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Implementing complex rehabilitation interventions in research: the example of vocational rehabilitation for people with traumatic brain injury

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"For good ideas and true innovation,
you need human interaction, conflict, argument, debate"

Margaret Heffernan, June 2012, TED

Abstract

Background: Research does not always translate into improved patient outcomes because of difficulties implementing complex health interventions. Distinguishing between effectiveness and factors affecting implementation is critical to improving trials of rehabilitation interventions. Understanding barriers and facilitators encountered when delivering complex interventions, such as rehabilitation, in the research environment requires examination. Implementation research is the study of methods to promote the uptake of research findings into routine practice and can help identify and explain barriers and facilitators. The aim of this project was to understand factors that affect the delivery of complex rehabilitation interventions in research, focussing on vocational rehabilitation for people with traumatic brain injury.

Methods: Exploratory mixed methods were used to understand factors (barriers and facilitators) affecting the implementation of rehabilitation interventions delivered in research for people with long term neurological conditions including traumatic brain injury. In study 1, a systematic review investigated barriers and facilitators to the implementation of complex rehabilitation interventions delivered in clinical trials and other research. The review method involved developing search terms and searches included 11 databases, trial registries and author citations. All research methodologies were included. After screening titles and abstracts, two reviewers independently shortlisted studies. A third resolved discrepancies. Studies were appraised using the Mixed Methods Appraisal Tool. One reviewer extracted data in two stages; 1) descriptive study data, 2) units of text describing barriers and facilitators to implementation. Data were synthesised by; 1) mapping determinants to the Conceptual Framework for

Implementation Fidelity and the Consolidated Framework for Implementation Research; 2) thematic analysis.

Study 2 describes the development of a training package, used as an implementation strategy, to train NHS occupational therapists to deliver Early Specialist Traumatic brain injury Vocational Rehabilitation in three English NHS sites in the context of a rehabilitation trial. The training package was developed by "experts" in vocational rehabilitation and traumatic brain injury. It included a manual, direct instruction and mentoring. The confidence of the occupational therapists to deliver the intervention to trial participants with traumatic brain injury was measured before and after training and its usefulness examined via mentoring records and through early and late interviews with the trained occupational therapists. Implementation issues were mapped to the Consolidated Framework for Implementation Research and Comprehensive Framework for Implementation Fidelity.

In Study 3 the extent to which the intervention was delivered as intended was investigated. A content form and fidelity checklist were developed. Fidelity was measured using these tools and triangulated with clinical and mentoring records. Barriers and facilitators were explored in interviews with the occupational therapists, trial participants, their employers and NHS staff in each site and triangulated with clinical and mentoring records and mapped to CFIR and CFIF.

Results: Study 1 found it was possible to identify factors affecting the implementation of complex interventions in rehabilitation trials, even when researchers had not set out to report these. Treatment adherence, its

acceptability and causes of attrition were the most frequently reported barriers and facilitators. The quality of intervention delivery, the preparedness of organisations to implement an intervention as part of a trial and the developmental readiness or 'trialability' of interventions were rarely reported. The findings from this study highlighted the potential barriers that trial occupational therapists might encounter when delivering Early Specialist Traumatic brain injury Vocational Rehabilitation.

Study 2 found that experienced occupational therapists can be trained to deliver a complex intervention in a rehabilitation trial. Barriers and facilitators identified individual and organisational level barriers and facilitators. Soon after being trained, occupational therapists identified that direct instruction and the training manual were important in helping them implement the intervention. However, later they indicated that the manual was not used. Mentoring was identified as the most useful element of the training package in both early and late interviews.

Study 3 found that occupational therapists delivered Early Specialist Traumatic brain injury Vocational Rehabilitation with fidelity. Factors facilitating implementation fidelity included expert mentoring, community rehabilitation experience and an intervention that could be tailored to individual need. Barriers included lack of access to NHS systems, backfill and support from NHS managers. The following factors both helped and hindered; communication with participants, acceptability of the intervention, individual and changing needs of study participants and interagency working.

Conclusion: Using implementation research frameworks, such as Consolidated Framework for Implementation Research and Conceptual Framework for Implementation Fidelity, to identify, measure and describe barriers and facilitators can elicit important information to assist researchers in improving rehabilitation trial design, ensuring more robust trial outcomes, reduce the risk of type III errors and expedite translation of research into improved patient outcomes. Expert mentoring was considered essential to ensuring implementation fidelity, alongside case discussions and direct instruction about research contamination issues. Implementation of complex rehabilitation interventions, such as Early Specialist Traumatic brain injury Vocational Rehabilitation, is affected by a number of factors acting as barriers and or facilitators at the individual and organisational level.

Peer Reviewed Publications

Holmes J (2014) Implementing evidence-based vocational rehabilitation. Vocational Rehabilitation Association conference 2014. Awarded winner of student bursary 2014. http://www.vra-uk.org/node/417
Holmes J., Phillips J., Morris R., et al. (2016) Development and evaluation of an early specialised traumatic brain injury vocational rehabilitation training package. *British Journal of Occupational Therapy* 79 (11): 693-702.
Holmes J., Phillips J., Jones T., et al. (2017) Factors affecting delivery of early specialised vocational rehabilitation to people with traumatic brain injury in a feasibility trial. Poster presentation. 14th Congress of the European Forum for Research in Rehabilitation. Glasgow: *International Journal of Rehabilitation Research* (in press).
Holmes J., Radford K. and Logan P. (2017) Barriers and facilitators to the implementation of evidence-based complex health interventions for adults with long term neurological conditions (LTNC): A systematic review. Oral presentation. 14th Congress of the European Forum for Research in Rehabilitation. Glasgow: *International Journal of Rehabilitation Research* (in press).
Radford K., Sutton C., Sach T., et al. (2017) FRESH - Facilitating Return to work through Early Specialist Health-based interventions: feasibility randomised controlled trial. Health Technology Assessment (in press).

Other dissemination outputs

Radford K., Watkins C., Sutton C., Tyreman A., Shakespeare D., Playford D., Greenwood R., Jones T., Whiteley G., Holmes J., Hammond A., Drummond A., Bhakta B., Sach T., Duley L., Walker M. (2013) FRESH - Facilitating Return to work through Early Specialist Health-based interventions. [online] Available at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/116602/#/ [Accessed 8 Oct. 2017].
Holmes J (2014) Can we train experienced OTs to facilitate return to work through early specialist health-based VR (ESTVR) for the TBI population? Paper presentation, TheOTShow 2014.
Holmes J., Radford K., Logan P. (2014) Can occupational therapists implement return to work rehabilitation into practice? Faculty of Medicine &Health Sciences Postgraduate Research Forum 25.6.14.
Holmes J (2015) Evaluating an early traumatic brain injury vocational rehabilitation training package Paper presentation, The College of Occupational Therapists 40th Annual Conference and Exhibition and the Specialist Section – Trauma & Orthopaedics, presentation 31.2. [online] Available at http://cotannualconference.org.uk/2016/programme
Holmes J., Radford K., Logan P., et al (2017) Determinants affecting delivery of early specialised vocational rehabilitation to people with traumatic brain injury in the National Health Service (NHS). Oral presentation. SIRC (Society for Implementation Research Collaboration) 4th Biennial Conference. Seattle, USA.
Holmes J., Radford K., Logan P. (2017) Key Findings: An exploration of the barriers and enablers to the implementation of a complex specialist vocational rehabilitation for people with traumatic brain injury in the NHS. The Royal College of Occupational Therapists. [online] Available at: https://www.rcot.co.uk/sites/default/files/UKOTRF%20Key%20findings%20J%20Holmes%20final.pdf

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List of Abbreviations

CCG – Clinical Commissioning Group

CFIF - Conceptual Framework for Implementation Fidelity

CFIR - Consolidated Framework for Implementation Research

CPD – Continuing professional development

ESTVR – Early Specialist Traumatic brain injury Vocational Rehabilitation

FRESH - Facilitating Return to work through Early Specialist Health based interventions

GCS – Glasgow Coma Scale

HTA – Health technology assessment

IPS – Individual Placement Support

LTNC - Long term neurological conditions

MRC – Medical Research Council

NHS – National Health Service

NIHR – National Institute for Health Research

NTBIS – Nottingham traumatic brain injury service

OH – Occupational health

OT – Occupational therapist

PTA – Post traumatic amnesia

PWTBI – Person/people with traumatic brain injury

RCT – Randomised controlled trial

RQ – Research question

RTW – Return to work

TBI - Traumatic brain injury

UK – United Kingdom

USA – United States of America

VR – Vocational rehabilitation

CHAPTER ONE

1. Summary of the Research

1.1. Background

This research pertains to understanding what affects the implementation of complex rehabilitation interventions for people with long term neurological conditions (LTNCs), specifically vocational rehabilitation for people with traumatic brain injury (TBI).

1.2. Context

A feasibility randomised controlled trial (RCT) **F**acilitating **R**eturn to work through **E**arly **S**pecialist **H**ealth based interventions (FRESH) (HTA FRESH 11/66/02), which delivered an **E**arly **S**pecialist **T**BI **V**ocational **R**ehabilitation intervention (ESTVR) across 3 English NHS sites (Site 1 was in the North West, Site 2 was in London, Site 3 was in Yorkshire) informed this research. ESTVR was delivered by trial occupational therapists to people with TBI who had been randomised to receive it.

I was a co-applicant on FRESH and contracted between March and October 2013 to train the trial occupational therapists to deliver ESTVR. After successfully being awarded a doctoral fellowship, I commenced my studies in January 2014, using the trial as an opportunity to generate and answer questions for this PhD research.

1.3. Research Approach

My research approach was influenced by my background as an occupational therapist and as a researcher on the FRESH project. However

I recognise that researchers should be reflexive and be clear outlining the basis for claiming to know what they know (O'Gorman and McIntosh, 2015).

The overarching design of the research was exploratory mixed methods, involving three sequential studies. It was iterative, with the findings of each study informing the next. The exploratory nature of the research questions required a combined understanding of both the numbers (quantitative data) and personal experiences (qualitative data), known as a mixed methods approach.

1.4. Research Questions

This research sought to inform future research by adding to the implementation research and rehabilitation evidence base knowledge about barriers and facilitators affecting the implementation of rehabilitation interventions within a research context. The studies that follow were executed to explore and understand the barriers and facilitators that affect the delivery and implementation of complex rehabilitation interventions in research. The **E**arly **S**pecialist **T**raumatic brain injury **V**ocational **R**ehabilitation, delivered to adults with TBI in the FRESH trial was an example of such a complex intervention. The central research questions (RQ) guiding this thesis were:

> **RQ1-** What are the barriers and facilitators to implementing complex rehabilitation as reported in previous research for people with LTNC?

RQ2- How can a training package prepare trial therapists to deliver a complex intervention (ESTVR) as part of an NHS clinical trial?

RQ3- Do trial therapists deliver the complex intervention, ESTVR, as intended (with fidelity)?

RQ4- What factors affect the implementation of the intervention from the perspective of the therapist, other NHS staff, commissioners, people with TBI and employers?

The relationship between the research questions, the studies, the methods used and their location within the thesis is summarised in Table 1-1.

Table 1-1 Research summary and thesis structure

Research Questions		**Study**	**Key Methods**	**Thesis Chapter**
RQ1	What are the barriers and facilitators to implementing complex rehabilitation as reported in previous trials for people with LTNC?	One	Systematic Review	Three
RQ2	How does a training package prepare trial therapists to deliver a complex intervention (ESTVR) as part of an NHS clinical trial?	Two	Quantitative pre and post self-report, interviews, analysis of records	Four
RQ3	Do trial therapists deliver the complex intervention, ESTVR, as intended (with fidelity)?	Three	Quantitative measurement, analysis of records, interviews.	Five
RQ4	What are the factors affecting the implementation of the intervention from the perspective of the therapist, other NHS staff, commissioners, people with TBI and employers?		Qualitative interviews	

Chapter six provides an overall synthesis and discussion of the findings of the research. It relates findings to the research aims and discusses the impact these have on the implementation of complex interventions within rehabilitation trials in the future and services in the NHS. The thesis ends with an overall conclusion.

CHAPTER TWO

2. Background literature review

2.1. Chapter Overview

This chapter will present the background to the three studies in this PhD. It will explain what is required by researchers when developing complex rehabilitation interventions before implementing them in studies in clinical environments such as the NHS. This will be achieved using the example of a complex vocational rehabilitation intervention to support people with traumatic brain injury (PWTBI) returning to work.

2.2. Rehabilitation

Rehabilitation is a broad term that covers many different types of intervention and involves, a process aimed at enabling people to reach and maintain their optimal physical, sensory, intellectual, psychological and social functional levels (World Health Organisation, 2017a). In the UK it is delivered by a variety of health and non-health professionals to people with a wide range of health conditions and disabilities, some as a result of damage to the neurological system. Neurological damage, either as a result of disease or trauma, results in incurable, lifelong LTNC. The number of people in the UK living with a neurological condition that significantly impacts their life ranges from 4.7 million to 12.5 million, dependant on which diagnoses are included (Royal College of Physicians et al., 2008, Neurological Alliance, 2014, Comptroller and Auditor General, 2015).

Rehabilitation is considered important because it benefits patients and healthcare systems (Wade, 2015a). It is formally recommended in the National Service Framework for long-term neurological conditions LTNCs (Department of Health, 2005, Department of Health, 2016) and is embedded within recommended treatment pathways by the National Institute for Health and Care Excellence (NICE) (National Institute for Health and Care Excellence, 2017). The Department for work and Pensions has recommendations for rehabilitation that relates to employment (Department for Work and Pensions and Department of Health, 2016). However, rehabilitation generally is sometimes considered a small and threatened speciality (Wade, 2015a) and vocational rehabilitation, which is related to employment, as a Cinderella service within the NHS (Radford et al., 2013). The threat of reduced commissioning of rehabilitation is real in the current climate of financial austerity in the UK. NHS Trust budgets are becoming ever leaner (Alderwick et al., 2015, Dunn, 2016). The need for high quality rehabilitation research that uses stretched resources efficiently and ensures that ineffective intervention are decommissioned in favour of effective ones is increasingly important.

2.3. Traumatic brain injury

TBI is a LTNC, defined as an injury to the brain caused by a trauma to the head (head injury) and includes the complications of that trauma including hypoxaemia, hypotension, intracranial haemorrhage and raised intracranial pressure (British Society of Rehabilitation Medicine, 1998).

Causes of TBI include road traffic accidents, assaults, falls and accidents at home or at work (Headway 2014b,) and all result in damage to brain tissues. Shearing forces, bleeding and swelling of the brain causes damage in closed head injuries. Whereas in open head injuries it is the penetration of the brain tissue by an object or skull fracture that causes damage (Brainline.org, 2017). Closed head injuries often result in diffuse damage to different areas of the brain and tend to be more difficult to treat but are more common than open injuries (Faul et al., 2010).

2.3.1. Incidence

An injury to the head does not necessarily result in a TBI but in the UK the number of adults admitted to hospital with an acquired brain injury has increased by 10% since 2005 with a 6% increase in head injury admissions (Headway, 2015). In 2013-14 there were 348, 934 admissions to hospital in the UK with an acquired brain injury related diagnosis, of which 162,544 sustained a non-superficial head, which equates to one every three minutes (Headway, 2015). Admissions are 1.6 times more likely for men than women (Headway, 2015). There is considerable impact, both economically and societally (Humphreys et al., 2013, Tuominen et al., 2012, Rickels et al., 2010), affecting the UK economy by an estimated £15 billion per year (Parsonage, 2016). Included are premature deaths, health and social care costs and lost work productivity and personal bankruptcy (Relyea-Chew et al., 2009). However, the cost to individuals may exceed the financial costs. Survivors of TBI are twice as likely to develop mental illness post injury (Parsonage, 2016) more likely to experience depression (Simpson and

Tate, 2007) and have poor quality of life (Berger et al., 1999, Polinder et al., 2015).

2.3.2. TBI Severity

The severity of the TBI is inferred from neurological findings that are recorded in clinical records on admission and thereafter at various stages (Rickels et al., 2010). There is no universally agreed classification system for TBI severity. Within research, definitions of TBI, classifications of severity, scales describing functional status of people with TBI and descriptions of outcomes vary widely (Saltychev et al., 2013), which means that direct comparison of studies citing TBI severity is not always possible. Severity is calculated on a number of clinical measurements of the person with TBI. These have included assessment of the; mechanism (closed versus penetrating), structural damage to the brain (by brain imaging), consciousness (Glasgow Coma Scale (GCS) (Teasdale et al., 2014)) and the period from injury until the patient is orientated, and able to recall new memories (post traumatic amnesia (PTA)) (Maas et al., 2008, Kay T et al., 1993, Friedland and Hutchinson, 2013). The most widely used measure of impaired consciousness after head injury is the GCS (Nell et al., 2000), in which clinicians apply a set of tests (eye opening, verbal response and motor response) to an individual that determine the level of consciousness and are recorded half-hourly to show changes with scores ranging from 3 - no response to 15 - normal eye, verbal and motor responses (Teasdale et al., 2014).

Due to differences in the major measures of severity, relying on a single severity indicator may be unreliable. Headway, the UK brain injury charity have amalgamated different severity indictors to aid brain injury classification. Mild brain injury is defined by Headway (2017) as a loss of consciousness for less than 15 minutes and PTA of less than one hour. Moderate brain injury is defined as a loss of consciousness from 20 minutes to six hours, resulting in PTA <24 hours or a GCS score of 9-12; severe injury is when unconsciousness is more than six hours, a GCS score of 3-8, or in post-traumatic amnesia of 24 hours or more (King et al., 1997, Teasdale et al., 2014). The clinical purpose of classifying the severity is to prescribe the correct treatment in the immediate and acute phase and provide some guidance to prognosis and future rehabilitation (Friedland and Hutchinson, 2013).

Some studies involving participants with TBI use severity scales as criteria to meet research requirements. Reasons vary but may be to control for heterogeneity, because the intervention has been designed for a specific severity and to control for the confounding effect that TBI severity may have on the relationship between the independent variable (the rehabilitation intervention) and the dependent variable (the outcome) (Barker-Collo et al., 2013, Grauwmeijer et al., 2014, Rickels et al., 2010, Soeker et al., 2012). Studies that have separated participants into groups according to severity sometimes stratify findings in the statistical analyses to allow a more detailed interpretation of the data (Thornhill et al., 2000).

2.3.3. Effects of TBI

No two TBIs are the same and neither are the premorbid states of the individuals, their physiological reserves, personalities or support systems (Reynolds 2011) but TBI is a major cause of long term disability (Saltychev et al., 2013). People with TBI may experience permanent symptoms involving physical, cognitive, perceptual, emotional or behavioural functions (Daisley, 2009; National Institute of Neurological Disorders and Stroke (NINDS), 2017). Typical problems include those that are more visible such as movement disorders, seizures, impaired speech, fatigue, memory loss, decision making difficulties, inattention, difficulty planning or initiating tasks, inability to express thoughts, visual and sensory problems (NINDS, 2017) and less visible, but no-less problematic, reduced awareness, anxiety, anger, depression and apathy, (Daisley, 2009; Shames, 2007). These symptoms can limit the capacity to work, integrate socially and damage confidence and quality of life (Cancelliere, 2014; Theadom, 2016) and are illustrated in Table 2-1. However, symptoms alone do not account for all participation limitations in everyday life.

The personal situation including demographic, pre-morbid personality, medical history, social situation and work context of each person with TBI is recognised as having an effect on outcome after injury (Carroll et al., 2014, Dahm and Ponsford, 2014).

Table 2-1 Possible consequences following TBI

Physical/sensory	**Communication**	**Cognitive**	**Behavioural/ Emotional**	**Financial impact**	**Social impact**

• Motor deficits:
  ○ paralysis
  ○ abnormal muscle tone
  ○ ataxia
  ○ coordination and balance
• Sensory deficits
  ○ visual problems
  ○ hearing loss
  ○ loss of taste and smell
• Symptoms e.g. headaches, pain
• Fatigue
• Seizures
	• Language deficits
	  ○ expression
	  ○ comprehension
	• dysarthria
	• dyslexia
	• dysgraphia
		• Impairment of:
		  ○ memory
		  ○ attention
		  ○ perception
		  ○ problem–solving
		  ○ planning
		  ○ safety awareness
		  ○ information processing
		• Reduced executive skills and insight
			• Increased irritability or aggression
			• Reduced initiation
			• Reduced motivation
			• Adjustment problems
			• Mood changes
			• Inappropriate sexual behaviour
			• Emotional liability
			• Disinhibition
				• Loss of employment
				• Reduced ability to work previous number of hours or previous level
				• Carers/partners need to reduce or give up work to undertake carers role
				• Increased cost of being at home more e.g. heating, more leisure time
					• Loss or change of role and status
					• Increased risk of relationship breakdown
					• Increased risk of losing friends
					• Decreased well-being due to loss of role, reduced income
					• Loss of ability to drive – need to use public transport, taxis or friends

Adapted from: Rehabilitation following Acquired Brain Injury (British Society of Rehabilitation Medicine and Royal College of Physicians, 2003) and Potential TBI sequelae (Phillips, 2013)

The social and environment contexts that each person experiences also has an effect on disability and participation in everyday life. This may include the access to and use of the following; healthcare and rehabilitation, the built environment such as housing and adaptations, employment and support into employment, social welfare benefits and family and carers (World Health Organisation, 2011, Laxe et al., 2012).

2.4. Return to work following TBI

Returning to work after a trauma is a common rehabilitation goal and being employed provides not only economic security, but also supports physical, psychological and social health (Saltychev et al., 2013). TBI can bring about physical and psychological impairments that may impact on the capacity to return to and remain in work (Ponsford and Spitz, 2015, Saltychev et al., 2013, Shames et al., 2007, Soeker et al., 2012). Therefore the ability to identify work needs, early (Donker-Cools et al., 2016) in the TBI rehabilitation pathway and clearly communicate these together with tailored support from professionals and family (Donker-Cools et al., 2016) is needed (Colantonio et al., 2016).

Drawing comparisons between studies about TBI and return to work (RTW) and work outcomes is difficult due to methodological differences such as sampling methods, definitions of work, length of follow up and loss to follow up (Saltychev et al., 2013). One systematic review reported that 41% (range 30–65%) of people who were in work prior to their TBI were working at one and two years post injury (Van Velzen et al., 2009). Low numbers of people with TBI returning to work indicates the process is difficult (Phillips et al., 2010).

Retaining work is also challenging with many people with TBI returning quickly but dropping out when brain injury symptoms such as fatigue, anxiety and depression start to affect their capacity to undertake job demands (Possl J et al., 2001, Tyerman A and Meehan MJ, 2004). Whilst some people with mild TBI successfully RTW without external support (Wade et al., 1997), some encounter difficulties (Cancelliere et al., 2014b, Wade et al., 1998, Twamley et al., 2014). Longer term follow-up research indicates that as people with TBI fail to retain work they experience a downward trend in earning potential (Johnson, 1998) and the challenge remains in identifying who needs help to ameliorate this problem (Wade et al., 1997).

2.4.1. Support for return to work

The 'right work is good for health and wellbeing' and being out of work has negative health consequences such as additional common mental ill-health (Black, 2012 p.241). Efforts to optimise RTW and job retention are a UK Government priority (Department for Work and Pensions and Department of Health, 2016), a recognised role for healthcare professionals (Black and Frost, 2011; Black, 2008), a quality requirement of the National Service Framework for Long Term Conditions (Department of Health, 2005) and detailed in outcome 2.2 of the 2016/17 NHS Outcomes Framework (Department of Health, 2016). Clinical guidelines and professional recommendations stipulate that RTW support should be provided to people with TBI (British Society of Rehabilitation Medicine, 2010, Turner-Strokes, 2003, Tyerman A and Meehan MJ, 2004). Disability discrimination is a crucial problem for society and rights are enshrined in UK law (Barnes and Holmes, 2007); excluding people from fully participating in work activities and potentially becoming a burden on social security and care (Prins

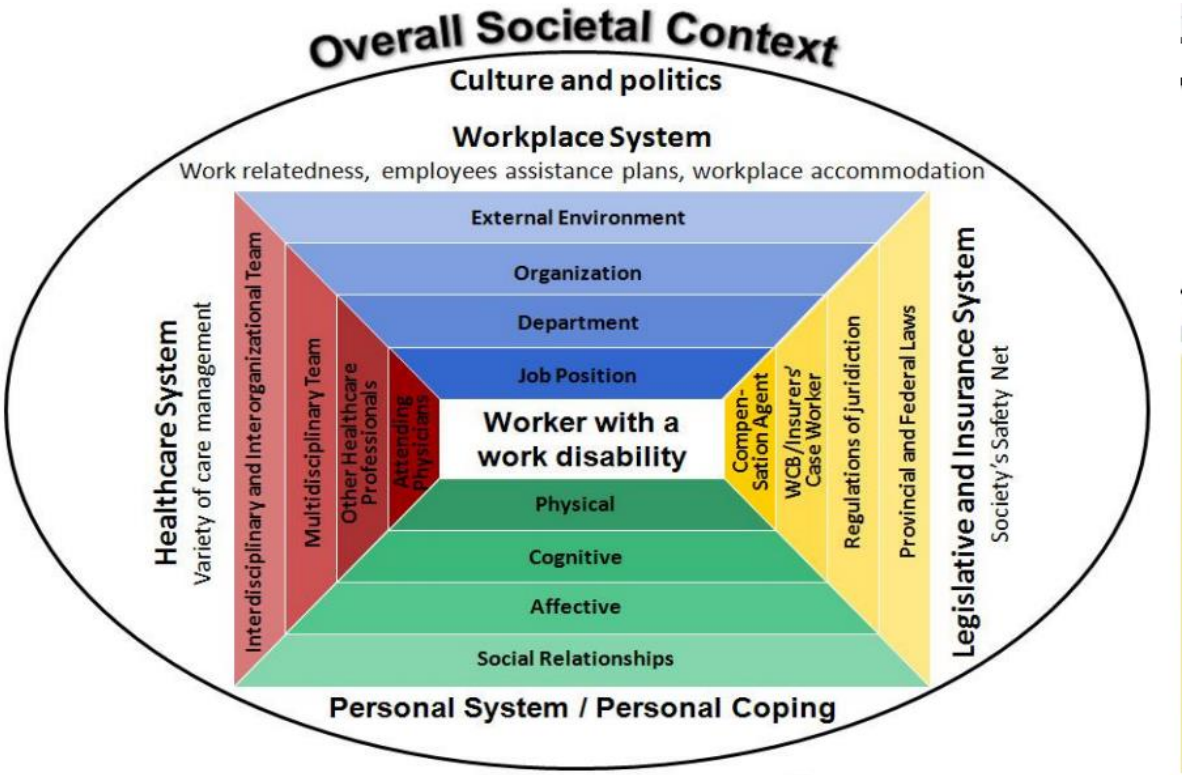
2014). However, UK NHS return to work support does not routinely extend to people with TBI (Playford et al., 2011) and commissioning services is patchy, meeting less than 10% of the estimated need for people with TBI (Playford et al., 2011, Deshpande and Turner-Stokes, 2004).

2.5. Vocational rehabilitation

Vocational Rehabilitation (VR) is defined as, "a multiprofessional approach that is provided to individuals of working age with health-related impairments, limitations, or restrictions with work functioning and whose primary aim is to optimise work participation" (Escorpizo et al., 2011, p 5). It involves support to find work, to stay at work and help career progression in spite of illness or disability (Loisel et al., 2005). Different models of VR exist (Fadyl and McPherson, 2009), to reflect different societal contexts in which they sit.

The societal contexts related to work disability (a person's inability to stay at or return to work after injury or illness) are illustrated in Loisel et al. (2005) case management ecological model. This is an operational model, also known as the 'arena of work disability', with the purpose of detecting the influences of systems on work disability to advise case managers. It illustrates the social structures of the personal, healthcare, workplace and legislative systems and corresponding representatives in each (Loisel et al., 2005) and is considered the most complete contemporary visual representation of the multiple systems influencing work disability (Costa-Black K., 2014).

Figure 2-1 Arena of work disability



(Loisel et al., 2005)

In different societal contexts, VR is organised and managed differently. VR is sometimes legislated for directly as in the United States (Workforce Innovation and Opportunity Act, 2014) and associated Office of Workers' Compensation Programs (U.S. Department of Labor, 2017). However, the responsibility for provision is often less clear in other countries, such as the UK, and spread across organisations associated with healthcare, workplace and legislative or insurance systems and sometimes only driven by the work-disabled person.

VR is often organised by specialised multi or inter-disciplinary teams consisting of a number of rehabilitation professionals, including occupational therapists, but also the patient, their family and employer (Cancelliere et al., 2014a). Typically seen as post-acute rehabilitation (Graham et al., 2016), VR crosses boundaries between health, employment, social care and welfare services. NHS

programmes are usually community-based, focussed on vocational and social reintegration (Shames et al., 2007).

In the UK VR is not provided as part of the legislative system and does not have clear lines of funding as in the USA. Provision sits in a complex system including the NHS, the Department for Work and Pensions (DWP), the private insurance system and third sector (Barnes and Holmes, 2006). It is most often provided by the NHS but requires the engagement of the person receiving the intervention, their carers and joint working across specialist departments within the NHS and community health, DWP and social care services. The NHS itself is a large and complicated service, requiring external funding from Clinical Commissioning Groups (CCGs) to provide interventions in a local population and there is a similar arrangement for social care provided through Local Authorities. Cooperative working is also required with the workplace including the line manager, Human Resources, Health and Safety, Occupational Health and the Trades Union. Additionally, joint working may be required with Job Centre Plus and personal advisors and externally provided programmes that support people to work who are claiming welfare benefits. In terms of those people who are pursuing an insurance and legal claim, cooperation is also required with solicitors, insurance claims handlers and case managers. In all situations, cooperation is required to optimise a RTW that will be sustained over the long term. It is this complex system in which VR sits, the way it is delivered, the people delivering it and receiving it that contributes to the intervention complexity (Costa-Black, 2014, Shiell et al., 2008).

2.5.1. Evidence for TBI VR

There is a lack of evidence to support the effectiveness of health-based VR for people with TBI (Graham et al., 2016, Saltychev et al., 2013) and two systematic reviews identified that high quality experimental and observational studies are needed. The systematic review by Saltychev et al. (2013) identified 80 studies, including 12 controlled (eight RCTs, two controlled clinical trials and two observational) and 68 uncontrolled observational reports of pre-and post-injury predictors of vocational outcome. No strong evidence that vocational outcomes after TBI could be predicted or improved was found. A review of processes and factors essential to vocational evaluation and the experiences of TBI survivors' RTW was conducted to develop a VR clinical practice guideline and described factors most strongly connected with RTW success for people with TBI (Stergiou-Kita et al., 2011). These were:

- Younger age
- Higher pre-injury education
- Higher post-injury neuropsychological function
- Better post-injury functional independence
- Continuous pre-injury work history
- More available environmental and workplace supports.

Published VR literature provides some descriptions of the core components of the intervention and outcomes, but do not provide sufficient contextual information pertaining to the details of what occurred; the rationale or theory supporting the intervention, the materials used, the mode of delivery, the environment and infrastructures required, who provided the intervention, when and how much of the intervention was provided, if and how the intervention was

tailored to the individual or context or whether the quality of the intervention was measured and if so how? (Hart, 2009, Hoffmann et al., 2014). Therefore, there remain gaps in understanding implementation, how the intervention can be translated to be used in further research or into clinical practice (Costa-Black, 2014).

VR has to be context specific, meaning its design and implementation is dependent on the structure of the local health care system, the legislative system, the local workplace system, the person who has sustained the TBI, how they cope and their own personal capacity to work (Loisel et al., 2005). In spite of growing evidence related to prevention of work disability, implementing VR is challenged because of the complex social systems in which people and services sit (Loisel et al., 2005).

