined was it reasonable to do so?
6. What are the overall results of the review?
7. How precise are the results?
8. Can the results be applied to the local population?
9. Were all important outcomes considered?
10. Are the benefits worth the harms and costs?

Full tool available at: <http://www.casp-uk.net/#!checklists/cb36>

## Appendix 1-continued

## Checklist for systematic reviews, based on QUOROM statement

## Review details:

When reading the systematic review, use this checklist which primarily applies to the methods used in the review process. The questions do not apply to the studies included in the review. Occasionally you may only find the answer in the Results section. For each question you should answer, on the basis of the information you can find easily:

2 = Yes, without doubt

1 = Only partially or with doubt

0 = No, not as far as can be determined easily

Process	Questions	Ans.
Search:	<b>Are:</b>	
	two or more databases named and used ( <i>score 1 if only 1 used</i> )	
	reference lists of selected articles searched	
	experts and trialists contacted	
	any journals searched by hand	
	databases searched from their inception ( <i>score 1 if later date fully justified</i> )	
	all languages accepted ( <i>score 1 if three or more accepted</i> )	
Selection:	<b>Is there a clear definition of:</b>	
	the population being studied	
	the interventions being investigated	
	the principal outcomes being studied	
	The study designs included (and excluded)	
Validity:	<b>Does the review process:</b>	
	Assess (measure, quantify) the quality of studies identified	
	Blind reviewers to study origin (authors, journal etc)	
	Abstract data into a structured data-base	
	Use two independent people to abstract data and assess study quality	
	Measure heterogeneity and bias of studies included	
Data:	<b>For each study are the details (or their absence) noted of:</b>	
	Participants included in study (number and type)	
	Interventions studied	
	Outcome	
Analysis:	<b>Does the review process:</b>	
	Undertake meta-analysis or state why not done	
	Investigate agreement between independent assessors	
	Give confidence intervals for outcomes reported	
	<b>TOTAL:</b>	

Adapted from QUORUM by the Intercollegiate Stroke Party (2012)

## Appendix 2

### The implementation of CIMT analysed using the domains of the CFIR (Damschroder et al., 2009)

Intervention Characteristics
<p>This domain recognises that interventions are often complex and requires that the core components of the intervention are clearly identified. Core components are those which are always a feature of the intervention. Where there are ‘peripheral’ components (components that are not central to the intervention and may alter depending on the situation in which the intervention is used) these must also be identified. By identifying these peripheral components, decisions can be made about whether adaptation to the peripheral components is feasible to improve the ‘fit’ of the intervention into practice, without losing the core components of the intervention.</p> <p>The core components of CIMT have been identified in the published literature. Whilst there are identifiable features of CIMT, namely constraint and training, the amounts of each component varies considerably. It is proposed that practice through training and constraint are core components of this intervention, but the dose of each of these requires further exploration. There may also be additional peripheral components that need to be identified.</p>
Outer Setting
<p>This domain recognises that any implementation process sits within a wider environment including aspects such as economic, political and social contexts.</p> <p>Therapists work with a professional expectation and are expected to adhere to the research tradition of evidence based medicine, although, since therapists are Allied Health Professionals, the term evidence based practice is more appropriate. There is an evidence-base for CIMT and as such recommendations for implementing CIMT has been integrated into clinical guidelines. This research tradition forms an important part of the ‘Outer Setting’ for therapists. Greenhalgh et al. (2005) describe a ‘tension’ between the rationalists who see a guideline based on evidence as the standard for practice, irrespective of context, and those holding a constructivist stance who are interested in the importance of context and believe there is a need to negotiate the implementation of the evidence within a given setting. Both implementation and the design of future implementation research will be directed by the stance of the stakeholders in the outer context.</p>

Inner Setting
<p>This domain includes structural, political and cultural contexts. Implementing CIMT requires consideration of the service in which the implementation is to take place, and encompasses the culture and shared beliefs of those working within the service. As each service differs, these factors should be assessed and local recommendations made.</p>
Individuals Involved
<p>There will be a number of stakeholders involved in implementation. For implementation of a therapeutic innovation, this includes service users and staff. This domain recognises that each individual will have knowledge, beliefs and feelings about the intervention, which will impact the choices they make.</p> <p>To transfer the research evidence and implement the intervention into therapeutic practice, a good understanding of the stakeholders' knowledge, beliefs and feelings is likely to be important: an understanding of the issues that might facilitate or deter use of CIMT; establishing whether the intervention is acceptable to the service users and whether therapists are able to provide the intervention in their therapeutic context.</p>
Implementation Process
<p>Meyers (2012) describes the implementation process as "a combination of multiple activities that include assessment, negotiation and collaboration, organized planning and structuring, and, finally, personal reflection and critical analysis."</p> <p>The implementation process is recognised as a change process and as such benefits from reflection on experience. Previous research has reported some qualitative findings following the implementation of CIMT with stroke survivors more than one year post-stroke. It is unclear if the findings are generalisable to stroke survivors who have experienced a stroke more recently.</p>

### Appendix 3

## CIMT Systematic Review

### Ranked Inclusion/Exclusion Flowchart

Inclusion/Exclusion Criteria	Exclusion Code
<b>CIMT</b> CIMT must include reduction of use in less affected upper limb and retraining of more affected upper limb, the duration of both elements and the length of the protocol must be stated, otherwise exclude	<b>1</b>
<b>Stroke</b> Exclusively stroke sample (ischaemic or haemorrhagic), or mixed sample with data that can be extracted for stroke sample, otherwise exclude	<b>2</b>
<b>Sub-acute phase of stroke on recruitment to study</b> Exclusively sub-acute (14 days to 9 months) sample, or mixed sample with data that can be extracted for sub-acute sample, otherwise exclude	<b>3</b>
<b>At least 18 years old</b> Exclusively 18 years or over sample, or mixed sample with data that can be extracted for 18 years or over sample, otherwise exclude	<b>4</b>
<b>Randomised Controlled Trial (RCTs)</b> Studies must be RCTs or additional analyses of RCTs Exclude studies that do not include a comparison group or if participants have not been randomised to these groups.	<b>5</b>
<b>Function measured in outcomes</b> Exclude if outcomes do not measure upper limb function (at body function, activity or participation level)	<b>6</b>
<b>Research with human participants</b> Exclude if research is non-human research	<b>7</b>
<b>Published in English language</b> Exclude if study is only published in non-English language	<b>8</b>
<b>Conference abstract/other abstract of a study reported in a journal or a paper that duplicates findings</b> In order to avoid duplication, where a study is reported in a conference abstract/other abstract or paper, this should be excluded if the same study is more fully reported elsewhere (usually in a peer-reviewed journal)	<b>9</b>
<b>Protocols for studies</b> Include only completed studies, protocols should be excluded	<b>10</b>
<b>Internet addresses</b> References that are web-based should be checked for inclusion. If the information has been removed from the internet the reference should be excluded	<b>11</b>

## Appendix 4



### CONSORT Statement 2001 Checklist Items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	<u>How participants were allocated to interventions</u> (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	<u>Scientific background and explanation of rationale.</u>	
METHODS Participants	3	<u>Eligibility criteria for participants</u> and the <u>settings and locations where the data were collected.</u>	
Interventions	4	<u>Precise details of the interventions intended for each group and how and when they were actually administered.</u>	
Objectives	5	<u>Specific objectives and hypotheses.</u>	
Outcomes	6	<u>Clearly defined primary and secondary outcome measures</u> and, when applicable, any <u>methods used to enhance the quality of measurements</u> (e.g., multiple observations, training of assessors).	
Sample size	7	<u>How sample size was determined</u> and, when applicable, <u>explanation of any interim analyses and stopping rules.</u>	
Randomization -- Sequence generation	8	<u>Method used to generate the random allocation sequence, including details of any restrictions</u> (e.g., blocking, stratification)	
Randomization -- Allocation concealment	9	<u>Method used to implement the random allocation sequence</u> (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	<u>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</u>	
Blinding (masking)	11	<u>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.</u> If done, <u>how the success of blinding was evaluated.</u>	
Statistical methods	12	<u>Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses,</u> such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	<u>Flow of participants through each stage</u> (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. <u>Describe protocol deviations from study as planned, together with reasons.</u>	
Recruitment	14	<u>Dates defining the periods of recruitment and follow-up.</u>	
Baseline data	15	<u>Baseline demographic and clinical characteristics of each group.</u>	
Numbers analyzed	16	<u>Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat".</u> State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	<u>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision</u> (e.g., 95% confidence interval).	
Ancillary analyses	18	<u>Address multiplicity by reporting any other analyses performed,</u> including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	<u>All important adverse events or side effects in each intervention group.</u>	
DISCUSSION Interpretation	20	<u>Interpretation of the results,</u> taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	<u>Generalizability (external validity) of the trial findings.</u>	
Overall evidence	22	<u>General interpretation of the results in the context of current evidence.</u>	

From Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001; 357(9263):1191-1194.

The CONSORT Statement 2001 checklist is intended to be accompanied with the explanatory document that facilitates its use. For more information, visit [www.consort-statement.org](http://www.consort-statement.org).

## Appendix 5

## CIMT in Sub-acute Stroke

## Data Extraction Form

General Information	
Date of extraction	
Author	
Title	
Source, year, volume, page numbers	
Population Characteristics & Care Setting	
Recruitment procedures	
Characteristics of participants (age, ethnicity, sex, geographical region)	
Number of participants in each group	
Were intervention and control group comparable?	Yes/No
Care setting	
Methodological Quality of study	
Design of study	
Quality assessment	This has been documented in separate table.
Intervention & control	
Content of intervention (duration, delivery mode, type of constraint, amount and description of 'practice')	
Content of control (duration, delivery mode, type of therapy)	
Outcomes	
Outcomes measured at baseline	
Outcomes measured after intervention	
Outcomes measured at follow-up (state timing of follow-up)	
Who completed measurements?	
Analysis	
Statistical measures used	
Attrition rate	
Was attrition adequately dealt with?	Yes/No
Quantitative results	
Sub-group analysis	
Qualitative analysis	
Conclusions	
Comments	

## Appendix 6

**Systematic Review**  
**Summary of Excluded Papers**

<b>Exclusion Criteria</b>	<b>Number excluded</b>
Intervention not CIMT	594
Population not stroke	64
Population not sub-acute phase of stroke on recruitment to study	195
Population less than 18 years old	41
Study design not Randomised Controlled Trial (RCT)	179
UL Function not measured in outcomes	14
Research not with human participants	11
Not published in English language	10
Conference abstract/other abstract of a study reported in a journal or a paper that duplicates findings	29
Protocols only	10
Internet addresses that are unavailable	3

## Appendix 7

## Systematic Review of Qualitative Data

## Ranked Inclusion/Exclusion Flowchart

Inclusion/Exclusion Criteria	Exclusion Code
<b>CIMT</b> CIMT must include reduction of use in less affected upper limb and retraining of more affected upper limb, the duration of both elements and the length of the protocol must be stated, otherwise exclude	1
<b>Stroke</b> Exclusively stroke sample (ischaemic or haemorrhagic), or mixed sample with data that can be extracted for stroke sample, otherwise exclude	2
<b>Sub-acute phase of stroke on recruitment to study</b> Exclusively sub-acute (14 days to 9 months) sample, or mixed sample with data that can be extracted for sub-acute sample, otherwise exclude	3
<b>At least 18 years old</b> Exclusively 18 years or over sample, or mixed sample with data that can be extracted for 18 years or over sample, otherwise exclude	4
<b>Primary research study</b> Exclude if not primary research.	5
<b>Qualitative findings</b> Exclude if outcomes do not include qualitative findings of service-user perspective of the acceptability of CIMT/mCIMT, a therapist perspective of experience of providing CIMT/mCIMT or reported barriers or facilitators of CIMT/mCIMT	6
<b>Research with human participants</b> Exclude if research is non-human research	7
<b>Published in English language</b> Exclude if study is only published in non-English language	8
<b>Conference abstract/other abstract of a study reported in a journal or a paper that duplicates findings</b> In order to avoid duplication, where a study is reported in a conference abstract/other abstract or paper, this should be excluded if the same study is more fully reported elsewhere (usually in a peer-reviewed journal)	9
<b>Protocols for studies</b> Include only completed studies, protocols should be excluded	10
<b>Internet addresses</b> References that are web-based should be checked for inclusion. If the information has been removed from the internet the reference should be excluded	11

**Appendix 8**

**Systematic Review of Qualitative Data**

**Summary of Excluded Papers**

<b>Exclusion Criteria</b>	<b>Number excluded</b>
Intervention not CIMT	594
Population not stroke	64
Population not sub-acute phase of stroke on recruitment to study	194
Population less than 18 years old	41
Not a primary study or qualitative data not collected	195
Research not with human participants	11
Not published in English language	10
Conference abstract/other abstract of a study reported in a journal or a paper that duplicates findings	27
Protocols only	10
Internet addresses that are unavailable	3

## Appendix 9



## RESEARCH AND ENTERPRISE SERVICES

26<sup>th</sup> February 2013

Kathryn Jarvis  
The Directorate of Occupational Therapy  
The University of Liverpool  
Thompson-Yates Building  
Brownlow Hill  
Liverpool  
L22 5PR

Dear Kathryn,

**Re: 'Implementing constraint induced movement therapy (CIMT) in a UK stroke service'**

Thank you for submitting your application for review.

I am pleased to inform you that your application has been approved by the Ethics Review Panel.

The following documents have been reviewed and approved by the panel as follows:

Document	Version	Date
Application Form	1	January 2013
Summary of Proposal	1	10/01/13
Information Sheet	1	24/02/12
Consent Form	1	24/02/12
Consent Form for use of quotes	1	24/02/12
Questionnaire	2	07/03/12
Interview Topic Guide	1	09/01/13

If the fieldwork goes beyond the date stated in your application 29<sup>th</sup> August 2014 you must notify the Ethical Review Panel via the ERP administrator at [uso.erps@keele.ac.uk](mailto:uso.erps@keele.ac.uk) stating ERP2 in the subject line of the e-mail.

If there are any other amendments to your study you must submit an 'application to amend study' form to the ERP administrator stating ERP2 in the subject line of the e-mail. This form is available via <http://www.keele.ac.uk/researchsupport/researchethics/>

If you have any queries, please do not hesitate to contact me via the ERP administrator on [uso.erps@keele.ac.uk](mailto:uso.erps@keele.ac.uk) stating ERP2 in the subject line of the e-mail.

Yours sincerely

A handwritten signature in black ink, appearing to read 'B Bartlam', with a long, sweeping horizontal flourish underneath.