2.5.2. Barriers implementing VR

Evidence-based medicine developed in the 1980's to improve patient outcomes and clinicians' decision-making and was defined as, "the conscientious, explicit and judicious use of current best evidence in making decisions about the individual patient" (Sackett et al., 1996 p71). Clinical guidelines were developed to help distil research findings into readable documents from which clinicians could discern appropriate working practices. However, studies demonstrated that clinicians did not change their behaviours (Cabana et al., 1999) and a knowledge-to-action gap was identified. Causes were identified at the individual level (patient and clinician), the organisation level and governance level (legal, political, economic issues) (Cabana et al., 1999, Saillour-Glenisson and Michel,

2003). Although published research exploring these barriers and facilitators remains sparse, awareness about them is on the increase.

Complexity related to implementing VR has been revealed in one exploratory qualitative study. Stergiou-Kita et al. (2016) that examined how closely VR evaluation was conducted in practice compared to an inter-professional guideline for VR evaluation following TBI in Canada through interviews and document analysis of 13 occupational therapy, physiotherapy, medicine, neuropsychology and rehabilitation support workers (Stergiou-Kita et al., 2016). Barriers implementing the guideline were not related to the clinicians or patient responsiveness, but rather related to an external organisation (the service commissioner) who imposed restrictions by not funding workplace visits even though this was recommended. Although this study focussed on issues related to a clinical guideline, it provides some insight into the contextual complexities surrounding the delivery of vocational rehabilitation.

Other relevant knowledge can be gained from VR for people with mental health problems, where Individual Placement Support (IPS), provides a systematic approach to supporting people with severe mental illness to gain employment (Bond et al., 2012). IPS is an evidence-based intervention that is well developed and there is a growing understanding of the barriers and facilitators to implementing it because there is a recognised tool to measure fidelity, which helps to highlight these issues (van Erp et al., 2007). In a study evaluating the fidelity of IPS in four services providing the intervention to 316 service mental health users in the Netherlands, only 57 obtained competitive employment. Services had been provided with training and support from experts in IPS and

were assessed at baseline, 12 and 24 months using a 15-item IPS fidelity scale. The scale covers staffing, the organisation and the service provided. Implementation was explored using semi-structured interviews at baseline, 12 and 24 months. Barriers to implementing IPS included: a lack of organisational standards, staff loss, funding problems, insufficient time for program leaders, and inadequate cooperation between the involved organisations. Facilitators were identified as the skills and commitment of the team members and the integration of vocational and mental health staff (van Erp et al., 2007). Understanding these implementation issues will help international dissemination of IPS and are important for policy planners and service providers to develop local facilitating strategies (Bond et al., 2012).

The musculoskeletal literature describing VR implementation also provides insights into the barriers and facilitators experienced. Fassier et al. (2011) reviewed the literature for barriers and facilitators to RTW following low back pain. The authors developed a conceptual framework that reflected these barriers and facilitators and these were related to the healthcare system, workplace system, insurance system and "inter-sectorial", between the systems (Fassier et al., 2011). In this study, most research reported barriers and few reported facilitators, which Fassier et al. (2011) concluded demonstrated a knowledge gap. Being able to articulate both barriers and facilitators is an important aspect to reducing the knowledge-to-action gap. For musculoskeletal conditions, Fassier et al (2011) recommends that identifying barriers and facilitators prior to implementing RTW interventions.

2.5.3. ESTVR

The complex rehabilitation intervention of interest in this thesis is Early Specialist TBI VR intervention (ESTVR), which is a community-based rehabilitation that supports people with TBI to RTW or study (Phillips, 2013, Phillips et al., 2010, Radford et al., 2013) following a case coordination model (Fadyl and McPherson, 2009). Findings from a previous pilot study (Radford et al., 2013) indicated the need for such an intervention. It suggested people with more moderate and severe TBI may struggle to return to work without support beyond three months after TBI.

ESTVR was originally provided as part of the NHS Nottingham Traumatic Brain Injury Service (NTBIS) by a TBI and VR-specialist OT and supported by a health-based TBI-specialist case manager to people with TBI (16≥ years old) who were working or in full time education at injury onset. The primary focus was preventing job loss and optimising employment and education outcomes by ensuring the brain injured person can RTW or study. Working alongside other relevant providers of health, social care and welfare services as well as employer services such as Occupational Health and Human Resources, to prevent duplication was also a key aspect of ESTVR.

ESTVR is described in more detail in chapter 4 (4.5.2). A brief description is provided next. ESTVR starts when the occupational therapist assesses the impact of the TBI on person's work role early (within eight, but preferably, four weeks of injury). The intervention is based on the understanding that returning to work need not mean to the same job. It can incorporate returning to different or modified work with an existing employer. The individual needs of the PWTBI

and the employer directs the tailored content of the intervention. Where return to a pre-existing employer is unsustainable or there is no job to return to anymore, alternative options such as returning to the same job with a new employer, entering a new field of work or stopping work entirely and engaging in purposeful occupations are explored. ESTVR is complete when the person with TBI accomplishes their RTW-related goals. The content and cost of ESTVR has been described in a cohort study (Phillips, 2013, Phillips et al., 2010, Radford et al., 2013).

As part of its development, a series of studies, were completed to test the feasibility of a future randomised control trial of ESTVR. The data collected for this thesis was one part of this programme. Before progressing to a definitive trial, there was a need to understand the complexities associated with ESTVR, namely:

- Whether NHS therapists in other centres could be trained to deliver ESTVR.
- Whether therapists would deliver ESTVR as intended.
- What factors might affect the implementation of ESTVR in a trial of its effectiveness in the NHS?

ESTVR was the subject of a feasibility randomised controlled trial (RCT) **F**acilitating **R**eturn to work through **E**arly **S**pecialist **H**ealth-based interventions (FRESH, HTA FRESH 11/66/02), which delivered ESTVR across three English NHS sites (1.2.1). This thesis uses process evaluation data from FRESH, one of the series of studies exploring ESTVR.

ESTVR is a complex intervention and this concept is first explored followed by what is meant by fidelity.

2.6. Complex interventions

Many health interventions can be considered "complex". Several definitions of complex interventions have evolved in recent years, developed from the suggestion, "the greater the difficulty in defining precisely what exactly are the active ingredients of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention" (Medical Research Council, 2000, p. 1) . Understanding of the complexity in health interventions has developed and is now recognised as being closely related to the context in which they are implemented (Hawe, 2015). The Medical Research Council (MRC) (Craig et al., 2008) describe the dimensions of complexity as:

- The number and difficulty (e.g. skill requirements) of behaviours required by those delivering the intervention;
- The number of groups or organisational levels targeted by the intervention;
- The number and variability of outcomes;
- The degree of flexibility or tailoring of the intervention permitted.

Using these dimensions and referring to the description of ESTVR in (4.5.2), it would be considered a complex intervention.

2.6.1. Tailoring a complex intervention

Part of an intervention's complexity is to meet the individual needs of the service-user by making relevant changes or tailoring its delivery to effect the required outcomes. Different therapists providing the same intervention, such

as ESTVR, to the same service-user may tailor it in different ways (Masterson-Algar et al., 2014), likewise therapists are likely to tailor ESTVR differently across service-users in order to meet their needs. When the same intervention is delivered in different environments, tailoring is often required to obtain successful outcomes, (Masterson-Algar et al., 2014, Moore et al., 2014) for example in a hospital ward therapists may need to fit around ward rounds and see the person at the bedside, in a workplace therapists may not be permitted to enter certain places and colleagues may be a distraction. These contexts should be measured in research to provide improved understanding (Carroll et al., 2007, Durlak and DuPre, 2008, Fixsen et al., 2005, Moore et al., 2014).

What remains unclear is how much tailoring is permitted and which intervention components are allowed flexibility and which should remain unchanged to retain the optimum outcomes before it becomes a different intervention. Before interventions can be delivered in research, clear descriptions of the intervention components are required (Hart, 2009, Hoffmann et al., 2014), as is a description of the proposed theory underlying how the intervention will have an effect, its mechanisms (Hawe, 2015). The MRC guidance recommends that the "core" or "key" components should remain unchanged across sites (Craig et al., 2008), whereas others suggest that the function of the component should remain standard across sites but that the form can be adapted (Hawe et al., 2004). For example, a core function of VR is communicating with an employer to arrange a RTW schedule, but how this is conducted may take several forms including telephone conversations, face-to-face meetings, emails, texts or via letters and may be open to tailoring. By delineating the boundaries of tailoring, it may be possible to understand whether the intervention is being delivered faithfully.

2.6.2. Measuring fidelity

The degree to which an intervention is delivered with integrity and as intended is called "fidelity" (Carroll et al., 2007). Fidelity is important to measure because it:

- Is a moderator of successful patient outcomes and it has been suggested that interventions implemented as intended (with fidelity) result in better outcomes (Forgatch et al., 2005, Cucciare et al., 2016, Durlak and DuPre, 2008).
- Prevents Type III errors, where outcomes are attributed erroneously to treatment effectiveness, even when an intervention has not been implemented as planned (Dusenbury et al., 2003).
- Helps researchers to understand implementation issues to consider in the design of future trials and some suggest that conflicting findings between similar studies or the same study in different sites may be accounted for by variations in intervention fidelity (Poltawski et al., 2014). In a meta-analysis of 542 interventions between 1976 and 2006, Durlak and DuPre (2008) emphasised that when implementation strategies are clearly defined, interventions were more effective.

Fidelity can be measured in different ways and a range of strategies are appropriate for rehabilitation interventions (Poltawski et al., 2014). Durlak and DuPre (2008) emphasised, "It is particularly important to specify the theoretically important components of interventions, and to determine how well these specific components are delivered or altered during implementation" (p. 341). In terms of behaviour change research, the US National Institute of Health (NIH) identifies five areas in which fidelity should be addressed: study

design, provider training, treatment delivery, treatment receipt and treatment enactment (Bellg et al., 2004). These recommendations indicate that measuring fidelity should occur at multiple stages and not just after the event.

The literature suggests that multiple methods such as; printed educational materials, educational meetings, local opinion leaders and reminders may be important in supporting clinicians delivering interventions that are new to them (Craig et al., 2008, Grimshaw et al., 2012, Walker M.F. et al., 2013), although there is little evidence to demonstrate the effectiveness of these support methods (LaRocca et al., 2012). Organisational and practitioner-level barriers such as insufficient time to learn new skills and low levels of confidence, and facilitators such as strong leadership have been identified as affecting the uptake of knowledge (Lal and Korner-Bitensky, 2012, Moran et al., 2014, Jones et al., 2014, Petzold et al., 2012).

Intervention fidelity is particularly important in trials where a complex intervention, such as ESTVR, is delivered because of the potential differences across sites and over time (Chesworth et al., 2015). The delivery of a new intervention within a trial environment is a joint responsibility between the researchers designing and managing the study and the clinicians delivering the intervention. Ultimately it is a moral obligation for researchers to ensure that clinicians are as prepared as possible to implement the intervention with fidelity in order to optimise patient outcomes (Döpp et al., 2011), in a trial environment and to prevent the waste of publicly funded studies (Grimshaw et al., 2012, Ioannidis et al., 2014), ultimately paid for by tax-payers.

2.7. Implementation of rehabilitation in trials

One aspect of moving rehabilitation from the research environment into everyday clinical practice is the need for it to be delivered as intended, in different contexts, achieving the required patient outcomes (Cucciare et al., 2016, Robb et al., 2011). However, this process is complicated because intervention complexity increases the unpredictability of results (Hawe, 2015). Research about rehabilitation interventions cannot change population health outcomes unless they are adopted (Eccles et al., 2009), and findings do not always translate into improved patient outcomes because of difficulties implementing the intervention (Eccles et al., 2005, Grimshaw et al., 2012). This results in a gap between what is achieved in research environments and what is done in everyday clinical practice. Testing how an intervention, such as vocational rehabilitation with people who have had a traumatic brain injury, is implemented in the real world within the research environment, is a first step towards narrowing this research to practice gap (Luker et al., 2016).

Distinguishing between the effectiveness of interventions and their implementation is critical in moving interventions into everyday clinical settings (Proctor et al., 2011) but studies of rehabilitation interventions tend to focus on effectiveness (Damschroder and Hagedorn, 2011). The risk of not reporting implementation issues could perpetuate poor patient outcomes (Colditz, 2012, Bosch et al., 2006), prevent trialists from the opportunity to design improved research (Allen JD. et al., 2012, BS., 2012) and halt the scientific discovery of interventions that have been wrongly determined ineffective (Walker et al., 2017), when in fact they have not been implemented correctly, thus impacting on people's lives by leaving effectiveness untested.

One systematic review investigating determinants of success for home-based stroke rehabilitation (Siemonsma et al., 2014), identified seven studies that provided some information on barriers and facilitators. An important aspect to this review was the successful use of pre-existing findings to answer a new research question, thus adhering to recommendations regarding the reduction of waste in research (Chalmers et al., 2014). Siemonsma (2014) found that while none of the studies set out to explicitly identify implementation issues, by using an implementation framework (Fleuren et al., 2012) it was possible to identify determinants (barriers and facilitators) to home-based stroke rehabilitation.

Issues affecting implementation are often reported as barriers and facilitators. Barriers to implementation hinder delivery, facilitators enable delivery and independently impact on implementation outcomes (Nilsen, 2015). A range of practical issues surrounding intervention delivery are sometimes described but comprehensive reporting of a range of implementation issues is rare. Studies tend to focus on intervention effectiveness (Damschroder and Hagedorn, 2011) but the risk of not reporting barriers and facilitators could result in misleading the public and wasting limited research resources through repeating known failures (Ioannidis et al., 2014).

Differences exist between investigating implementation of complex interventions within a trial compared to clinical practice but little is known about the unique context of the trial setting (Luker et al., 2016, Brady et al., 2011). The implementation of VR within the trial setting of FRESH is the focus of this thesis. These contexts will include the systems of working within hospital and community healthcare settings and staff working on trials will often have to

deliver the trial intervention, sometimes with no or limited experience of it, alongside their usual work (Luker et al., 2016). Process evaluations aim to, "understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors" (Moore G. et al., 2014). They report barriers and facilitators more often and in more detail. Process evaluations can be nested within a study, such as a randomised controlled feasibility study and seek to unpick a range of research processes, such as recruitment and completion of outcome measures as well as barriers and facilitators to implementing the intervention under investigation (Moore G. et al., 2014, Masterson-Algar et al., 2014). The purpose of this data is to inform future trial design, aiming to optimise implementation fidelity and patient outcomes (O'Cathain et al., 2015) but also can provide additional information to policy-makers and commissioners so they can be confident in understanding the outcomes when an intervention is delivered in different places, by different people and have ways to manage different contexts (Moore G. et al., 2014).

Implementation of the intervention within a trial would be supported by identifying facilitators and barriers to the deployment of the complex intervention by practitioners, as well as understanding contextual factors (Masterson-Algar et al., 2016). Implementation of evidence also requires changing the habits of clinicians delivering a new intervention and this can be dependent on the practitioner's knowledge, skills, confidence and attitudes (Lal and Korner-Bitensky, 2012, Damschroder et al., 2009, Graham et al., 2006). However, the best way to accomplish this is unclear because putting new learning into practice is complex (Farmer et al., 2012, Grimshaw et al., 2006, LaRocca et al., 2012, Jones et al., 2014).

This research to practice gap is prevalent in VR (Graham et al., 2016, Graham et al., 2013, Playford et al., 2011, Stergiou-Kita et al., 2016). Suggestions have been made as to how to improve patient outcomes in TBI VR. Educating the specialist professionals with TBI-specific knowledge in VR (Donker-Cools et al., 2016), disability discrimination (Playford et al., 2011), how to evaluate jobs and assess work capability and match people with TBI's abilities to job demands (Donker-Cools et al., 2016, Soeker, 2014); how to engage with employers, and other employment sector stakeholders (O'Brien L, 2007), go into the workplace (Donker-Cools et al., 2016) and how to negotiate reasonable adjustment and phased RTW (Donker-Cools et al., 2016, Fadyl and McPherson, 2009) will enable the support of people with TBI to RTW and retain jobs (Donker-Cools et al., 2016). However, unless there is a greater understanding of the, "dynamic interplay between individuals and the organizations in which they work, and how that interplay influences individual and organisational behaviour change" (Damschroder et al., 2009, p5), the gap between research and practice may continue to be unplugged.

2.8. Implementation Research

Implementing complex interventions, such as ESTVR, is itself a complex process and the routes are non-linear (Greenhalgh et al., 2004). Implementation research is the study of methods to promote the uptake of research findings into routine practice (Bhattacharyya et al., 2009) and studies should be guided by theory (Rabin et al., 2008, Martinez et al., 2014).

2.8.1. Implementation research theory

Implementation research theory is useful in categorising factors across multiple domains where implementation issues are known to emanate and there are over

60 frameworks in use to help to understand these issues (Tabak et al., 2012). Although this large choice is sometimes seen as confusing (Martinez et al., 2014), implementation research frameworks can be helpful for understanding the barriers and facilitators to implementing complex interventions (Kirk et al., 2016, McEvoy et al., 2014, Chaudoir et al., 2013). However, they have differing foci, with overlapping and similar concepts, they use terminology in a non-standardised fashion (Brownson et al., 2012, Damschroder et al., 2009, Graham et al., 2006, Greenhalgh et al., 2004) and most do not provide a sufficiently inclusive picture of implementation (Damschroder et al., 2009).

Many frameworks do not explain clearly how construct definitions compare to those in other frameworks, models, and theories potentially leading to difficulties determining which is most appropriate and which instruments to use (Martinez et al., 2014). This ambiguity could negatively affect measurement of constructs and lead to similar constructs being measured differently or different constructs being measured similarly, reflecting linguistic and or conceptual ambiguity (Martinez et al., 2014). Some measures of key constructs within frameworks have been validated and comparative effectiveness studies of implementation strategies are increasing in number (Chambers, 2012).

2.8.2. CFIR

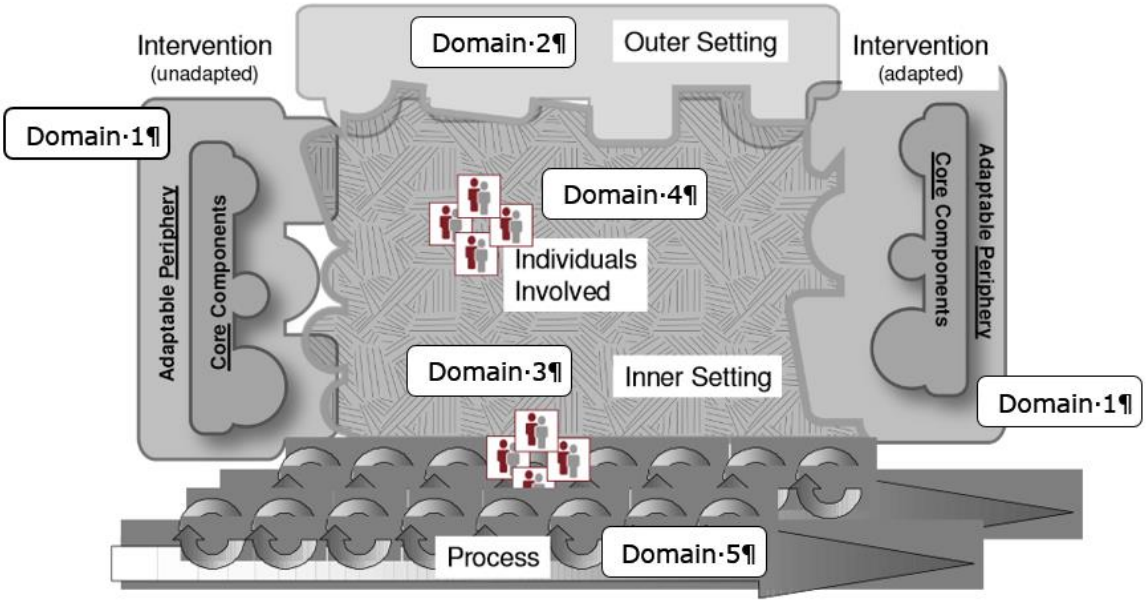
In 2009 Damschroder and colleagues conducted a review of existing published implementation models, theories and frameworks within healthcare. Starting with the comprehensive review by Greenhalgh et al. (2004), a snowball sampling approach identified further literature. The synthesis produced a meta-theory or 'overarching' typology guiding future research and developing implementation

theory (Damschroder et al., 2009). The **C**onsolidated **F**ramework for **I**mplementation **R**esearch (CFIR) is the most comprehensive, bringing together 19 existing theories and incorporates a range of concepts in its 39 constructs arranged across five domains (intervention characteristics, outer setting, inner setting, individuals involved and the process of implementation). The CFIR embraces its contributory theories and models and acknowledges the contribution that each has made to research related to implementation science (Damschroder et al., 2009). CFIR is not a theory, as it does not hypothesize interrelations among constructs (Martinez et al., 2014) and this was recognised by the authors; development of theories hypothesising ways that constructs and domains interact and change requires development and testing (Damschroder et al., 2009). It aimed to produce a comprehensive framework that standardised terminology and developed definitions that could be operationalised and provide clarification about what works, where and why across multiple contexts (Damschroder et al., 2009, Tabak et al., 2012).

CFIR provides a way to understand the 'arena' in which the implementation of a new complex intervention, such as ESTVR, occurs in contexts such as an English NHS Trust and workplaces. Within the CFIR arena metaphor, implementation takes place in five different areas (domains) as seen in Figure 2-2. These domains and their constituent parts (constructs) should be considered when investigating implementation of a new complex intervention, such as ESTVR.
A systematic review of CFIR use showed extensive citation (429 papers) but few (26) had utilised the framework comprehensively, according to the selection criteria of the review (Kirk et al., 2016). The majority of studies (20) were from healthcare, using the framework to retrospectively evaluate implementation of

an intervention. Most studies sought to understand practitioner's experiences (barriers and facilitators) of implementing the intervention in feasibility studies (Kirk et al., 2016).

Figure 2-2 Domains of CFIR

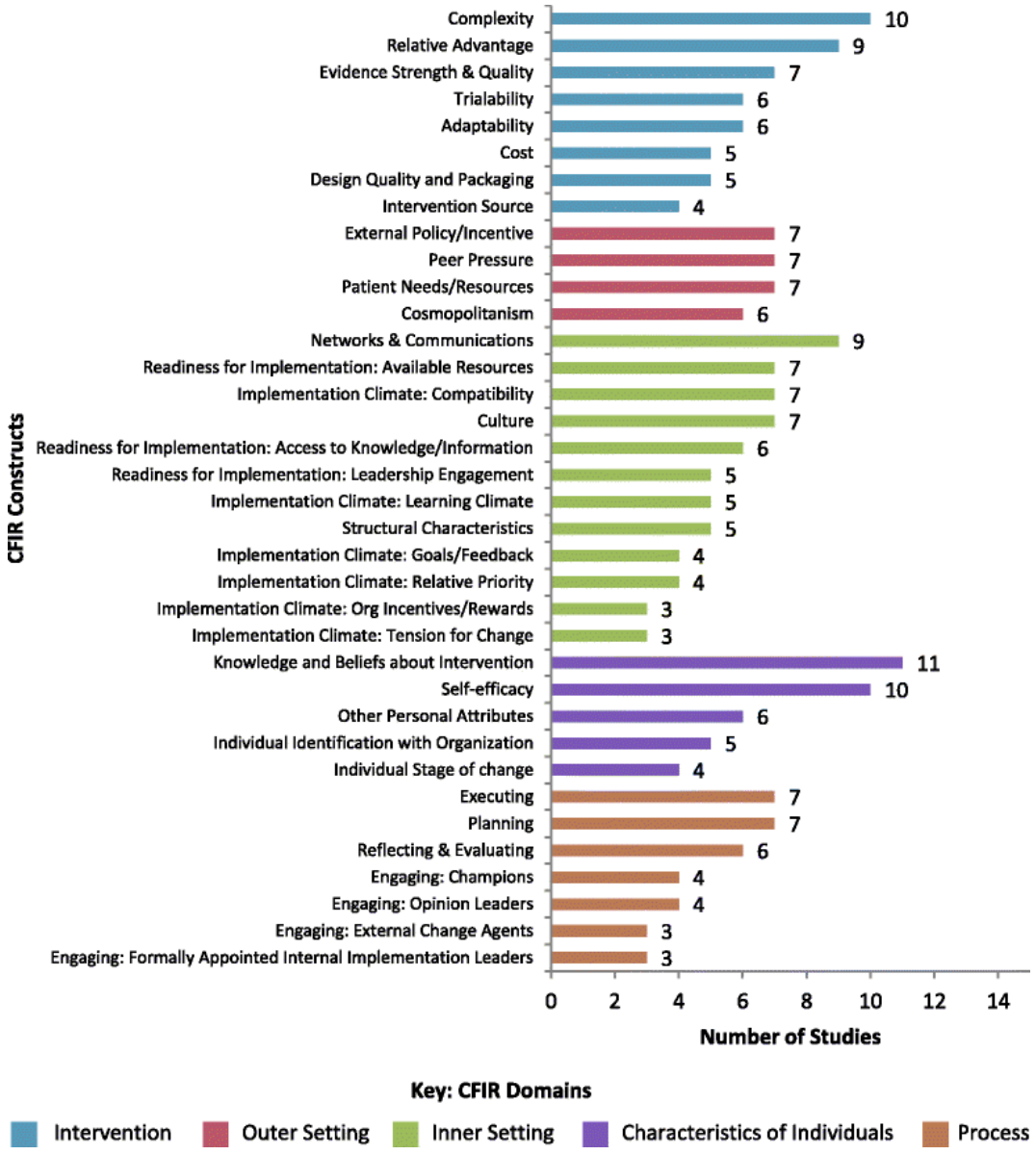


The unadapted intervention (left) (Figure 2-2), has irregular boundaries, as do the outer (domain two, where the patient is positioned) and inner (domain three) settings, indicating that there is unlikely to be a neat fit, with gaps and overlaps occurring. The individuals involved (domain 4) in delivering the intervention sit within the inner setting and touch all other domains. The adapted intervention (right), which also has irregular boundaries, has been through a cyclical and forward moving process of implementation (domain five) and retains its irregularity, but now fits with domains two and three. Constructs within each of the five CIFR domains are listed in Figure 2-3.

A recent review to explore the use of CFIR in empirical qualitative, quantitative and mixed methods research published in English between 2009 and 2015,

describes how the framework's constructs have been used (Kirk et al., 2016). Analysis of the 26 included papers demonstrated, amongst other findings, that although the entire range of constructs were reported across the studies, few studies using CFIR reported on all the constructs and only 3/26 justified the selection of the chosen constructs. Reported justifications included prior knowledge about the constructs and piloting an interview guide to determine the appropriate construct selection. The top five constructs used were knowledge and beliefs about the intervention and self-efficacy (characteristics of individuals domain), complexity and relative advantage (intervention domain), networks and communications (inner setting domain). The four least used constructs were engaging external change agents and engaging formally appointed internal implementation leaders (process domain) and organisational incentives or rewards and tension for change of the implementation climate (inner setting domain). Kirk et al. (2016) interpreted these findings as a gap that limits the contribution of CFIR to implementation science and suggested that researchers follow the guidance provided by the framework to justify choices and explain methods for choosing constructs, which will ensure that the most salient implementation-related factors are investigated and improve comparisons across studies.

Figure 2-3 CFIR constructs and range of use



(Kirk et al., 2016, p.8.)[1]

CFIR is adopted as the overarching framework for the following studies in this thesis where the intervention, ESTVR, is delivered through the inner setting of an NHS Trust to people with TBI and their employers in the outer setting by trial occupational therapists employed on the FRESH RCT. Understanding the

[1] Count of CFIR constructs used in studies. Note: This figure includes only studies which specified CFIR constructs used (*n*=15). Nine studies specified only domains that were used and no constructs. Two studies made no explicit reference to any CFIR domains or constructs.

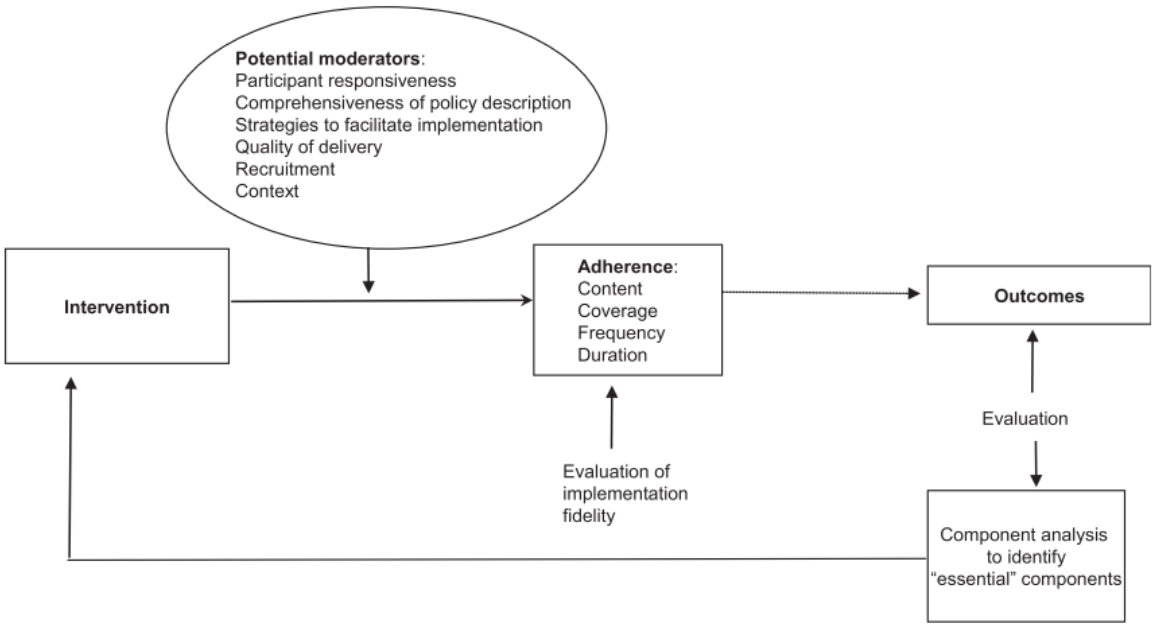
irregularities of the boundaries and the fit to the domains, is the focus of interest in this research. CFIR allows a structured framework to investigate implementation of ESTVR. However, it does not provide a way to examine whether the intervention was delivered as intended in the FRESH RCT.

2.8.3. CFIF

Implementation fidelity has been studied by a number of scholars (Perrin et al., 2006, Forgatch et al., 2005, Fixsen et al., 2005, Bellg et al., 2004, Hennessey and Rumrill, 2003, Dusenbury et al., 2003, Brandt et al., 2004, Borrelli et al., 2005, Moncher and Prinz, 1991). The **C**onceptual **F**ramework for **I**mplementation **F**idelity (CFIF) (Carroll et al., 2007) brings together this body of knowledge to provide a conceptual framework for analysing implementation fidelity.

CFIF conceptualises fidelity under two domains; adherence and potential moderating factors. Adherence concerns whether a service-user has received the "core" of an intervention in the right amount and for the right period of time. Constructs of adherence include content, coverage, frequency and duration of treatment (also known as dose). In understanding what affects implementation fidelity, Carroll describes moderating factors involving constructs of; participant responsiveness, comprehensiveness of policy description (intervention complexity), facilitation strategies and quality of delivery. Following a systematic evaluation, this framework was further developed with two extra elements added to the moderating factors: participant recruitment and context (Hasson, 2010) (Figure 2-4).