**Dr Bernadette Bartlam**  
**Chair – Ethical Review Panel**

CC     RI Manager  
         Supervisor

## Appendix 10



### Participant Information Sheet

**Title of Project:**

**Implementing Constraint Induced Movement Therapy (CIMT) in a UK Stroke Service**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

If there is anything that is unclear or you would like more information, please contact Kathryn Jarvis (Chief Investigator) whose contact details are on page 4 of this information sheet. Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

**What is the purpose of this study?**

Constraint induced movement therapy (CIMT) is a therapy treatment that has been shown to improve arm and hand function in some stroke survivors. There is limited evidence that constraint induced movement therapy is being used in practice, and there appears to be discrepancies between the CIMT described in the literature and the CIMT used in practice. The aim of this study is to establish therapist and stroke survivor perceptions (CIMT) when it is implemented in a UK healthcare setting.

As an occupational therapist or physiotherapist working in a stroke service you are being asked to consider participating in the first phase of this study which will aim to gather the views of therapists.

**Who is organising and funding the research?**

Kathryn Jarvis is organising this research study. She is an Occupational Therapist who is employed by the University of Liverpool as a Lecturer in Occupational Therapy. The study will form part of the work for a higher degree in the Research Institute for Social Sciences at Keele University, supervised by Dr Sue Hunter and Dr Nicky Edelstyn.

The study has been reviewed and approved by Keele University.

There is funding allocated to this study from the Constance Owens Fund.

**What will happen to the results of the research study?**

The results of this study will form a part of Kathryn Jarvis' PhD thesis. The results will be shared with service-users, clinicians and researchers, and will be presented nationally and internationally. This will be through publication in medical or therapy journals, such as the International Journal of Therapy and Rehabilitation, and presentations at conferences. Details of any publications will be made available to the therapists taking part in the research. If any quotes are used in these publications or presentations they will not contain any information that could identify the person who made the quote.

**Why have I been chosen?**

As implementation of a specific therapy treatment may vary depending on the service context, this research will be based in one NHS Trust, namely the RLBH. Your service manager has identified you as a therapist working in a stroke service in at the RLBH and has given permission for me to contact you and invite you to participate. All therapists identified in this way have been contacted.

**What do I have to do if I decide to participate?**

If you decide to participate you will be asked to take part in one focus group. The focus group will take place at the University of Liverpool and is expected to last no more than 1½ hours. The group will consist of other therapists from RLBH who are taking part in the research, Kathryn Jarvis who will lead the discussion and a note-taker. The aim of the focus group will be to establish therapist views on the evidence-based CIMT protocols and to consider which of the protocols, if any, could be provided at the RLBH. Participants will be asked to consider facilitators and barriers to using CIMT in practice. The focus group will be audio-recorded.

### **Do I have to take part and what will happen if I take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to complete a brief questionnaire and to sign a consent form.

If there are 10 or less therapists interested in participating, all will be invited to take part in the study. If there are more than 10 potential participants, Kathryn Jarvis will consider each participant's experience and select 10 participants who can best represent the variety of experience of therapists working in stroke. The aim will be to ensure that the group includes a range of experience across the two professions.

If you decide to take part you are free to withdraw at any time, without giving a reason.

### **What are the possible disadvantages and risks of taking part?**

The focus group will take place at a time that is mutually convenient for the participants, researcher and service.

In the unlikely event that a therapist discloses unethical or unsafe practice, the researcher has a professional duty to inform the therapist's manager. This is in line with the College of Occupational Therapy Code of Ethics and Professional Conduct which states:

"Occupational therapy personnel who witness or have reason to believe that the client has been the victim of dangerous, abusive, discriminatory or exploitative behaviour or practice shall use local policies to notify a line manager or other appropriate person as soon as reasonably possible."

(<http://www.cot.co.uk/MainWebSite/Resources/Document/Code%20Ethics%20Reprint%202009.pdf>)

### **What are the possible benefits of taking part?**

The aim of the study is to better understand the issues of implementing CIMT into a specific setting. It is anticipated that this study will provide information to guide therapists in their use of CIMT in the future.

### **What will happen to the information I provide in the study?**

If you decide to participate you will be allocated a Participant Identification Number (PIN). This PIN will be used to ensure that no personal details are attached to the information you provide. Your contact details will be kept separate from the information you provide at all times.

The recordings from the focus group will be converted into text by a transcriber. The information will be seen by Kathryn Jarvis (Chief Investigator), Dr Sue Hunter and Dr Nicky Edelstyn (Kathryn Jarvis' Supervisors) and a transcriber. Any personal information on the audio-recording will not appear in the text documents. Once the study is complete the audio-recording will be destroyed.

All recordings and documents will be kept in accordance with the Data Protection Act (1998) and will be stored either in a locked secure office or on a password protected computer at the University of Liverpool (School of Health Sciences) or Keele University

(Department of Physiotherapy) during the study and at Keele University once the project is complete. All data will be destroyed 5 years after completion of the study.

### **What if there is a problem?**

If you have a concern about any aspect of this study you should ask to speak with **Kathryn Jarvis (Chief Investigator)** who will do her best to answer your questions (contact details are at the end of this information sheet).

This research project is being sponsored by Keele University. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is Keele University's contact for complaints regarding research at the following address:-

Nicola Leighton  
Research Governance Officer  
Research & Enterprise Services  
Dorothy Hodgkin Building  
Keele University  
ST5 5BG

### **What should I do if I would like to participate in this study?**

If you are willing to participate in this study, please complete the enclosed questionnaire and consent form, and return them to Kathryn Jarvis prior to the start of the focus group. A copy of the Participant Information Sheet and signed Consent Form will be given to you to keep.

If you would like to discuss any aspect of the study before making any decision, then please contact me.

### **Contact details:**

Kathryn Jarvis  
Directorate of Occupational Therapy  
Thompson Yates Building  
University of Liverpool  
Brownlow Hill  
Liverpool L69 3GB

Telephone: 0151 794 5721  
E-mail: k.jarvis@liverpool.ac.uk

I would like to thank you for your time in reading this information sheet.

Kathryn Jarvis  
Chief Investigator

## Appendix 11

**CONSENT FORM**

**Title of Project:**      **Implementing Constraint Induced Movement Therapy (CIMT) in a UK Stroke Service**

**Investigator:**          **Kathryn Jarvis**

- |   |        |
|---|--------|
| I have read and understood the participant information sheet explaining this study  | YES/NO |
| I have had the opportunity to ask questions and discuss this study  | YES/NO |
| I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, and without my legal rights being affected  | YES/NO |
| I agree to the use of audio-taping to record the focus group discussions  | YES/NO |
| I agree that information may be collected about me by Kathryn Jarvis, and that the results of the study may be published, but that my identity will be protected at all times   | YES/NO |
| I freely consent to take part in this study   | YES/NO |
| I agree to allow the dataset collected to be used for future research projects  | YES/NO |
| I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give my permission for these individuals to have access to this information. | YES/NO |

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## Appendix 12



## SECOND STAGE CONSENT FORM

**Title of Project:**      **Implementing Constraint Induced Movement Therapy (CMT) in a UK Stroke Service**

**Investigator:** Kathryn Jarvis

**Please consider the following statements and tick the box by the appropriate statement**

I am happy for any of my quotes to be used in the dissemination of this study

☐

I do not want any of my quotes to be used in the dissemination of this study

☐

I want to have the opportunity to consider any quotes prior to them being used in the dissemination of this study

☐

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## Appendix 13



### Implementing Constraint Induced Movement Therapy (CIMT) in a UK Stroke Service

#### Focus Group Schedule

**Research Project title:**

Implementing constraint induced movement therapy (CIMT) in a UK stroke service

**Aim:**

To collect the views of the participants on:

- Which of the evidence-based CIMT protocols do therapists perceive could be provided within a UK stroke service
- In what circumstances might each CIMT protocol be selected ie when (time post-stroke), where (in what therapeutic environment) and with whom (with which stroke survivors)
- Are there factors that would assist or hinder the provision of the CIMT protocols

**Invited Participants:**

Occupational Therapists and Physiotherapists employed by Royal Liverpool and Broadgreen University Hospital Trust working in the stroke services

**Facilitated by:**

Kathryn Jarvis (Principal Investigator) and Gaynor Reid (Co-facilitator)

## Group Interview Schedule

### Introduction and Background

*Recorder to be turned on*

9.30

1. Welcome and thank you for participating
2. Introduction of facilitator and scribe
3. Explanation for the need to record group interview
4. Anonymisation of transcript, recording deleted once analysis complete. Transcript will be destroyed after 5 years.
5. Expectation of maintaining confidentiality within group-happy for sharing of paperwork I give you
6. Second stage consent to be completed after the interview

9.35

7. An overview of the project and development of research questions-*original question, interest in sub-acute stroke*
  - systematic review x 2
  - findings from modelling study
8. Explanation of the purpose of the group interview
  - Which of the evidence-based CIMT protocols do you perceive could be provided within a UK stroke service
  - In what circumstances might you select each CIMT protocol
  - Are there factors that you think would assist or hinder the provision of the CIMT protocols
9. Introductions-ask each participant to introduce themselves and indicate professional background and the setting in which they work with stroke survivors and any personal experience of using CIMT

9.45

### Main Focus Group Discussion

10. Facilitator to present and give an overview of the evidence-based CIMT protocols-*black and white version*

9.50

11. Main questions to be addressed:
  - a) Do you think any of the protocols could be provided in the stroke service? If so, which ones?  
*Introduce colour version*

10.10 Explore under what circumstances the protocols could be provided

- b) Where (in what therapeutic setting, home, hospital, clinic, other...) should/could a CIMT protocol be provided?
- c) With whom (movement, cognition, carer...) should/could a CIMT protocol be provided?
- d) When (time-post stroke) should/could a CIMT protocol be provided?

10.25

- e) Do you think there are factors that would help the provision of CIMT protocol (may be broad, or specific to one protocol)? *personal (therapist or stroke survivor)*  
*organisational/institutional*
- f) Do you think there are factors that would hinder the provision of CIMT protocol (may be broad, or specific to one protocol)?

10.40

### Final Comments

- 12. An explanation of what will happen next in terms of analysing data and progression of the project
  - transcribed and analysed by 2 researchers
  - this analysis will inform next Phase
  - complete 2<sup>nd</sup> stage consent

13. Thank you

10.45 finish









## Appendix 14

### Nodes

Name	
activities in therapy	
list of activities for CIMT therapy	
additional support when introducing CIMT	
amount of restraint	
amount of training	
carers	
change of ethos	
characteristics of people able to undertake protocol	
checklist for protocol	
cognition	
compliance	
concentration	
confidence in using protocol	
crossroads	
day care support	
education of intervention for patient and carers	
environment	
equipment needs	
ethical considerations	
evidence of therapists' need for information or education about CI	
fatigue	
group CIMT	
homework	
impact on other aspects of care or rehab	
importance of therapists' knowledge	
intervention for OT and PTs	
involvement in research for therapists and patients	
length of protocol	
living alone	
low mood	
MDT	
mobility	
motivation	
number of days of therapy	
organisation of therapist time	
part of research	
previous experience	
promotion of independence	
reducing independence	
risk assessment and safety	
self-management	
setting	
skills mix	
sling and mitts	
staffing	

## Appendix 14-continued

### Nodes

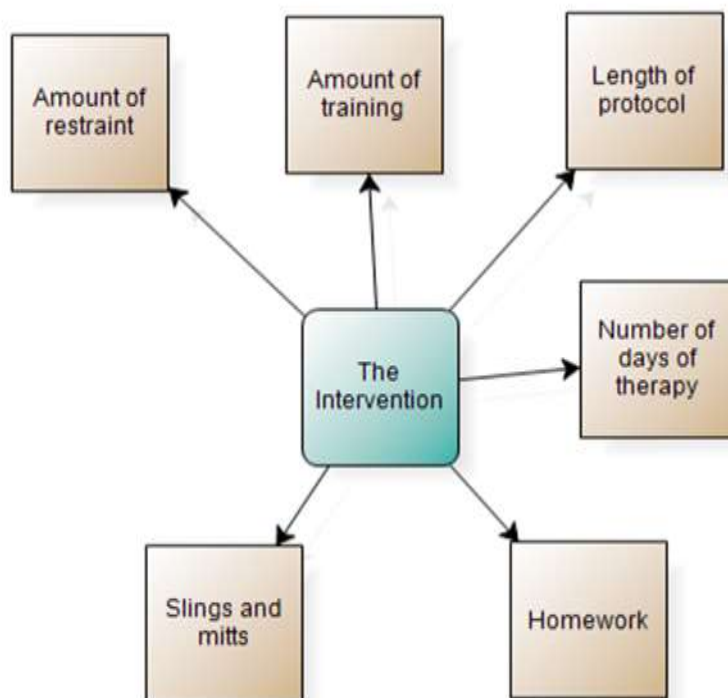
 Name	
 supervision	
 time post-stroke	
 time-general	
 traditionally an OT intervention	
 use of facilitation	
 venmore	
 which protocols can be used	