Figure 2-4 Modified CFIF



CFIF has been found useful by others in examining the fidelity of interventions (Augustsson et al., 2015, Hasson, 2010, Hasson et al., 2012, Hasson et al., 2014, Masterson-Algar et al., 2014). Its comprehensiveness fitted the needs of this research to analyse and measure the fidelity of ESTVR delivered by the FRESH trial occupational therapists.

Some implementation science researchers combine theoretical frameworks. However, justifying why and how is needed to prevent unnecessary complexity (Birken et al., 2017). CFIF was used by Augustsson et al. (2015) in combination with the Framework for Evaluating Organizational-level Interventions (Nielsen and Randall, 2013). CFIR was used by Birken et al. (2017) together with the Theoretical Domains Framework (Michie et al., 2005). CFIF and CFIR have also been used together (Connell, 2014, Masterson-Algar et al., 2014). Both frameworks operate over multiple conceptual levels (individual and organisational), their theoretical heritage is similar, having combined multiple theories and both have been utilised in research. CFIR has considerably more

tools and resources to help people use it, which are located in a central web-based repository compared to CFIF, which does not and both differ in their purpose. Where CFIF helps to guide measurement of implementation fidelity, CFIR helps to identify determinants of implementation (what works, where and why in different contexts (Gould et al., 2014)) and adds a way to interpret moderating factors construct offered by CFIF. For these reasons, both frameworks fit the needs of the following studies in this thesis.

2.9. Justification for the current study

There is little known about the barriers and facilitators that affect the implementation of rehabilitation delivered to adults with long term neurological conditions and even less about delivering VR to people with TBI. This knowledge is essential to provide a greater understanding of how ESTVR should be implemented in the real world ready for a definitive multi centre randomised controlled trial to evaluate its clinical and cost effectiveness. It is also essential to provide a description of what affects implementation of complex rehabilitation interventions that can be used by other researchers to prevent further research waste.

2.10. Research Aim

The aim of this project was to understand factors that affect the delivery of complex rehabilitation interventions in research, specifically focussing on vocational rehabilitation for people with traumatic brain injury.

2.11. Research Objectives

- To understand the barriers and enablers to implementing complex interventions as reported in previous trials for people with LTNC.
- To determine whether NHS therapists could be trained, using a manual, face-to-face teaching and mentoring, to deliver a complex vocational rehabilitation intervention as part of an NHS rehabilitation trial.
- To examine whether therapists delivered the intervention as trained (with fidelity).
- To understand factors affecting intervention delivery from the perspective of the therapist delivering it, other NHS staff, commissioners, recipient with TBI and employers.

2.12. Research Approach

To answer the research questions and achieve the objectives, a number of different methodologies and approaches were considered. In each of the following chapters the chosen method is described but as a whole thesis the following presents a rationale for the mixed methods approach.

2.12.1. Mixed Methodology

The combination of both quantitative and qualitative data in health research is recognised as providing greater knowledge than separate analysis (O'Cathain et al., 2010). Combining methods is called mixed methods research. A mixed methods design was considered appropriate for integrating qualitative and quantitative data to address the study aims and objectives.

Using both the objective and subjective paradigms together reflects the philosophy of pragmatism, where the objective of the study is more important than the selected methods and knowledge is created by both (Borglin, 2015). Pragmatism is associated with the 'free choice' of methods and is not pre-assigned to either objective or subjective paradigms (Creswell, 2003) and encompasses a pluralistic position. Mixing methods, using quantitative and qualitative methods in a single study, helps to understand the research problem better than either approach would provide alone (Creswell and Plano Clark, 2007). Creswell (2003) explains that mixed-methods designs are complementary, practical, strengthen trustworthiness and provide a stepwise development of knowledge. The numerical (quantitative) and textual (qualitative) data are combined in a study in complementary ways so the limitations of each method are moderated whilst the strengths remain. The pragmatic and practical aspect comes from the choice afforded to meet the needs of the research problem and using qualitative and quantitative data together can support the researcher's interpretation of findings and trust worthiness. Stepwise knowledge development comes from the use of a feedback loop so one methodological stream informs subsequent ones and both explanatory and exploratory research questions can be addressed (Borglin, 2015).

Using mixed methods has been encouraged by the MRC framework (Medical Research Council, 2000, Medical Research Council, 2008) and it sits comfortably in the recommended process of 'development-testing-evaluation-implementation' of complex health interventions. In terms of this research, the complex intervention being examined (ESTVR) is at the feasibility and piloting

phase, being implemented in the feasibility RCT, FRESH, and it was appropriate to select a mixed methods approach that was exploratory in nature.

2.12.2. Personal approach

I am an Occupational Therapist, with 26 years of clinical experience, primarily focussed on delivering VR in the UK and USA to people with LTNCs and 16 years' developing and delivering clinical training to health professionals about VR. I was aware that those who participated in my VR training sometimes reported finding it difficult to change their habits and implement new practices, even though they recognised the positive gains for service-users.

A wide range of implementation problems were reported to me and clinicians lacked local experts to support them and there was a paucity of relevant literature to guide them regarding these issues. For some, I would become involved in providing mentoring to guide them in implementing what they had learned. This was valued by therapists and feedback indicated that their practice and confidence improved.

This experience provided a specific direction for the research; to understand what affects implementation of rehabilitation for people with LTNCs and in particular after therapists have engaged in learning a new VR intervention. Without understanding the barriers and facilitators, designing strategies to overcome them is at risk of failure.

2.12.3. Philosophical approach

Researchers should be reflexive; be clear outlining the basis for claiming to know what they know (O'Gorman and McIntosh, 2015). The overall paradigm of the author should be well-defined putting findings into context. The personal background and philosophical stance of the author and the research topics introduced in chapter two, were the basis for the chosen research methodology. The world view of the author is that there are multiple perspectives of truth and therefore using multiple perspectives of enquiry, offered by mixed methodology provides a more complete understanding.

Although mixed methodologies can be seen as dualistic, the author judged that aspects of implementing VR within a trial had a reality that exists independent of her comprehension of it, a positivist or objective view. For example, the time a therapist spends delivering one component of VR, can be examined by logical, value-free methods to explain facts. At the same time however, the delivery and receipt of rehabilitation is experienced differently each time an interaction occurs between a therapist and a patient, a constructivist or subjective view. This viewpoint points to the usefulness of a mixed methods approach.

2.12.4. Strengths

More health research studies are designed to combine quantitative and qualitative data and this is recognised as providing increased knowledge than separate analysis (O'Cathain et al., 2010). Research in health services and the clinicians providing interventions exist in a highly complex environment and as such it is recognised that a single research perspective will not suffice (Borglin, 2015). To have taken a singular perspective of reality and used a mono-method

may have ignored something important or misunderstood some of the issues under investigation (Mayoh et al., 2012).

2.12.5. Limitations

Purists would argue mixing philosophical paradigms is confusing and inappropriate because the world views are dialectically opposed, that knowledge cannot be gained from each other's perspectives and methods would not blend together as a whole (O'Gorman and McIntosh, 2015). Mixed methods is known as the 'third research paradigm' and considered a relatively new world view. Its methodological development is still evolving and as such guidance to researchers is limited by comparison (Borglin, 2015). However, the aim of this research requires both objective and subjective views and I reject the premise that a choice between these opposing world views is required and agree with Newman and Benz (1998) that the argument is nebulous if one considers that the traditional paradigms are on a continuum.

2.13. Conclusion

It is recognised that barriers and facilitators affect the implementation of rehabilitation delivered to adults with LTNCs. There is virtually nothing written about those implementation factors associated with delivering VR to people with TBI. Therefore the aims of the proposed research will provide knowledge about the barriers and facilitators faced when delivering complex rehabilitation interventions within the research environment, provide an understanding of whether a training package prepares trial therapists to deliver VR, as part of an NHS rehabilitation trial, whether they deliver the intervention as intended and what affects the implementation fidelity of the VR intervention.

CHAPTER 3

3. Study One: Systematic Review

3.1. Chapter Overview

Chapter two introduced the important background related to delivering a complex rehabilitation intervention and in particular, vocational rehabilitation to people with the long term condition, traumatic brain injury. It also introduced the science of implementation and frameworks that help to understand and interpret implementation, which includes identifying what helps (facilitators) and what impedes (barriers) the process.

This chapter describes the aims, methods and results of a systematic review and narrative analysis, which describes the barriers and facilitators to implementing complex rehabilitation interventions for people with LTNC within the context of research. The review was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 13th May 2015 and updated in May 2017 (registration number CRD42015020423) Available at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015020423

3.2. Introduction

To improve outcomes for people with LTNC and achieve return on research and healthcare investments, there is a need to understand factors that affect the implementation of complex interventions they receive (Colditz, 2012, Bosch et al., 2006). These factors are often identified together as 'determinants' or separately as barriers (hindering delivery) and facilitators (enabling delivery) that independently impact on implementation outcomes (Nilsen, 2015). For example a lack of training provided to clinicians may be a barrier to their

delivering the intervention under investigation and result in the dose being changed and protocol not being followed. A facilitator to patients receiving an intervention could be that they are provided with free transport to a rehabilitation department, which results in high attendance and adherence to the intervention protocol.

If trialists understand implementation issues, they are able to design improved strategies to implement interventions (Allen J.D. et al., 2012, Mittman B.S., 2012). But few studies describe rehabilitation in detail (Hoffmann et al., 2014) or report implementation successes and failures during the exploratory phase of complex intervention development (Walker et al., 2017). Studies tend to focus on intervention effectiveness (Damschroder and Hagedorn, 2011).

Factors necessary to inform intervention fidelity or those likely to affect its delivery in the research context are not well understood (Proctor et al., 2013, Birken et al., 2017), which may result in misinterpretation of findings and ineffective or harmful interventions being delivered to people with LTNCs (Walker et al., 2017). The implementation of complex interventions, in adults with a LTNC has not been fully explored. Only a single study has reviewed implementation issues related to a specific Stroke intervention (Siemonsma et al., 2014).

3.3. Study aim

The aim of this study was to identify the published barriers and facilitators affecting the implementation of complex rehabilitation interventions with adults with LTNCs.

3.3.1. Objectives

The objectives of this systematic review were to:

- Identify the barriers and facilitators to the implementation of complex health interventions for adults with LTNC.
- Identify gaps in reporting of barriers and facilitators based on two complementary implementation research frameworks.
- Identify how implementation issues are reported across studies.

3.4. Methods

A comprehensive review of the literature was required in order to achieve the study aim to identify the published barriers and facilitators affecting the implementation of complex rehabilitation interventions with adults with LTNCs. There were a number of literature review methodologies that offered potential procedures and all offered a systematic approach in order to identify a comprehensive body of knowledge and to reduce the potential for bias (Booth, 2012). The resources required to conduct a review of the literature were considered. A rapid review may require fewer resources in terms of time and the size of the research team and is typically used when the breadth and depth of the enquiry is not of paramount importance (Gough et al., 2012). A scoping review is also considered a briefer method that can serve the purpose to describe the breadth of a topic area before a systematic review takes place (Gough et al., 2012). Whilst time constraints were of some concern and the review would be led by a single researcher, they were not as important as ensuring the breadth and depth of the review.

Systematic reviews identify, collate, synthesize and analyse the available literature and are therefore fundamental to progressing knowledge in intervention development (Craig et al., 2008, Cullum, 2015). A systematic review was chosen to bring together what was known about issues that are encountered when delivering rehabilitation within the research environment because it offered explicit and accountable methods (Cooper, 1994).

3.4.1. Eligibility criteria

Studies were included if they:

- reported barriers and facilitators,
- implementing a complex health (rehabilitation) intervention,
- with adults,
- with long term neurological conditions,
- in developed countries.

No studies were excluded on the basis of research methodology in order to capture as many relevant studies as possible, as recommended by Dixon-Woods et al. (2005). Studies published from inception until December 2015 were eligible. Published studies and grey literature were included to ensure a broad search and opinion pieces and non-systematic literature reviews were excluded as these were unlikely to be sufficiently unbiased. These were citation searched.

Studies where the sample was adult, aged 16 or above with a LTNC were considered. Where the study defined adults as younger than 16 then these were also included. If the majority (more than 50%) of a study population was considered adult, this was included in the review but the results discussed separately to ensure transparency.

In this review a LTNC was defined as a neurological condition that cannot be cured; but can be controlled by medication and other therapies.

The intervention of interest was any complex health (rehabilitation) intervention as defined by the MRC guidelines (2008) provided to adults with a LTNC. Complex interventions that were not health-related were excluded. During initial trial searches, this definition was found to be too broad and produced unmanageable amounts of data and therefore further refined to complex interventions with a rehabilitation focus. The definition used for rehabilitation is that of the World Health Organisation, "Rehabilitation of people with disabilities is a process aimed at enabling them to reach and maintain their optimal physical, sensory, intellectual, psychological and social functional levels. Rehabilitation provides disabled people with the tools they need to attain independence and self-determination" (World Health Organisation, 2017a).

Complex interventions that were solely related to medications, medical or surgical procedures, or were specifically related to health technology such as

rehabilitation aids and e-health, or solely focussed on environmental changes such as home adaptations were excluded.

This research is related to implementing complex rehabilitation interventions in the NHS and as such studies in healthcare systems comparable to the NHS were best suited. Therefore studies that were conducted in developed countries supporting comprehensive health care systems comparable to the NHS were included whilst studies conducted in developing and under-developed countries as listed in the United Nations Composition of macro geographical (continental) regions, geographical sub-regions, and selected economic and other groupings (United Nations Statistics Division, 2017) were excluded.

3.4.2. Search terms

Literature search strategies were developed using medical subject headings (MeSH) and non-MeSH terms related to implementation of complex interventions. The search algorithm included the following three main concepts, "barriers and facilitators to implementation", "long-term neurological conditions" and "complex interventions". A general guide to the search algorithm based on MEDLINE can be found in Appendix 1.

The search strategy was adjusted to match each database. The databases searched were: MEDLINE, EMBASE, PsycINFO, HTA, PROSPERO, Cochrane Collaboration, Joanna Briggs Institute library, NIHR Journals Library, CINHAL, ASSIA, SSSCI. The UK Clinical Trials Gateway and ClinicalTrials.gov register

were searched to identify studies in progress. Citation searches of included studies were undertaken using the Web of Science and Google Scholar citation search facility. Hand searches of references of relevant papers were conducted. Reference lists of those included studies were checked. A bibliography of the included studies was discussed with the systematic review team and implementation research experts as identified by the review team (the author (JH), Dr Kate Radford (KR) and Professor Pip Logan (PL)) to ascertain any known missing papers. Opportunistic identification of papers were included and marked as not being gathered from other systematised strategies.

Literature search results for each information source were recorded in Excel. Additionally, searches were saved by date on each database where possible. An EndNote library was created with repositories for "included" and "excluded" studies to enable cross-referencing and recording reviewers' decisions about inclusion or exclusion.

3.4.3. Screening process

The author developed screening questions and forms based on the inclusion and exclusion criteria. These were refined iteratively through testing and discussion with the review team until a final version was agreed. The final screening form (Appendix 2) included information on the author(s), the study (title, abstract, patient population, complex intervention, barrier or facilitators described, study design, publication language, date of publication), the initial screening decision (by which reviewer and date, further comments/describe further action required)

and the final decision (by which reviewer and date of agreement, disagreement and adjudication).

Titles and abstracts were screened against the inclusion and exclusion criteria. Full texts were obtained for all titles that appeared to meet the inclusion criteria or where there was uncertainty. The author screened all texts and a proportion (30%) were divided and sent to the review team (KR and PL). Discrepancies were discussed between reviewers to gain a consensus and disagreements were sorted by using a third reviewer. Additional study information was not required from study authors to resolve questions about eligibility. Reasons for excluding studies were documented (Figure 3-1).

3.4.4. Assessment of Methodological Quality

Whilst there are a range of critical appraisal tools for both quantitative and qualitative research (O'Cathain, 2008), appraising the quality of how the primary studies were originally conducted was not of chief concern foir this review. The adjectives describing barriers and facilitators reported in each study were of key importance rather than the primary studies' effectiveness outcomes. It was expected that a wide range of adjectives would be used that would aid interpretation of reported barriers and facilitators to implementing a complex rehabilitation intervention within a research context, which were not appropriate to assess for quality.

3.4.5. Accounting for bias

Reviewers were not blinded to publication sources, authors, or the countries in which the studies were conducted. However, publisher bias was addressed by maintaining a list of publication sources for all studies to ensure that the search was not limited. Author bias was treated in the same way. Bias towards particular developed countries was addressed by ensuring that the search strategy included a wide range of terms (Appendix 1).

In relation to the thematic analysis, it is important to recognise the potential bias from experience and professional background of the author (occupational therapist) (Bowling, 2014). However, the review team discussed interpretations to minimise bias.

3.4.6. Data Extraction

To organise data, two stages of extraction occurred:

1. Data on country of origin, study setting and design, number of and participants' age, details of the LTNC and intervention being delivered and by whom, outcome measures, barriers and facilitators and underlying implementation research theory were extracted and organised in Excel (Appendix 3).
2. Units of text (a sentence, word or paragraph) describing barriers and facilitators to implementing the complex intervention (the outcome of interest) were identified and entered onto the same data extraction sheet in Excel.

3.4.7. Data Synthesis

The purpose of data synthesis was to understand the barriers and facilitators affecting the implementation of complex intervention with LTNC. Synthesis was of a narrative style considered appropriate because of the broad nature of the research question and the qualitative data extracted (Snilstveit et al., 2012) and conducted in two stages:

Stage one

Extracted data, which were units of text describing barriers and facilitators, were individually mapped to constructs of the CFIF, in particular the adapted version by (Hasson, 2010) and CFIR frameworks. Mapping barriers and facilitators in this way provided a visual comparison across studies and constructs and highlighted root causes to implementation issues across studies and highlighted gaps i.e. constructs with nothing mapped to them.

Stage two

To aggregate findings, the units of text describing barriers and facilitators were thematically analysed (Lau et al., 2016). These themes and sub-themes are mapped to the implementation frameworks and initial discussion takes place in this section.

3.5. Results

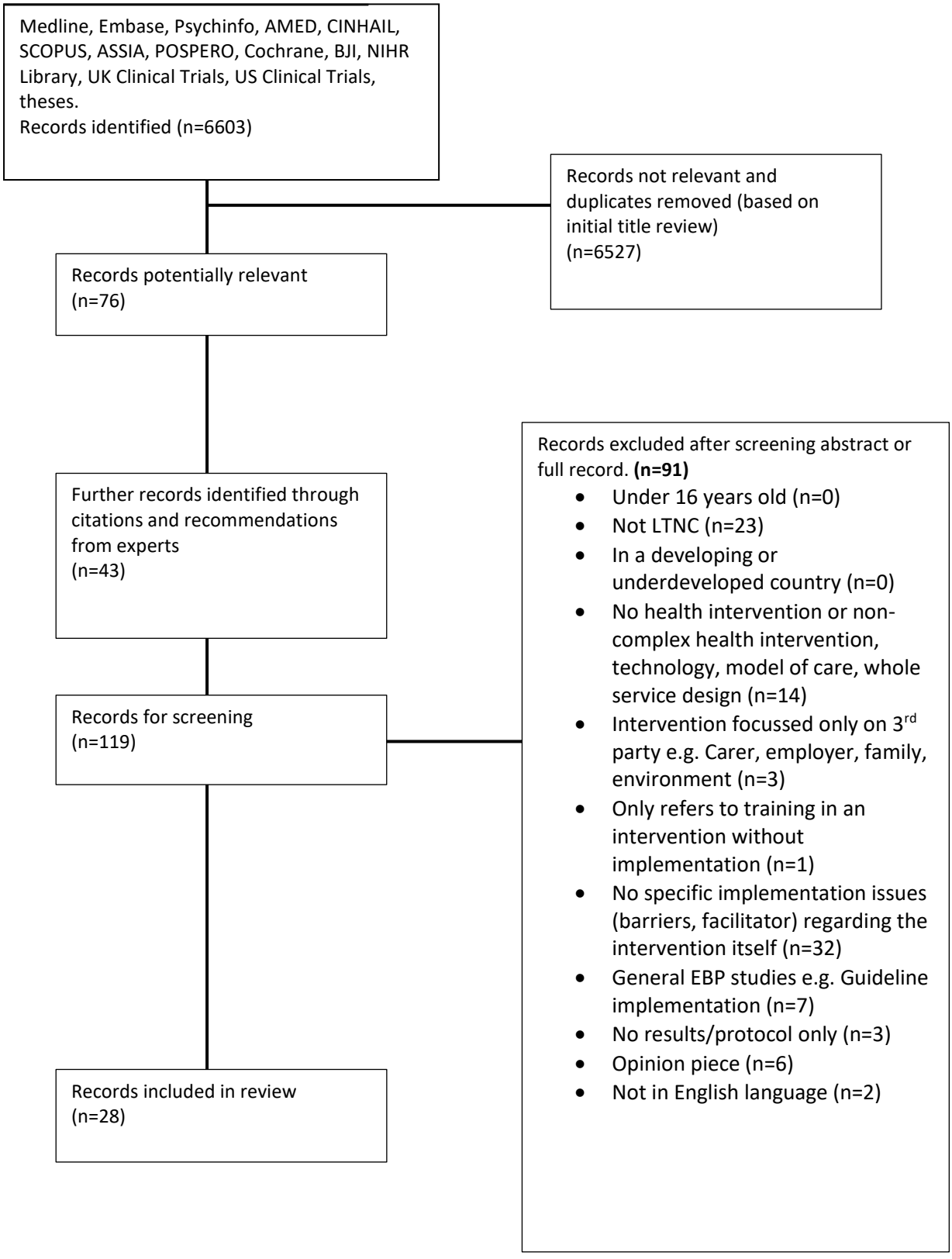
3.5.1. Included studies

Twenty eight studies met the inclusion criteria and 6575 were excluded, as shown in Figure 3-1. Selected studies were published between 2006 and 2015 with the majority (n=11) published in 2014. Two studies published in German were not included (Lauterberg et al., 2007, Muller et al., 2014).

Studies included one systematic review (with seven studies), 11 randomised controlled trials (RCT) (including feasibility and mixed methods designs), five non-randomised studies (pre and post-test and mixed methods designs), two process evaluations (embedded in RCTs), five qualitative studies (one embedded in a RCT) and four case reports.

Papers were from a broad range of publications (n=22). Studies reported data published from patients and healthcare professionals in eight developed countries. Twenty three studies reported the numbers of patients involved (n= 1731 in total) and ten studies reported the numbers of healthcare professionals (n= 202 in total). Nine studies were from the Netherlands, four each from England and the USA, three from Australia and Canada, two each from Germany and Scotland and one from Norway.

Figure 3-1 PRISMA-P flow diagram illustrating selection of studies



Studies were related to a variety of complex interventions delivered by a range of health professionals to people who had a variety of LTNCs. Exercise-based interventions featured in eight studies (Allison and Dennett, 2007, Demers and McKinley, 2015, Haines et al., 2007, Merlo et al., 2013, Morrison and Backus, 2007, Prick et al., 2014, Speelman et al., 2014, Wesson et al., 2013). Home-based rehabilitation in six (Gage et al., 2014, Nanninga et al., 2015, Siemonsma et al., 2014, Sturkenboom et al., 2013, Van't Leven et al., 2012, Voigt-Radloff et al., 2011). Psychosocial and educational interventions in four (Bentley et al., 2014, Cup et al., 2011, Johannessen et al., 2014, Veenhuizen et al., 2011). Communication (Halle et al., 2014, Mackenzie et al., 2014) and motor imagery (Bovend'Eerdt et al., 2010, Braun et al., 2010) interventions each in two studies. Constraint induced movement therapy (Barzel et al., 2015), oral care (Brady et al., 2011), memory aids (Douglas, 2014), bathing (Mahoney et al., 2006), self-management (Richardson et al., 2015) and continence (Thomas et al., 2014) interventions.

The interventions were delivered primarily by occupational therapists and Physiotherapists, Speech and Language Therapists, Psychologists, Nursing and Social Workers. Some studies amalgamated all rehabilitation professionals as a single multidisciplinary team and didn't detail the individual professional backgrounds.

In terms of the LTNCs, stroke featured in 13 studies, dementia in seven, Parkinson's disease in three and mixed LTNCs in two. Motor Neurone Disease, spinal cord injury and Huntingdon's Chorea each featured once.

An overview of important study characteristics of the studies are seen in Appendix 4. The majority [23] of studies did not report using any implementation framework to identify barriers and facilitators. Three studies reported using theories that are frequently used alongside implementation research but these were not used to identify the barriers and facilitators. These were the MRC's framework for complex interventions (Craig et al., 2008) cited by (Brady et al., 2011) and Knowledge to Action process (Graham et al., 2006) cited by (Nanninga et al., 2015, Richardson et al., 2015). Five studies reported using implementation research theories to collect barriers and facilitators data:

1. Promoting Action on Research Implementation in Health Services (PARiHS) (Kitson et al., 1998) used by (Douglas, 2014),
2. an adaptation by Burgio et al. (2001) of Lichstein et al. (1994) Treatment Implementation model used by (Mahoney et al., 2006),
3. Framework for the Introduction and Evaluation of Innovations (Fleuren et al., 2014) used by (Siemonsma et al., 2014),
4. Normalisation Process Theory (May, 2006) used by (Thomas et al., 2014) and
5. Combinaties van interventies, an implementation model developed in the Netherlands by Grol R (2006) used by (Van't Leven et al., 2012).

Two studies (Speelman et al., 2014, Voigt-Radloff et al., 2011) specifically indicated collecting data to identify barriers and facilitators without using an underpinning theory.

Most [25] studies reported varying amounts of detail on the methods used to gather data about barriers and facilitators. Three did not describe a method. These inferred that participants were either asked or spontaneously proffered the data (Allison and Dennett, 2007, Barzel et al., 2015) or that data arose from a researcher's observations and/or reflections (Demers and McKinley, 2015).

Of the reported methodologies: 12 were mixed incorporating semi-structured interviews, questionnaires, logs, observations and reflective accounts; 11 were qualitative incorporating semi-structured interviews, observations, reflective accounts and focus groups; and three were quantitative and used questionnaires and cost analysis.

3.5.2. Data Synthesis

3.5.2.1. Stage one - mapping

Table 3-2 is a visual representation of reported barriers and facilitators mapped to the constructs of CFIF and CFIR. All studies reported barriers and or facilitators to implementing the complex intervention under investigation, as this was part of inclusion criteria. Most [26] studies reported both barriers and facilitators and two reported only barriers (Allison and Dennett, 2007, Haines et al., 2007). Few studies presented implementation issues explicitly as barriers and or facilitators but this was implied when exploring feasibility and or acceptability of the intervention as found by others (Siemonsma et al., 2014). Overall, the 28 studies reported over 200 barriers or facilitators across the frameworks' constructs. Constructs attracted 111 barriers, 59 facilitators and 63 co-mapped as both barriers and facilitators.

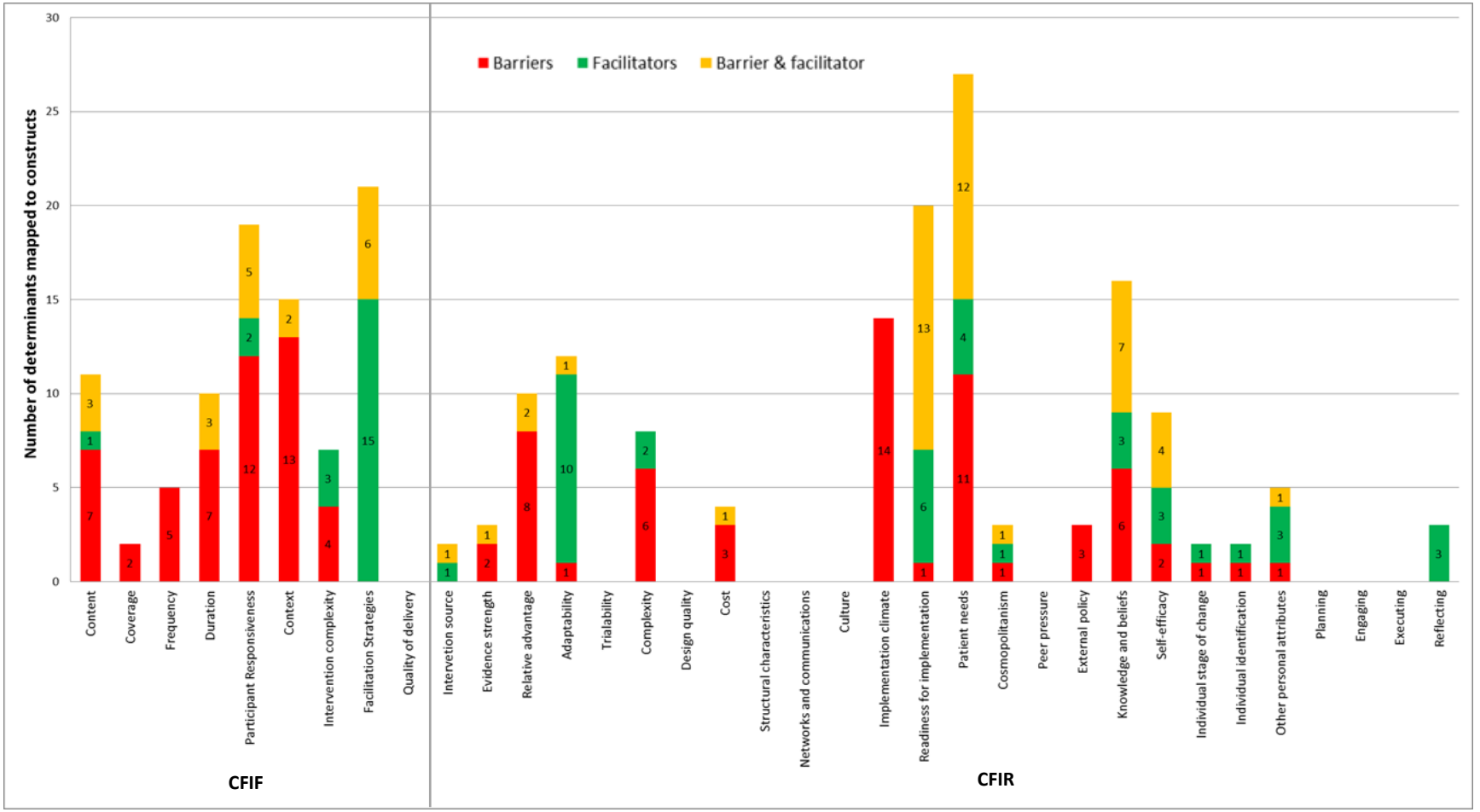
Table 3-1 Matrix of framework constructs to barriers and facilitators

| Theoretical Framework | | CFIF | | | | | | | | | CFIR | | | | | | | | |

Most [22 studies] identified more barriers than facilitators, but the exceptions were (Gage et al., 2014, Johannessen et al., 2014, Morrison and Backus, 2007, Richardson et al., 2015, Speelman et al., 2014, Veenhuizen et al., 2011). Twenty four of the studies described implementation factors that were co-mapped as both positive and negative. Barriers and facilitators identified in four studies (Allison and Dennett, 2007, Merlo et al., 2013, Morrison and Backus, 2007, Veenhuizen et al., 2011) mapped to four or fewer constructs whereas they were mapped to more than 12 constructs in two studies (Sturkenboom et al., 2013, Van't Leven et al., 2012).

Figure 3-2 shows the number of barriers and facilitators mapped to individual constructs. Most constructs [22] had barriers mapped to them but 10 had no barriers or facilitators mapped to them (CFIF's quality of delivery, CFIR's trialability, design quality and packaging, structural characteristics, networks and communications, culture, peer pressure, planning, engaging, executing). Three constructs (CFIF's facilitation strategies, CFIR's adaptability, reflecting and feedback) attracted more facilitators and four constructs (CFIF's coverage, frequency, CFIR's implementation climate, external policy and incentives) attracted only barriers. Four constructs (CFIF's participant responsiveness, facilitation strategies, CFIR's patient needs and resources, readiness for implementation) attracted the majority of barriers and facilitators.

Figure 3-2 Number of barriers and facilitators mapped to each construct



3.5.2.2. Stage two – thematic analysis

Thematic analysis of extracted units of text revealed that barriers and facilitators were reported in similar ways across the 28 studies. This different perspective revealed six themes that demonstrated how researchers reported barriers and facilitators (see Table 3-2):

1. Non-adherence / adherence can refer to the recipient and provider of an intervention and is regarded as an important determinant of intervention effectiveness (Carroll et al., 2007). When an intervention is "adhered to" it means that the intervention was delivered as intended (Proctor et al., 2011).
2. Perception of the intervention indicating a barrier / facilitator relates to understanding the perceptions held by stakeholders about a new intervention and can involve patient responsiveness. Perceptions included general acceptability and personal meaning of the intervention as well as the evidence-base of the intervention, the external setting and cost.
3. Attrition is a required reportable component of the results of any high quality trial because it identifies the numbers of and reasons for participant drop out, which may account for limitations in outcome data (Moher et al., 2010).
4. Trial-related barriers / facilitators included participant recruitment and research trial processes such as not receiving funding to deliver an intervention.
5. Training barrier / facilitator related to the specific instruction and or resources provided to those people who would be delivering the intervention.

6. Cost barrier / facilitator. Early cost analysis in the development of new health interventions is recognised as important in closing the research-practice gap (Gitlin, 2013).

Most [25] studies reported barriers and or facilitators related to adherence; more than half reported what people thought of the intervention, either negatively [16] or positively [21] or both [14] and just under half of studies [10] described reasons for attrition. Table 3-3 details the barriers and facilitators presented in each study and the associated themes in order to demonstrate similarities and differences across the studies.

Table 3-2 Summary of Barriers and Facilitators Themes

		Barriers						Facilitators					
		Non-adherence	Perception of intervention	Attrition	Trial-related	Training	Resources & cost	Adherence	Perception of intervention	Training	Trial-related	Resources & cost	None
Study ID													
1	Allison & Dennett	✓*		✓									✓
2	Barzel et al	✓		✓				✓					
3	Bentley et al	✓		✓				✓	✓				
4	Bovend'Eerdt et al	✓						✓					
5	Brady et al	✓	✓		✓	✓		✓	✓	✓			
6	Braun et al	✓	✓	✓	✓			✓	✓				
7	Cup et al	✓	✓						✓				
8	Demers & McKinley	✓	✓	✓			✓	✓	✓				
9	Douglas	✓	✓					✓	✓				
10	Gage et al		✓		✓			✓	✓				
11	Haines et al	✓											✓
12	Halle & Guylaine Mingant	✓						✓	✓				
13	Johannessen et al		✓		✓			✓	✓		✓		
14	Mackenzie et al	✓*		✓*				✓	✓				
15	Mahoney et al	✓			✓			✓	✓				
16	Merlo et al		✓						✓				
17	Morrison & Backus						✓					✓	
18	Nanninga et al	✓	✓					✓	✓				
19	Prick et al	✓		✓	✓			✓	✓		✓		
20	Richardson et al	✓		✓				✓	✓	✓			
21	Siemonsma et al	✓	✓					✓	✓				
22	Speelman et al	✓	✓					✓	✓				
23	Sturkenboom et al	✓		✓		✓		✓	✓				
24	Thomas et al	✓	✓		✓			✓	✓				
25	Van't Leven et al	✓	✓					✓	✓				
26	Veenhuizen et al		✓					✓	✓				
27	Voigt-Radloff et al	✓	✓					✓					
28	Wesson et al	✓	✓	✓				✓					
	Counts	24	16	10	7	2	2	23	21	2	2	1	2
Key: * = implied barriers as none explicitly stated													

Table 3-3 Overview of reported barriers and facilitators

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
1	(Allison and Dennett, 2007)	Stroke	Conventional PT - 45 minutes plus additional standing practice - 45 minutes per PT session. Aim to increase motor recovery and mobility post stroke during hospital admission.	• Attrition/non-adherence - patient symptoms interfering with participation in intervention.	• None reported.
2	(Barzel et al., 2015)	Stroke	Home-based Constraint Induced Movement Therapy (CIMT). 5 hours contact in 4 weeks. Coaches in home CIMT. Aim to improve movement in affected limb.	• Non-adherence - insufficient exercise time (adherence to protocol defined as minimum - 75% of agreed exercise time for home CIMT and minimum - 75% of the required standard therapy), therapy considered too difficult by patient or caregiver, therapist did not follow the protocol. • Attrition - patients reported adverse events that caused attrition, reduced participation, admission to hospital, death.	• Adherence - relatively low dose and intensity of intervention (compared with other CIMT); increased self-efficacy, motivation might have triggered positive responses in home CIMT group.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
3	(Bentley et al., 2014)	Motor Neurone Disease	Dignity therapy (brief psychotherapy) recorded life reflection by a person with terminal disease. Aim to provide the opportunity to discuss significant memories, meaningful events, important accomplishments, leave messages for loved ones.	• Attrition – patient changed their mind after entering the study, death, excluded due to cognitive impairment. • Non-adherence - (often in combination) participants' speech impairment "prohibitively difficult", travel (to participants in rural areas), hospital or respite care admissions, family and employment obligations, desire for more time to work on the document.	• Patient perceptions - feedback questionnaire indicates intervention is highly acceptable to people with MND. • Adherence - assisted communication methods helped those with speech impairment complete the intervention e.g. using email or utilising videoconferencing.
4	(Bovend'Eerdt et al., 2010)	Stroke, brain injury, multiple sclerosis	Motor imagery strategy taught (the person imagining himself undertaking the movement without actually doing the movement) in usual therapy time. Aim to improve functional use of affected limb.	• Non-adherence - poor in 85% of therapists and in 72% of the patients; patient seen by an assistant or student not trained in the intervention, outpatients received fewer therapy sessions, therapists on vacation, therapists forgot to deliver the intervention. Therapist felt intervention was inappropriate because of cognitive problems (seen as main barrier), some daily activities deemed inappropriate to practice with imagery, patients who were "uncooperative" or unwell.	• Adherence - involving therapists in intervention development; patient-tailored intervention with individual treatment goals; multidisciplinary approach.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
5	(Brady et al., 2011)	Stroke	Complex, multidimensional oral care intervention for people in stroke rehabilitation. Components targeted three systems of care - (i) patient, (ii) staff and (iii) services. Aim to improve oral health.	• Patient perceptions - staff did not prioritise intervention over other tasks, lack of appropriate equipment, lack of self-interest in the goal of the intervention, lack of support in adapting oral routine to overcome stroke related impairment(s). • Staff perceptions - acceptance of evidence-based intervention protocol uncertain. • Non-adherence – returning to previous ward routines, perceived health and safety issues, family refusing consent, not using the MDT specifically trained in the intervention for support e.g. no adaptive equipment issued to support participants. • Trial related barrier - recruitment not open to all inpatients, staff found providing different interventions difficult. • Intervention training - staff commented this was only useful if adhered to.	• Patient perceptions - keen awareness of own oral health issues meant the intervention had meaning; • Adherence – some patients well supported by staff; provision of basic equipment helped; support was available adapting routines to overcome stroke related impairment(s). Intervention protocol relating to care, cleaning dentures - particularly helpful; planning, advisory group perceived useful in developing assessment tool and protocol; availability of basic equipment on ward essential; Intervention assessment easy to use; nursing staff (nurses and clinical support workers) equally able to use the tool was looked upon favourably. • Intervention training - improved attitudes and knowledge of staff following the training. Individualised OHC plans; positive benefits for the care patients received.

6	(Braun et al., 2010)	Stroke	Motor imagery treatment framework within usual therapy sessions - 30 minutes over six week mental practice (imagining movement patterns) intervention - four phases: 1. explanation of imagery, 2. teaching patients how to use imagery, 3. using imagery as part of therapy, 4. facilitating patient using it alone and new tasks. Aim to improve motor function.	• Patient perceptions – some could not remember what helped most, some indicated the intervention was effortful. • Staff perceptions – some doubted they would use the entire intervention and some not at all. • Staff attrition - perceived as not worthwhile, other reasons not reported. One PT left due to a change in employment and one OT missed a part because of maternity leave. • Non-adherence - short illness, doctor's appointment, therapists thought patients did not understand the intervention, therapists perceived patients unwilling; some therapists used additional time reasons not reported, missing data. Difficult to check compliance of the patient resulting in longer instruction time. • Trial related barrier - data on intervention dose not available because therapists error in documenting – using own files (affecting the registered dose of the intervention).	• Patient perceptions – observing others a helpful learning method; observing followed by practicing; talking through the movement' most effective continuously repeating; supportive therapists. • Therapist perceptions –intervention clear, felt able to request assistance; one could anticipate which patients practiced the intervention, others cannot be anticipated. This was not elaborated further; some saw the intervention as beneficial. • Adherence - therapists gained confidence with experience; most therapists considered themselves capable of delivering intervention; some reported implemented the intervention as planned; all therapists thought patient logs useful recording unguided imagery but had doubts on validity of reported information; some therapists would continue using the intervention.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
7	(Cup et al., 2011)	Neuromuscular Disorders (NMD)	Specialist multidisciplinary advice provided by NMD experts (in a specialist outpatient unit) regarding management of patients. Provided to OT, PT and SLT or rehabilitation physician in community setting. Integrated advice from consultations and multidisciplinary meeting. Aim to optimise patient outcomes by upskilling local MDT.	• Patient perceptions – intervention not appreciated when no problems experienced. • Staff perceptions–some unclear advice, some reported a waiting list to obtain the intervention (advice). • Non-adherence - OTs often preferred to treat a patient at home, disagreeing with advice to treat in hospital department. Problems related to lack of funding. Adherence to advice to change the dose of PT was reported without reasons.	• Staff and patient perceptions – Most patients and staff valued the assessments and attention paid to their needs; most patients agreed with the advice given by therapists; most OTs agreed with therapy goals advised by NMD experts; nearly half agreed that NMD experts were easy to contact; all PTs appreciated receiving advice; most PTs agreed with six statements related to implementation of advice(clarity of treatment location, feasibility of therapy duration, feasibility of treatment location, completeness of advice, ability to provide information and opportunity for discussion).

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
8	(Demers and McKinley, 2015)	Stroke	Biweekly 45-min group-based dance intervention over 4 weeks. Followed structure of usual dance classes, exercises modified and progressed to meet individual's needs. Aim to improve multiple components of physical functioning.	• Attrition - participants discharged from rehabilitation before the completing intervention; some did not like the intervention, often experiencing mild to moderate fatigue afterwards; significant increase in fatigue reported, even when exercises were modified to increase rest time. • Staff perceptions - open (treatment) room resulted in temporary loss of space for other therapists, possible noise disturbance.	• Patient perceptions –some satisfied with intervention; preferred fast, strong rhythmic music; challenging, but enjoyable activity. • Researcher perceptions – low frequency ensured therapists availability; space, equipment helped; additional assistance helped; acceptable to stroke team, program coordinators, perceived as fun, innovative, did not impact usual care. • Adherence - intensity graded for each participant according to endurance levels.
9	(Douglas, 2014)	Dementia	Non-electronic external memory aids (large print visual schedules, reminders, memory wallets with pictures, family scrapbooks with important events). Aim to increase positive communicative interactions and decrease negative behavioural problems.	• Perceptions of the intervention - lack of necessary staff to both implement, sustain intervention; lack of physical materials, time to create memory aids; outcomes must match the research evidence for payment. • Non-adherence - dignity and confidentiality worries concerning country legislation; memory aid was hidden from patient, other staff.	• Caregiver perceptions - caregivers' positive attitudes and engagement in the intervention; caregivers willing to engage. • Staff perceptions - facility director supporting "any" perceived useful intervention; multidisciplinary support. • Adherence - visibility of memory aid; supportive staff continuing the intervention after SLT has left.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
10	(Gage et al., 2014)	Parkinson's Disease	Six week specialist domiciliary rehabilitation service for people with Parkinson's and carers. One visit from one professionals each week. Aim not explicitly reported. Implied as optimising knowledge and skills to cope with everyday life, improve or maintain independence.	• Patient perceptions of the intervention - least acceptable components included the briefness of the intervention - insufficient time and felt some parts of intervention not required. • Trial related barriers - workload, available resources, constraints imposed by the research environment e.g. staff lack of research experience and perceiving research would constrain their practice.	• Staff perceptions - team perceived themselves as effective; strong leadership, involvement of team members in the development of the intervention, regular case review meetings, administrative support, underlying intervention philosophy all helped. • Adherence - team meetings improved patient care and provided support, team cohesion, staff development (improved knowledge and understanding), and hence enhancing job satisfaction. • Patient perceptions - positive acceptability and usefulness of intervention by patients and carers.
11	(Haines et al., 2007)	Included Stroke	Exercise programme, three times per week - 45 minutes. Used visualisation and tai chi with functional movements. Aim to prevent falls in the subacute hospital setting.	• Non-adherence - refusal (being too tired from earlier 'usual care' physiotherapy session); ill-health, alternate appointment (such as an occupational therapy home visit).	• Not described.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
12	(Halle et al., 2014)	Stroke	Family (significant other) based aphasia rehabilitation. Aim to positive changes in significant others' (carers) psychosocial well-being, improvements in significant others' skills and behaviours in conversation and communication.	• Non-adherence – Unavailability of significant others, "challenges" to include them, affected intervention delivery; lack of therapist experience in including significant others; lack of time to meet significant others during shortened hospital admission; dealing with broader psychological adjustment issues of significant others; significant others were not invited to assessments perceived as too demanding.	• Adherence – experience of the intervention helped SLTs include significant others; flexible locations offered; provision of printed information; information from the significant other ensured meaningful therapy; use of natural context (e.g. home). • Perceptions - including significant others perceived as a bonus; because of the intervention, SLTs were able to refer significant others to social workers or psychologists or collaborated with those professionals.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
13	(Johannessen et al., 2014)	Dementia	Psychosocial and educational intervention. Carers - five counselling sessions. The person with dementia - two meetings, extended family participated - one meeting. Carers introduced to cognitive techniques. Aim to provide home-dwelling people with dementia and families with knowledge and skills to cope with everyday emerging problems, stresses.	• Staff perceptions – health professionals lacked knowledge about community lives of service users and awareness of participants' abilities to problem-solve; difficulties following the manual during group meetings. • Trial related barriers - recruitment difficult due to carers being unable to leave the person with dementia without care; carers did not want to sit in a group talking about their problems; recruiters did not "hear" about new cases.	• Adherence – trained, knowledgeable health professionals; structured tailoring group interventions, using activity helped engagement; structured individual interventions helped engagement; two leaders supported each other; group leaders supervision helped; meeting other health professionals helpful; time and space for the intervention; listening to carers needs. • Staff perceptions – patients with earlier stages of dementia used the group setting therapeutically; carers felt more comfortable to engage when family member safely cared for. • Trial related facilitators - collaboration between the specialist health services, GPs and health workers in the municipalities to aid recruitment; pre-existing communication channels with patient groups aided recruitment.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
14	(Mackenzie et al., 2014)	Stroke	Behavioural dysarthria intervention over eight home-based sessions, included practice (appropriate words, sentences, conversation), plus non-speech oro-motor exercises. Aim to improve word intelligibility and communication effectiveness.	Barriers were not formally identified. • (Inferred) Attrition or non-adherence - personal, domestic situations e.g. work commitments, family members' health, support; practice records recorded amount of practice time not how practice was approached; DVD format difficult to use for some living alone, some unable to use consistently.	• Adherence – experienced therapists to deliver the intervention; practice along with the demonstration DVD, imitating the speech models presented; home-based intervention supported attendance and engagement; individualised practice stimuli helped engagement; providing assistance helped records to be completed and family volunteers assisted maintaining records and practice of intervention. • Perceptions of intervention –positively received by patients; most participants recommended more sessions required; none thought there should be fewer sessions.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
15	(Mahoney et al., 2006)	Dementia	Home-based bathing intervention involved teaching, role-modelling, and coaching patients and carer dyads over 3 weeks. Aim to improve behavioural symptoms and caregiver self-efficacy to improve the bathing experience at home.	• Non-adherence - most homes lacked safety equipment; many caregivers were frail and safety was a concern, fear was antecedent of resistance to bathing; home environment sometimes chaotic; unpredictability of care recipient behaviour; refusing entry to the home; caregivers perceiving that they did not have capacity to have another person in the house; caregiver hearing impairment affected ability to receive information and respond to cues; some caregivers believed they had ''tried that before'' or attributed behaviour to obstinacy not disease and context; dyad's relationship powerful influence; frailty of caregivers affected ability to carry out advice; caregiver self-efficacy affected learning new skills. • Trial related barriers - difficulty accessing the population in the community.	• Adherence – early identification of caring dyads prior to crisis; in vivo observation essential to develop individualised interventions, developing caregiver skills; trained nurse; nurse experienced with study population; flexible timing to meet needs; trusting relationship between the nurse and dyad is vital; recognition of complex caregiver situations; motivation of caregivers positively affected intervention receipt; time for coaching, practice, and support. • Perceptions of intervention –some caregivers wanted to learn new skills, contribute to research, some saw study as best hope for care at home.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
16	(Merlo et al., 2013)	Stroke	Intensive mobility training performed 3 hours per day for 10 consecutive weekdays. Aim to stimulate functional recovery of gait, balance, and mobility.	• Patient perceptions - frustrated about short duration perceived as taking away a helpful intervention; one individual negative experience secondary to fear of falling; fatigue temporarily affected levels of functioning; intensity of the intervention perceived as difficult initially.	• Patient perceptions - frequent comments on their level of satisfaction and enjoyment of the therapeutic experience.
17	(Morrison and Backus, 2007)	Spinal cord injury	Locomotor training modalities, such as body weight-supported treadmill training. Aim to improve the recovery of walking in individuals with motor incomplete spinal cord injury.	• Intervention cost - profit margin for the three different payer mix types: Medicare and Medicaid showed a net loss per visit of $63.99 and $112.77 respectively. • No other barriers reported.	• Intervention cost - profit margin for the three different payer mix types: commercial insurer showed a net revenue per visit of $204.84. Commercial insurance showed a net income per visit of $43.44. • No other facilitators reported.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
18	(Nanninga et al., 2015)	Stroke	Combined Clinical and Home Rehabilitation (CCHR) - task and context-specific training. Two 45-minute home sessions weekly for two to five weeks. Aim to improve functional independence at home.	• Non-adherence - starting early (i.e. within four weeks) became a barrier for some (not explained); therapists unfamiliar with community locations, required adjustment time; logistically the team was restricted in providing community intervention and covering existing clinic demands; travel time and tailor intervention components. • Stakeholder perception - board of directors and health insurance experts foresaw financial and legislative problems because Dutch inpatient and outpatient therapists work in separate organisations with different employment relationships and financing agencies.	• Adherence – therapists embraced the intervention and were engaged with it; because the intervention provided therapists with insight into the home environment, therapists were able to tailor the intervention more effectively; • Patient perceptions - considered intervention appropriate and helpful; home treatments made family members feel competent in the absence of the therapist; appropriately connected to weekend leave from hospital. • Stakeholder perceptions - redefining the problem and integrating practical and contextual knowledge of regional managers, therapists, and financial and policy experts in the local knowledge co-creation process helped to gain ownership of the intervention for sustainability; all participants supportive of improved integration between primary and secondary stroke care services.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
19	(Prick et al., 2014)	Dementia	Exercise and support intervention the person with dementia and caregiver. Support component, included: (a) psycho-education; (b) communication skills training; (c) pleasant activities training. Aim to motivate dyads to complete 30 minutes exercise at least 3 days a week.	• Attrition - morbidity; caregiver perceived burden of providing care, health problems. • Non-adherence - cancelling or rescheduling session for health issues participant or caregiver, health care visits, funerals, work obligations of the caregiver, change in day-care, planned holidays of the dyads; homework exercise not carried out due to physical impairments, fatigue of the person with dementia, time constraints, caregiver burden, difficulties for caregiver to motivate participant; the intervention negatively revealed impairments to the participant. • Trial related barriers - recruitment barriers included reconsidering participation intensity; expected caregiver burden; lack of time, lack of participant cooperation, advising against participation by neurologist.	• Adherence –motivated dyads, specifically for exercise component, dyads interested in sport and/or healthy; some participants and caregivers found pictures in the manual most useful; most caregivers found the exercise coach had most influence. • Patient perceptions - most experienced some benefits from the exercises. • Trial related facilitators - recruitment aided because of hope they derived and a positive effect of on cognitive functioning.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
20	(Richardson et al., 2015)	Stroke	Self-management and task-orientated functional training with 10 visits per patient. Home-based Aim to optimize physical function and self-management skills.	• Attrition - mortality and morbidity. • Non-adherence –more difficult for patients with cognitive issues; newer stroke survivors had more difficulty understanding the relevance of the intervention; patients with a personal support workers to assist them were less motivated to engage; older patients, were less engaged; unusual practice for some therapists to provide rehabilitation in the home.	• Adherence –motivated patients with minimal cognitive impairment; joint OT and PT working facilitated problem-solving, with consistent goal setting; intervention relevant at home and motivated the patient; practice helped therapists' competency delivering the intervention. • Staff perceptions - motivated patients with adequate cognitive function were easiest to engage. • Intervention training - therapist training programme that involved patients for practice sessions enabled improved therapists' competency before engaging with trial participants.
21	(Siemonsma et al., 2014)	Stroke	Home-based rehabilitation - task and context-specific training replacing inpatient rehabilitation. Aim to increase participation in daily life.	• Perception of the intervention - perceived as time consuming; collaboration and client involvement; lack of appropriate equipment in the home environment; cost of innovation where the financial burden loaded on the acute hospital setting.	• Perceptions –relevant, encouraged active patient involvement; relative advantage related to perceived effectiveness, reduced hospital stay, no adverse events reported, reduced carer strain; participant, carer acceptability positively affected motivation. • Adherence –collaboration of whole team positive; organisation, coordination, transition of intervention into the home.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
22	(Speelman et al., 2014)	Parkinson's Disease	Multifaceted intervention (PARKFIT). PTs as activity coaches guided patients in active lifestyle during monthly individual sessions, educated patients about the benefits and suitable activities. Group exercise to experience social support. Also included regular PT. Aim to promote physical activity.	• Intervention training - some therapists indicated that training lacked sufficient information on theories about behavioural change but it is not clear if this presented a barrier. • Non-adherence - co-morbidity; cognitive limitations; lack of motivation; increased disease severity; physical limitations and cognitive decline main reasons for goal setting difficulties.	• Perceptions – patients indicated they would recommend the program to others; PTs indicated they wanted to use the intervention with others. • Adherence – most therapists felt competent to offer the intervention (an assumed facilitator of implementation); most popular tool - (electronic) Activity Monitor; individually tailored intervention enhanced adherence but there was no specific clarification of this assumption; the disease-specific knowledge of the therapists may explain the high adherence - therapists anticipated potential adherence barriers that were then addressed.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
23	(Sturkenboom et al., 2013)	Parkinson's Disease	Home-based OT. Delivered for 10 weeks and up to 16 sessions (45–60 minutes). Aim to optimise a person's functional performance and engagement in everyday activities and life roles.	• Intervention training - adaptations in instructions and training are needed to use outcome measures. • Attrition - patient morbidity or worsening of symptoms. • Non-adherence – formulating treatment goals was implied as a barrier but without further explanation; lack of willingness or ability to change behaviour (skills or routines) in some patients; duration of 10 weeks perceived too short by some therapists and patients and caregivers to achieve behavioural changes, delivery of some aids and adaptations; therapists perceived diagnostic phase too lengthy for some patients.	• Perceptions – patients and caregivers valued the intervention especially the diagnostic phase, client-centred approach, involvement of the caregiver and the home setting; therapists were satisfied with the outcomes. • Adherence – expertise of the therapist and "personal click" (rapport) were deemed important, as well as unity and sharing between patient and caregiver; the structure of the protocol was helpful to therapists; time and coaching in the intervention improved confidence and competence in conducting the intervention according to the protocol.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
24	(Thomas et al., 2014)	Stroke	Systematic voiding programme (SVP) for patients with urinary incontinence. Individualised SVPs tailored to the physical and cognitive capabilities of each patient, weekly progress review. Aim to improve urinary continence.	• Non-adherence –choosing schedule for voiding, increasing time between voids was confusing; not all aspects of the new practice (e.g. giving praise) were liked; intervention not prioritised over 'technical', aspects of acute care; adequate staffing to toilet patients; division of labour, responsibility for changes to patient's programme; • Staff perceptions - value of intervention less visible, could increase feelings of guilt; perceived as ''extra work'' main challenge; difficult to judge success, did not receive outcome feedback; patients could be ''stressed out'' by intervention. • Trial related barriers - the ward did not always receive the extra staff funded by the study.	• Staff perceptions - shared understanding, no disagreement about intervention aim; appreciated potential intervention benefits, including improved self-esteem and independence; intervention gave patients a goal, patients could see improvement, which boosted their morale; benefits in terms of ''saving effort later'', such as less washing and changing beds, were recognised. • Adherence –The study healthcare assistant took responsibility for paperwork and communicating with ward staff, aiding implementation; qualified staff involved in inducting new staff and ensuring that everyone was aware of the study on the morning ward handover; ward staff organised daily tasks in order to implement the intervention.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
25	(Van't Leven et al., 2012)	Dementia	Community OT in Dementia (COTiD), psychosocial interventions for dementia patients and carers. Ten 1-hour sessions in a 5-week period. Participants learn to choose and prioritise meaningful activities to improve. Total time about 18 h for one client carer dyad (Graff et al. 2006, 2010). Aim to improve functional performance.	• Stakeholder perceptions - need for more defined indicators of functional issues, relative advantage of the intervention to aid referral decisions; reimbursement and lack of available trained OTs. • Non-adherence – therapists did not feel competent following the intervention protocol; reported a lack of specific knowledge about dementia; role models and feedback about their performance (as therapists) missing, felt unsure about encouraging referrals for the intervention; difficulties prioritising the intervention in relation to health insurance system i.e. Dutch health insurance provide 10 hours occupational therapy per year. Most OTs did not prioritise using this quota for the intervention; intervention development did not fit with strategic goals of OT departments; OTs unsure of minimal adherence criteria; intensity perceived as too high without sufficiently quick solutions; overlap and competition with other service providers.	• Adherence –the intervention guide's content and focus helps the OTs in marketing activities, positive feedback from a referring physician and commitment from management or other departments helped OTs engage with the intervention. • Stakeholder perceptions - physicians and managers found the evidence in the intervention guide useful; the direct benefits of the intervention for clients and carers was better understood.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
26	(Veenhuizen et al., 2011)	Huntingdon's Chorea	Outreaching multidisciplinary intervention. Assesses disease stage, formulates, coordinates and implements individual in the home. Aim to optimise functioning and quality of life.	• Staff perceptions - Working in a chain of therapists and caregivers, professional and informal, on implementing the care plan is often successful, although sometimes difficult to organise.	• Perceptions – most patients, carers and health professionals saw the intervention as beneficial. • Adherence –trained doctors and therapists are necessary to identify problems and their solutions.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
27	(Voigt-Radloff et al., 2011)	Dementia	Community OT in Dementia (COTiD) programme (as above but delivered in a different country). Aim to improve functional performance.	• Non-adherence – (perceived by OTs) some received inaccurate patient details; some patients missed appointments due to competing appointments, forgetting; cognitive deficits, disorientation; some patients with functional problems did value the benefit of the intervention, actively refused; carer burden, unwilling to change routines; extended travel time; some patients did not understand the intervention, inability to differentiate the intervention from usual care, communication, cognition or mood problems; some family conflicts; lack of awareness of dementia by some carers. • Patient perceptions – some were sceptical or abrasive about the intervention.	• Adherence –OTs rated how influential perceived apriori facilitators were in supporting implementation of the intervention and these were 1. Pre-existing knowledge [of condition and interventions], 2. Preparation to deliver the intervention [training] and 3. Support provided from the site. These were not found to be closely related to performance of therapists in the study.

Study ID	Author(s)	LTNC	Complex intervention(s)	Barriers	Facilitators
28	(Wesson et al., 2013)	Dementia	Fall prevention programme with strength and balance training exercises and home hazard reduction. The 12 week intervention program was conducted in participants' homes. Tailored to participant's individual cognitive levels and implemented as a carer-supported intervention. Aim to reduce falls.	• Patient perceptions – some lack of receptiveness to intervention; Complaints of minor muscle pain following exercise. • Non-adherence – some patients refusing one element (home safety recommendations); higher carer stress tended to result in lower adherence; physical illness and hospitalisation, or residential care placements, or availability of carers to assist, or being inactive prior to intervention interfered with some elements of the intervention. • Attrition - carer/patient not interested, or had a lack of time, or the intervention was seen as unnecessary or the timing not good, or patient was admitted to hospital, or unwell and then ceased intervention).	• Adherence – 1. For the home safety component older participants (>80years old) with a high fall history resulted in higher enthusiasm to engage, straightforward home changes also resulted in higher adherence; 2. For the exercise component those who found the intervention acceptable, a history of falls and a poorer cognition showed greater adherence. Key: PT = Physiotherapy / Physiotherapist OT = Occupational Therapy / Occupational Therapist SLT = Speech and Language Therapy / Speech and Language Therapist RCT = Randomised controlled trial MDT = Multidisciplinary team

3.5.2.3. Relations to implementation frameworks

Individual themes of the barriers and facilitators identified are now explained in more detail and their root causes described using the constructs from the implementation frameworks CFIF and CFIR. Some discussion related to the findings will occur within this section.

Theme 1 - Adherence to the complex intervention

Most studies described or implied barriers or facilitators to adherence and of these, 24 studies described barriers and 23 studies described facilitators. Whether an intervention was adhered to was reflected in terms of both the provider and the recipient and described in varying detail. Studies used textual descriptions and two studies also included numerical results (Barzel et al., 2015, Bovend'Eerdt et al., 2010). Descriptions provided a rich understanding of factors that moderated adherence as well as an understanding of how well a protocol was adhered to.

The adherence theme mapped to the CFIF construct "adherence" in terms of content, coverage, frequency duration and the construct "moderating factors" in terms of participant responsiveness, intervention complexity, and facilitation strategies. None of the studies reported against quality of delivery. Under moderating factors some studies explained how the context affected adherence. For example, Brady et al. (2011) reported that some patients perceived a, "lack of appropriate equipment" to be able to carry out the intervention, whilst others the opposite. Similarly, in terms of practicing the intervention, some participants perceived a "lack of support in adapting their oral routine to

overcome stroke related impairment(s)", while others perceived receiving support. These factors seemed closely linked to the fidelity of the intervention but not related to adherence (content, coverage, frequency or duration). They were also both described at opposite poles (barriers and facilitators) as if they were a moderating construct i.e. when the equipment was available to a patient they were able to be supported by the health professional to practice or receive the oral health care intervention. The absence of appropriate equipment and or health professional support resulted in the intervention's implementation being affected negatively i.e. not carried out at all or less frequently.

The frequency of each unit of text that mapped to a CFIF construct was counted. The most frequently occurring CFIF constructs were all Moderating Factors that describe why an intervention was or was not adhered to:

- Facilitation strategies (59 units of text) reported in 23 of the 28 studies.
- Participant responsiveness (40 units of text).
- Context (34 units of text).