## Appendix 15

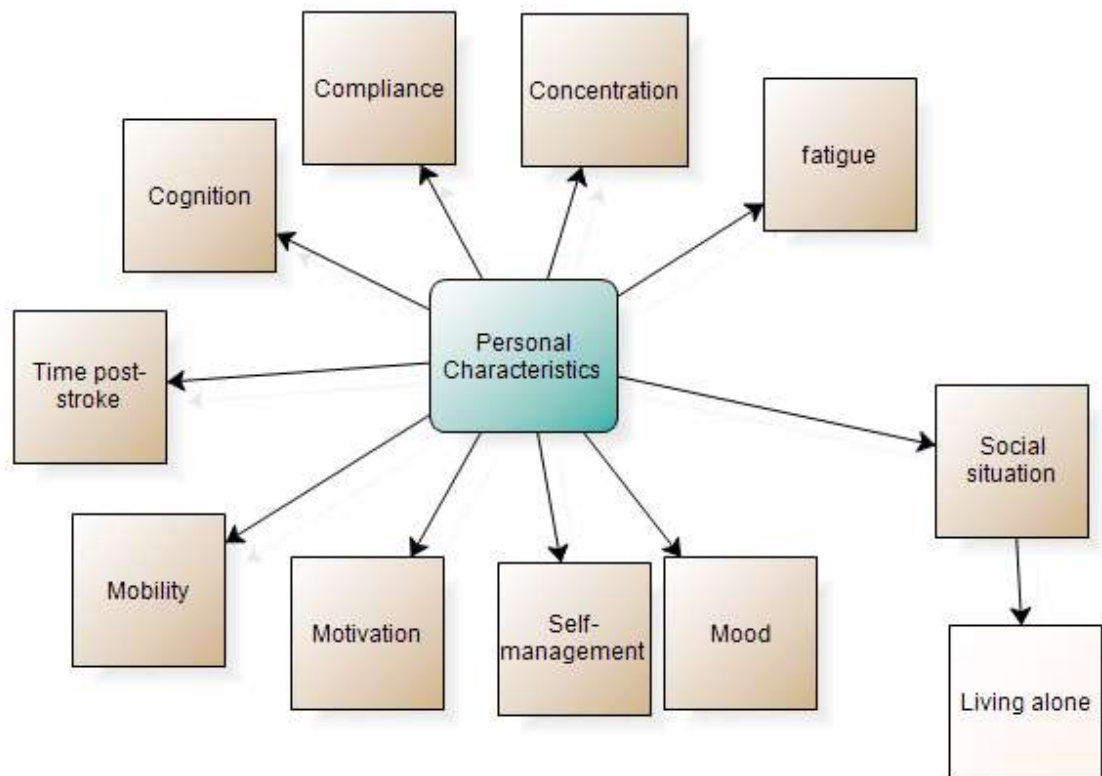
### Therapist Focus Group Analysis

#### Spider Diagrams

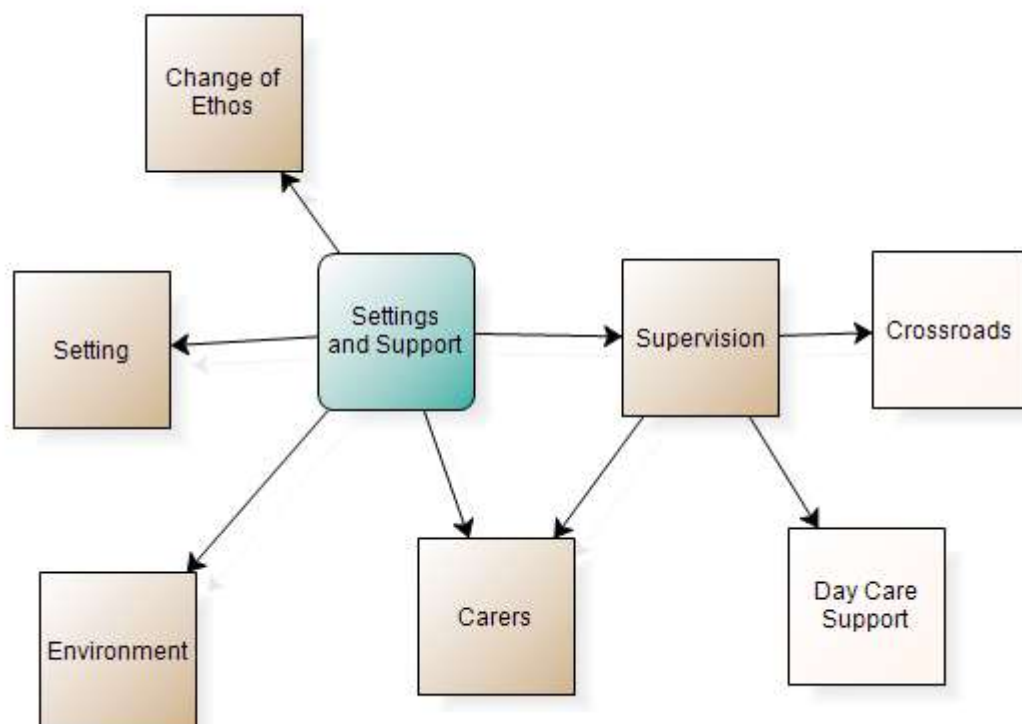
##### The CIMT intervention theme



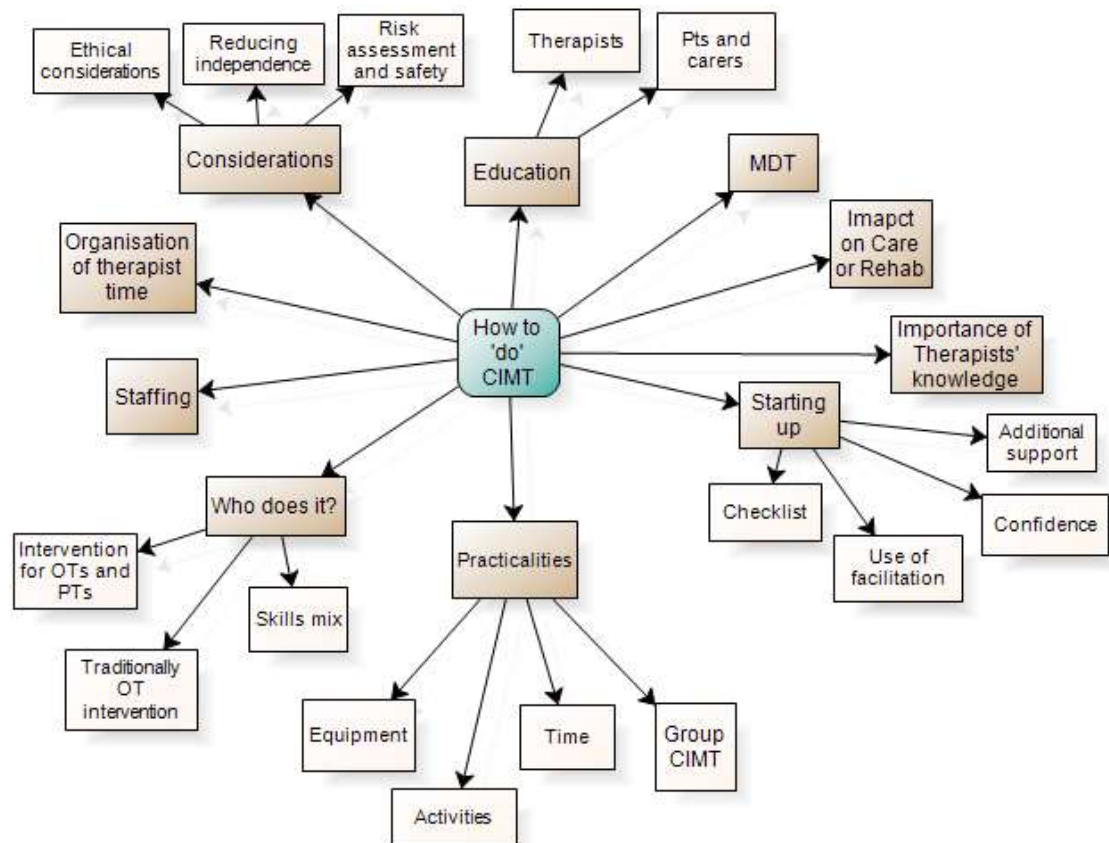
## Personal characteristics theme



## Settings and support theme



## How to 'do' CIMT theme



## **Appendix 16**

Ethical approval letters



**NRES Committee North West - Lancaster**

HRA NRES Centre - Manchester  
Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3DZ

Telephone: 0161 625 7818  
Facsimile: 0161 625 7299

13 May 2013

Ms Kathryn Jarvis  
Directorate of Occupational Therapy  
University of Liverpool  
Liverpool  
L69 3GB

Dear Ms Jarvis

<b>Study title:</b>	<b>Implementing constraint induced movement therapy (CIMT) in a UK stroke service</b>
<b>REC reference:</b>	<b>13/NW/0309</b>
<b>IRAS project ID:</b>	<b>65154</b>

The Research Ethics Committee reviewed the above application at the meeting held on 09 May 2013. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Carol Ebenezer, [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net).

**Ethical opinion**

The Chair welcomed you to the REC and thanked you for attending to discuss the study.

The Committee asked whether Phase 1 has now been completed and you said that it has not as yet. You are aiming for a provisional date of the beginning of June and hope to start Phase 2 in the latter part of the year. This will complete the PhD.

The Committee asked whether 4 participants are sufficient as validation. You stated that in terms of the PhD you have done other studies, and as to the scientific value, this started out as a larger project and you want to test out data collection and outcome measures with 4 participants. You will possibly submit an amendment to increase the number of participants if the techniques are appropriate.

The Committee asked how many therapists there are, and you stated that there is one. You confirmed that the therapist will be able to carry out all interventions. You told the Committee that you have strong links with RLBUHT, and the therapist arrangements have not been finalised yet but you have funding from the Vreeburg Bursary fund to pay for this.

You told the Committee that the two researchers who will do the analysis are you and your supervisor.

The Committee asked for a brief guide to the therapy, and you explained that the theory is that by constraining the better arm the patients can train the arm most affected by the stroke.

The Committee asked that the information that the interviews be recorded be included in the paragraph on What do I have to do if I decide to participate? .

The Committee asked that participants be told that their care will not be affected if they choose not to participate.

The Committee asked the reason for the two consent forms. You told the Committee that you had taken advice from your supervisor on this.

The Committee asked that the word anonymised be included before quotes.

The Committee advised that the GP does not need to be informed of participation in this study.

The Committee asked you whether you are a member of the direct care team. You told the Committee that you are not. You will not look at patient records. The research therapist may do this but she is a member of the direct care team.

The Committee asked what information will be stored on a lap-top. You stated that this will only be used to transfer data from Liverpool to Keele and the data will therefore be kept on the laptop for a very short time. You confirmed that it will be password protected and that you have a locked cupboard at home where it could be stored.

The Committee asked whether the assessment forms are all validated, and you said that they have all been tested for reliability in other studies.

You had no questions for the Committee.

The Committee told you that this is an interesting piece of work

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

#### **Ethical review of research sites**

##### **NHS Sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- a. The Committee would like to see the Participant Information Sheet revised to
  - i) Include the sentence "If you agree, the interviews will be audio-recorded" at the end of What do I have to do if I decide to participate?
  - ii) Omit the information that their GP will be informed of their participation
  - iii) Include at the end of Do I have to take part...? The sentence "if you

choose not to take part, or if you withdraw from the study your medical care will not be affected"

- b. The Committee would like to see the Consent Form revised to
  - i) Include the word anonymised before quotes on all three points of the second stage consent form
  - ii) Omit the yes/no on the first one and include boxes which the participant should be asked to initial
  - iii) Request that the boxes be initialled, not ticked on the second form

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

**It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		09 April 2013
Evidence of insurance or indemnity		26 July 2012
GP/Consultant Information Sheets	1	25 February 2013
Investigator CV	Kathryn Javis	
Investigator CV	Dr Sue Hunter	19 March 2013
Investigator CV	NMJ Edelstyn	21 February 2013
Other: Appendix 5 - Demographic Form	1	24 February 2012
Participant Consent Form: Appendix 3	1	24 February 2012
Participant Consent Form: Appendix 4 - Second Stage	1	24 February 2012
Participant Information Sheet: Appendix 2	1	24 February 2012

Protocol	1	15 March 2013
Questionnaire: Appendix 6 -Pre-CIMT Interview Schedule	1	03 August 2012
Questionnaire: Appendix 7 -Post-CIMT Interview Schedule	1	03 August 2012
REC application	3.5	09 April 2013
Referees or other scientific critique report		25 October 2012
Summary/Synopsis	1	09 January 2013

### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

<b>13/NW/0309</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'N. Calvert', written in a cursive style.

**Dr Nigel Calvert**  
**Vice-Chair**

Email: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments  
"After ethical review – guidance for researchers"*

*Copy to: Nicola Leighton  
Heather Rogers*

**NRES Committee North West - Lancaster**

HRA NRES Centre - Manchester  
Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3DZ

Telephone: 0161 625 7818  
Facsimile: 0161 625 7299

16 May 2013

Ms Kathryn Jarvis  
Directorate of Occupational Therapy  
University of Liverpool  
Liverpool  
L69 3GB

Dear Ms Jarvis

**Study title:** Implementing constraint induced movement therapy (CIMT) in a UK stroke service  
**REC reference:** 13/NW/0309  
**IRAS project ID:** 65154

Thank you for your email of 15 May. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 13 May 2013

**Documents received**

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other: Canadian Occupational Performance 1		
Other: Nottingham Extended Activity 2		
Other: Pain Visual Analogue		
Other: Wolf Motor Function Test		
Other: Albert's Test 2		
Other: MOCA 1		
Other: MOCA admin		
Participant Consent Form	2	15 May 2013
Participant Consent Form: Second Stage	2	15 May 2013
Participant Information Sheet	2	15 May 2013
Questionnaire: Connor Davidson Scale		
Questionnaire: Fatigue Visual Analogue		
Questionnaire: HADS		

Questionnaire: Nottingham Extended Activity 1		
Questionnaire: Canadian Occupational Performance 2		

### Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		09 April 2013
Evidence of insurance or indemnity		26 July 2012
GP/Consultant Information Sheets	1	25 February 2013
Investigator CV	Kathryn Javis	
Investigator CV	Dr Sue Hunter	19 March 2013
Investigator CV	NMJ Edelstyn	21 February 2013
Other: Appendix 5 - Demographic Form	1	24 February 2012
Other: Canadian Occupational Performance 1		
Other: Nottingham Extended Activity 2		
Other: Pain Visual Analogue		
Other: Wolf Motor Function Test		
Other: Albert's Test 2		
Other: MOCA 1		
Other: MOCA admin		
Participant Consent Form	2	15 May 2013
Participant Consent Form: Second Stage	2	15 May 2013
Participant Information Sheet	2	15 May 2013
Protocol	1	15 March 2013
Questionnaire: Appendix 6 -Pre-CIMT Interview Schedule	1	03 August 2012
Questionnaire: Appendix 7 -Post-CIMT Interview Schedule	1	03 August 2012
Questionnaire: Connor Davidson Scale		
Questionnaire: Fatigue Visual Analogue		
Questionnaire: HADS		
Questionnaire: Nottingham Extended Activity 1		
Questionnaire: Canadian Occupational Performance 2		
REC application	3.5	09 April 2013
Referees or other scientific critique report		25 October 2012
Summary/Synopsis	1	09 January 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/NW/0309

Please quote this number on all correspondence

Yours sincerely

pp. 

**Mrs Carol Ebenezer**  
**Committee Co-ordinator**

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

Copy to: *Nicola Leighton,*  
*Heather Rogers, Royal Liverpool and Broadgreen University Hospitals Trust*

# Appendix 17

## The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
L7 8XP

### TRUST APPROVAL LETTER FOR NON-CTIMP STUDIES

Tel: 0151 706 2000  
Fax: 0151 706 5806

Ms Kathryn Jarvis  
University of Liverpool  
Directorate of Occupational Therapy  
Thompson-Yates Building, Brownlow Hill  
Liverpool  
L69 3GB

REC: 13/NW/0309  
Date: 07/10/2013

Dear Ms Jarvis

RD&I No: 4359

Implementing constraint induced movement therapy (CIMT) in a UK stroke service

The above study is a Non-Commercial, Qualitative Only study, sponsored by Keele University and funded by The Constance Owens Trust. The Trust is now happy for you to commence work on this study, using the following ethically approved documents.

Document	Version	Dated
GP/Consultant Information Sheets	1	25 February 2013
Participant Consent Form	2	15 May 2013
Participant Consent Form: Second Stage	2	15 May 2013
Participant Information Sheet	2	15 May 2013
Protocol	1	15 March 2013
Questionnaire: Appendix 6 – Pre-CIMT Interview Schedule	1	03 August 2012
Questionnaire: Appendix 7 – Pre-CIMT Interview Schedule	1	03 August 2012
Questionnaire: Connor Davidson Scale		
Questionnaire: Fatigue Visual Analogue		
Questionnaire: HADS		
Questionnaire: Nottingham Extended Activity 1		
Questionnaire: Canadian Occupational Performance 2		
Summary/Synopsis	1	09 January 2013

May I to take this opportunity to remind you of your responsibilities as PI for this study to:-

- Report SAE's as per protocol and Trust policy and record total number on OSIRIS
- Ensure that all screening and recruitment activity is updated on OSIRIS every Friday (training can be obtained if required by phoning Ext 3782)

- Department of Health target for this study is first patient recruited by **11 December 2013**.
- Please provide a timely response to requests for information regarding achievement of this target
- For Trust sponsored studies, provide RD&I with copies of regulatory annual progress and safety reports to Ethics
- Complete and return the RD&I annual report form in a timely manner
- Comply with the Research Governance Framework 2<sup>nd</sup> Ed 2005 including but not limited to the Medicines for Human use (Clinical Trials) 2004 act plus it's appendices and the Data Protection Act 1998
- Read, disseminate to research team and acknowledge to RD&I, Trust research SOP announcements (details of relevant SOP's can be found at [http://staffintranet/departments\\_and\\_services/corporate\\_services/research\\_and\\_development/documents/documents.aspx](http://staffintranet/departments_and_services/corporate_services/research_and_development/documents/documents.aspx))
- Inform RD&I of any amendments to, or changes of status in, the study.
- Ensure any conditions to approval stipulated by the MHRA/ REC have been addressed prior to implementation of approved changes
- Maintain the study site file (if not provided by the sponsor a template is available on the Trust intranet)
- Provide copies of publications

Investigators who do not comply with the above will be dealt with in accordance with the Trust Disciplinary policy and/or will have their research stopped.

I wish you every success with your research. Please contact the RD&I Department if you require any advice on the above points.

Yours sincerely

Julia West  
Operational Director RD&I

cc Head of Directorate  
Keele University

## Appendix 18



The Royal Liverpool and Broadgreen University Hospitals  
NHS Trust

### Participant Information Sheet

Implementing constraint induced movement therapy (CIMT) in a UK stroke service: Phase 2

**Title of Project:**

**Implementing constraint induced movement therapy (CIMT) in a UK stroke service**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

If there is anything that is unclear or you would like more information, please contact Kathryn Jarvis (Chief Investigator) whose contact details are on page 4 of this information sheet. Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

**What is the purpose of this study?**

Constraint induced movement therapy (CIMT) is a therapy treatment that has been shown to improve arm and hand function in some stroke survivors. There is limited evidence that constraint induced movement therapy is being used in practice, and there appears to be discrepancies between the CIMT described in the research literature and the CIMT used in practice. The aim of this study is to establish therapist and stroke survivor perceptions of CIMT when it is implemented in a UK healthcare setting.

You are being asked to consider participating in the second phase of this study which will aim to gather views of stroke survivors about CIMT. You do not need to have any previous knowledge about CIMT to participate in this study.

**Who is organising and funding the research?**

Kathryn Jarvis is organising this research study. She is an Occupational Therapist who is employed by the University of Liverpool as a Lecturer in Occupational Therapy. The study will form part of the work for a higher degree in the Research Institute for Life Course Studies at Keele University, supervised by Dr Sue Hunter and Dr Nicky Edelstyn.

The study has been reviewed and approved by NRES Committee North West-Lancaster. Research Ethics Committee Reference: 13/NW/0309.

There is funding allocated to this study from the Constance Owens Fund and the Vreeburg Bursary Award.

**What will happen to the results of the research study?**

The results of this study will form a part of Kathryn Jarvis' PhD thesis. The results will be shared with service-users, clinicians and researchers, and will be presented nationally and internationally. This will be through publication in medical or therapy journals and presentations at conferences. If any quotes are used in these publications or presentations they will not contain any information that could identify the person who made the quote.

**Why have I been chosen?**

Your therapists have identified you as a having had a stroke within the last nine months that has affected the use in your arm and hand.

**What do I have to do if I decide to participate?**

If you decide to participate you will be invited to take part in one interview which is expected to last no more than 60 minutes. During the interview you will be asked to consider what may help or hinder you in using CIMT. You will then be asked to talk with a therapist to agree a CIMT protocol that would be acceptable to you to undertake. Once this is agreed, you will be offered a course of CIMT. The CIMT will include restraining the use of your stronger arm and hand, along with training of the arm and hand affected by the stroke. Your stronger arm will be restrained by a hand mitt. The CIMT will be undertaken as agreed between yourself and the therapist. There are several different protocols, the more intense schedules are usually undertaken over 2 weeks, with less intense schedules being undertaken over a longer period (up to 10 weeks). Before and after the course of CIMT you will be asked to participate in a number of assessments.

These assessments are to help understand the effects your stroke has had on you and to establish whether changes have occurred following the CIMT. If you agree, one of the assessments to measure the function in your hand and arm will be video-recorded. In addition, following the course of CIMT, you will be invited to participate in a second interview which is also expected to last no more than 60 minutes. In this second interview you will be asked if there were factors that helped or hindered you in undertaking the CIMT. If you agree, the interviews will be audio-recorded.

### **Do I have to take part and what will happen if I take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Kathryn Jarvis will then contact you to organise the research

If you decide to take part you are free to withdraw at any time, without giving a reason. If you choose not to take part, or if you withdraw from the study your medical care will not be affected.

### **What are the possible disadvantages and risks of taking part?**

It is possible that as a result of the restraint of your stronger arm and hand, you may be less steady than without the restraint. This will be assessed at the start of the CIMT protocol and any measures to reduce the impact of the restraint on your steadiness will be put in place. Previous CIMT studies indicate that there may be a risk of increased tiredness when undertaking the CIMT, this will be monitored during the CIMT. There is also a possibility that the additional therapy to your arm that has been affected by the stroke, may cause some discomfort or pain in this arm. This will be assessed on each day of CIMT treatment so that if discomfort or pain does occur appropriate action can be taken.

### **What are the possible benefits of taking part?**

The aim of the study is to better understand the issues of implementing CIMT into a specific setting. It is anticipated that this study will provide information to guide therapists in their use of CIMT in the future. It is possible that you will gain additional movement or control in your arm and hand that has been affected by the stroke.

### **What will happen to the information I provide in the study?**

If you decide to participate you will be allocated a Participant Identification Number (PIN). This PIN will be used to ensure that no personal details are attached to the information you provide. Your contact details will be kept separate from the information you provide at all times.

The recordings from the interview will be converted into text by a transcriber. The information will be seen by Kathryn Jarvis (Chief Investigator), Dr Sue Hunter and Dr Nicky Edelstyn (Kathryn Jarvis' Supervisors) and the transcriber. Any personal information on the audio-recording will not appear in the text documents. Once the study is complete the audio-recording will be destroyed.

All recordings and documents will be kept in accordance with the Data Protection Act (1998) and will be stored either in a locked secure office or on a password protected computer at the University of Liverpool (School of Health Sciences) or Keele University

(School of Health and Rehabilitation) during the study and at Keele University once the project is complete. All data will be destroyed 5 years after completion of the study.

**What if there is a problem?**

If you have a concern about any aspect of this study you should ask to speak with **Kathryn Jarvis (Chief Investigator)** who will do her best to answer your questions (contact details are at the end of this information sheet).

This research project is being sponsored by Keele University. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is Keele University's contact for complaints regarding research at the following address:-

Nicola Leighton  
Research Governance Officer  
Research & Enterprise Services  
Dorothy Hodgkin Building  
Keele University  
ST5 5BG

**What should I do if I would like to participate in this study?**

If you are willing to participate in this study, you will be invited to complete the consent form. A copy of this Participant Information Sheet and signed Consent Form will be given to you to keep.

If you would like to discuss any aspect of the study before making any decision, then please contact me.

**Contact details:**

Kathryn Jarvis  
Directorate of Occupational Therapy  
Thompson Yates Building  
University of Liverpool  
Brownlow Hill  
Liverpool L69 3GB

Telephone: 0151 794 5721  
E-mail: k.jarvis@liverpool.ac.uk

I would like to thank you for your time in reading this information sheet.

Kathryn Jarvis  
Chief Investigator

## **Appendix 19**

### Consent Form



The Royal Liverpool and Broadgreen University Hospitals  
NHS Trust

## CONSENT FORM

### Implementing Constraint Induced Movement Therapy Study: Phase 2

**Title of Project:** Implementing constraint induced movement therapy (CIMT) in a UK stroke service

**Investigator:** Kathryn Jarvis

**Please consider the following statements and initial the boxes to indicate your consent:**

I have read and understood the participant information sheet explaining this study

☐

I have had the opportunity to ask questions and discuss this study

☐

I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time, without giving any reason, and without my legal rights being affected

☐

I agree to the use of audio-taping to record the two interviews

☐

I **will consider/decline/agree to\*** the video-recording of an assessment of my arm function on two occasions (\*delete as appropriate)

☐

I agree that information may be collected about me by Kathryn Jarvis or by a research therapist, and that the results of the study may be published, but that my identity will be protected at all times

☐

I freely consent to take part in this study

☐

I agree to allow the dataset collected to be used for future research projects

☐

I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give my permission for these individuals to have access to this information.

☐

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## **Appendix 20**

Ethical approval and R&D approval for Amendment 1

**NRES Committee North West - Lancaster**

HRA NRES Centre - Manchester  
Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3D

Tel: 0161 625 781  
Fax: 0161 625 725

22 April 2014

Ms Kathryn Jarvis  
Directorate of Occupational Therapy  
University of Liverpool  
Liverpool  
L69 3GB

Dear Ms Jarvis

**Study title:** Implementing constraint induced movement therapy  
(CIMT) in a UK stroke service  
**REC reference:** 13/NW/0309  
**Amendment number:** 1  
**Amendment date:** 27 March 2014  
**IRAS project ID:** 65154

Video record intervention

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

Although the Committee had no ethical issues with the amendment the members suggest that the Consent Form is revised to enable participants to consider, decline or agree to be videoed in that order (i.e. separate points).

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	1	27 March 2014
Protocol	2	18 March 2014
Participant Information Sheet	3	18 March 2014

2

Participant Consent Form	3	18 March 2014
Participant Consent Form: post video recording	1	18 March 2014

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.


### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/NW/0309:	Please quote this number on all correspondence
-------------	--

Yours sincerely



pp.  
Dr Lisa Booth  
Chair

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Heather Rogers, Royal Liverpool and Broadgreen University Hospitals Trust  
Nicola Leighton*

# The Royal Liverpool and Broadgreen University Hospitals



NHS Trust

Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
L7 8XP

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## AMENDMENT APPROVAL LETTER AND NOTIFICATION OF CONTINUED NHS PERMISSION

Tel: 0151 706 2000  
Fax: 0151 706 5806

Ms Kathryn Jarvis  
University of Liverpool  
Directorate of Occupational Therapy  
Thompson-Yates Building, Brownlow Hill  
Liverpool  
L69 3GB

REC: 13/NW/0309  
Date: 01/10/2014

Dear Ms Jarvis

**RD&I No: 4359**

**Implementing constraint induced movement therapy (CIMT) in a UK stroke service**

**Amendment number: 1**

**Amendment date: 27 March 2014**

I can confirm that the Trust is happy to continue its permission for this study to take place on its premises in accordance with the amended documentation listed on the ethics amendment approval letter dated 22 April 2014.

The study should be conducted in compliance with the Research Governance Framework 2<sup>nd</sup> Ed 2005. Please ensure you inform your research team of this amendment.

Yours sincerely

**Heather Rogers**  
Research Governance Manager

## **Appendix 21**

Ethical approval and R&D approval for Amendment 2

**NRES Committee North West - Lancaste**

HRA NRES Centre - Manchest  
 Barlow Hous  
 3rd Floo  
 4 Minshull Stree  
 Manchest  
 M1 3D

Tel: 0161 625 783  
 Fax: 0161 625 791

09 May 2014

Ms Kathryn Jarvis  
 Directorate of Occupational Therapy  
 University of Liverpool  
 Liverpool  
 L69 3GB

Dear Ms Jarvis

**Study title:** Implementing constraint induced movement therapy  
 (CMT) in a UK stroke service  
**REC reference:** 13/NW/0309  
**Amendment number:** 2  
**Amendment date:** 24 April 2014  
**IRAS project ID:** 65154

Change to Inclusion Criteria

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	2	24 April 2014
Protocol	3	22 April 2014
Covering Letter		28 April 2014
Participant Information Sheet	4	22 April 2014

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

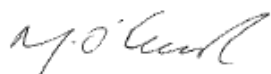
**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>13/NW/0309:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely



pp

**Dr Lisa Booth**  
**Chair**

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Heather Rogers, Royal Liverpool and Broadgreen University Hospitals Trust  
Nicola Leighton*

The Royal Liverpool and  
Broadgreen University Hospitals



NHS Trust

Royal Liverpool University Hospital

Prescot Street

Liverpool

L7 8XP

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**AMENDMENT APPROVAL LETTER AND NOTIFICATION  
OF CONTINUED NHS PERMISSION**

Tel: 0151 706 2000

Fax: 0151 706 5806

Ms Kathryn Jarvis  
University of Liverpool  
Directorate of Occupational Therapy  
Thompson-Yates Building, Brownlow Hill  
Liverpool  
L69 3GB

REC: 13/NW/0309

Date: 01/10/2014

---

Dear Ms Jarvis

**RD&I No: 4359**

**Implementing constraint induced movement therapy (CIMT) in a UK stroke service**

**Amendment number: 2**

**Amendment date: 24 April 2014**

I can confirm that the Trust is happy to continue its permission for this study to take place on its premises in accordance with the amended documentation listed on the ethics amendment approval letter dated 9 May 2014.

The study should be conducted in compliance with the Research Governance Framework 2<sup>nd</sup> Ed 2005. Please ensure you inform your research team of this amendment.