A lack of resources affected adherence negatively (Mackenzie et al., 2014, Mahoney et al., 2006). Tools and aids were not always available (Mahoney et al., 2006). Equipment could not be adapted to meet patient needs (Mackenzie et al., 2014). Some studies reported resources were available to clinicians who used these to aid adherence. Experts in an intervention were used for advice (Brady et al., 2011) and tools used to deliver an intervention (Brady et al., 2011, Douglas, 2014, Halle et al., 2014, Mackenzie et al., 2014, Prick et al., 2014, Speelman et al., 2014). Environments were also a facilitating resource in

terms of space offered (Johannessen et al., 2014, Mackenzie et al., 2014) and the naturalistic environments in which to deliver the intervention (Halle et al., 2014, Mackenzie et al., 2014, Mahoney et al., 2006, Nanninga et al., 2015, Richardson et al., 2015). These were mapped to Damschroder et al. (2009) available resources part of the construct readiness for implementation in the inner setting.

Training in conducting the intervention was seen as a facilitative strategy (Gage et al., 2014, Johannessen et al., 2014, Sturkenboom et al., 2013, Thomas et al., 2014, Veenhuizen et al., 2011, Voigt-Radloff et al., 2011) and mapped to available resources. Working as part of a multidisciplinary team was a supportive resource for adherence (Bovend'Eerdt et al., 2010, Gage et al., 2014, Richardson et al., 2015, Siemonsma et al., 2014) that was also mapped to available resources.

Studies reported the availability of support to practice the intervention and record practice sessions, aided adherence (Brady et al., 2011, Braun et al., 2010, Douglas, 2014, Johannessen et al., 2014, Mackenzie et al., 2014, Mahoney et al., 2006, Prick et al., 2014, Richardson et al., 2015, Thomas et al., 2014). These were also mapped to available resources. Even where resources were available, some studies reported that clinicians did not use them (Brady et al., 2011). The reasons for this are not explained and as such mapping this to the CFIR becomes harder.

Studies indicated that some adherence issues were due to prioritising the intervention above other competing work demands (Nanninga et al., 2015, Thomas et al., 2014). This was seen as a barrier to adherence (Siemonsma et al., 2014, Thomas et al., 2014) and mapped to relative priority, part of the construct implementation climate.

Receiving team feedback was seen as important (Gage et al., 2014, Johannessen et al., 2014, Van't Leven et al., 2012, Voigt-Radloff et al., 2011) and studies indicated that a lack of feedback negatively affected adherence (Voigt-Radloff et al., 2011). Receiving feedback was mapped to goals and feedback under the implementation climate construct.

Adherence was described as 'accomplished' if tailoring was possible (Bovend'Eerdt et al., 2010, Demers and McKinley, 2015, Halle et al., 2014, Johannessen et al., 2014, Mackenzie et al., 2014, Nanninga et al., 2015, Richardson et al., 2015). Using alternative communication methods to meet patient needs such as email (Bentley et al., 2014) and spending time building rapport (Mahoney et al., 2006, Sturkenboom et al., 2013) were all mapped to adaptability of the intervention in the intervention characteristics domain.

There were 41 examples of participant responsiveness reported. Factors including age, disease severity e.g. extent of cognitive impairment, physical limitations, sensory impairment and symptoms such as behavioural problems and fatigue interfering with adherence (Allison and Dennett, 2007, Bentley et al.,

2014, Bovend'Eerdt et al., 2010, Demers and McKinley, 2015, Haines et al., 2007, Halle et al., 2014, Mahoney et al., 2006, Prick et al., 2014, Richardson et al., 2015, Speelman et al., 2014, Voigt-Radloff et al., 2011, Wesson et al., 2013). Clinicians reported that those people with intact cognition adhered better to interventions (Richardson et al., 2015) whereas others reported that people with poorer cognition and who were older adhered better (Wesson et al., 2013). This view was not universal though as one study reported that older people adhered less well compared to younger people (Richardson et al., 2015). Illness affected the intervention delivery (Braun et al., 2010, Haines et al., 2007, Prick et al., 2014, Speelman et al., 2014, Sturkenboom et al., 2013, Wesson et al., 2013). Similarly, where dyads where the recipient of an intervention and the carer became frail or ill this impacted negatively on the patient (Halle et al., 2014, Mahoney et al., 2006, Wesson et al., 2013).

In some studies, carers and clinicians reported that patients were unable to engage with an intervention. This was sometimes linked to specific behaviours for example patients becoming frustrated by 'thinking too much' (Braun et al., 2010). In others no reason was given. (Braun et al., 2010, Sturkenboom et al., 2013, Voigt-Radloff et al., 2011).

Two studies reported that clinicians listening to their patients and hearing their needs aided adherence (Halle et al., 2014, Johannessen et al., 2014). One study reported that adherence was affected by patients misunderstanding the intervention (Voigt-Radloff et al., 2011). All of these participant responsiveness

issues were related to patients or their carer's needs and therefore mapped to patient needs and resources in the outer setting domain of CFIR.

Clinicians reported that patient/participant motivation affected adherence. (Prick et al., 2014, Speelman et al., 2014). This was not detailed any further but might have been reflected as fear about some aspect of the intervention as identified by some clinicians (Mahoney et al., 2006, Merlo et al., 2013) or that the intervention was too difficult to engage with fully (Barzel et al., 2015). Adherence and participant responsiveness improved with practice and as self-efficacy increased (Barzel et al., 2015, Braun et al., 2010) alongside increasing motivation of patients, carers and clinicians (Barzel et al., 2015, Nanninga et al., 2015, Prick et al., 2014, Richardson et al., 2015). A lack of contextual description in the studies mean that mapping these factors onto CFIR is open to interpretation. However, the construct most closely aligned with motivational aspects is self-efficacy in the individuals involved domain. This is not a close fit in terms of the current definition because the domain is said to encompass those who deliver the intervention. However, as rehabilitation relies on active participation of the patient and the clinician (Wade, 2015b), then the author has suggested that service-users (patients, carers and anyone else in receipt of the intervention) are also included in this domain.

There were 33 examples reported where contextual factors affected adherence. Some positive and some negative. Clinicians noted that adherence was affected because other providers were already delivering all or part of the new intervention locally (Van't Leven et al., 2012). This was not well described but

was mapped to tension for change, as it was thought that the tension for change locally was not present. Tension for change is part of the implementation climate construct in the inner setting in CFIR.

Studies reported that clinicians competed with other health and care providers for the patient's time (Bentley et al., 2014, Braun et al., 2010, Haines et al., 2007, Prick et al., 2014, Voigt-Radloff et al., 2011, Wesson et al., 2013) and that patients were discharged resulting in insufficient time to deliver interventions (Demers and McKinley, 2015, Halle et al., 2014). These contextual barriers imply that the new intervention took second place to other occurrences out with the control of the trialists and therefore mapped to relative priority in the implementation climate construct.

Patients and clinicians reported that the amount of travel required to provide or receive an intervention resulted in a barrier to adherence (Bentley et al., 2014, Nanninga et al., 2015, Voigt-Radloff et al., 2011). Others reported that having the ability to provide flexible locations and appointments was a facilitator to adherence (Halle et al., 2014, Mahoney et al., 2006). Travel requires multiple resources including time, capacity to drive and funding and as such was mapped to available resources in the readiness for implementation construct in the inner setting domain.

In some studies, the new intervention needed to be delivered in a setting outside of the clinicians' usual practice and this was indicated as a barrier to

adherence (Cup et al., 2011, Nanninga et al., 2015, Richardson et al., 2015, Van't Leven et al., 2012). Detail to explain this was not available but implied to be due to a lack of self-efficacy on the part of the clinician and mapped to the self-efficacy construct in the individuals involved domain.

Carer burden affected their ability to support patients in receiving interventions (Bentley et al., 2014, Mahoney et al., 2006, Prick et al., 2014, Voigt-Radloff et al., 2011, Wesson et al., 2013). Competing wider family obligations and chaotic home situations affected adherence (Bentley et al., 2014, Mackenzie et al., 2014, Voigt-Radloff et al., 2011, Mahoney et al., 2006) as did work commitments (Bentley et al., 2014, Braun et al., 2010, Mackenzie et al., 2014, Prick et al., 2014, Veenhuizen et al., 2011). These issues were related to the needs of patients or their carers and as such were mapped to the construct patient needs and resources in the outer setting domain.

One study raised potential issues related to breaches of confidentiality, dignity legislation and an organisation's policies that affected adherence to the intervention (Douglas, 2014). This was mapped to the construct external policy and incentives in the outer setting domain because legislation acted as a barrier to part or all of an intervention.

Theme 2 - Perceptions of the Intervention

Fourteen studies reported providers' perceptions of the intervention, 16 from service-users, five from carers, and one from a board of directors. Two studies

reported perceptions of wider stakeholders i.e. funding agencies. Thematic analysis suggests these were perceptions about general acceptability and personal meaning, specific intervention-related, evidence-base, the external setting and cost and finally patient responsiveness. Some studies [14] reported in a single identified theme whereas eight studies reported perceptions from multiple themes.

Understanding the perceptions held by stakeholders about a new intervention can help to demonstrate its acceptance and therefore the willingness to change the status quo. Even if the quality of an intervention is high, the effect it has on patient outcomes might be zero if the acceptance is zero (Sermeus, 2015). Acceptance might be preferred with a suboptimal intervention. Thus when designing interventions, researchers should be cognizant of how perceptions are altered and behaviours changed to optimise acceptance.

Perceptions specifically related to patient responsiveness were reported by two studies (Richardson et al., 2015, Siemonsma et al., 2014) and both were reported as facilitative. Two studies (Brady et al., 2011, Douglas, 2014) reported concerns about the evidence-base (CFIR domain one; Intervention Characteristics) and one of these then related this to cost and perceived reimbursement problems from a funding agency (Douglas, 2014). Two studies identified negative perceptions related to the policy context of the provider i.e. policy and legislation (Nanninga et al., 2015, Van't Leven et al., 2012). Perceptions of acceptability and personal meaning are represented by the construct patient needs (CFIR Domain two; Outer Setting). These were reported

in 13 studies, with only two (Merlo et al., 2013, Voigt-Radloff et al., 2011) describing barriers (negative perceptions). All others (Barzel et al., 2015, Cup et al., 2011, Douglas, 2014, Gage et al., 2014, Haines et al., 2007, Mackenzie et al., 2014, Merlo et al., 2013, Prick et al., 2014, Siemonsma et al., 2014, Speelman et al., 2014, Veenhuizen et al., 2011) indicated that perceptions were positive and facilitative. Perceptions related to the details of the intervention itself (CFIR Domain 4; Individuals involved) were reported negatively in four studies (Demers and McKinley, 2015, Douglas, 2014, Siemonsma et al., 2014, Veenhuizen et al., 2011) and positively in four studies (Haines et al., 2007, Mackenzie et al., 2014, Sturkenboom et al., 2013, Wesson et al., 2013) and seven studies (Braun et al., 2010, Cup et al., 2011, Gage et al., 2014, Johannessen et al., 2014, Thomas et al., 2014, Van't Leven et al., 2012) reported both positive and negative perceptions.

Theme 3- Attrition

Problems with retaining participants in trials can increase the risk of Type II errors, incorrectly concluding that there is no effect between an intervention and a control (Adamson et al., 2015). Current understanding of attrition is lacking but its importance is recognised (Adamson et al., 2015, Treweek, 2015). To comprehend attrition will improve the implementation of interventions in future trials.

Further thematic analysis of the 10 studies reporting the attrition theme resulted in sub-themes:

- Intervention intensity

- Personal relevance
- External factors.

All studies [10] reporting attrition barriers were mapped to both CFIF and CFIR constructs. The first being Carroll et al. (2007) Patient Responsiveness construct under Moderating Factors and Damschroder et al. (2009) Patient Needs and Resources within the Outer Setting. Simultaneous mapping was considered the best fit is because both constructs cover issues associated with participating in interventions and whether an organisation (in this case the trial) fully understands the target patients sufficiently well.

Attrition can be associated with the intervention or trial failure to meet the needs of the participants, placing too high a burden on individuals (Treweek, 2015). None of the studies reported success with resolving attrition. However, two studies reported that attrition occurred even when the intervention intensity was modified to try and meet participant need (Allison and Dennett, 2007, Demers and McKinley, 2015). In both cases the intervention resulted in fatigue not tolerated by participants. The reported intervention intensity issue is reflected in the Frequency construct of CFIF and attempts to ameliorate the problem are reflected in the Adaptability construct of CFIR. Both studies report detail about the burden on participants suggesting that trialists considered the patient needs and resources in the outer setting.

Attrition may occur because the participant does not see its relevance personally (Sermeus, 2015). Four studies reported participants' negative views of the interventions, such as not perceiving the benefit or disliking it and dropped out (Braun et al., 2010, Cup et al., 2011, Demers and McKinley, 2015, Wesson et al., 2013); whereas some participants reported dropping out of the trial because they had changed their minds (Bentley et al., 2014). These barriers are mapped to the patient needs and resources in the outer setting domain.

Attrition may be due to factors beyond the control of the participant, trialists or clinician. One study reported that hospital discharge was the cause of the attrition (Demers and McKinley, 2015). This example is mapped as a barrier to Implementation Climate in the Inner Setting of CFIR because it reflects the lack of relative priority given to implement the intervention versus other competing priorities. Eight studies reported other external factors such as carer burden, illness and death (Barzel et al., 2015, Bentley et al., 2014, Mackenzie et al., 2014, Nanninga et al., 2015, Prick et al., 2014, Richardson et al., 2015, Sturkenboom et al., 2013, Wesson et al., 2013). All nine studies were mapped onto the Context construct in Moderating Factors in CFIF and patient needs and resources in the outer setting domain.

Theme 4 - Trial Related Issues

Seven studies reported trial-related barriers (Brady et al., 2011, Braun et al., 2010, Gage et al., 2014, Johannessen et al., 2014, Mahoney et al., 2006, Prick et al., 2014, Thomas et al., 2014). Two of these also reported trial-related

facilitators (Johannessen et al., 2014, Prick et al., 2014). Varying levels of detail are provided.

Further thematic analysis of the 10 studies reporting trial-related issues resulted in two sub-themes, 'participant recruitment' and 'trial processes'. The method of reaching a designated population on which to test health interventions is one of great importance and difficult to achieve. It is known that approximately half of all trials do not meet recruitment targets and even with extensions, some still fail (Sully et al., 2013, Treweek, 2015). Some of the reasons for recruitment issues are known through a review (Sully et al., 2013) and methods to overcome recruitment problems are explored in a further review (Treweek et al., 2010). However, these represent only RCTs and they were not focussed solely on LTNCs. Not only does recruitment pose an economic issue for trial funders but also an innovation problem, increasing the risk that new interventions will be abandoned before their true effectiveness is known and potentially allow patients to continue to receive ineffective treatments (Treweek, 2015).

Studies reported barriers associated with accessing the right population in the community (Mahoney et al., 2006) and recruiters not "hearing" about the relevant population to invite (Johannessen et al., 2014). Recruitment barriers that reflect identifying potential populations in communities were mapped to Cosmopolitanism in the Outer Setting in CFIR because this construct relates to the connectedness of the trial organisation and networks it has with relevant external stakeholders. Likewise, two studies report how collaboration with the inner and outer setting and communication channels facilitated recruitment

(Johannessen et al., 2014, Prick et al., 2014) and these facilitators were also mapped to Cosmopolitanism.

Less specific recruitment problems were also identified as trial-related issues (Johannessen et al., 2014, Prick et al., 2014). For example, carers felt burdened by the demands of the study and so did not consent. These included being unable to leave the person who had dementia without care, implying that care was not provided by the study (Johannessen et al., 2014), carers did not want to be in a group and talk about their problems (Johannessen et al., 2014), the intensity of the intervention was perceived as too high and carers didn't have sufficient time and participants were not "cooperative" (Prick et al., 2014). All of these barriers were mapped to a lack of understanding of Patient Needs and Resources in the Outer Setting of CFIR on the assumption that either recruitment criteria and or methods did not meet the needs of the target population as suggested by Treweek (2015). One study reported that participants felt the research gave them "hope" of improved health outcomes and this helped with recruitment (Prick et al., 2014). This was also mapped to Patient Needs and Resources as a facilitator.

Other recruitment issues included physicians advising people against becoming involved (Prick et al., 2014) and mapped to Relative Advantage in the Intervention domain. This construct reflects whether key people, such as referrers, perceive the intervention to be more beneficial than an existing alternative, for instance what occurs in usual practice.

Further trial-related issues were connected to processes. One study reported that the ward on which an intervention was being delivered did not receive the additional staff for which funds (Excess Treatment Costs) had been allocated (Thomas et al., 2014). The Department of Health funding mechanism for non-commercial health and social care research changed in the UK in 2012 (Attributing costs of health and social care research and development (AcoRD) (Department of Health, 2012). The introduction of excess treatment costs of patients under meant that those delivering trial interventions were not "specialist" research therapists employed by research teams but rather everyday practicing NHS healthcare practitioners. The management of Excess Treatment Costs within the NHS remains an issue that the Department of Health and commissioners continue to struggle with (Palmer et al., 2016). This was mapped to Readiness for Implementation in the Inner Setting in CFIR because it relates to adequate access to resources, such as additional clinical staff needed to implement a new intervention within a trial. Another study reported issues to do with insufficient training, which affected intervention adherence (Braun et al., 2010) and was mapped to Readiness for Implementation.

Research staff experienced workload issues and tensions with research constraints in two studies. In the first, ward staff found it challenging to provide the research intervention to the right patients because not all inpatients were recruited to the trial (Brady et al., 2011). In the second clinicians implementing the intervention perceived the workload as overly intensive, that working to a trial protocol was daunting and recruitment allocation frustrating when they were aware that some patients had not been allocated to receive the new intervention (Gage et al., 2014). These aspects were mapped to Implementation Climate in

the Inner Setting of CFIR because this construct reflects the receptivity to implementation. Within this construct are further sub-constructs that are considered appropriate matches; compatibility of the new intervention with the values held by those who implement it, the Relative Priority that the organisation demonstrates (through its staff) of implementing new interventions and the degree to which staff perceive the status quo as Tension for Change.

Theme 5 - Training to Deliver the Intervention

Training was specifically reported in three studies (Brady et al., 2011, Richardson et al., 2015, Speelman et al., 2014). All examples were mapped onto Readiness for Implementation in the Inner Setting because this specifically addresses training of staff in readiness to deliver the intervention.

Training was only seen as useful if it was adhered to and subsequently had the additional benefit of improving attitudes to patients and knowledge (Brady et al., 2011). This was mapped onto Knowledge and Beliefs in the Individuals Domain. Structured practice sessions with feedback following training was cited as the reason why therapists became proficient and adhered (Richardson et al., 2015). Training was perceived to lack some core behaviour change constructs, which while not specifically presented as a barrier, were assumed to be one (Speelman et al., 2014). These two barriers were mapped onto Individual State of Change, which reflects the process of becoming skilled in implementing the intervention.

Theme 6 - Costs

Only three studies reported issues related to cost and only one study had as its main aim to understand whether the intervention was financially viable; whether cost was a barrier or facilitator (Morrison and Backus, 2007). In identifying the three funders, the intervention cost was seen as a barrier for government-funded health insurance and a facilitator for the commercial health insurer.

A further two studies reported issues with finances. Siemonsma et al. (2014) commented that detailed costs related to delivering complex interventions for LTNCs were required by insurers and policymakers but were lacking. An example of a cost and trial-related barrier was provided by Thomas et al. (2014), where Excess Treatment Costs did not result in additional staff to deliver the intervention. Costs associated with intervention delivery were perceived as negative in an already stretched acute hospital setting (Siemonsma et al., 2014, Thomas et al., 2014). These barriers were mapped onto Cost in the Intervention Characteristics Domain.

Another study reported negative perceptions of the intervention's cost-effectiveness and a lack of awareness of reimbursement rules by managers, which resulted in clinicians not being contracted to provide the intervention. In the same study, occupational therapists providing the intervention were reluctant to use up all the health benefit paid by insurance companies with the intervention (Van't Leven et al., 2012). It seems that key stakeholders therefore prioritised finances over the proven effectiveness of the intervention and (Gitlin, 2013) commented that, "demonstrating efficacy is only the first

requirement on the long road to introducing an intervention into standard care." Similarly Douglas (2014) reflected that clear health outcomes were necessary to attract government health insurance funding and this requirement was unlikely to be met. Both of these reported barriers were mapped onto Relative Advantage in Intervention Characteristics because they relate to whether key people, such as clinicians, managers or funders perceive the intervention to be more beneficial than an existing alternative, for instance what occurs in usual practice. Additionally the barriers were co-mapped onto Evidence Strength and Quality, in the same domain, relating to the perception that the intervention will have the desired outcome.

Studies conducted in countries outside the UK presented country-specific implementation issues related to healthcare reimbursement costs in particular. For example, in the UK funding for healthcare interventions is organised quite differently to those in the Netherlands or America but nevertheless healthcare has to be paid for and justified. Awareness that researchers face challenges in trying to justify costs may prompt others to consider the Relative Advantage or Evidence Strength and Quality in Intervention Characteristics constructs in CFIR.

3.6. Discussion

3.6.1. Summary of Findings

The purpose of this review was to identify the barriers and facilitators affecting the implementation of complex health interventions in adults with long-term neurological conditions (LTNC) in developed countries. This review identified 28 studies from eight countries, which described the delivery of complex

interventions including, exercise, home-based rehabilitation, psychosocial and educational interventions, constraint induced movement therapy, memory aids, self-management and continence training. These were delivered to over 1700 people with LTNC's (stroke, dementia, Parkinson's disease, Motor Neurone Disease, spinal cord injury and Huntingdon's chorea) by clinicians including, occupational therapists and physiotherapists, speech and language therapists, psychologists, nursing and social workers.

Two hundred and thirty three barriers or facilitators (111 barriers, 59 facilitators and 63 identified as both barriers and facilitators) were identified and mapped onto constructs of two frameworks; CFIF (Carroll et al., 2007) and CFIR (Damschroder et al., 2009).

3.6.2. Strengths

This review was a comprehensive, systematic and rigorous appraisal of factors affecting implementation that are reported in research. It was underpinned by a thorough and systematic search, using broad inclusion criteria to maximise the identification of published research. The quality of this evidence was appraised using a peer reviewed and publicly published set of criteria. Theoretical frameworks were used to underpin the review and facilitate an in-depth, two-stage analysis of the data. The review has focussed on a range of important implementation issues that have not been included in previous literature reviews for LTNCs.

The team approach to this review helped to address bias in both the selection of the studies, data extraction and analysis through discussions and reaching consensus. The author's background as a practising clinician was made explicit as a potential source of bias during thematic analysis and data interpretation (Bowling, 2014).

The use of two complementary theoretical frameworks, each with a different focus on implementation provided structure to the analysis (Flottorp et al., 2013, McEvoy et al., 2014) and helped to ensure the results are applicable across settings (McEvoy et al., 2014).

The choice of frameworks has been discussed comprehensively in the introduction (2.8). CFIF focusses on the fidelity of the intervention being delivered and considers why and how intervention adherence may waiver from a protocol. CFIR focusses on the wider perspective of implementation, with the intervention as one of its constructs. Using both frameworks together allowed an understanding of how they relate to each other, similarities and differences in language and potential gaps in the theory, which inform its theoretical development (Damschroder et al., 2009, Kirk et al., 2016).

3.6.3. Limitations

Although the search strategy was designed to be comprehensive and was confirmed by the systematic review team, it is possible that some relevant studies were missed.

Twenty five studies reported various methods for identifying barriers and facilitators. Researchers most frequently used qualitative or mixed methods designs. There is currently no standardised method for collecting or analysing data about implementation barriers and facilitators (Nilsen, 2015). Therefore barriers and facilitators identification is limited by the researcher's knowledge of possible determinants, which means each study is inherently biased. Nilsen (2015) reflects that implementation researchers and theorists cannot yet agree on best methods to identify barriers and facilitators, analyse and interpret data.

The two frameworks used in this review offer little guidance on how to identify barriers and facilitators but Damschroder has developed an online forum for knowledge sharing aimed at developing tools for data collection (CFIR Research Team, 2016). To progress this work further, researchers should engage in moving theories forward to include practical guidance and tools (Proctor et al., 2009, Nilsen, 2015, Proctor et al., 2011).

Most studies [23] did not set out to describe barriers and facilitators to implementing a LTNC intervention. The five remaining studies either explicitly stated the intent or implied this through the study design. It could be argued that this premise should have formed part of the study inclusion criteria. However, this would have resulted in too few studies from which any conclusions could be drawn for the purpose of this PhD.

Even though the intent to identify barriers and facilitators was not explicitly stated, it was possible to extract them from the text as others have also found (Siemonsma et al., 2014). However, this was not ideal as this process requires subjective judgement and is open to interpretation. Additionally, identifying relevant text within studies was a lengthy process because the language and definitions used were not standardised. This has been found by others who suggested that the language of implementation research would benefit from being standardised (Proctor et al., 2009, Pinnock et al., 2015).

Conversely the five studies, which used a theoretical framework, presented barriers and facilitators clearly in an organised way. The brief explanation of the theory within the study also aided interpretation. Using a theoretical framework can help to identify, name and define barriers and facilitators, which then allows comparison across studies (Nilsen, 2015). However, the use of multiple frameworks remains problematic because whilst there are similarities in semantics there remain sufficient differences that require the reader to make a subjective judgement. One reason for this is the lack of consensus about theories, models and frameworks (Nilsen, 2015).

The lack of budget for foreign language translations meant the review was limited to the English language. However, the papers excluded on the basis of language are identified in this report.

3.6.4. Implications for practice and research

Barrier and facilitator themes

The synthesis identified six themes of barriers and facilitators and of these 'adherence' and 'perceptions of the intervention' were mapped to the most constructs (25 out of a total of 35), across both implementation frameworks used in the review, demonstrating that barriers and facilitators emanated from individual and organisational origins. The two most frequently mapped to constructs were 'patient needs and resources' in the outer setting of CFIR and 'facilitation strategies' in the moderating factors of CFIF. Patient needs and resources is a wide construct that relates to any needs the patient has and may be condition-related, work-related, and family-related. Resources relate to those things the patient requires and may relate to appropriate equipment to engage in the intervention, available transport, appropriate timing for carer to attend appointments. Facilitation strategies relate to the positive methods used to improve adherence to delivering the intervention as intended such as training in the intervention, available expert advice to support clinicians, prioritising the intervention above other routine ones.

The theme addressing participants' and service providers' perceptions about an intervention was reported in 21 of the 28 studies. Determinants were primarily associated with the intervention's acceptability. This commonly reported area is historically linked to reporting the quality of healthcare interventions but can also be interpreted as an implementation issue (Proctor et al., 2011). The units of text associated with this theme were mapped most often to patient needs and resources if perceptions came from patients or carers and knowledge and beliefs

of the intervention if the perceptions were reported by clinicians (individuals involved domain) in CFIR.

The concept of "acceptability" is important when considering positive or negative participant responsiveness to an intervention (Sermeus, 2015). When moving from single studies to larger multi-centre trials involving complex interventions, problems may arise that negatively affect the acceptability and intervention delivery. This ultimately affects the chances researchers have to evaluate the optimum intervention and trial design (O'Cathain et al., 2015).

Adherence (facilitator) and non-adherence (barrier) to intervention protocols were reported in 24 of the 28 studies, indicating that health researchers commonly report on these aspects. Adherence is a quality indicator, which may explain the frequent reporting (Hoffmann et al., 2013). Adherence can refer to the recipient and provider of an intervention and is regarded as an important determinant of its effectiveness (Carroll et al., 2007). Most units of text in this theme were mapped to 'facilitation strategies' in CFIF. This construct relates to positive strategies undertaken to improve adherence. Trialists should utilise data about adherence and facilitation strategies to identify potential implementation issues and solutions in designing trials for LTNCs.

The fact that it was possible to map barriers and facilitators to so many constructs of CFIF and CFIR serves to validate their utility (Liang et al., 2016). Most studies reported multiple examples of barriers and facilitators suggesting

that multiple implementation issues should be considered before embarking on the delivery of a new intervention for LTNCs within a trial. Evaluating barriers and facilitators reported in existing studies, using the methods described in this review would be one way of achieving this.

Gaps in reporting

Mapping revealed 10 constructs that had no barriers and facilitators mapped to them. These gaps relate to:

- the quality of intervention delivery in CFIF,
- whether the intervention was tested before implementation (trialability) in CFIR,
- design quality and packaging of the intervention in CFIR,
- organisational aspects that support implementation (structural characteristics, networks and communications, culture) in CFIR,
- external (peer) pressure to implement the intervention in CFIR and
- the process aspects of implementing the intervention (planning, engaging and executing) in CFIR.

This may suggest that studies for LTNCs did not encounter these issues but more likely that researchers did not recognise barriers or their potential to affect implementation (Nilsen, 2015).

The lack of differentiation between implementation theories, models and frameworks and the overlap between theoretical frameworks (Bhattacharyya et al., 2006, Damschroder et al., 2009, Nilsen, 2015) adds to the difficulty in

choosing a framework (Flottorp et al., 2013, Nilsen, 2015, The Improved Clinical Effectiveness through Behavioural Research Group (ICEBeRG), 2006). But in being uninformed, researchers risk repeating known implementation mistakes (ICEBeRG, 2006, Proctor et al., 2009, Nilsen, 2015). It is important for researchers to be aware of implementation theory and to build in its measurement to study designs. Without this knowledge it may be difficult to explain why an intervention works or not and the chances of predicting success and designing strategies to ensure success are limited (Nilsen, 2015). Likewise clinicians would also benefit from an understanding of how implementation theory and research findings could help them to understand why complex interventions are difficult to implement and how to overcome local contextual implementation barriers.

CFIR attempted to amalgamate existing implementation research theories available at the time (Damschroder et al., 2009), in an attempt to provide some consolidation and parity of constructs. Researchers have used CFIR to understand implementation issues (Damschroder et al., 2011, Damschroder and Hagedorn, 2011, Damschroder and Lowery, 2013, Helfrich et al., 2010, Kirk et al., 2016, Krein et al., 2010, Lutes et al., 2011, Lutes et al., 2013, Smith et al., 2012, Stetler et al., 2011). However, other determinant frameworks exist (Grol et al., 2013, Kitson et al., 1998, Cochrane et al., 2007) and researchers should adopt the framework that most comprehensively guides the study design and use a comparison checklist to help in deciding which will work best (Flottorp et al., 2013).

Gaps in reporting may also be a symptom of historical reporting requirements. Researchers focussed on disseminating findings in scientific papers will customarily report elements that ensure publication, such as acceptability, adherence and attrition. As part of the process of developing new rehabilitation interventions, researchers are encouraged to carry out process evaluations and feasibility studies that provide the opportunity to explore implementation issues thoroughly before further phases are funded (Richards and Hallberg, 2015, Craig et al., 2008). In the future it is expected that more journals will encourage publication of process evaluations and implementation research that is underpinned by a theoretical framework, resulting in better reporting of factors that may limit intervention implementation and trial success.

Implementation strategies

The findings suggest that links between gathering data on determinants and making recommendations for future implementation strategies are rarely made. This has been found elsewhere (Bosch et al., 2006). This may be because many of the studies in this review did not set out to identify factors affecting the intervention implementation and may not have been aware of frameworks to support their measurement or reporting. In the five studies that did intend to identify barriers and facilitators, the links were not explicit either. The risk of only identifying barriers is that the range of potential implementation strategies is not offered or tested. Studies that identify facilitators as well as barriers provide a useful starting point to progress implementation issues. It is recommended that studies identify barriers, facilitators, potential implementation strategies and potential testing methods. This would require

closer analysis of the relationship between determinants and the overall context (Lau et al., 2016).