Yours sincerely

**Heather Rogers**  
Research Governance Manager

## **Appendix 22**

### **Record Form for OT-STAR**

## Occupational Therapy Stroke Arm & Hand Treatment Record (OT-STAR)

**Name:** \_\_\_\_\_ **NHS No.:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_  
**Hand Dominance:** right left both (please circle) **Date of Session:** \_\_\_\_\_  
**Therapist's Name:** \_\_\_\_\_ **Duration of Session:** \_\_\_\_\_ **No. of Staff:** \_\_\_\_\_

### Body Structure and Function

<b>JOINTS/ BONES</b>	<input type="checkbox"/> Re-alignment of joints & bones	<input type="checkbox"/> Compression	<input type="checkbox"/> Distraction
<b>MUSCLE</b>	<input type="checkbox"/> Cognitively reducing tone <input type="checkbox"/> Strengthening	<input type="checkbox"/> Mobilising muscles & soft tissue <input type="checkbox"/> Electrical stimulation	<input type="checkbox"/> Re-alignment of muscles
<b>MOVEMENT</b>	<input type="checkbox"/> Supporting/guiding/assisting an action <input type="checkbox"/> Facilitation of movement <input type="checkbox"/> Passive movements <input type="checkbox"/> Positioning of UL	<input type="checkbox"/> Stabilising aspect of UL to enable movement <input type="checkbox"/> Weight transfer in UL <input type="checkbox"/> Sensory in-put/priming	<input type="checkbox"/> Consideration of body to enable UL movement.
<b>SENSORY</b>	<input type="checkbox"/> Proprioception <input type="checkbox"/> Stereognosis interventions	<input type="checkbox"/> Temperature <input type="checkbox"/> Desensitisation techniques	<input type="checkbox"/> Touch & texture
<b>COMBINED</b>	<input type="checkbox"/> Massage <input type="checkbox"/> Retrograde massage/effleurage	<input type="checkbox"/> Weight-bearing	<input type="checkbox"/> Provision of orthoses. Give details:
<b>OTHER</b>	Please state:		

### Activity

<b>Activity</b>	<b>Postural set:</b>
<b>MOTOR &amp; SENSORY COMPONENTS OF FUNCTION</b>	
<input type="checkbox"/> Dexterity & fine motor skills <input type="checkbox"/> Grasp & release <input type="checkbox"/> Reach & grasp <input type="checkbox"/> Push & pull <input type="checkbox"/> Polishing <input type="checkbox"/> Working to place UL in activity <input type="checkbox"/> Remedial activities (motor) <input type="checkbox"/> Hand-washing-exfoliation <input type="checkbox"/> Bilateral interventions <input type="checkbox"/> CIMT/mCIMT <input type="checkbox"/> FES <input type="checkbox"/> Mirror use <input type="checkbox"/> Imagery/visualisation <input type="checkbox"/> Mirror therapy <input type="checkbox"/> Working on functional task components <input type="checkbox"/> Other, please state:	
<b>COGNITIVE COMPONENTS OF FUNCTION</b>	
<input type="checkbox"/> Conceptualisation of goal <input type="checkbox"/> Increasing attention to task <input type="checkbox"/> Increasing attention to UL <input type="checkbox"/> Remedial activities (cognition) <input type="checkbox"/> Use of unaffected UL to gain feeling of movement <input type="checkbox"/> Use of grading to moderate complexity of task <input type="checkbox"/> Strategies to reinforce therapy <input type="checkbox"/> Other, please state:	

### Participation (circle occupational performance area of focus below)

Self-care (PADL)	IADL	Work	Leisure	Education	Social participation
<b>Work on a specific function, state which:</b>					
<b>Support required:</b> <input type="checkbox"/> Supervision <input type="checkbox"/> Verbal prompts <input type="checkbox"/> Assistance <input type="checkbox"/> Facilitation <input type="checkbox"/> Independent					
<b>Activity undertaken:</b> <input type="checkbox"/> Bilaterally <input type="checkbox"/> Unilaterally-left hand <input type="checkbox"/> Unilaterally-right hand					
<b>Compensation for lost function</b>		<input type="checkbox"/> Equipment provision (including practice of equipment) State equipment:			
		<input type="checkbox"/> Teaching of alternative techniques, state techniques taught:			
		<input type="checkbox"/> Adaptation, state adaptations made to environment:			
		<input type="checkbox"/> Functional orthoses, state which:			

### Other

<b>Psychosocial</b>	Details:	
<b>Advice &amp; education</b>	verbal/written/pictorial	Details:
<b>Homework &amp; practice</b>	verbal/written/pictorial	Details:

**Key:** (m)CIMT- (modified) constraint induced movement therapy    FES-functional electrical stimulation    UL-upper limb

OT-STAR developed by: Jarvis K, Reid G, Edelstyn N and Hunter S

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**Participation** (circle occupational performance area of focus below)

Self-care (PADL)	IADL	Work	Leisure	Education	Social participation
<b>Work on a specific function, state which:</b> <b>Support required:</b> <input type="checkbox"/> Supervision <input type="checkbox"/> Verbal prompts <input type="checkbox"/> Assistance <input type="checkbox"/> Facilitation <input type="checkbox"/> Independent <b>Activity undertaken:</b> <input type="checkbox"/> Bilaterally <input type="checkbox"/> Unilaterally-left hand <input type="checkbox"/> Unilaterally-right hand					
<b>Compensation for lost function</b>		<input type="checkbox"/> Equipment provision (including practice of equipment) State equipment:			
		<input type="checkbox"/> Teaching of alternative techniques, state techniques taught:			
		<input type="checkbox"/> Adaptation, state adaptations made to environment:			
		<input type="checkbox"/> Functional orthoses, state which:			

**Participation** (circle occupational performance area of focus below)

Self-care (PADL)	IADL	Work	Leisure	Education	Social participation
<b>Work on a specific function, state which:</b> <b>Support required:</b> <input type="checkbox"/> Supervision <input type="checkbox"/> Verbal prompts <input type="checkbox"/> Assistance <input type="checkbox"/> Facilitation <input type="checkbox"/> Independent <b>Activity undertaken:</b> <input type="checkbox"/> Bilaterally <input type="checkbox"/> Unilaterally-left hand <input type="checkbox"/> Unilaterally-right hand					
<b>Compensation for lost function</b>		<input type="checkbox"/> Equipment provision (including practice of equipment) State equipment:			
		<input type="checkbox"/> Teaching of alternative techniques, state techniques taught:			
		<input type="checkbox"/> Adaptation, state adaptations made to environment:			
		<input type="checkbox"/> Functional orthoses, state which:			

## Additional Comments:

[illegible]

## **Appendix 23**

### **Instruction booklet for OT-STAR**

**Occupational Therapy Stroke Arm & Hand Treatment Record (OT-STAR) Booklet:**  
for use in conjunction with the Occupational Therapy Stroke Arm & Hand Treatment Record



**Contact:**

Kathryn Jarvis  
Division of Occupational Therapy  
University of Liverpool  
Thompson-Yates Building  
Brownlow Hill  
Liverpool  
L22 5PR

E-mail: [k.jarvis@liv.ac.uk](mailto:k.jarvis@liv.ac.uk)

This research was supported by the Constance Owens Trust

## Contents

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## Background

Both good clinical practice and research require a means to document therapy in an accurate and comprehensive manner. A consensus development study was undertaken to interview occupational therapists to establish which upper limb interventions they use when working with stroke survivors. The responses from the interviews were analysed to develop a comprehensive treatment record of upper limb interventions and a definition of each intervention.

The International Classification of Functioning (ICF)<sup>1</sup> has been used to provide a framework for the analyses. This framework was selected after consideration of the data, as it appeared to offer a structure for the wide variety of interventions provided by occupational therapists. The document has been split into four sections which reflect the ICF, these sections are as follows:

1. Interventions that Address Body Structure and Functions: Preparation for Activity
2. Interventions that Address Activity (Performance/Function Skills)
3. Interventions that Address Participation (Function/Occupation)
4. Other Aspects

It is hoped that the treatment record provides a concise and user-friendly tool. Every effort has been made to ensure that the treatment record represents the full range of occupational therapy upper limb interventions in current stroke practice. Please do not hesitate to contact me with any feedback or queries:

Kathryn Jarvis, Division of Occupational Therapy, University of Liverpool, Thompson-Yates Building, Brownlow Hill, Liverpool, L22 5PR

E-mail: k.jarvis@liv.ac.uk

## Instructions for completion of the Occupational Therapy Upper Limb Treatment Record

This treatment record has been designed to record occupational therapy upper limb interventions, where a stroke survivor service-user is undertaking therapy by a qualified occupational therapist.

1. Please complete one form for each treatment session
2. Record client and therapist details, date and duration of session and number of staff involved in the session.
3. Place a tick by all the 'body structure and function' interventions that have been undertaken during the treatment session, and state postural set for the interventions
4. Place a tick by all the 'activity' interventions that have been undertaken during the treatment session, and state postural set for the interventions
5. Circle the main occupational performance area for first 'participation' intervention undertaken
6. Place a tick by all the appropriate 'participation' boxes
7. If more than one 'participation' intervention was undertaken, use the additional 'participation' sections on the reverse of the treatment record
8. Record any additional interventions including any advice given or any practice recommended
9. Add any additional comments

The next section of the document provides definitions to assist in the completion of the treatment record

## Definitions

### 1: Interventions that Address Body Structure and Function: Preparation for Activity

Body functions: physiological functions of body systems (ICF, 2002)<sup>1</sup>

Body structures: anatomical parts of the body such as organs, limbs and their components (ICF, 2002)<sup>1</sup>

Theme	Definition
<b>Functions of Joints and Bones</b>	<b>Interventions that focus on the structure and function of joints and bones</b>
Re-alignment of joints and bones	Altering position of muscles, soft tissues and bones to re-align joints with aim of re-gaining normal alignment. Therapist uses hands, equipment or activity to align bones to a position that will allow movement.
Compression at joint	Application of pressure to increase sensory awareness of a joint. The pressure applied increases the proximity of the articulating surfaces of the joint. This pressure is usually, but not exclusive applied by the therapists hands.
Distraction	Therapist uses their hands to decrease the proximity of the articulating surfaces. The aim of this may be to alter alignment or to provide sensory in-put at the joint.
<b>Muscle Functions</b>	<b>Interventions that focus on the structure and function of the muscle</b>
Cognitively reducing tone	Service-user actively using mental functions to alter muscle tone.
Mobilising specific muscles and soft tissue	Therapist uses hands to effect a change to specific muscles/soft tissue through stretch of muscle/soft tissue. The aim may be to gain length in a muscle, alter tone, alignment or structure of muscle/soft tissue.
Re-alignment of muscles	Altering position of muscles and soft tissues with aim of re-gaining normal alignment.
Strengthening incl resistance training eg putty)	Use of specific activities to increase muscle strength. This might include use of equipment such as putty, theraband and exercises against resistance.
Neuromuscular electrical stimulation	Application of electrical stimulation to stimulate activity specific muscles, not related to a task.
<b>Movement Functions</b>	<b>Interventions that focus on movement without a task/activity</b>

Supporting, guiding, assisting an action	Offering assistance to undertake a movement, this is not facilitated (ie focus is not on providing sensory stimuli to alter outcome of movement). Therapist providing assistance if required, service-user actively focused on increasing movement. May be carried out by carer/relative. Incorporates 'active assisted' movements.
Facilitation of movement	Application of a sensory stimulus to access a desired active response from the service-user <sup>2</sup> This is facilitation of a movement without involvement of a specific activity or function/occupation.
Passive movements	Taking a limb or an aspect of a limb through its range of motion. During this process, the therapist aims for the service-user to attend to the movement. In a passive movement, the therapist is providing all of the movement.
Positioning of upper limb	Positioning of upper limb to enable movement, eg to increase access to activity that exists, or to decrease risk of future complications.
Stabilising an aspect of upper limb to enable a movement	Stabilising aspects of upper limb to enable movement in upper limb. Therapist often uses hands to provide this stability.
Weight transfer between upper limbs	Encouraging an equal weight distribution between both upper limbs during a task, eg in sit to stand.
Sensory input or priming	Provision of sensory information with the goal of increasing awareness of upper limb (priming) to improve movement, eg tactile, proprioceptive, thermal in-put to increase awareness. The aim is to increase movement, rather than to re-educate sensory functions.

Consideration of body to enable upper limb movement	Recognition that the upper limb doesn't work in isolation and that the rest of the body impacts on upper limb movement. Examples of interventions in this category include weight transfer (transfer of body weight from one part of body to another), positioning of body other than upper limb and stabilising aspects of body (non-upper limb) to enable movement in upper limb.
<b>Sensory Functions</b>	<b>Interventions that focus on sensory re-training, ie interventions that aim to re-train the sensory aspects of the upper limb, these often, but not exclusively focus on the hand.</b>
Proprioception	Interventions that require a person to develop their ability to know their position in space. This may involve the therapist increasing awareness of position, this may be done whilst restricting the use of sight.
Temperature	Interventions to re-train temperature, for example using different temperatures which a service-user identifies as warm, cold, or checking the water before washing. Often focuses on hand, but not exclusively.
Touch and texture	Interventions to re-train touch and texture, often, but not exclusively within hand. Usually involves using different types of material to allow service-user to experience textures through touch. This may be used as part of an activity eg washing.
Stereognosis interventions	Interventions where a person is required to identify an object through tactile stimuli and without the use of sight.
Desensitisation techniques	Interventions that aim to desensitize areas (particularly the hand) where this area is considered hyper-sensitive (ie more sensitive to stimuli than prior to stroke). Pain, unpleasant sensations, hyperreflexivity. May include using a 'rice bowl', massage, stretch, hand hygiene
<b>Combined Body Functions/Structures</b>	<b>Interventions that address body structure and function, but address more than one of the above areas</b>
Massage	Therapist moves hands over skin with enough pressure to manipulate skin, muscle and other soft tissue. The gliding movements made by the therapist's hands may be circular, unidirectional or multi-directional. The aim may be oedema management, increasing awareness of the upper limb, desensitization or altering structure of muscle/soft tissue. May be undertaken by therapist, service-user or other person.

Retrograde Massage/Effleurage	A gliding manipulation which involves rhythmical, sweeping strokes moving distally to proximally over treatment area. <sup>3</sup>
Weight-bearing	Taking weight through more affected upper limb, on supporting surface, equipment or therapist.
Provision of orthoses	A device that is applied to the upper limb or body to provide support, re-alignment or facilitate movement, alter tone or reduce oedema. Eg splints, strapping, casting, shoulder supports, pressure garments. To include provision, education, adaptation of orthoses or use of orthoses.
Other	Document any additional interventions that address body structure or function. An example of this may be Proprioceptive Neuromuscular Facilitation (PNF)

## Definitions cont'd

### 2: Interventions that Address Activity (Performance/Function Skills)

Activity: the execution of a task or action by an individual (ICF, 2002)<sup>1</sup>

Theme	Definition
<b>Motor and Sensory Components of Function</b>	<b>Interventions that address the motor and sensory components of activity</b>
Dexterity & Fine Motor Skills	Use of hand/s to undertake dexterous tasks/activities.
Grasp and release	Use of different grips to pick up and let go of objects. Different grips including gross grip, lumbrical grip, tripod grip, pincer grip.
Reach and grasp	Tasks which require service-user to grasp an object with a linked reach from upper arm.
Pull and push	Use of pull and push, using therapist or equipment.
Polishing	Use of polishing movements on a horizontal, vertical or angled surface.
Working to enable placing of upper limb in an activity	Focusing on a part of an activity with the aim of enabling a service-user to place their paretic upper limb in/during the activity.
Remedial activities to address a motor and sensory impairment	Use of activities to improve motor/sensory performance skills, these activities do not relate directly to a goal set by service-user.
Hand washing-with active involvement	Washing hands with service-user actively involved in achieving task. May include applying hand cream.
Exfoliation-with active involvement	Removal of outer layer of skin with the aim of improving the skin condition (with service-user involved). Used in conjunction with hand-washing.
Bilateral interventions	Use of both hands in a task either performing similar (symmetrical) movements or different movements.