3.7. Conclusion

This review has described the barriers and facilitators identified in studies implementing complex interventions for people with LTNCs. Studies adopting an implementation framework simplified the identification of barriers and facilitators, an important consideration for busy researchers and clinicians. In the development of a new complex intervention, it is vital to learn from previous experiences to prevent unnecessary repetitions of implementation failure at both trial and service provision levels. Therefore trialists should be cognizant of and choose implementation theory and implementation frameworks appropriate for the study to guide the identification and reporting of implementation issues in future trials. Clinicians should look to trials that have utilised implementation theory to make use of reported strategies in overcoming implementation issues.

This review provided important information regarding the potential barriers that trial occupational therapists may encounter when delivering a complex rehabilitation intervention in a research context. The review also provided practical information related to how best to facilitate the delivery of a complex rehabilitation intervention. In the next two studies knowledge of these barriers and facilitators are used to inform the training and support of the trial occupational therapists to anticipate and overcome any implementation issues when delivering the new complex intervention "ESTVR".

CHAPTER FOUR

4. Study Two: Preparing occupational therapists to deliver a complex intervention

4.1. Chapter Overview

Chapter three described the systematic review and narrative analysis of barriers and facilitators to implementing complex rehabilitation interventions for people with long term neurological conditions (LTNC) within the context of research. It provided important information about the potential barriers that trial occupational therapists might encounter when receiving instruction for and delivering a complex rehabilitation intervention in a research context.

This chapter describes the aims, methods and results of research, which investigated how trial therapists were prepared and supported to deliver a vocational rehabilitation intervention in a multi-centre feasibility randomised controlled trial (FRESH) described in chapter 1 (1.2) to people with a traumatic brain injury. Parts of this chapter have been published (Holmes et al., 2016, Holmes, 2016)

4.2. Introduction

The delivery of a new intervention within a research environment is the joint responsibility of researchers designing and managing the study and the clinicians delivering the intervention. Ultimately it is incumbent on researchers to ensure that clinicians are adequately prepared to implement the intervention in order to optimise patient outcomes (Döpp et al., 2011). There is published guidance on managing trials and the role of clinicians deployed to deliver trial interventions

on (Fletcher et al., 2012, National Institute for Health Research (NIHR), 2015) but none that describes the recommended components necessary to support clinicians delivering trial interventions to ensure fidelity. Therefore the author drew on literature related to developing complex interventions, knowledge transfer and implementation research for guidance.

This literature suggests that multiple methods may be important in supporting clinicians to deliver interventions (Craig et al., 2008, Grimshaw et al., 2012, Walker M.F. et al., 2013) although there is little evidence to demonstrate effectiveness (LaRocca et al., 2012).

Implementation research offers frameworks by which to categorise and further understand the barriers and facilitators influencing the delivery of new interventions. Two such frameworks are the Comprehensive Fidelity Implementation Framework (CFIF) (Carroll et al., 2007) and the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) described earlier (2.8). CFIF has been used to examine how well an intervention is delivered and what factors moderate delivery and CFIR has been used to identify the root causes of implementation issues. Multilevel organisational and practitioner-based barriers such as providing time away from patients to learn interventions and low levels of confidence and facilitators such as strong leadership have been identified as affecting the uptake of knowledge (Lal and Korner-Bitensky, 2012, Moran et al., 2014, Jones et al., 2014, Petzold et al., 2012).

Implementing a new intervention requires changing habits. This can be dependent on the practitioner's knowledge, skills, confidence and attitudes (Lal and Korner-Bitensky, 2012, Damschroder et al., 2009, Graham et al., 2006). However, studies have shown that making recommendations for specific knowledge transfer methods is not straightforward because putting new learning into practice is complex (Farmer et al., 2012, Grimshaw et al., 2006, LaRocca et al., 2012, Jones et al., 2014). Strategies that address these barriers that were also familiar to NHS therapists include an intervention manual, direct teaching and mentoring.

4.2.1. Intervention Manual

Training manuals are generally accepted as a common and low cost knowledge transfer method that has been shown to have modest effects (Grimshaw et al., 2006). However, training manuals alone are not effective in changing practice (Farmer et al., 2012, LaRocca et al., 2012). Using only a manual would be considered a single, passive knowledge transfer strategy and has been found to be less effective than using multiple active strategies.

4.2.2. Direct Teaching

Direct teaching is a common knowledge transfer strategy for medical professionals (Grimshaw et al., 2006) and the most prominent among allied health professionals (Jones et al., 2014, Scott et al., 2012). Although it is commonly believed that active involvement of learners in a classroom should be the most effective, the evidence comparing passive presentation of information and active discussion groups and problem-solving tasks is equivocal (Buchanan

et al., 2014, Forsetlund et al., 2009). Research suggests that a multi-modal approach to communicate the details of an intervention and potential implementation issues, that blends direct instruction with case vignette discussions, role play, problem-solving and ongoing mentoring is important to achieve learning (Petzold et al., 2010, Döpp et al., 2013, Döpp et al., 2011)

4.2.3. Mentoring

The purpose of mentoring is to support therapists. Definitions of mentoring overlap with clinical supervision and professional support and this is acknowledged (Moran et al., 2014) but indicates a two-way process between the mentor and mentee. For professional support to be called mentoring authors cite particular characteristics including regular meetings over a period of time, delivered individually or in groups, is a relationship where the mentor is more experienced than the mentee and where there is a process to match mentee and mentor. (Abdullah et al., 2014, Sambunjak and Marušić, 2009).

There is no consensus among authors about the activities that constitute mentoring identified as including individual and group face-to-face meetings, email and or telephone contact, coaching, audit and feedback and educational outreach (Sambunjak et al., 2006, Moran et al., 2014, Sambunjak and Marušić, 2009, Abdullah et al., 2014). Supplementing training with ongoing support has been found successful in implementing complex therapy interventions (McCormack et al., 2013).

When combined with multifaceted knowledge transfer strategies, studies have shown that mentoring can change knowledge and beliefs that then impact organisational outcomes and desirable behavioural change in the practitioner. However, gains have not been significant and the added benefit of mentoring requires further research (Abdullah et al., 2014, Sambunjak et al., 2006).

When supporting therapists to learn how to deliver a new complex intervention, such as vocational rehabilitation, the strategies, outlined above, should all clearly describe the intervention. This is recognised as an important mediator for helping clinicians understand interventions and replicate them in practice (Hart, 2009). For researchers providing learning materials to therapists working in the context of a trial, clear descriptions are essential and can help to inform robust research design, particularly when moving from single centre to multi-centre studies (Hoffmann et al., 2013, Wade DT, 2005). These descriptions should include the elements of complexity that affect the intervention's implementation (Richards and Hallberg, 2015) and when supported by descriptions from previous studies, they can also help in understanding issues likely to be encountered in similar situations in the new trial and prevent unnecessary repetitions of implementation failure (Flottorp et al., 2013). The findings from the systematic review reported in chapter three indicate that there are many potential barriers to implementing interventions for people with long term neurological conditions (LTNC).

The specific VR used in this study was previously introduced (2.5.3) and will be described in detail (4.5.2). The intervention was called ESTVR in the NIHR-

funded multi-centre feasibility randomised controlled trial FRESH (Facilitating return to work (RTW) through Early Specialist Health-based interventions FRESH (Radford et al., 2013)) which has also been described (1.2). The trial therapists required training to provide ESTVR.

4.3. Study Aim

To design a training package that prepared trial therapist participants, to deliver the ESTVR intervention.

4.3.1. Objectives

1. To identify and describe the key ESTVR components for inclusion in the intervention manual.
2. To construct an intervention manual.
3. To design and deliver direct teaching of the intervention.
4. To design, organise and deliver mentoring to support trial occupational therapists.
5. To evaluate the combined training package (manual, teaching and mentoring) and describe barriers and facilitators.
6. To describe recommendations for future training packages.

4.4. Methods

The WIDER guidelines (Albrecht L et al., 2013) were used to ensure a detailed description of the training package. Table 4-1 provides an overview of the

methods used to develop the training package, which was an iterative and cyclical process that took place in two stages over six-months. The first stage focussed on understanding the intervention and describing its components. The second stage focussed on designing the training package. Trial occupational therapists were nominated members of the rehabilitation team in three centres and recruited by the FRESH trial to deliver ESTVR and was out with the remit of this study. Further information about the recruitment process of trial therapists will be published by the Healthcare Technology Assessment report of FRESH and protocol paper (Radford K.A. et al., 2015).

Table 4-1 Planned ESTVR training development and delivery process

<table>
<tr><th>March 2013</th><th>September 2013</th><th>October 2013</th><th>April 2014</th><th>October 2014</th><th>October 2015</th></tr>
<tr><td>Stage 1 - Manual development</td><td rowspan="2">Training delivered to trial therapists</td><td rowspan="2">FRESH trial starts recruitment</td><td rowspan="2">Refresher training delivered to trial therapists</td><td rowspan="2">FRESH trial stops recruitment</td><td rowspan="2">FRESH trial ends</td></tr>
<tr><td>Stage 2 - Training package development</td></tr>
<tr><td colspan="2"></td><td colspan="4">Trial therapists deliver ESTVR</td></tr>
<tr><td colspan="2"></td><td colspan="4">Mentoring provided</td></tr>
</table>

4.4.1. Expert group

An 'expert' group was convened with members, identified through professional contacts for their expertise in VR, traumatic brain injury (TBI) and training delivery. Experts were considered appropriate to inform best practice and clinical experience in delivering vocational rehabilitation to patients and teaching

occupational therapists in vocational rehabilitation. Four full day meetings were held by the expert group and supplemented by email and telephone communication. The aims of the expert group were to:

1. Describe the components of the intervention.
2. Design the training package and deliver the direct teaching.

4.4.2. Stage One: Understanding the intervention

Kothari et al. (2012) explains that both explicit and tacit knowledge are required when describing the complex aspects of interventions. The existing NTBIS manual and published descriptions of the content of the intervention, (Phillips et al., 2010, Phillips, J. 2013) were used as starting points to understand and describe the intervention. This method provided the explicit knowledge but what previous descriptions lacked was detail related to clinical decisions about when to use different components, specific processes and some of the resources required to deliver components.

The NTBIS OT had delivered ESTVR for 20 years and was therefore recognised as having important experiential, tacit or "know-how" knowledge of the delivery of the intervention and the service-user had know-how of its receipt. Therefore both the NTBIS OT and service-user (a former patient of the therapist) were informally interviewed in depth by the expert group to extract this knowledge. This method provided the tacit or "know how" knowledge. The theoretical underpinnings of the intervention components were discussed in the expert group meetings. The explicit and tacit knowledge helped to develop a set of

assumptions about the intervention; the programme theory (Atkins, 2015, Rossi, 2004).

4.4.3. Stage Two: Development of the training package

It was assumed that trial therapists recruited by the FRESH trial would have sufficient clinical experience in neurology therefore training focussed on VR and ESTVR.

4.4.3.1. Intervention manual

A literature review of UK clinical guidelines on TBI and RTW were collated and integrated into the manual with the intervention description (College of Occupational Therapists, 2008, College of Occupational Therapists, 2010, das Nair et al., 2012, Phillips J., 2013, Playford and Sweetland, 2010). It was anticipated that a range of resources would be needed for trial therapists to use and hand out to patients, family and employers and these were included in the manual. The expert group gathered examples of suitable resources to be included. Published complex intervention manuals served as design examples (das Nair et al., 2012, Garfield et al., 2013, Logan et al., 2014, Walker et al., 2012).

Four draft copies of the manual were written and reviewed by the expert group each time until they agreed upon the end product.

4.4.3.2. Direct teaching

As research suggests multi-modal approaches in direct instruction is important to achieve learning this was chosen for the teaching component. The direct teaching was scheduled to start within a month of the start of the FRESH trial recruitment phase to ensure learning remained current (Table 4-1). Refresher training was scheduled six months afterwards to provide peer support and consolidation of learning once trial therapists had case experience (Table 4-1).

The expert group did not have prior knowledge of the trial therapists' knowledge of TBI and VR. In order to understand if any would require specific additional support during the direct teaching, a learning needs analysis (LNA) was developed [using a scale of (1) not very confident or knowledgeable to (5) already really confident and knowledgeable]. The LNA (Appendix 5) was emailed to trial therapists, one month before the direct teaching was scheduled. This was not a formal measure of training success but a way to ensure that teaching would be delivered to target identified needs.

To ensure that the Trial therapists who under took the training had the same grounding in VR, a pre-training reading pack was developed and sent two weeks before the teaching event. Pre-training reading was prepared by the author (JH) and NTBIS OT (JP) and included an introduction to VR, theoretical underpinnings of VR and assessment, useful websites and relevant scientific papers.

4.4.3.3. Mentoring

Mentoring was provided to the trial therapists and had the purpose of ensuring ongoing support in the delivery of the intervention, problem-solving issues that might arise in clinical aspects and in its implementation. It was therefore considered important that mentors were occupational therapists, experienced in TBI and VR, clinical supervision and providing CPD training. All needed to be more experienced than mentees in relation to the VR intervention, as the literature suggested (Abdullah et al., 2014, Gagliardi et al., 2015).

Each mentor was paired with one trial therapist. Mentors were allocated mentees based on location and on learning needs. Having a pool of mentors allowed sharing of experiences and problem-solving issues. If required trial therapists could, via their mentor, ask the FRESH research team questions as required. As mentoring uses interpersonal interactions to influence the Trial therapists' behaviours and attitudes (Abdullah et al., 2014), reallocation was possible if a mentor and mentee did not develop a working relationship.

Mentoring was delivered flexibly and included meetings, telephone calls, emails or texts as agreed between the trial occupational therapist and mentor. It was recommended by the expert group that one hour per month was a suitable amount of mentor time per person and comparable with the amount of formal supervision meetings recommended for occupational therapists (College of Occupational Therapists, 2015). Mentors documented the date, length of the mentoring session, the mode and key points from the mentoring session on a Mentoring Form, which also served as an aide memoire in sessions (Appendix

14). No patient identifying data was recorded. Mentoring forms were collected from each mentor after the session, sent by email and stored securely. Additional electronic mentoring such as emails were collected at the end of the trial and stored securely.

4.4.4. Evaluation of the Training Package

One way of testing the effectiveness of the training was to analyse how faithfully the Trial therapists delivered the intervention, also known as measuring intervention fidelity (Hasson, 2015). Interventions measured to be delivered with fidelity have been shown to have better outcomes than those with lower fidelity (Hasson, 2015). The fidelity data is presented in Study Three (chapter five).

The success of the training package to prepare trial therapists to deliver the intervention was further evaluated using mixed methods to address different aspects. These are summarised in (Table 4-2).

Table 4-2 Summary of methods to evaluate the training package

Training Package Component	**Evaluation Methods**	
ESTVR manual	Early and late stage interview	Audit of intervention manual adaptations
2-day teaching		Self-perceived knowledge and confidence questionnaire
Mentoring		Analysis of mentoring records and communications

4.4.4.1. Early and late stage interviews

Trial therapists who engaged in the training package were interviewed after they had an opportunity to deliver ESTVR and engage in the refresher training. The purpose of the interviews was to explore the trial therapists' views of the training package (ESTVR manual, direct teaching and mentoring). Individual interviews were considered appropriate to elicit the depth and richness of data regarding the trial therapists' thoughts and experiences.

Trial therapists were interviewed twice; initially in the early weeks after starting to deliver the intervention and again after having delivered the intervention for two years. The purpose of selecting two time points was to explore the therapists' perceptions over time and to ensure that early experiences of receiving the training and delivering the intervention were not forgotten.

Ethical approval was gained for the interviews (HTA FRESH, REC Ref 13/EM/0353 and University of Nottingham ethics ref No. D14112013 FRESH SoM Rehab & Ageing). Trial therapists provided written and verbal consent to be

interviewed. As the framework method was used, a topic guide (Appendix 7) was developed using a priori concepts based on theoretical concepts of implementation which are described in chapter 2 (2.8). The main topics included the trial occupational therapists' professional experience followed by reflections on the training they attended. Using a conversational style, questions then related to the perceived effectiveness of the training package and experiences of putting the intervention into practice and finally the therapists' perceptions of changes required to improve future training packages.

As the author was involved in the development and delivery of the training package an independent researcher conducted the telephone interviews by phone. The interviewer explained that all data would be transcribed and anonymised prior to analysis by the author. The aim was to reduce interviewer bias and to get an honest account.

An iterative process was used to reflect on data collected, and refine the topic guide for subsequent interviews, with initial themes informing questions for subsequent interviews (Grbich 1999). Interviews were digitally recorded, transcribed, cleaned and stored securely.

The framework method was used to analyse the interview data. This allowed for a priori concepts from implementation research frameworks, CFIF and CFIR, to act as a "framework", used to explore and interpret what occurred (Ritchie, 1994). The iterative approach to data collection and analysis facilitated data

reduction through summarisation and synthesis whilst allowing links to the original data to be retained. Analysis of the interviews was conducted by the author in consultation with the independent researcher who performed the interviews. NVivo 10 for Windows software was used for data management. Lastly, in order to identify the root causes of any implementation factors, findings were mapped to CFIF and CFIR to provide a comprehensive comparison to the CFIF and CFIR frameworks

4.4.4.2. Audit of changes to the intervention manual

Trial therapists were informed that they would need to return their manual once they had finished delivering the intervention without making any further changes to it. They were specifically requested not to "tidy up" or "reorganise" the manual in order that adaptations to the manual could be analysed. A comparison between what the trial therapists were given and the returned manual was made by noting additions or other modifications.

4.4.4.3. Self-perceived knowledge and confidence questionnaire

In order to indicate whether a change in self-perception had occurred after attending direct teaching, Trial therapists were asked to assess their knowledge of and confidence to deliver ESTVR before and after training by completing a questionnaire developed by O'Brien et al. (2013) for occupational therapists delivering a VR training programme in rheumatology and adapted for use in this study. The adapted questionnaire sought the trial occupational therapists' perceptions of their knowledge about key aspects of TBI and their confidence to

deliver ESTVR (Appendix 8) [using a scale of poor (1) to very good (5)]. Open-ended questions asking for reflections on the most and least useful elements and suggestions to improve the programme were included.

4.4.4.4. Analysis of mentoring

The frequency and total time spent mentoring was calculated using descriptive statistics to provide a summary comparison between therapists and sites. Text describing the content of mentoring sessions was analysed using the framework method described above. This data has also informed the evaluation of the fidelity of the intervention delivered and can be seen in chapter 5 (5.5.4).

4.5. Results

Findings are presented in two parts; from the expert group who developed the training package and the evaluation of the training package, once delivered.

4.5.1. Participants

4.5.1.1. Expert group

The expert group included the author, an OT and experienced in developing VR training courses (JH); the Nottingham Traumatic Brain Injury Service (NTBIS) OT who developed ESTVR and has 15 years' experience of its delivery in Nottingham (JP); a Clinical Neuropsychologist and author of clinical guideline about VR and TBI (The Royal College of Physicians and The British Society of Rehabilitation Medicine, 2003) (AT); an ESTVR service user and project manager (TJ); an independent OT experienced at delivering RTW support for people with

TBI (YB); an OT and manager of a community NHS VR service for people with TBI (RT) and the feasibility trial (FRESH) chief investigator (KR).

This small group worked efficiently over the four meetings and between via email to meet the group aims to describe the components of the intervention, design the training package and deliver the direct teaching. Compiling the explicit, published, materials was straightforward and relatively quick. However, extracting the tacit (experiential and skills-based) knowledge from the NTBIS OT took longer than expected.

4.5.1.2. Mentors

Mentoring was offered to trial therapists by four OT members of the expert group (author (JH), NTBIS OT (JP), OT manager (RT), Neuro OT (YB)). Mentors had been qualified between 15 and 36 years (average 27 years), all met the criteria as previously described.

4.5.1.3. Trial therapist participants

The training package was delivered to five trial occupational therapists who were selected to work on the FRESH trial but only four went on to deliver ESTVR.

Four were initially recruited and trained, two from one site and one from each of the remaining sites. One of these therapists withdrew from the study and was replaced by another occupational therapist who was also trained. Therefore five trial occupational therapists underwent training in total, four female and one

male; mean age 39.2 years (range 34 to 47 years). The therapists had been qualified a mean of 11.4 years (range 12 to 15 years). Two participants were trained as occupational therapists in the UK and three qualified overseas (South Africa, New Zealand and Australia). One held a higher degree in VR. All had experience of working within the NHS and working with people with neurological conditions (mean 9.7 years, range 3-15 years). Two therapists worked directly for NHS Trusts (one community and one acute hospital) and two therapists had their own business and were contracted to work for the NHS Trust site.

Three of the five trial occupational therapists attended training on the scheduled dates. The remaining two received adapted training because one person was unable to attend the original course and the other was recruited later. One of these trial occupational therapists received their direct teaching at the University of Nottingham and the other at their hospital site. They viewed video recordings (from the ECHO Recording) of the original direct teaching before receiving a single day of direct teaching providing orientation to the manual, associated paperwork and discussing case studies. Both of these trial occupational therapists watched the video recordings prior to training.

Four trial occupational therapist attended refresher training in April 2014 and the fifth received a summary of the day's events from the mentor.

All five trial occupational therapists who attended the training were interviewed as planned. Five early interviews occurred a mean of 4.2 months after the trial

occupational therapists had seen their first patient (range 2-6 months) and a mean of 7.8 months after the initial training days (range 3-12 months). The therapist who left the project before recruitment commenced never held a caseload. It is not unusual to have staff changes within the NHS and even though the trial occupational therapist did not implement the ESTVR it was felt appropriate to include data from the early interview to gain insight into the direct teaching experience.

The four remaining trial occupational therapists who delivered the intervention were interviewed again at the end of the trial, a mean of 24.25 months after the initial training days (range 24-25 months).

4.5.2. Description of the intervention

The content of the ESTVR intervention is described elsewhere (Phillips, J. 2013, Phillips, J., et al., 2010, Radford et al., 2013) and an intervention delivered by the Nottingham Traumatic Brain Injury Service (NTBIS). The description of the ESTVR intervention here is informed by the TIDieR reporting guidelines.

ESTVR was delivered by a TBI and VR specialist occupational therapists and supported by a health-based TBI specialist case manager to PWTBI (16≥ years old) who were working or in full time education at injury onset.

4.5.2.1. Goal and rationale of ESTVR

The expert group determined that the primary focus of ESTVR was preventing job loss and optimising employment and education outcomes. In brief, the

intervention aimed to start within eight (but ideally four) weeks of injury. The occupational therapist made contact with the PWTBI and assessed the impact of the TBI on person's work role. Thereafter the focus was on developing acceptable strategies to overcome barriers to RTW and determining the success. This pattern continued in a cyclical manner until the individual had met their goals and discharge was determined appropriate.

The expert group determined that ESTVR was based on the premise that the right work is a health benefit (Black, 2012). RTW need not involve a return to the same job with the same roles and responsibilities but could include a return to some form of work or modified job with an existing employer. This would be negotiated as part of the employer's requirement to make reasonable adjustments to support their employee back to work. Where return to a pre-existing employer was not feasible or was unsustainable, alternatives were explored.

4.5.2.2. ESTVR resources

The resources required to deliver the intervention included:

- Legal framework and policies that were facilitative e.g. the Equality Act actively enacted in workplace policies.
- Skilled and knowledgeable TBI/VR therapist.
- PWTBI with a job or registered in fulltime education.
- The ability to work across boundaries between health services, employment and charities.
- Multi-stakeholder engagement.

4.5.2.3. ESTVR processes

The initial element of the intervention was for the therapist to assess the PWTBI and their situation. The assessment period also involved providing initial advice about RTW, with the goal to prevent action by the PWTBI without considering the potential impact of the TBI on person's work role.

The intervention did not require any specialist equipment and could be conducted on a hospital ward or at home when the person was discharged. Assessment included:

- Assessing occupational status and vocational aspirations and needs.
- Exploring the current job role, tasks, the work environment, workplace policies, procedures and culture regarding support for RTW.
- Identifying barriers and facilitators for RTW.
- Individual work-related goal setting.
- Problem-solving barriers to RTW.
- Seeking input from other relevant stakeholders who form part of the PWTBI's wider multidisciplinary team and coordinated by the trial occupational therapist or case manager.

Thereafter, the individual needs of the PWTBI and the employer directed the tailored content of the intervention, delivered flexibly and included:

- Liaison with family members and carers.
- Openly communicating, in written form, to stakeholders about the impact of the TBI on the PWTBI and the effect this would have at work,

summarising each treatment session[2], noting actions required to achieve the next goal and providing recommendations.

- Providing advice and information about RTW or education e.g. issuing advice materials from relevant charities and NTBIS.
- Provision of TBI education.
- Teaching psychosocial and coping skills strategies.
- Liaison with employers and employer agencies e.g. occupational health, human resources.
- Partnership work and coordination with statutory, voluntary and private sector providers to address associated issues e.g. physical symptoms, cognitive symptoms, emotional distress, welfare benefits advice, family relationship breakdowns.
- Planning and implementing graded return to work and job accommodations, including changes to the work environment.
- Monitoring the RTW for safety and sustainability.
- If a PWTBI did not have a job to return to then the intervention involved exploring a wide range of alternative outcomes including engaging in purposeful occupations.

The intervention was completed when the PWTBI accomplished their RTW-related goals. For the purpose of the FRESH trial, the intervention could last up to 12 months.

[2] Treatment session is a single discrete period of time working on a case and could range from 10 minutes to several hours.

4.5.2.4. Impact and outcomes of ESTVR

By delivering the intervention components, it was anticipated that the expected impacts would be achieved. Intervention components were activities that the trial occupational therapists should deliver with or for the PWTBI in order to adhere to the intervention. A number of components were described in terms of timings against which fidelity could be measured e.g. "within 10 days" or specific tasks e.g. "clarify what was said and agreed in meetings afterwards in writing". The early impact of ESTVR included:

- PWTBI does not make rapid RTW decisions.
- PWTBI aware of available support & how to access.
- Therapist has early and regular contact with the trauma survivor, family, and other stakeholders.
- PWTBI & stakeholders aware of residual problems & coping strategies.
- PWTBI, employer aware of impact of TBI on work.
- PWTBI & stakeholders aware of residual TBI problems.
- Coping strategies in place.
- Referrals made for relevant support.

Later impacts included:

- PWTBI & employer satisfaction.
- PWTBI confident & able to self-manage.
- Stakeholders report to one key contact, all aware of stakeholders involved and work towards RTW.
- Conflicting RTW advice prevented.
- Everyone is heard, no confusing communications.
- Considered decisions made regarding RTW.

- Employment environment Optimised.
- Workplace accommodations in place.
- Phased return to work facilitated.
- PWTBI able to cope with work.
- Contributes to the economy.

Following the delivery of ESTVR, a number of outcomes were recognised by the expert group. ESTVR would contribute to:

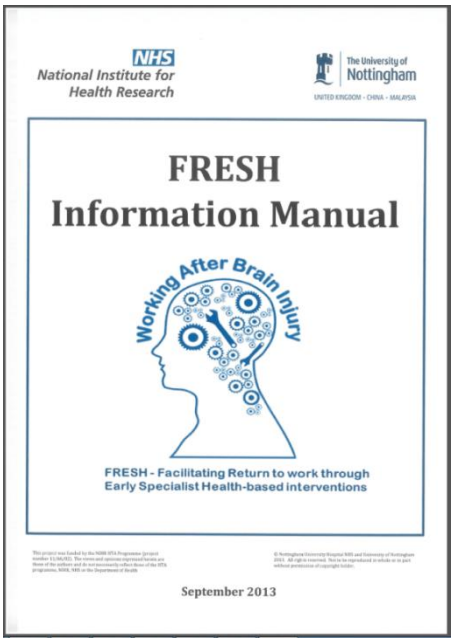
- Prevent job loss.
- Improved physical and mental health.
- Personal and financial wellbeing.
- Reduced sickness absence.
- Reduced health resource use.
- PWTBI in sustainable employment.

4.5.3. Training package

4.5.3.1. Description of the manual

The manual about ESTVR was compiled to follow the patient journey from early after TBI to sustained return to work, describing the processes and actions required by the occupational therapists to deliver the intervention. In order to optimise local implementation, local adaptations of the manual were anticipated e.g. adding additional local contact details such as charity support groups and welfare advice centres. The manual was designed to be produced in hard copy and provided to the trial occupational therapists during the teaching. Chapter topics are detailed in Table 4-3.

Table 4-3 ESTVR Manual



Chapter	Content
	Introduction to ESTVR, TBI and RTW
One	Initial work preparation prior to RTW
Two	Graded RTW process
Three	Job retention support
Four	Alternative occupation options if returning to a former job was not appropriate
Five	Discharge process from ESTVR
Six	Supporting documentation to deliver ESTVR
Seven	References and resources related to TBI and RTW
Eight	Templates for paperwork (letter examples, information leaflets about TBI symptoms)
Nine	RTW research for therapists, employers and people with TBI

Chapters two to five had the same structure covering; the aims of ESTVR; examples of specific intervention activities; the role of the trial occupational therapists delivering the intervention and providing case management; information on the frequency of treatments and a section on common TBI issues related to RTW. The final output was a manual with 35 pages, produced in hard and electronic copies.

4.5.3.2. Description of the direct teaching

Four out of five of the trial occupational therapists reported having no TBI learning needs. The fifth had neurological experience with progressive conditions and identified that they had TBI learning needs. The greatest learning needs identified were; completion of the supplementary RTW advice that can be provided by allied health professionals (AHPs) (AHP Fitness for Work Report), completion of the formal sick leave forms used in the UK provided by doctors and the research processes directly related to the FRESH trial. These aspects were added to the direct teaching programme.

The expert group decided that direct teaching was best delivered by the group members, NTBIS case managers and three volunteer former service-users. Two-days of teaching was considered pragmatic for busy NHS staff while also allowing enough time to cover all the required components. It was intended that all trial occupational therapists were taught together so that they met and formed relationships with trial occupational therapists from the other centres as a mechanism of peer support.

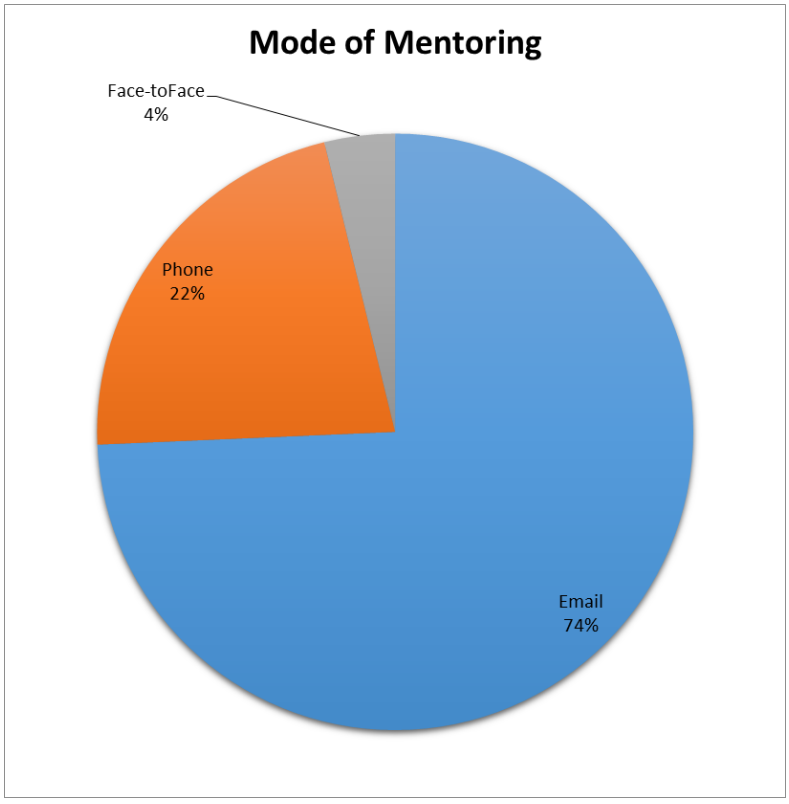
Hard copies of presentations given by the trainers were issued during the teaching (teaching timetable Appendix 6). At the end of day one homework (case study problem based learning) was provided with the aim to embed learning.

The training was video-recorded using the University of Nottingham's Echo 360 service and made available to all the trial occupational therapists as a resource. The author can be contacted for more details about the ESTVR Manual, pre-reading handout and teaching.

4.5.3.3. Description of the mentoring

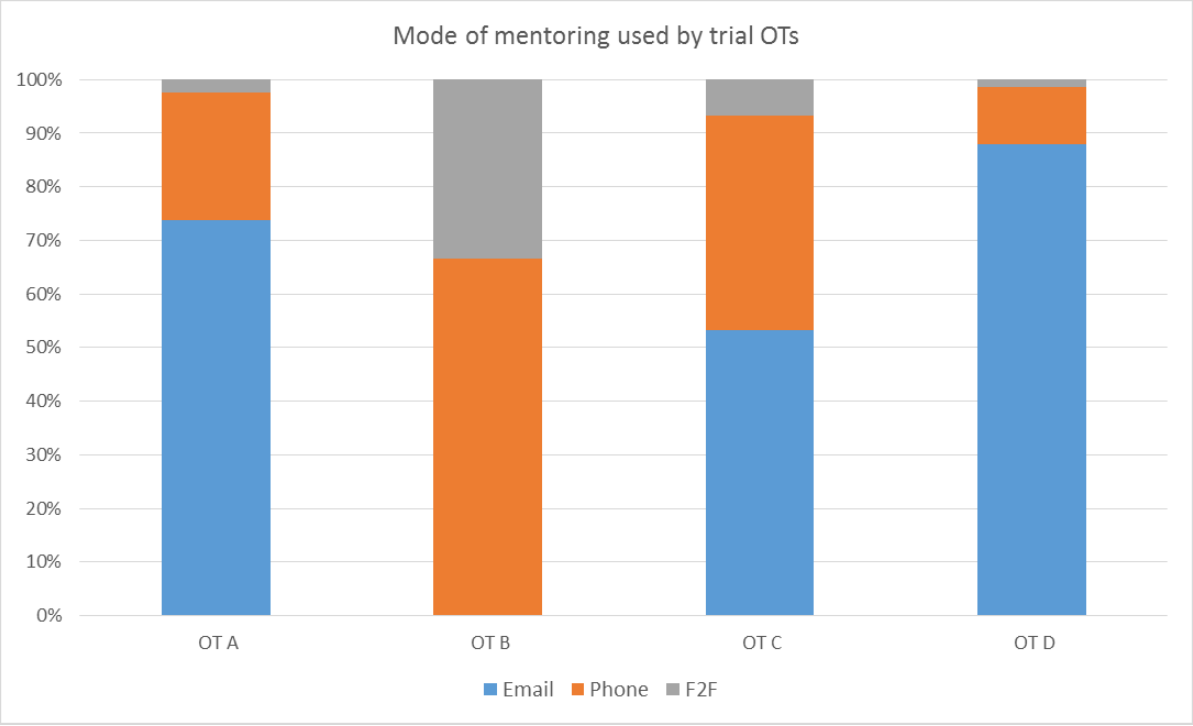
Mentoring was provided to the four trial occupational therapists, who delivered the intervention, by email for the majority of sessions (n=136), followed by telephone (n=40) and face-to-face meetings (n=7) (Figure 4-1). Texts were also used but a record of these proved unfeasible to record accurately. Two geographically local trial occupational therapists and two mentors had a joint session because they wanted to discuss cases collaboratively.

Figure 4-1 Mode of mentoring delivered over 24 months



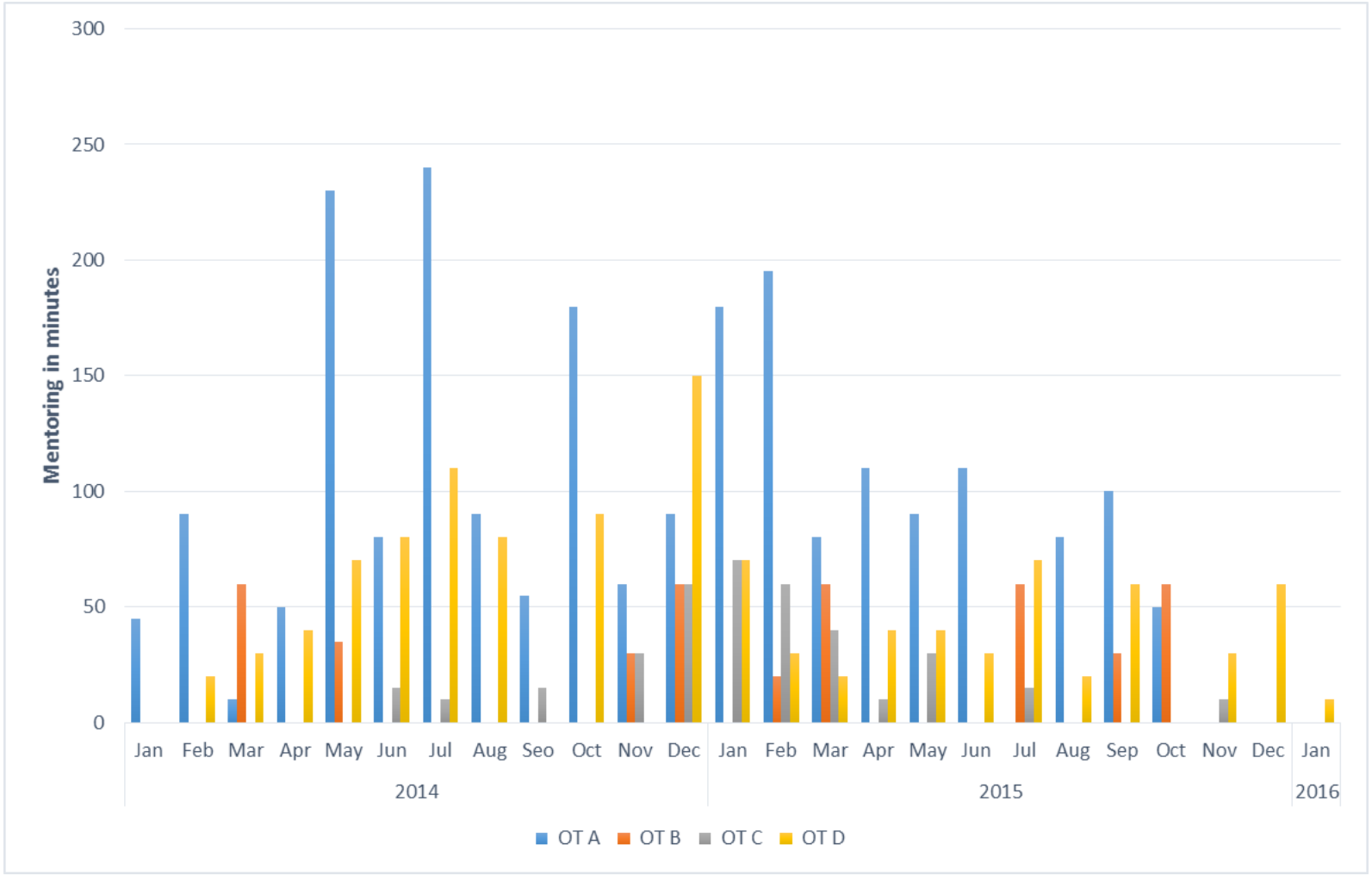
Trial occupational therapists used different proportions of email, phone and meetings in their mentoring sessions (Figure 4-2).

Figure 4-2 Mode of mentoring per trial therapist over 24 months



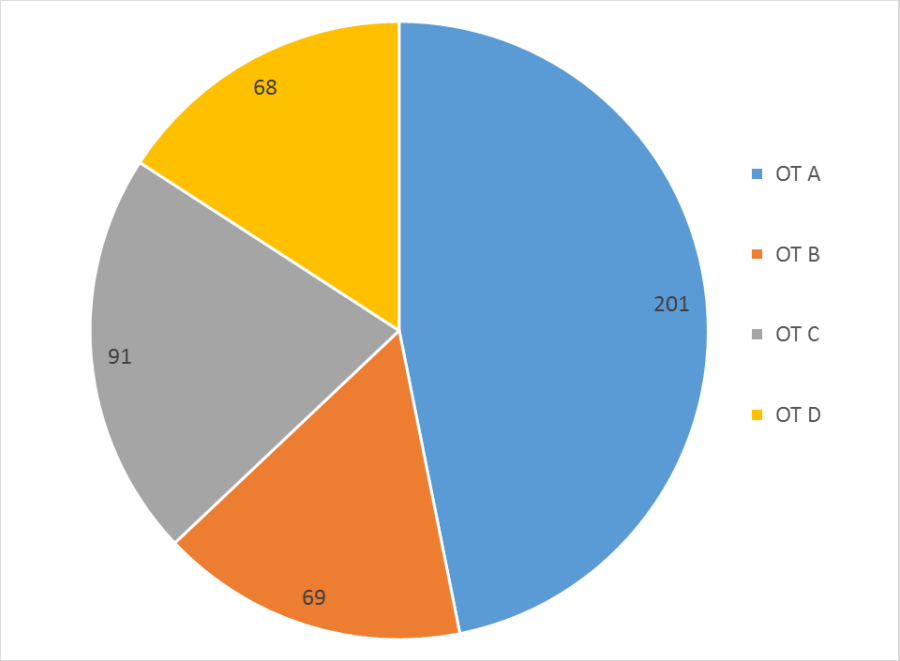
Frequency of mentoring was flexible and driven by therapist need and were provided with an average of 45 minutes mentoring per month. This was 15 minutes under the anticipated 60 minutes per month. The average amount of mentoring ranged across trial occupational therapists from 15 to 92 minutes per month. As trial occupational therapists could contact their mentor for additional advice if a query arose, some sessions were ad hoc and tended to be shorter than the pre-planned sessions. The amount of mentoring provided generally reduced over time with as much as 220 minutes provided in a single month for one therapist in the first year to as little as 10 minutes in a month by the end (Figure 4-3).

Figure 4-3 Mentoring (minutes) provided per trial therapist



There was a wide variation between individual trial occupational therapists over the amount of mentoring received ranging from a total of 365 to 2215 minutes per therapist over the two years trial occupational therapists delivered intervention. In relation to their caseloads, each received between 68 to 201 minutes mentoring per participant (Figure 4-4).

Figure 4-4 Total mentoring (minutes) per trial therapist per participant



4.5.4. Summary of interview data

Interviews were deliberately conversational, although steered by the topic guide, to encourage the participant (trial therapist) to reflect on their experiences of becoming prepared to deliver ESTVR. As such, not all constructs of CFIF and CFIR theoretical frameworks featured in conversations. Mapping the data onto the CFIF and CFIR frameworks facilitated comparisons between early and late interview data. This comparison demonstrated that later interviews featured descriptions of more constructs across both frameworks than in early interviews and that both early and late interviews involved individual and organisational

level barriers and facilitators. Table 4-4 illustrates that the later interview data was mapped to a wider range of implementation issues than the early interviews.

Table 4-4 Interview data mapped to implementation

Domains	**Constructs**	**Interview data**	
CFIF		**Early**	**Late**
Adherence	Content		✓
	Duration		✓
Moderating factors	Participant responsiveness	✓	✓
	Context		✓
	Facilitation Strategies		✓
CFIR			
Intervention characteristics	Intervention source		✓
	Evidence Strength & quality		
	Relative advantage		✓
	Trialability		
	Complexity	✓	✓
	Design quality & packaging		
	Cost		
Outer setting	Patient needs and resources		✓
	Cosmopolitanism		
	Peer pressure		
	External policies & incentives		
Inner setting	Structural characteristics		✓
	Networks & communications		✓
	Culture		
	Implementation climate	✓	✓
	Readiness for implementation	✓	✓
Individuals involved	Knowledge & beliefs about the intervention		✓
	Self-efficacy	✓	✓
	Individual stage of change	✓	✓
	Individual identification with organisation		

	Other personal attributes		✓
Process	Planning		✓
	Engaging	✓	✓
	Executing		✓
	Reflecting & evaluating		✓

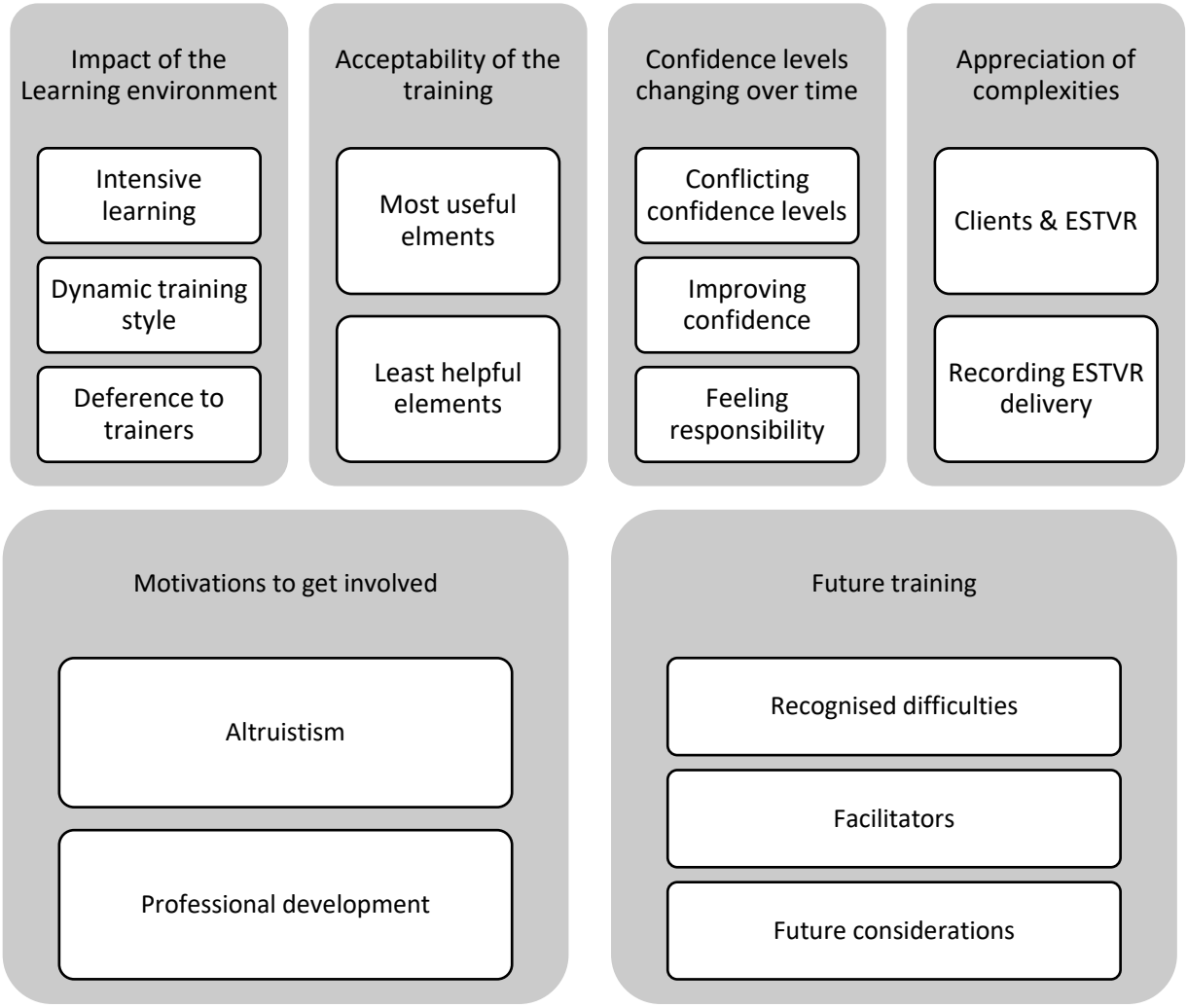
In addition to understanding the implementation issues related to training, interview data revealed that trial occupational therapists were able to reflect on how the training package prepared them and gave multiple examples. Trial occupational therapists tended to provide similar comments regarding the training package at the different time points, for instance reflecting how useful they found the training and mentoring. However, some provided contrary comments, for instance initially viewing the manual as very important and then later reflecting that the manual was not so important. Interviews revealed six major categories (Figure 4-5). The first four categories related to the usefulness of the training to prepare the trial occupational therapists:

- Impact of the learning environment.
- Acceptability of the training.
- Confidence levels changing over time.
- Appreciation of complexities.

The last two categories related to understanding why the trial occupational therapists dedicated time to their role and to understanding barriers, facilitators and considerations for future training:

- Motivations to get involved.
- Future training.

Figure 4-5 Interview themes



In order to answer the research objectives, interview data, questionnaires, audit and mentoring records were combined and the results presented against each aim.

4.5.4.1. Usefulness of the training package

Impact of the learning environment

When asked if the training was about the right length, trial occupational therapists (OT) reflected in early interviews that it felt intensive but: *"looking at*

what needed to be covered, it couldn't have been done any shorter. You know, if you didn't know anything about TBI or VR, any shorter than two days, it would have been too rushed and too much information." (OTE). Later comments in mentoring suggested that a third day of direct teaching could have been useful to extend the time to assimilate the new learning. However, it was thought too long to be away from their regular role and would not be permitted by managers.

The trial occupational therapists recognised the dynamic training style as flexible to meet individual needs. The flexibility facilitated communication and built confidence: *"I think having access to them any time during the day to ask anything daft, or to just kind of put things in perspective, was very helpful."* (OTA). Later interviews indicated trial occupational therapists valued the flexible mode of mentoring as the medium through which they checked their knowledge and practice: *"It [mentoring] hasn't always had to be face to face, if anything I've probably found the emails or telephone calls perfectly suitable. And if anything, I probably haven't got time to meet face to face either. It's not been any weaker for it all being by email or telephone, it's been great."* (OTD).

The training group was recognised and valued for its subject expertise in the early interviews: *"we're being up-trained or trained by specialist OTs [named] so what's not to like about that?"* (OTD). This was also mixed with some deference: *"they just were standing there like these fountains of knowledge, that you could ask them anything and they would answer you."* (OTB). Trial occupational therapists continued to highly value the expertise in their mentors:

"to be able to pick someone's brain who clearly has much more experience than I do and to utilise that experience rather than just muddling your way through or trying to work stuff out for yourself. It's that old adage; there's no point in reinventing the wheel." (OTC)

Acceptability of the training package

The questionnaire indicated that trial occupational therapists found detailed discussions of the intervention helped them understand the essential components. This links with the element identified as most useful, which were case discussions that provided opportunity for group clinical reasoning practice. This was echoed in both early and late interviews. Early on trial occupational therapists reported that discussing cases was helpful in implementing ESTVR locally, they said they could: "discuss it [case scenario] in a group, and then learn from that and see how the FRESH process *[ESTVR] actually applies to different individuals."* (OTC). Later trial occupational therapists explained: *"I valued the days when we met together and discussed the cases. I think that was really valuable, because I think that's such good learning and to get a better spin on it [intervention]."* (OTB).

From the questionnaire, trial occupational therapists indicated that reminders about resources in the manual were useful. The resources supported the trial occupational therapists to become independent in their clinical reasoning and whilst not specifically mentioned in the interviews, mentors encouraged trial occupational therapists to use resources in the manual.

Within training sessions, service users provided opportunities for role play and early interviews indicated this was a positive learning experience: *"We had actual clients coming in that we can role play and practise with, which was great. I thought that was really, really good."* (OTB). However, there was ambivalence about this method too: *"I kind of felt that you were being assessed. That's probably more my anxiety really in that you want to try and get it right"* (OTA).

Trial occupational therapists reported in the questionnaire that reviewing trial research aims, processes and documentation provided a framework within which to understand their role. However, this was also seen as one of the least helpful aspects of the training in early interviews. The perceived lack of clarity and separation between learning about the intervention and learning about the trial processes was confusing: *"I think one of the things that I found the most confusing about the training in this study, in this sort of trial study was that it was a mix between sort of trial procedure and training, if you know what I mean."* (OTB). In later interviews the trial occupational therapists reflected that they had worried about the trial aspect of delivering the intervention: *"I don't think I understood that concept at the beginning. Yeah, that's right. The feas- perhaps the feasibility nature of it wasn't explained. I didn't understand properly because my background is not research."* (OTB).

The time lag between training and intervention delivery was considered unhelpful: *"If we went through the training in the week before and they started recruiting the week after, and in two weeks we had our first client recruited or patient recruited into the study and we were able to get straight into it, that*

would be an ideal situation for consolidated learning. But it was literally six months later." (OTC).

The OT who joined the study later reported that extra learning outside of work time was required to assimilate all the information: *"I think the only challenge was trying to fit it all in my own time and trying to get up to speed, because as I say, I joined the study late, so I felt a bit behind and I was really pushing myself and my time to try and catch up with the other people that had already been on the training."* (OTD).

In later interviews trial occupational therapists were able to identify knowledge that they gained in mentoring sessions but thought would have been useful to include in the training:

- Recording an intervention session in sufficient detail.
- Locating relevant services for PWTBI.
- Working with higher education and children's services for 16 and 17 year olds.

4.5.4.2. Usefulness of the intervention manual

All manuals from the four trial occupational therapists who delivered the intervention were collected after the delivery of the intervention had finished. It was anticipated that trial occupational therapists would need to adapt their

manual to their local situation, inserting additional local resources such as community rehabilitation teams and charitable organisations.

The audit of the manuals indicated that two trial occupational therapists had made no changes and during interviews and mentoring records reported that they had not utilised the resources as reminders to deliver ESTVR. The remaining two trial occupational therapists' manuals had been reorganised and had additional resources inserted. Additional resources were a mixture of those sourced by the trial occupational therapist and provided through mentoring.

After the refresher training, the free text section of self-rating questionnaires indicated that reminders about the resources held in the manual was useful but this was not indicative of how the manual would be utilised. Trial occupational therapists had expected that the manual might prove useful: *"I'm sure that at some point I may go back and revisit those things, depending on the clients I get, and … revisit those sections as you go along."* (OTB). However, late interviews confirmed that the confidence of this OT to deliver the intervention resulted in little to no use of the manual: *"The manual I feel gave me more of what I knew already. Like for example I didn't even use any of the templates for letters or things like that, I free wrote my letters on headed paper. I haven't had to rely on any of those things…"* (OTB).

Early interview data indicated that the trial occupational therapists had referred back to the manual on the first few occasions they delivered the intervention but

late interview data indicated the manual was not seen as an important resource. One trial occupational therapist reflected that: *"over the months I referred to it less, you know, because I've felt I've not needed to, or I'd built up my learning and experience from situations that have arisen."* (OTA) whereas early on the manual had been perceived as highly important, *"You know, it's twice as full now because of stuff that I've kind of added to it constantly, and it's been a really guide of the whole process...I kind of see it [the manual] as my vocational rehab bible."* (OTA).

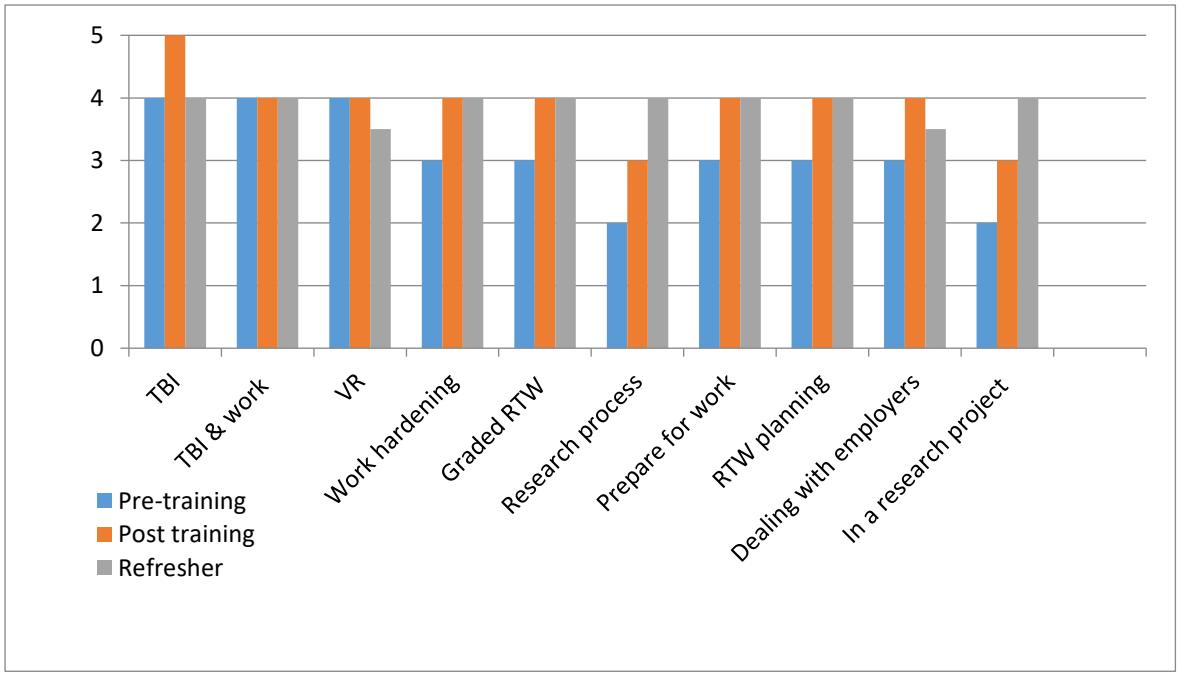
Early on, the manual was found to be useful only alongside teaching and mentoring: *"if I didn't have the folder and the training, I wouldn't just manage with the mentor… I think it's essential that both are in place."* (OTD). Reflecting in late interviews some trial occupational therapists had found the mentoring more useful: *"I think the mentor was more valuable than the manual"* (OTB) and: *"I don't think the training upfront was enough for me alone. Even if I read it [manual] all I might not have understood it all or processed it all or checked it all out… . So if [mentor] hadn't been there I would have had to find support elsewhere"* (OTD).

All trial occupational therapists reported utilising multiple copies of the same resource (TBI Information Booklet) that they could give to PWTBI and their families that explained TBI, return to work and rehabilitation. From mentoring records, trial occupational therapists reported finding there was too much information in the manual that made it unwieldy and time consuming to find resources and this was confirmed in the late interviews.

4.5.5. Knowledge and confidence

All five trial occupational therapists who completed the initial training completed the self-perceived knowledge and confidence questionnaire and all four trial occupational therapists who attended the refresher training six months later completed the same questionnaire. The results can be seen in Figure 4-6. Overall trial occupational therapists perceived that their knowledge had either remained the same or improved and that their confidence to deliver the intervention had improved.

Figure 4-6 Self-perceived knowledge and confidence in providing ESTVR



Key: 1=poor; 2=limited; 3=average; 4=good; 5=very good

To report the reflections about confidence, data is presented using the interview theme of confidence levels changing over time.

Confidence levels changing over time theme

From early interviews the trial occupational therapists reported different levels of confidence prior to training and described lacking confidence in either their skills in community work or specific clinical knowledge due to a lack of experience: *"I just worry a bit about not knowing the in-depth neuro cognitive bit"* (OTD). This finding was corroborated by the LNA in planning the direct teaching.

All reported improved knowledge about the intervention following training and reflected that "higher level" reasoning skills were required to individualise ESTVR: *"for me, being relatively experienced, it's sort of bread and butter type stuff, just your critical reasoning is a bit higher level and you should be able to apply high-level clinical reasoning to individual clients."* (OTC). One OT recognised in hindsight a lack of in-depth VR knowledge and was supported by the self-rated confidence scores: *"from having done the training, I think you kind of realise how much more there is to know or how many more angles there are that you didn't ever know about. And so all of a sudden you just have much more of a conscious incompetence – a sort of awareness of your incompetence more"* (OTB).

Where knowledge and confidence levels were reported as low this highlighted a need to explore this during mentoring and late interviews indicated support had been helpful: *"So there's a few areas that perhaps even now I could and should know better. But again, I hope I haven't done my client a dis-service by not knowing it or not doing it. But yeah, they're the areas that I think I'm a bit patchy on even now, or not as confident on. And I guess you [mentor] and*

[another mentor] have been great in supporting knowledge and gaps in knowledge." (OTD)

Although their knowledge improved and they had confidence in implementing ESTVR, trial occupational therapists were conscious that their confidence was likely to increase further with experience of delivering the intervention: *"It's still kind of a learning curve for me and I'm still finding out."* (OTA). On reflection the trial occupational therapists recognised that they had been unable to anticipate all their learning needs ahead of or during training and only appreciated this later once they'd had the opportunity to meet again. Some had seen participants by the time the refresher training took place, which helped this process. Late interviews confirmed this earlier reflection, *"My learning and confidence has gone up in understanding processes and reasoning things through."* (OTA).

Internally and externally imposed pressure could affect confidence. In early interviews some reported feeling responsibility to deliver the intervention correctly for the trial and to succeed: *"I think, initially, there was an overload of paperwork... Keeping track of all the communication in the early days when obviously things are, … kind of fresh in terms of a lot to learn...I understand why that needed to be done, but you're thinking, oh, I'm just trying to get my head round the whole thing."* (OTA). Trial occupational therapists also identified pressure, although challenging their confidence levels, was not externally imposed: *"I always put pressure on myself that my interventions are going to result in something good and I always take it personally if it doesn't. I just think*

I'm that kind of person. I don't think the trial is putting us under any pressure at all, no. And in actual fact, they [research team], you know, constantly reiterated they're not expecting us to be perfect." (OTB). In late interviews others predicted pressure could come from the trial occupational therapist's existing role and this could affect confidence: *"the acute OTs would struggle to be released from the ward when they've got patients in beds who are acutely ill and there's pressure on the beds to unblock... maybe they wouldn't have felt as confident going out, we're talking up to an hour's drive to employers."* (OTD).

4.5.6. Barriers and facilitators

Data indicated that the most frequently voiced determinants of preparedness to deliver ESTVR were associated with the complexities of the intervention and the readiness of the local organisation to support learning. Knowledge that was felt to have been missing from the teaching and manual was also perceived as a potential barrier and this has already been described. Facilitators to learning were identified as: regular mentoring, case discussions between trial occupational therapists and mentors and the opportunity to raise questions via the mentor to the research team.

<u>Appreciation of complexities</u>

Trial occupational therapists talked about the complexities surrounding the client group and tailoring the intervention being delivered: *"You might think, "Okay, I can do just the same as the first one" but, no, it might look the same, it's a TBI going back to a bank but the boss might be different, the relationships are different. Everything is completely different. And, it's not as simple as saying,*

right, "I'll pull this tool out and I'll use the same thing." Every single one has to be different, doesn't it?" (OTE). Trial occupational therapists reported that the case discussions and mentoring facilitated clinical reasoning that assisted with further learning and confidence building.

Communicating successfully with PWTBI was identified as problematic in some cases. This was understood as a potential consequence of TBI and may not have had a solution that could have be taught. However, training could have acknowledged this and provided clearer guidance: *"there's a line in the sand as to how much you can throw at these clients before you need to be able to say, well, you've been discharged, or you're on hold at the moment so I can take on other clients."* (OTC).