CIMT or mCIMT	Restraint of less affected arm (including encouraging not to use this arm) usually with practice of tasks with more affected arm. Also includes forced-use, where only a restraint is worn.
Functional electrical stimulation (FES)	Use of electrical stimulation to increase activity of specific muscle/s whilst participating in a task/activity.
Mirror use (to provide alternative feedback ie visual)	Use of mirror to provide visual feedback with the aim of increasing knowledge of body position.
Imagery or visualization	Use of service-user mental imagery to augment motor re-learning.
Mirror therapy	Use of a mirror to reflect non-paretic upper limb while practicing symmetrical movements with both upper limbs and with paretic upper limb out of sight.
Working on components of functional task	Includes breaking down an activity into its component parts, this may include practicing component parts of an activity to be able to put these back together to perform that activity. May involve practice, provision of supervision, verbal prompts, assistance or facilitation.
Other	Document any additional interventions that address the motor and sensory components of activity.
<b>Cognitive Components of Function</b>	<b>Interventions that address the cognitive components of activity</b>
Conceptualisation of goal	Techniques to enable the stroke survivor to conceptualise a goal and understand the requirements of an intervention with the aim of increasing ability to achieve goal. May include discussion or demonstration.
Increasing attention to task	Prompting to task to increase attention to task. Prompting may be verbal, visual, or tactile. The cues may be therapist initiated, and may include encouraging service-user to self-cue.
Increasing attention to upper limb	Prompting to increase attention to upper limb. Prompting may be verbal, visual, or tactile. The cues may be therapist initiated, and may include encouraging service-user to self-cue.
Remedial activities to address cognitive impairment	Use of activities to improve cognitive (processing) performance skills, these activities do not relate directly to a goal set by service-user.
Use of unaffected upper limb to gain feeling of movement	Practicing a movement with non-paretic upper limb prior to attempting with paretic upper limb.

Use of grading to moderate complexity of task	Use of grading to support cognitive (processing) skills, eg length of session (might adapt by providing additional shorter sessions to support cognitive abilities) or prompts in different forms
Strategies to reinforce therapy	Methods that a therapist may use to reinforce the therapy they are providing. This might include providing feedback in alternative forms and the use of repetition.
Other	Document any additional interventions that address the cognitive components of activity.

## Definitions cont'd

### 3: Interventions that Address Participation (Function/Occupation)

Participation: involvement in a life situation (ICF, 2002)<sup>1</sup>

Function can be described in the following functional/occupational categories:

**Basic (self-care) activities of daily living:** activities that involve taking care of one's own body<sup>4</sup>

**Instrumental activities of daily living:** activities which are orientated towards 'self maintenance, requiring interactions in the home and in the community'<sup>4</sup>

**Work:** all activities involved in gaining, seeking and retaining remunerative employment or volunteer activities<sup>5</sup>

**Leisure:** 'a non-obligatory activity that is intrinsically motivated and engaged in during discretionary time, that is, time not committed to obligatory occupations such as work, self-care or sleep' <sup>6</sup>

**Education:** all activities involved in being a student, including establishing learning needs, accessing education and participating in formal and informal education<sup>5</sup>

**Social participation:** interaction with social activities and networks, these may be linked to the community, one's own family or friends<sup>5</sup>

Theme	Definition
Work on a specific function	Working on a function or occupation in its entirety. Assistance may be required, supervision, verbal prompts, assistance, facilitation or may be carried out independently. Function may be bilateral or unilateral.
Support	<b>Independent:</b> service-user able to complete function independently (ie without supervision). <b>Supervision:</b> no physical assistance is given, but a person is required to ensure safety. <b>Verbal prompts:</b> no physical assistance is given, but verbal prompts are provided.

	<p><b>Assistance:</b> physical assistance is given to undertake a function, this is not facilitated (ie focus is not on providing sensory stimuli to alter outcome of movement). Incorporates 'active assisted' movements. Therapist provides assistance.</p> <p><b>Facilitation:</b> Application of a sensory stimulus to access the desired active response from the service-user<sup>2</sup> during the function/occupation.</p>
Activity undertaken	<p><b>Bilateral:</b> undertaken with both upper limbs.</p> <p><b>Unilateral:</b> undertaken with one upper limb only.</p>
Compensation for lost function:	Alternative ways of achieving a function.
<ul style="list-style-type: none"> <li>Equipment</li> </ul>	Equipment that is provided or recommended to overcome a specific functional barrier.
<ul style="list-style-type: none"> <li>Techniques</li> </ul>	Teaching of alternative techniques/ways to achieve a function. This includes teaching scanning to compensate for neglect and the use of vision to compensate for lost movement or sensation.
<ul style="list-style-type: none"> <li>Adaptation</li> </ul>	Changes to environment to facilitate function, for example moving or altering furniture/tools to improve ability to participate in function, or using vision to compensate for lost movement or sensation.
<ul style="list-style-type: none"> <li>Functional orthoses</li> </ul>	Splinting to increase function, eg dynamic splint, static splint or pressure garment to assist in a specific function.

## Definitions cont'd

### 4: Other Aspects

These aspects overarch the ICF framework and may relate to any of the previous sections

Theme	Definition
<b>Psychosocial interventions</b>	Interventions to address mood, motivation, confidence, anxiety, eg counseling, anxiety management strategies, motivational interviewing, confidence building strategies.
<b>Advice and Education</b>	Any advice or education provided to service-user, carer/relative or other members of healthcare team. This advice/education can be provided as verbal, written or pictorial instructions.
<b>Homework and practice outside therapy</b>	Any activities, tasks recommended for practice outside the therapy sessions. These may be completed individually or with a carer/relative/other member of healthcare team. This practice/homework can be provided verbally, as a written document or pictorially.

## References

1. World Health Organization (2002) 'Towards a common language for functioning, disability and health ICF'. Geneva: World Health Organization.
2. Hunter, S.H. et al (2006) 'Development of treatment schedules for research: a structured review to identify methodologies used and a worked example of 'mobilisation and tactile stimulation' for stroke patients', *Physiotherapy*, 92, pp.195-207.
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5. Adapted from The Commission on Practice (2002) 'Occupational therapy practice framework: domain and process', *American Journal of Occupational Therapy*, 56, pp. 609-39.
6. Adapted from Parham, L.D. and Fazio, L.S. eds. (1997) 'Play in occupational therapy for children' in Pendleton, H.M. and Schultz-Krohn, W. eds. (2006) *Pedretti's occupational therapy practice skills for physical dysfunction*. 6<sup>th</sup> edn. St Louis: Mosby Elsevier.

## **Appendix 24**

Participant demographic form



## Implementing Constraint Induced Movement Therapy Study (CIMT) in a UK Stroke Service: Phase 2

### Demographic Form

Participant Identification Number:

Date of Birth:

GP Name:

GP Address:

Date of Stroke:

Side of Lesion:                      Left                      Right                      Neither

Type of Stroke:                      Ischaemic                      Haemorrhagic

Distribution of stroke:                      Cortical                      Subcortical                      Mixed

Handedness of Participant:                      Left                      Right                      Neither

**Appendix 25**  
**Connor-Davidson Resilience Scale (CD-RISC)**

ID:

Date and time of assessment:

Assessor:

Description of Item	Response				
	Not true at all 0	Rarely true 1	Sometimes true 2	Often true 3	True nearly all the time 4
Able to adapt to change					
Close and secure relationships					
Sometimes fate or God can help					
Can deal with whatever comes					
Past success gives confidence for new challenge					
See the humorous side of things					
Coping with stress strengthens					
Tend to bounce back after illness or hardship					
Things happen for a reason					
Best effort no matter what					
You can achieve your goals					
When things look hopeless, I don't give up					
Know where to turn for help					
Under pressure, focus and think clearly					
Prefer to take the lead in problem solving					
Not easily distracted by failure					
Think of self as a strong person					
Make unpopular or difficult decisions					
Can handle unpleasant feelings					
Have to act on a hunch					
Strong sense of purpose					
In control of your life					
I like challenges					
You work to attain your goals					
Pride in your achievements					

**Appendix 25-continued****Line Crossing**

ID:

Date and time of assessment:

Assessor:

Place sheet in front of person in midline.

Instruction to say:

“On this page we have many lines pointing in different directions. Follow my pen as I indicate these lines”

*Move pen right to left, top to bottom over all the lines on the page.*

“Now with this pen, I want you to cross out all the lines which you can see on the page, like this...”

*Illustrate by crossing out 2 of the 4 central lines.*

*If person only crosses out lines in similar orientation prompt to cross out all the lines.*

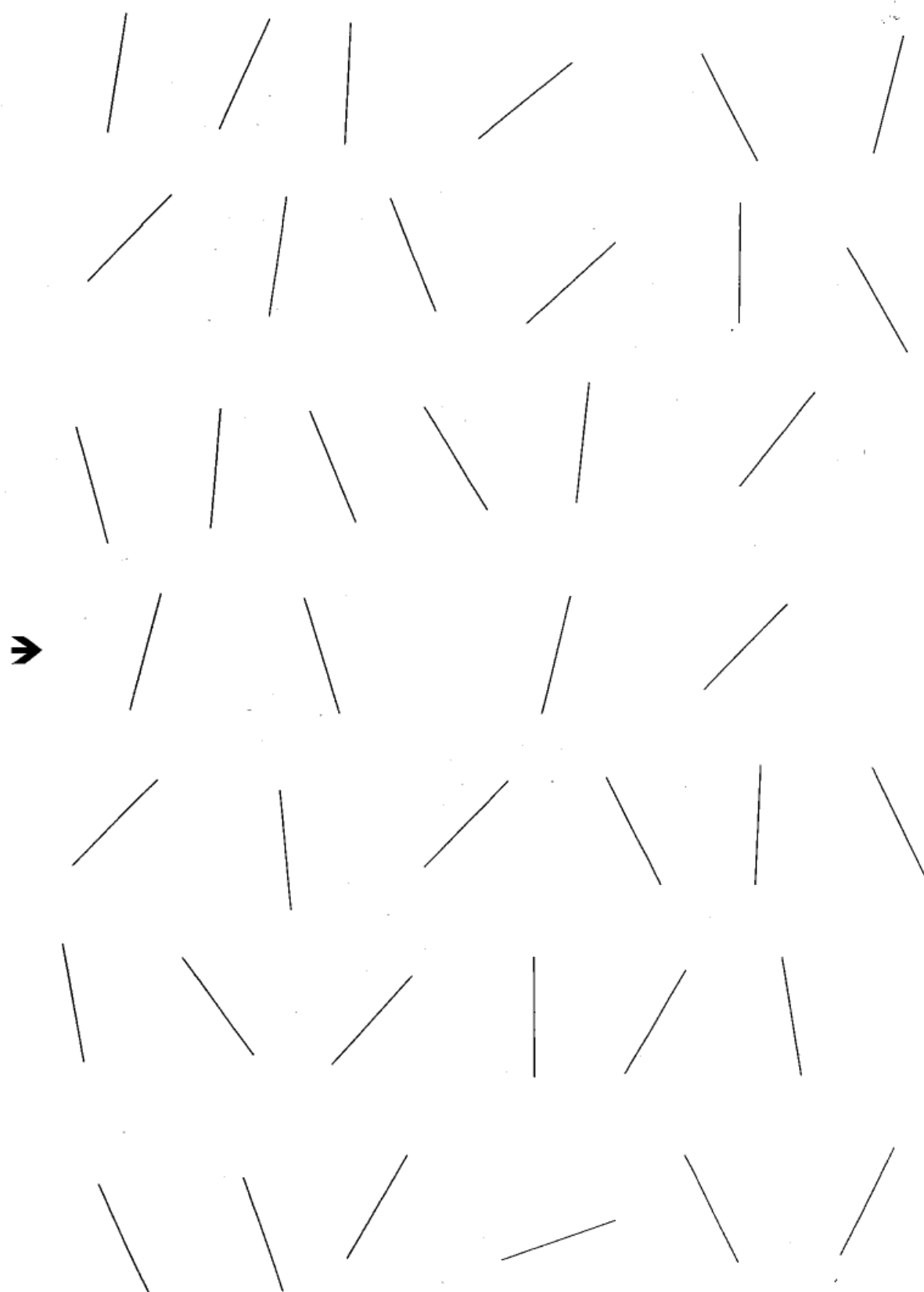
Score out of 36 (4 in the centre not scored) also score left side out of 18 and right side out of 18.

(Instructions adapted from the Behavioural Inattention Test)

Total score out of 36

Left side score out of 18

Right side score out of 18



## Appendix 26



The Royal Liverpool and  
Broadgreen University Hospitals **NHS**  
NHS Trust

Implementing Constraint Induced Movement Therapy (CIMT) in a UK Stroke Service:  
Phase 2

### Pre-CIMT Interview Schedule

**Research Project Title:** Implementing constraint induced movement therapy (CIMT) in a UK Stroke Service

**Aim:**

To collect views from stroke survivors about:

- Previous experience of CIMT
- Perceptions of CIMT and the various protocols
- Potential barriers to, and facilitators of undertaking a CIMT protocol

## Introduction

1. Thank you for participating
2. Purpose of Interview-*to collect views on one therapeutic upper limb intervention (CIMT)*
3. The reasons for audio-recording (*Accurate record, reflection, transcription and analysis*)
4. Confirm consent to audio-record and turn on recorder
5. Discuss second stage consent (*to be completed after the interview, option to delete words during the interview or after*)

*Recorder to be turned on*

6. Structure of interview (facilitator to *describe CIMT and different protocols, then would like to discuss your experience of CIMT (if any) and find out your views and thoughts on the different protocols*)
7. Confirm consent to audio-record on recorder.
8. Discuss the ways in which the information will be dealt with to ensure anonymity (*recording, transcripts, personal data, destroying data*)

## Background Information

9. Facilitator to describe CIMT
10. Facilitator to present and give an overview of the evidence-based CIMT protocols

## Main Discussion

11. Main questions to be addressed:
  - a. Do you think you have experienced CIMT as part of the therapy you have received? If so, what did it entail, can you tell me what you thought about the CIMT intervention (prompts if required for benefit/no benefit and feelings/emotional response to CIMT)
  - b. Do you think you would be able to undertake a full CIMT protocol (as described earlier)? May need to review protocols and discuss each one separately  
 If **yes** go to qu 11c.  
 If **no**, go to qu 11f.
  - c. Which protocol/s do you feel you would be able to undertake and why? (Facilitator may need to prompt about specific protocols).

- d. Are there factors that would help you to undertake a CIMT protocol (discuss protocols collectively or individually)
- e. Are there factors that would make it harder for you to undertake a CIMT protocol (discuss protocols collectively or individually)  
**Prompts**-carer, time, setting (home/hosp/clinic), improvement, intensity, constraint etc  
**Go to Conclusion.**
- f. If no, why do you feel you would be unable to undertake a CIMT protocol?
- g. Is there anything that would make undertaking a CIMT protocol more acceptable?  
**Prompts**-carer, time, setting (home/hosp/clinic), improvement, intensity, constraint etc

### Conclusion

- 12. Draw interview to a close
- 13. Review what will happen to the results
- 14. Completion of second stage consent form
- 15. Thank participant for their time and participation

## Appendix 27



The Royal Liverpool and Broadgreen University Hospitals   
NHS Trust

Implementing Constraint Induced Movement Therapy (CIMT) in a UK Stroke Service:  
Phase 2

### Post-CIMT Interview Schedule

**Research Project Title:** Implementing constraint induced movement therapy (CIMT) in a UK Stroke Service

**Aim:**

To collect views from stroke survivors about:

- Experience of undertaking a CIMT protocol
- Barriers and facilitators experienced when undertaking the CIMT protocol

## Introduction

16. Thank you for participating
17. Purpose of Interview- *to find out your experiences of CIMT*
18. The reasons for audio-recording (*Accurate record, reflection, transcription and analysis*)
19. Confirm consent to audio-record and turn on recorder
20. Discuss second stage consent (*to be completed after the interview, option to delete words during the interview or after*)

*Recorder to be turned on*

21. Structure of interview (facilitator to *describe CIMT and different protocols, then would like to discuss your experience of CIMT (if any) and find out your views and thoughts on the different protocols*)
22. Confirm consent to audio-record on recorder.
23. Discuss the ways in which the information will be dealt with to ensure anonymity (*recording, transcripts, personal data, destroying data*)

## Main Discussion

24. Main Questions:

- a. Can you tell me about the CIMT you experienced? Prompts may be necessary to find out about constraint, training, activities undertaken etc.
- b. How did it feel to have your hand restrained?
- c. How did it feel to undertake the practice of activities?
- d. Were you able to carry out the CIMT as it was planned?
- e. Were there benefits in undertaking CIMT?
- f. Were there disadvantages to undertaking CIMT?
- g. Did you feel your ability to use your arm and hand changed with the CIMT?
- h. How did you feel during the CIMT? (Emotional response eg liked/disliked, frustration, fatigued etc)
- i. Were there factors that helped you to undertake the CIMT protocol?
- j. Were there factors that made it harder for you to undertake a CIMT protocol?

- k. If you were offered CIMT again would you take it?

**Conclusion**

- 25. Draw interview to a close
- 26. Review what will happen to the results
- 27. Completion of second stage consent form
- 28. Thank participant for their time and participation

## Appendix 28



The Royal Liverpool and  
Broadgreen University Hospitals **NHS**  
NHS Trust

# SECOND STAGE CONSENT FORM

## Implementing Constraint Induced Movement Therapy Study:

### Phase 2

**Title of Project:** Implementing constraint induced movement therapy (CIMT) in a UK stroke service

**Investigator:** Kathryn Jarvis

**Please consider the following statements and initial the box by the appropriate statement to indicate your consent:**

I am happy for any of my anonymised quotes to be used

☐

I do not want any of my anonymised quotes to be used

☐

I want to have the opportunity to consider any anonymised quotes prior to them being used

☐

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## Appendix 29

### Wolf Motor Function Test

ID:

Date and time of assessment:

Assessor:

#### Measurements (in cms)

Distance between top of table and chair seat (with table positioned at mid-abdomen height)	<input type="text"/>
Distance from side of the back of the chair to edge of table (items 1-4)	<input type="text"/>
Distance from back of the seat of the chair to edge of table (items 5, 6, 8-15)	<input type="text"/>
Distance from back of the seat of the chair to edge of table (item 7)	<input type="text"/>
Box height	<input type="text"/>
Table height	<input type="text"/>

#### Scoring

Please use the following Functional Ability Scores when completing the tables on the following table:

- |   |   |
|---|---|
| 0 | Does not attempt with upper extremity (UE) being tested.  |
| 1 | UE being tested does not participate functionally; however attempt is made to use the UE. In unilateral tasks the upper limb not being tested may be used to move the UE being tested.  |
| 2 | UE being tested participates functionally, but requires assistance of the UE not being tested for minor readjustments or change of position, or requires more than two attempts to complete, or accomplishes very slowly. In bilateral tasks, the UE being tested may serve only as a helper. |
| 3 | UE being tested participates functionally, but movement is influenced to some degree by synergy or is performed slowly or with effort.  |
| 4 | UE being tested participates functionally; movement is close to normal*, but slightly slower; may lack precision, fine coordination, or fluidity.   |
| 5 | UE being tested participates functionally; movements appear to be normal.   |

\*For the determination of “normal”, the less-involved upper limb can be used as an available index for comparison, with premorbid upper limb dominance taken into consideration.

Non-paretic UL: Right/Left (delete as appropriate)

		Time	Functional ability Score 0-5
1	Forearm to table	_____ secs OR <input type="checkbox"/> 120+ secs	
2	Forearm to box	_____ secs OR <input type="checkbox"/> 120+ secs	
3	Extend elbow	_____ secs OR <input type="checkbox"/> 120+ secs	
4	Extend elbow to side with weight	_____ secs OR <input type="checkbox"/> 120+ secs	
5	Hand to table	_____ secs OR <input type="checkbox"/> 120+ secs	
6	Hand to box	_____ secs OR <input type="checkbox"/> 120+ secs	
7	Reach and retrieve	_____ secs OR <input type="checkbox"/> 120+ secs	
8	Lift can	_____ secs OR <input type="checkbox"/> 120+ secs	
9	Lift pencil	_____ secs OR <input type="checkbox"/> 120+ secs	
10	Lift paperclip	_____ secs OR <input type="checkbox"/> 120+ secs	
11	Stack checkers	_____ secs OR <input type="checkbox"/> 120+ secs	
12	Flip cards	_____ secs OR <input type="checkbox"/> 120+ secs	
13	Turning key in lock	_____ secs OR <input type="checkbox"/> 120+ secs	
14	Fold towel	_____ secs OR <input type="checkbox"/> 120+ secs	
15	Lift basket	_____ secs OR <input type="checkbox"/> 120+ secs	

Paretic UL: Right/Left (delete as appropriate)

		Time	Functional ability Score 0-5
1	Forearm to table	_____ secs OR <input type="checkbox"/> 120+ secs	
2	Forearm to box	_____ secs OR <input type="checkbox"/> 120+ secs	
3	Extend elbow	_____ secs OR <input type="checkbox"/> 120+ secs	
4	Extend elbow to side with weight	_____ secs OR <input type="checkbox"/> 120+ secs	
5	Hand to table	_____ secs OR <input type="checkbox"/> 120+ secs	
6	Hand to box	_____ secs OR <input type="checkbox"/> 120+ secs	
7	Reach and retrieve	_____ secs OR <input type="checkbox"/> 120+ secs	
8	Lift can	_____ secs OR <input type="checkbox"/> 120+ secs	
9	Lift pencil	_____ secs OR <input type="checkbox"/> 120+ secs	
10	Lift paperclip	_____ secs OR <input type="checkbox"/> 120+ secs	
11	Stack checkers	_____ secs OR <input type="checkbox"/> 120+ secs	
12	Flip cards	_____ secs OR <input type="checkbox"/> 120+ secs	
13	Turning key in lock	_____ secs OR <input type="checkbox"/> 120+ secs	
14	Fold towel	_____ secs OR <input type="checkbox"/> 120+ secs	
15	Lift basket	_____ secs OR <input type="checkbox"/> 120+ secs	

Adapted from FAST INDICATE Study documentation

## **Appendix 30**

Ethical approval and R&D approval for Amendment 3

**NRES Committee North West - Lancaster**

Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3DZ

Tel: 0161 625 7109  
Fax: 0161 625 7919

26 September 2014

Ms Kathryn Jarvis  
Directorate of Occupational Therapy  
University of Liverpool  
Liverpool  
L69 3GB

Dear Ms Jarvis

**Study title:** Implementing constraint induced movement therapy (CIMT)  
in a UK stroke service  
**REC reference:** 13/NW/0309  
**Amendment number:** Substantial Amendment 3  
**Amendment date:** 02 September 2014  
**IRAS project ID:** 65154

Change to Recruitment Strategy

The above amendment was reviewed on 26 September 2014 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		16 September 2014
Notice of Substantial Amendment (non-CTIMP)	3	02 September 2014
Research protocol or project proposal	4	28 August 2014

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

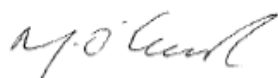
**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>13/NW/0309:</b>	<b>Please quote this number on all correspondence</b>
--------------------	---

Yours sincerely



pp  
**Dr Lisa Booth**  
**Chair**

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Heather Rogers, Royal Liverpool and Broadgreen University Hospitals Trust  
 Nicola Leighton*

# The Royal Liverpool and Broadgreen University Hospitals



NHS Trust

Royal Liverpool University Hospital

Prescot Street

Liverpool

L7 8XP

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## AMENDMENT APPROVAL LETTER AND NOTIFICATION OF CONTINUED NHS PERMISSION

Tel: 0151 706 2000

Fax: 0151 706 5806

Ms Kathryn Jarvis  
University of Liverpool  
Directorate of Occupational Therapy  
Thompson-Yates Building, Brownlow Hill  
Liverpool  
L69 3GB

REC: 13/NW/0309

Date: 01/10/2014

Dear Ms Jarvis

**RD&I No: 4359**

**Implementing constraint induced movement therapy (CIMT) in a UK stroke service**

**Amendment number: 3**

**Amendment date: 2 September 2014**

I can confirm that the Trust is happy to continue its permission for this study to take place on its premises in accordance with the amended documentation listed on the ethics amendment approval letter dated 26 September 2014.

The study should be conducted in compliance with the Research Governance Framework 2<sup>nd</sup> Ed 2005. Please ensure you inform your research team of this amendment.

Yours sincerely

**Heather Rogers**  
Research Governance Manager

## Appendix 31

## Example of IPA

Section of transcript from Janet's post-CIMT interview with examples of some codes:

R: I'm sleeping better, I feel livelier, you know, because I'm not just going home, sitting down and going to sleep, I'm doing things, playing in the garden with the ball with the dogs, you know. Now that the weather's nicer, I thought, well, play with the ball, because I've been bowling in here and my aim wasn't very good. So we played with the ball in the garden the day before yesterday, I think it was. But I feel livelier and everybody says how I've put much weight. Like, these have seen me for the last three months, so they can see the difference.

I: And you said you went to see...who did you say...?

R: I went to see my sister last night. I haven't seen her since I was in [intermediate care unit]. And she said I look a lot brighter. My brother who takes me everywhere, he says I look livelier, I don't look as drained. Because you don't sleep properly. Because you're bored, you'll sleep all the time, so you don't have hours and hours and sleep, it's fits and starts. But I think it's because I'm occupied, I feel more confident in myself. Like, when I went out last night, I left the stick at home, like.

I: So what do you think's made you more confident?

R: Coming out every day, meeting more people, being able to use my hand more. Because I know if anything happens, I can stop myself falling with my hand. Because that's how I fell originally, I couldn't get hold of the ambulance with that hand, because I didn't have the movement. But I have now.

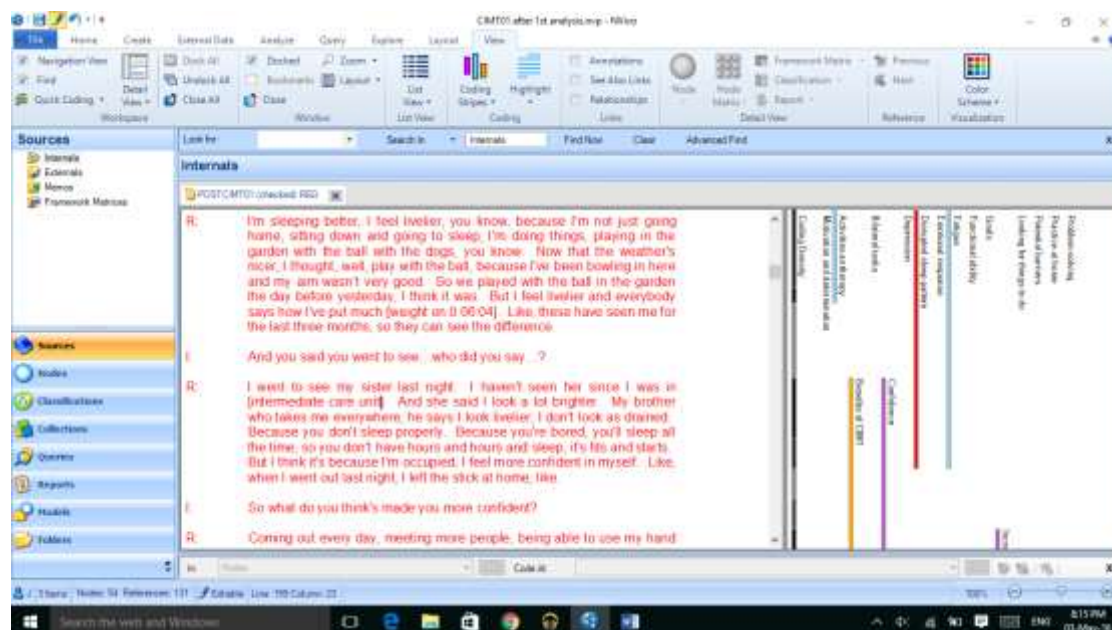
--- Disrupted sleep pattern

--- Activities as therapy

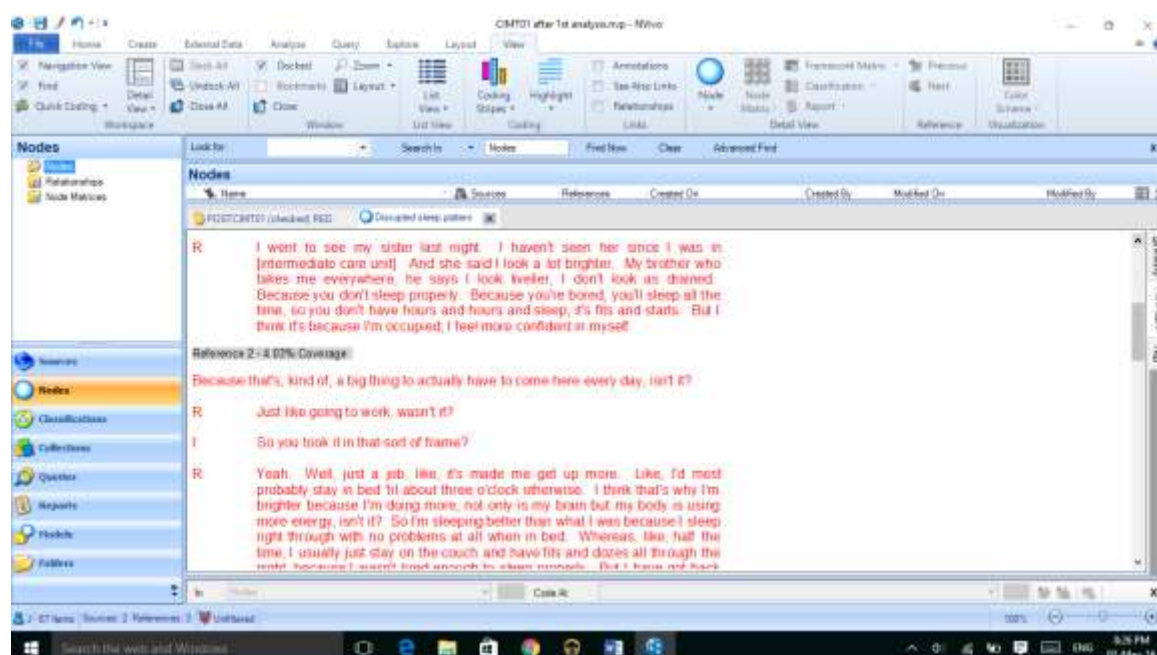
--- Confidence

## Appendix 31-continued

The transcript was placed in, and coded within the NVivo programme. Fragments of text were coded. The codes for the above section of transcript are shown on the right hand side of the screen shot below:



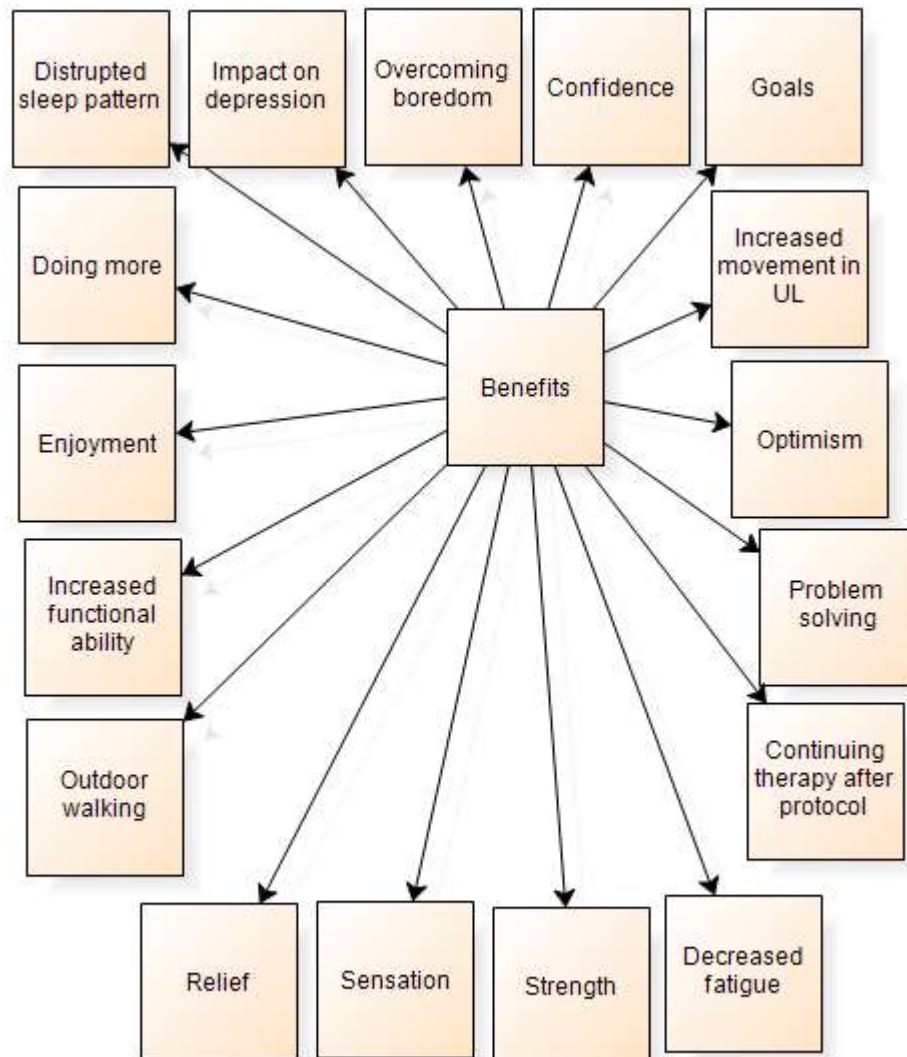
The codes were organised, using NVivo into superordinate themes and subthemes as discussed in Chapter 6. Diagrammatical representation of superordinate and subthemes are shown in Chapter 6 (Figure 6.2). Instead of presenting the codes in a table as is usual for IPA, the codes and the data relating to that code were held within NVivo. In the screenshot below part of the text relating to **disrupted sleep pattern** is presented. This code held three 'chunks' of data including aspects of the transcript above. In this way it was possible to access data relating to each code and develop the analysis.



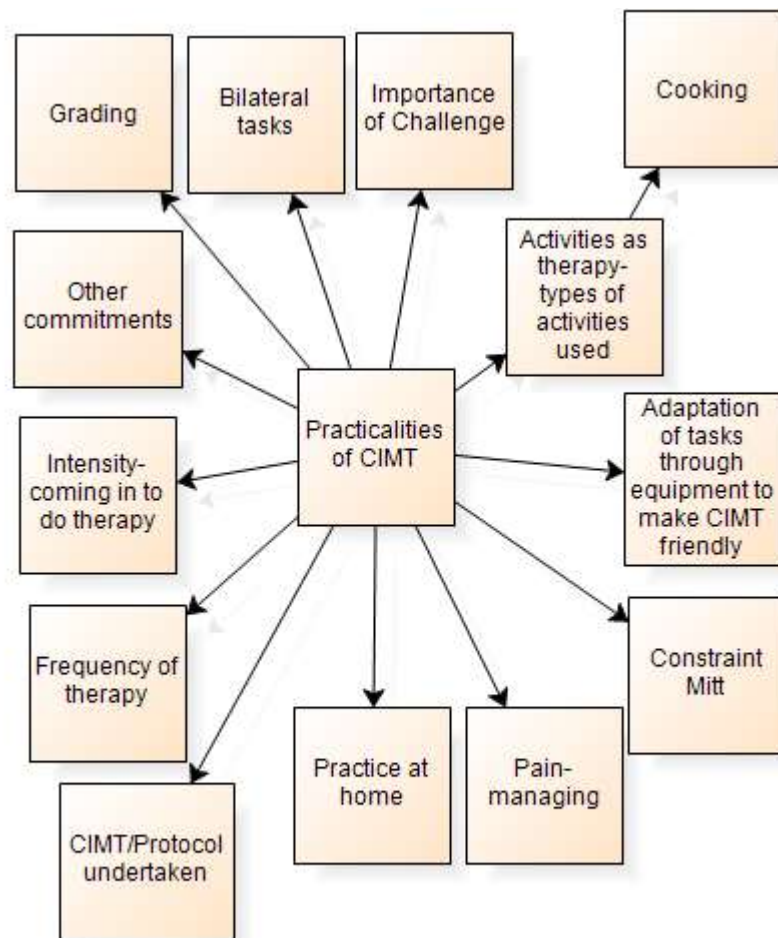
## Appendix 32

### Janet's Experience of CIMT: Initial Themes

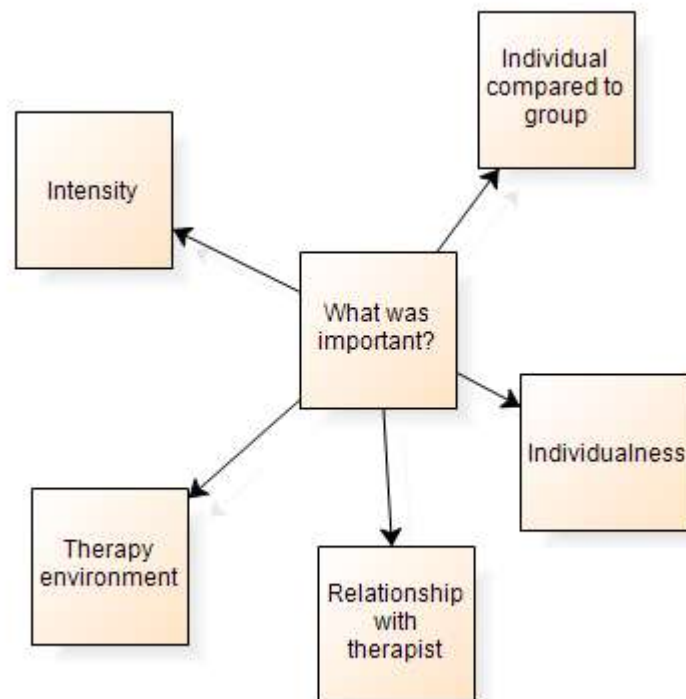
#### Theme 1: Benefits



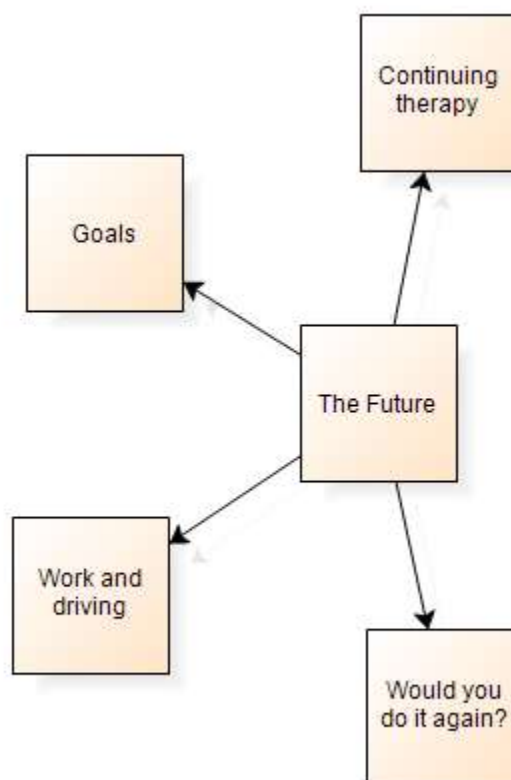
## Theme 2: Practicalities of CIMT



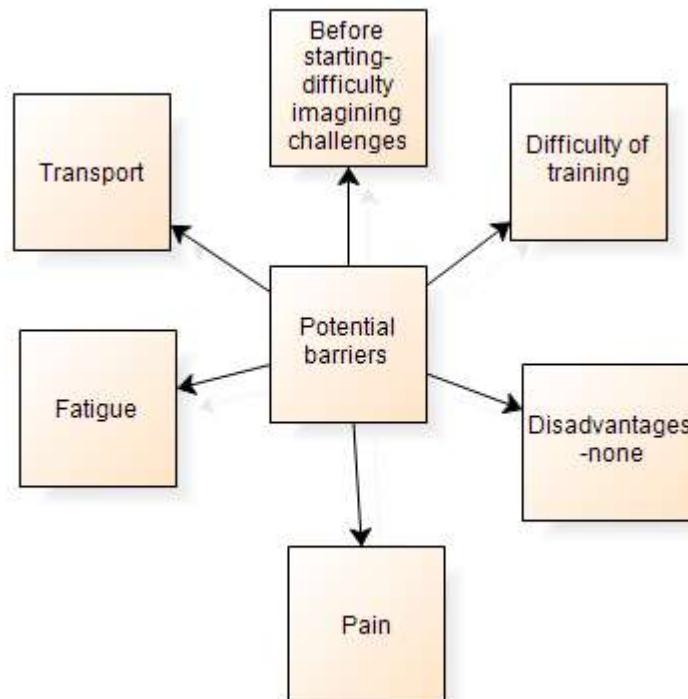
### Theme 3: What was important?



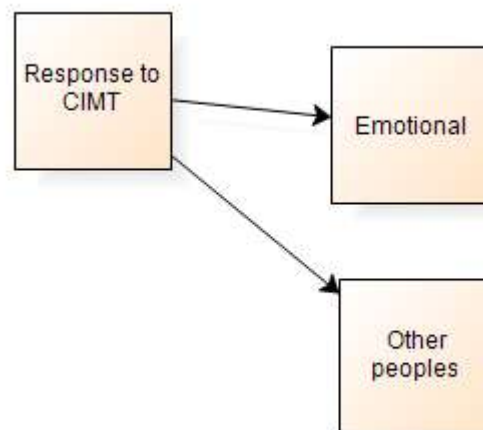
### Theme 4: The future



### Theme 5: Potential Barriers



### Theme 6: Response to CIMT



## Appendix 33

### Research Therapist Reflections

Notes Taken During a Meeting between Research Therapist and Chief Investigator

Date: 16/12/15

Notes written by Kathryn Jarvis

#### **Barriers and Facilitators after CIMT 03 16/12/15**

Facilitator-second Research Therapist helping-better for both stroke survivor and staff if not same person constantly

Coming into Unit-easier to find things to do and set up activities

Baking activities good facilitators of activity that took time

People being around in the Unit-less intense

Morning better as ?both stroke survivors and staff are more awake-definitely participant

Personalities/development of a rapport could be facilitator or barrier

Need a lot of activities

- good to have opportunity to be creative

- some therapists might need ideas/guidance

Have to keep focused over a long time (both stroke survivor and staff), need to be plan time and choosing next activity

Can slow down approach, luxury to spend time with one person

#### **Balance of repetitive tasks and function?**

Used a mix of functional and remedial/task based activities

Usually started with function and when ran out or when tired went on to remedial/task-based

***Note: check out OT-STARs***

**Appendix 33-continued**

**Shaping interventions:**

Facilitated movement-a little

Verbal prompts

Adapting the activity

Activity had to be challenging-if too easy changed (built in to OTs)