Early on some trial occupational therapists reported finding the requirements to document intervention sessions as complex*: "completely new documentation that I've never ever been savvy with and never seen before. I've never had to record my intervention and break it all down, ever. And that's kind of really hard because I think, as an OT with experience ...you do a damn sight more than what you think."* (OTA). Mentoring provided the opportunity to support trial occupational therapists with documentation but in future opportunity to practice this aspect could be presented in the direct teaching.

Trial occupational therapists indicated in mentoring that their own NHS lacked the ability to support learning technology (USB sticks and access to some

websites) provided by the training group. This resulted in trial occupational therapists having to access these resources at home and in non-work hours. Some trial occupational therapists were comfortable with this arrangement while others not. From an implementation perspective investigating the capacity of an organisation to support all aspects of learning for the trial occupational therapist's new role would be beneficial. Those trial occupational therapists in independent practice did not experience this issue.

Case discussions at the refresher training and in mentoring were based on practice rather than being theoretical and this was repeatedly reported as helpful: "*that's where it all comes together, isn't it, when you can actually hear about how, what's written in the book translates into practice and then have an end result for a client."* (OTE).

4.5.7. Recommendations to prepare trial occupational therapists

Motivations to get involved

Altruistic motivations to get involved with the trial dominated the Trial occupational therapists reflections: *"Obviously, one, because there's not a heck of a lot of evidence in OT and VR and TBI, so anything that, I think, as a clinician, any of us can do to kind of help that evidence to be established is fantastic."* (OTE) *and: "Interest in those patients that I've been involved with in an acute setting, you know, and kind of want to extend my therapy relationship with them and try and see if I could make more of a difference, to be honest, in terms of a long-term outcome."* (OTA). Trial occupational therapists also

reflected that the trial would provide opportunity for professional development: *"I wanted it to be a part of my – further my professional learning, basically, and I wanted the opportunity to sort of access a few skilled practitioners and experienced practitioners."* (OTB) and: *"I also quite liked that it was still being involved again in research and the NHS. I thought that would be quite nice actually to be involved somehow there."* (OTD). Attracting trial occupational therapists to be deliver interventions in future studies may need to take account of what motivates them to become involved.

Future training

Barriers associated with releasing NHS staff to work part time on trials despite secured funding for backfill were highlighted: *"They've got no leeway to release anyone … They just are running on such low staffing levels that they can't afford, even if they're being funded for it, they can't afford to release someone for a day a week."* (OTB). In addition identifying trial occupational therapists with the right experience was considered important for future studies: *"I think in some respects a community OT doing [this work] has more of an advantage... we [acute occupational therapists] don't have the expertise and the skill base that an established community brain injury team, or voc therapist, has already."* (OTA) and a similar view: *"the acute OTs would struggle to be released from the ward when they've got patients in beds who are acutely ill and there's pressure on the beds to unblock... maybe they wouldn't have felt as confident going out, we're talking up to an hour's drive to employers."* (OTD).

Data from the knowledge and confidence questionnaires and interviews suggested the following improvements to the future training package:

- Using technology to improve access to learning materials before training and afterwards to build a community of practice for knowledge sharing.
- Explaining key intervention concepts early in the training.
- The continued use of service users.
- Flexible training, with increased prescriptiveness for trial occupational therapists who are less experienced in TBI and or VR.
- An extra day focussing on describing specific research processes.
- Minimising the delay between training and intervention delivery.
- Greater use of case discussions and scenarios.
- Sufficient time for familiarisation with the manual and its resources and allowing time for discussion.
- Learning by watching videos only if time is specifically allocated.
- Face-to-face learning.

4.6. Discussion

4.6.1. Summary of findings

This study has fulfilled its aim, which was to develop a training package to prepare trial occupational therapists to deliver ESTVR. A training package was developed by a group of experts experienced in VR, TBI and designing training courses. Training included; an intervention manual, a mentor programme and direct teaching.

The expert group identified the key components and processes of ESTVR and developed these into a 35-page manual. Direct teaching was designed, delivered by the expert group, case managers from the Nottingham TBI Service and people with traumatic brain injury (PWTBI). Teaching took place over two days and included a mix of didactic sessions, group-work alongside PWTBI and peer discussion. The manual was provided during the teaching. Mentoring was designed to support the trial occupational therapists to deliver the intervention over a 24-month period and provided by four trial occupational therapists from the expert group.

Training was evaluated in terms of usefulness, whether trial occupational therapists reported a change in their knowledge and confidence across relevant topics and acceptability, whether trial occupational therapists considered the three components of the training package had prepared them adequately. Overall, trial occupational therapists indicated they had learned about the intervention to be able to deliver it in the FRESH trial and the training was perceived as acceptable. Using experts to deliver the training, who then provided ongoing monthly support to the trial occupational therapists was the most likely way to achieve fidelity of intervention delivery in a multi- centre study. Fidelity is tested in chapter five.

In interviews that occurred early and late after training, trial occupational therapists identified ways in which the training package helped them implement ESTVR and some barriers that hindered them. These were mapped onto

implementation research frameworks to categorise root causes, identified by the framework constructs. In later interviews, trial occupational therapists could reflect on many more aspects of implementation than in the early stages after training. These findings are discussed below.

4.6.1.1. Training package development

Some argue that tacit knowledge cannot be articulated (Polanyi, 1966) whereas others argue it can (Nonaka and Toyama, 2002). This study found tacit knowledge provided the most useful detail in terms of the intervention's processes, resources required and expected outcomes. This detail contributed not only to the manual, direct teaching materials and informing mentors, it also aided the development of data collection forms in Study Three (5.4.9). The importance of drawing on tacit knowledge from experienced therapists cannot be underestimated when developing a deeper understanding of a programme details in a complex intervention like ESTVR (Kothari et al., 2012).

4.6.1.2. Knowledge and confidence of therapists

Measuring knowledge and confidence before and after direct teaching indicated that some improvement had occurred. This information was supplemented with the use of qualitative data. Different levels of confidence should be expected dependant on the pre-existing experience and knowledge of trial occupational therapists. Identifying this early, as this study achieved, allows anticipation of learning support required. A trial occupational therapist with no community experience required the most mentoring support, well above the predicted amount of an hour a month. This is not unexpected because the intervention is

community-based but indicates that therapists with community experience require less support in mentoring. Future studies of this intervention should select therapists who have some community rehabilitation experience.

A criticism of knowledge transfer methods (including training programmes) is that whilst knowledge may improve, this does not guarantee that behaviour will change in the required way (Scott et al., 2012). Opportunities to demonstrate this learning in future, would be for therapists to work through preassigned vignettes of PWTBI who have a job to return to in in the direct teaching. Using vignettes in a problem-based learning style would require therapists to consolidate learning and utilise pre-existing experience as clinicians (Schmidt H.G. et al., 2011). Measuring the clinical reasoning and behaviour change achieved requires further examination.

4.6.1.3. What trial occupational therapists said they needed

Trial occupational therapists reported they required all three elements of the training package in order to feel prepared to deliver the intervention. They reported appreciating the different modes in which training was provided, even though some were challenging, such as the role play. Using a mixture of learning approaches has been recognised by others (Döpp et al., 2013, Petzold et al., 2012) but others suggest modest learning effects by a manual alone (Grimshaw et al., 2006). Still others question the effectiveness of multimodal learning (LaRocca et al., 2012). Like other similar studies of training occupational therapists in a VR intervention (O'Brien et al., 2013), they requested more case discussions with their peers because they found this mode

of learning particularly helpful. This mode would be supported by those who recommend problem-based learning; a way of cognitively solving a novel problem that has particular meaning and draws on prior knowledge applied to the new situation (Schmidt H.G. et al., 2011).

Trial occupational therapists indicated that an extra day of direct teaching may accomplish this but an extra time away from work can also be a barrier for some organisations (Jones et al., 2014). However, when considering the best way to use time during direct teaching, one should consider that a function is to meet others to exchange information. Therefore, making use of this to increase time on case discussions could be facilitated if didactic materials (PowerPoint presentations) were provided ahead of meeting as a prerequisite part of training.

This approach could minimise time away from the busy workplace, often a barrier for organisations allowing therapists to attend training (Mitton et al., 2007), but moving future training away from a face-to-face model entirely would require caution as trial occupational therapists preferred training with peers. Trial occupational therapists also suggested that any learning at work would require formal protected time, which could be explored with each workplace and allowable CPD time negotiated in advance.

Mentoring was an important part of the training package and an essential mechanism for supporting therapists deliver the intervention as found by others (Abdullah et al., 2014, Sambunjak et al., 2006). Trial occupational therapists

valued contact with experienced trainers in the first instance and experienced mentors later on to guide new practice. Strong professional leadership is recognised as a facilitator when changing practice (Lal and Korner-Bitensky, 2012). Early mentoring focussed on consolidating learning about the intervention and exploring how best to accomplish this within the research environment. Later mentoring supported trial occupational therapists' ongoing learning through case discussions that involved problem-solving, clinical reasoning and reminders about key components of the intervention.

It is recognised that providing mentoring in a variety of ways (face-to-face, email, telephone and text messages) to meet therapists' needs is important and this was valued by trial occupational therapists (Moran et al., 2014, Abdullah et al., 2014). Provision requires adequate resourcing in future trials and the added effect of mentoring requires further investigation (Abdullah et al., 2014).

Trial occupational therapists had different preferences with learning materials. All trial occupational therapists reflected that they would have struggled to deliver the intervention with only a manual to support implementation and this has been found elsewhere (Farmer et al., 2012, LaRocca et al., 2012). Manuals were more useful for some trial occupational therapists and those who did not use the manual reported they felt sufficiently confident with the support of the mentor and from direct teaching. Less confident trial occupational therapists used the manual until they became confident in delivering the intervention and having a manual as a reminder of the intervention's components was seen as a safety net by most trial occupational therapists.

Some trial occupational therapists found the manual had too much information and was not easily accessible. Resources in the manual designed for PWTBI, their family and employers were used by all trial occupational therapists because this facilitated one component of the intervention (educating PWTBI about their condition). Researchers should expect that manuals may not be utilised by all therapists as expected and ensure there are other support mechanisms such as mentoring in place. Manuals may be more valuable to therapists when they contain patient resources.

Trial occupational therapists had concerns about implementing the intervention as part of research. Reasons included worries about contaminating the research and because of the perceived difference in delivering an intervention within a trial as opposed to the usual service setting. Training about the intervention and the processes of the trial needs to be clear and separate to support therapists understand their role and have the opportunity to explore their concerns.

4.6.1.4. Implementation factors

As well as asking trial occupational therapists about their experiences of receiving the training package to understand how useful and acceptable they found it, findings were also mapped onto research implementation frameworks; Conceptual Fidelity Implementation Framework (CFIF) (Carroll et al., 2007) and the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). The identification of barriers and facilitators to knowledge transfer has been extensively studied (Mitton et al., 2007) and also in allied health

professionals (Lal and Korner-Bitensky, 2012, Scott et al., 2012). But few have undertaken this second level analysis that permits a deeper understanding of the root causes (Döpp et al., 2013). By mapping what trial occupational therapists reported as helping or hindering knowledge transfer onto implementation research frameworks, this study has made a further contribution to implementation and knowledge transfer.

Findings from early interviews mapped to fewer implementation constructs in the implementation frameworks compared to later interview findings. Only with the experience of delivering the intervention for an extended period, could trial occupational therapists reflect whether they had been adequately prepared to deliver the intervention and a wider range of factors that interfered with this. Virtually all constructs from both implementation frameworks had barriers and or facilitators mapped to them from the later interviews, indicating the complexity of learning and delivering a new intervention as found by others (Farmer et al., 2012, Grimshaw et al., 2006, LaRocca et al., 2012). The data gathered in this study suggests the implementation constructs, which should be focussed upon when considering the preparedness of therapists to deliver a new intervention.

4.6.2. Strengths and limitations

This study used mixed methods in an explanatory approach (Cresswell, 2007) in order to provide a comprehensive understanding of the research issue (Bowling, 2014), if trial occupational therapists could be taught to deliver a complex intervention (ESTVR) within a rehabilitation trial setting. The purpose was to describe the amount that trial occupational therapists perceived they had

improved in being able to deliver ESTVR and how much mentoring support was provided using quantitative methods and use the qualitative method to explain findings in more detail, exploring the trial occupational therapists' experience of the ESTVR training package. Although the development of training packages for knowledge transfer have previously been described for allied health professionals, these have tended to lack detail (Scott SD et al., 2012). There has not been a detailed description of the process to develop a training package for ESTVR and the mixed methods allowed a comprehensive description of this to emerge. The importance of describing training packages in detail is emphasised by the Workgroup for Intervention Development and Evaluation Research (WIDER) and cited as an important aspect in narrowing the research to practice gap (Albrecht et al., 2013, Scott SD et al., 2012).

Early interviews were also important however, as they provided reflections of the training package shortly after the first few intervention sessions had been delivered. Early and late interviews showed that some trial occupational therapists changed their ideas about the training between the two time points. This reflects that needs may change over time and it is recognised that serial interviews are useful in understanding the changing needs and experiences of participants over time (Murray et al., 2009). Future studies should consider interviewing therapists early after training and then later to capture changing thoughts and needs and to make use of the breadth of experience gained.

The findings report on the experiences of all five trial occupational therapists who undertook a new training programme and are therefore representative of

therapists who may undertake the same training in the future. The recommendations trial occupational therapists made to the training package will be implemented in future training. It was not the intention to compare the training package described in this study with a control. However, in order to progress understanding about the effectiveness of this training package and its use as strategy to optimise the implementation of a complex intervention, further evaluation of its core components is recommended.

Mapping the findings from trial occupational therapists' interviews to implementation frameworks was relatively straightforward. Definitions of constructs are clear and it is possible to map data onto multiple constructs where there is overlap (CFIR Research Team, 2016, Ilott et al., 2013). Theoretical frameworks are expected to evolve as more data becomes available to refine them (Proctor et al., 2009) and this study may add to the body of knowledge influencing CFIR revealing the range of issues important to trial occupational therapists and revealing what trial occupational therapists did not talk about.

4.6.3. Implications for practice and research

Therapists that engage in providing interventions in a research trial can expect to learn new skills with regards to research and in relation to the intervention they are expected to deliver. With the appropriate training and support, therapists can feel confident to deliver a new complex intervention within the NHS context. Therapists benefit from a training package that is provided flexibly

to meet learning needs and mentoring is valued most over direct teaching and a manual but all three elements are needed.

Determining the key components of a complex intervention that has developed from practice, bottom up, is a time consuming process requiring careful analysis of explicit and tacit knowledge. Future trials should allow sufficient time to develop detailed descriptions of the intervention. Trial occupational therapists described a number of future recommendations for training and in particular that future trials should aim to coordinate the commencement of participant recruitment and therapist training to deliver the intervention. The use of implementation theory helped to frame semi-structured interviews and reveal a range of barriers and facilitators. Future trials of rehabilitation interventions are recommended to consider using an implementation framework that is suitable to understand the experiences of the trial therapists. Although this study found CFIR and CFIF useful, other studies may choose differently and gain equally useful data.

4.7. Conclusion

Evaluation of the training package confirmed that knowledge of a specific vocational rehabilitation intervention for people with traumatic brain injury can be transferred to occupational therapists recruited to deliver it in a feasibility RCT context. The training package was found to be acceptable and useful and highlighted important factors for consideration in developing and delivering training packages in future trials of vocational rehabilitation for people with traumatic brain injury. This study provided knowledge of barriers and facilitators

experienced by the trial occupational therapists during their receipt of the training and ongoing mentoring delivering the complex intervention “ESTVR”.

Study Three will utilise the knowledge of barriers and facilitators, gained through training and mentoring, to help explain the fidelity of intervention delivery, which is examined in chapter five.

CHAPTER FIVE

5. Study Three: Measuring the implementation fidelity of a complex intervention delivered by occupational therapists.

5.1. Chapter Overview

Chapter Four described how trial occupational therapists were prepared and supported to deliver a vocational rehabilitation intervention in a multi-centre feasibility randomised controlled trial (FRESH) described in chapter 1 (1.2) to people with a traumatic brain injury. In evaluating the training package, the study identified barriers and facilitators related to learning about the intervention and then putting this into practice. Chapter two provided descriptions of reported barriers that were encountered when delivering a complex rehabilitation intervention in a research context.

This chapter describes the mixed methods research undertaken to measure the extent to which ESTVR, a complex occupational therapy vocational rehabilitation intervention was delivered as intended. Findings from Studies One and Two will help to explain the fidelity of the intervention. Data is drawn from the FRESH feasibility randomised controlled trial (see 1.2). Additionally, this chapter includes qualitative research that explored perceptions of the trial occupational therapists delivering the ESTVR intervention, service-users and NHS staff exploring factors affecting implementation fidelity.

5.2. Introduction

The degree to which an intervention is delivered with integrity and as intended is called "fidelity" (Carroll et al., 2007). The importance of examining implementation fidelity in studies of complex interventions and its measurement

(2.6.2) and the conceptual framework for implementation fidelity (CFIF) (2.8.3) have been described.

Intervention fidelity is particularly important in trials where a complex intervention, such as ESTVR, is delivered because of the potential differences across sites and over time (Chesworth et al., 2015). The delivery of a new intervention within a trial environment is the joint responsibility of the researchers designing and managing the study and the clinicians delivering the intervention. Ultimately it is incumbent on researchers to ensure that clinicians are adequately prepared to implement the intervention with fidelity in order to optimise patient outcomes (Döpp et al., 2011). The preparation of trial therapists was the focus of study 2 (chapter 4).

Implementation fidelity has been studied by a number of scholars (Perrin et al., 2006, Forgatch et al., 2005, Fixsen et al., 2005, Bellg et al., 2004, Hennessey and Rumrill, 2003, Dusenbury et al., 2003, Brandt et al., 2004, Borrelli et al., 2005, Moncher and Prinz, 1991) who, from the early 1990's, have described the importance of confirming, or stating otherwise, that the operation of the independent variable (the intervention) occurred as planned in order to be certain that valid comparisons can be made for replicated studies (Moncher and Prinz, 1991). The importance of ensuring fidelity for vocational rehabilitation services research, in the USA, was reinforced by Hennessey and Rumrill (2003) a decade later but was still identified as a gap in rehabilitation research two decades after Moncher and Prinz's initial work (Hildebrand et al., 2012). In their

latest study, Hildebrand et al. (2012) recommend that all researchers of rehabilitation interventions measure the fidelity of novel treatment development.

Following the training of the trial therapists, it was identified as essential to measure fidelity to establish whether therapists delivered the intervention as they were trained and as the intervention was planned. It was also important to understand what, if anything, affected it's delivery across the three NHS sites and across the four trial therapists.

5.3. Study Aims

1. Evaluate the implementation fidelity of ESTVR intervention.
2. Understand factors affecting the implementation of ESTVR intervention.

5.3.1. Objectives

1. Determine the trial occupational therapists' fidelity to the core components of the intervention using multiple data collection tools and mixed-methods.
2. Describe moderating factors affecting delivery of the intervention from multiple people's perspectives.
3. Understand the barriers and facilitators to implementing the intervention.

5.4. Methods

5.4.1. Setting

This study focusses on the implementation of ESTVR, a complex occupational therapy rehabilitation intervention, delivered in a research environment, in the English NHS.

5.4.2. Study Design

This study integrated qualitative and quantitative methods to address the first aim that reflects research question three (1.4) and qualitative data alone to answer the second aim that reflects research question four (1.4). Integration can occur in a range of ways where findings agree (convergence), provide complementary information (complementarity), or disagree (discrepancy or dissonance) and this study required triangulation of findings (Farmer et al., 2006, O'Cathain et al., 2010) to explore these aspects. Further, it is recommended that analysing disagreement is particularly important in understanding the research questions. One aspect in a triangulation protocol, sitting between agreement and disagreement is 'silence'; where a theme may be found in one data set and not another, or where a surprise phenomenon arises that enhances knowledge (Farmer et al., 2006). One such aspect may be 'gaps' that are identified in the findings i.e. where an implementation framework indicates possible barriers or facilitators but none are identified.

Qualitative methods deal with language rather than numbers and provide a way to understand the perspectives and experiences of other people (Carter et al., 2011). The world is constructed of multiple realities as people experience

situations differently (Lincoln and Guba, 1985). This study involves multiple actors (people with traumatic brain injury (PWTBI) and their employers, trial therapists and NHS staff) associated with the complex intervention.

When exploring issues associated with implementation, it is important for the researcher to understand the situation from the participants' viewpoint; only by doing this can the topic be interpreted holistically and in context. Qualitative methods were considered appropriate here because they respect the uniqueness of each case as well as allowing for cross-case analysis (Ritchie and Lewis, 2009). Qualitative methods allowed exploration of the factors affecting the implementation of ESTVR from multiple perspectives reflecting research question four (1.4). These details could then be understood in a real-world context, helping to explain why ESTVR was delivered in a particular way. Comparing the different perspectives was expected to provide an opportunity for improved understanding of the factors affecting implementation.

Semi-structured interviews were considered the most appropriate method for the study population and to answer the research questions. Interviews provided participants, especially the PWTBI, time to reflect on their experiences (Paterson and Scott-Findlay, 2002), whilst the structure ensured comparability between respondents. An iterative process was used to reflect on data collected and refine interview questions, with initial themes informing questions for subsequent interviews (Grbich 1999).

Framework analysis was the chosen method for interview analysis as it has been used successfully in research for over 25 years (Gale et al., 2013). It is driven by the original accounts of the people interviewed (Srivastava and Thomson, 2009). The analytical framework is a set of codes (conceptual label) organised into categories (similar concepts) that create a new structure for data, rather than full original accounts provided by participants, and which help to answer the research question (Gale et al., 2013). The method is suited to the large amounts of data that qualitative methods produce (Ritchie and Spencer, 2002). It is a systematic analysis method and suits the current experience of the researcher (Lacey and Luff, 2009, Srivastava and Thomson, 2009). The method allows inclusion of a priori concepts (Srivastava and Thomson, 2009) such as those related to implementation research.

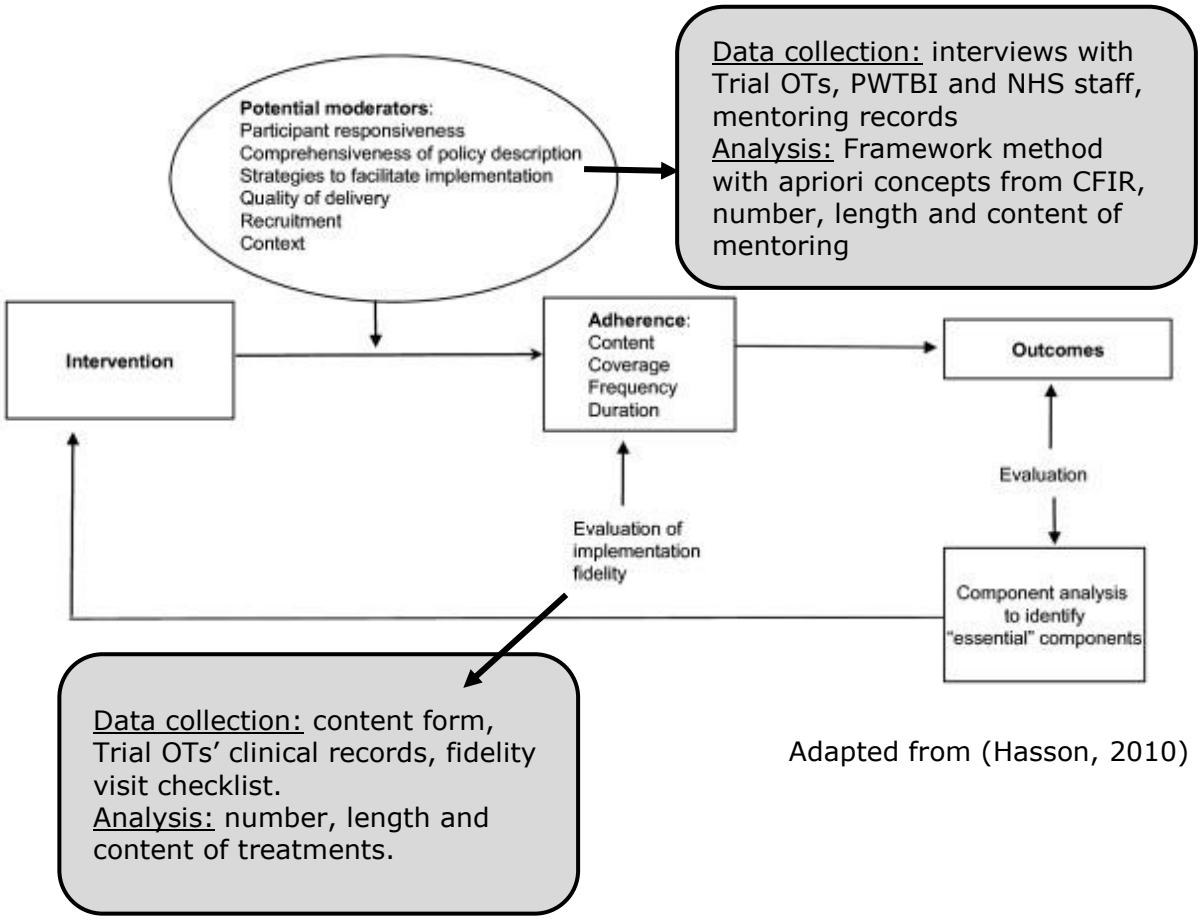
This study required a quantitative method that could examine numerical data associated with intervention adherence. It was anticipated that a sizable set of data, from multiple sources, would be collected over the duration of the study. NHS staff participants described in terms of number, department, role, grade and experience in terms of trial therapists. People with TBI described in terms of age, sex, TBI severity and employment and their employers in terms of role and business type. The number and length of intervention sessions required recording and describing in terms of dose. The content of the intervention required extracting form records, coding and describing. Both dose and content were used to analyse the implementation fidelity.

Descriptive statistics were appropriate to analyse the large quantities of data, which were collapsed into a single score (mean, median or mode), known as central tendency (Carter et al., 2011).

5.4.3. Frameworks for Analysis

Both the CFIF and CFIR were used in the study because a single framework could not comprehensively address the study needs. CFIF helps to guide measurement of implementation fidelity, whereas CFIR helps to identify determinants of implementation (what works, where and why in different contexts (Gould et al., 2014)) and sheds light on the moderating factors identified by CFIF. Figure 5-1 illustrates how both frameworks are combined in the study method and Table 5-2 details when each framework is used in detail.

Figure 5-1 Study methods superimposed on CFIF in combination with CFIR



Adapted from (Hasson, 2010)

5.4.4. Components of the intervention

The Early Specialist Traumatic Brain Injury Vocational Rehabilitation (ESTVR) intervention is described earlier (4.5.2). The components that were measured are described in Table 5-1.

Table 5-1 Intervention components

Make contact with the PWTBI in hospital or at home to establish a rapport, commence the TBI & RTW education and support PWTBI & family.
Visit or contact weekly on ward or within 10 days, if at home
Advice not to RTW too soon i.e. until impact of TBI is understood and coping strategies formulated.
Conduct a risk assessment of the home situation prior to visit.
Commence the CM Ax form (assessment of general and vocational rehabilitation needs).
CM reviews each participant every 6-8 weeks except in cases where more frequent contact is needed.
Establish which other community services e.g. ABI team, SALT are involved and collect relevant contact information, their intervention criteria e.g. typical duration and if vocational issues are addressed and how, details of team members
OT establishes and maintains communication in writing with the employer (if PWTBI consents) i.e. liaises with workplace as required and inform them of rehab goals.
OT & CM advise the PWTBI that CM is available for problem solving and assistance.
Patient's GP is informed by letter that the individual is receiving ESTVR and contact details of therapist provided.
OT has contact every 1-2 weeks except in cases where more frequent contact is needed.
OT actively liaises and communicate in writing with everyone involved (health teams, family and work), to provide information to PWTBI prior to sessions (especially if this involves the employer) and to clarify what was said and agreed afterwards in writing.
OT and CM ensure individualised interventions are explicitly work-focused
OT assesses the impact of TBI on function and work role and provides individualised education about impact to PWTBI, family and employer.
OT and CM develops strategies with and for the PWTBI to explain the effects of their TBI to others.
OT and CM develop strategies to manage effects of their TBI in everyday life and work/study.
OT assesses the work/study role, work duties/functions, work/job demands.
OT and CM support the PWTBI in seeking and accepting feedback about their (work) function.

OT explores RTW options with PWTBI and employer.
OT devises a programme of work preparation to practice work skills/functions.
OT negotiates a graded RTW with PWTBI and employer along to monitor at least weekly in the 1st 1-2 weeks then weekly for the next 4 weeks then every 2 weeks for the next 8 weeks then checks every 6-8 weeks unless decided otherwise by PWTBI.
OT and CM support PWTBI and family with feedback about work issues i.e. meet before & after workplace review meetings.
OT and CM support PWTBI to develop and maintain coping skills to deal with risks to job retention. Monitors every 4-8 weeks once the graded RTW plan is completed.
The (vocational) rehab plan is based on the results of the assessments.
All planning is done in consultation with the PWTBI.
CM ensures that non-work focused activities are coordinated and remain on-going.
At the end of the intervention, OT writes discharge letter to employer and GP confirming the outcome and detailing any ongoing plans.
Key: OT = occupational therapist; Ax = assessment; CM = case manager; ABI = acquired brain injury; SALT = Speech and Language Therapy

5.4.5. Participants

5.4.5.1. Trial occupational therapists

Local therapy managers from the three NHS Trusts participating as sites in the FRESH RCT identified appropriate personnel. The intervention had been developed to require two specialist healthcare professionals; an occupational therapist with specialist TBI-knowledge to provide vocational rehabilitation, and another healthcare professional who could be an occupational therapist, Physiotherapist or a TBI Specialist Nurse but with specialist knowledge and experience in TBI and rehabilitation. It was anticipated that the trial occupational therapists' workload would equate, on average, to one day per week. The remainder of the week would be spent in their existing role. It was intended that the trial occupational therapists were identified and employed or

seconded prior to the trial start date so that training could be delivered in preparation to deliver ESTVR (this was the focus of study two). Trial occupational therapists were expected to deliver ESTVR for ≤ 12 months to PWTBI who were randomised to receive it, over the duration of the trial (12 months participant recruitment). Trial occupational therapists were required to maintain records of each session of ESTVR provided to PWTBI.

All trial occupational therapists (≤6) seconded to work on the trial were interviewed. It was important to understand how each therapist experienced delivering the intervention throughout the study period and therefore interviews were scheduled soon after starting a caseload and once all intervention had ended.

5.4.5.2. Participants with TBI

PWTBI were those who had already been recruited to the FRESH RCT across the three sites and randomised to receive ESTVR for up to 12 months from the trial therapists.

Sampling

Purposive sampling (Carter et al., 2011) was used to identify and recruit five PWTBI from each site who had received the ESTVR intervention (15 in total) It was considered appropriate to interview a range of participants based on their demographics and TBI severity. It was also considered appropriate to interview participants throughout the trial, so that there would be some interviewed when trial therapists had less experience and some when trial therapists had

developed more experience delivering ESTVR. The purposive sampling record of can be seen in Appendix 10. This was considered sufficient to yield diverse experiences and viewpoints to allow a variety of phenomena to emerge across cases (Ritchie and Lewis 2009).

Eligibility

People were eligible if they were admitted to one of the three participating sites with a TBI of any severity and had received ESTVR. Eligibility criteria for PWTBI in the FRESH RCT are explained elsewhere (Radford K.A. et al., 2015).

5.4.5.3. Employers

ESTVR provided support to employers at the same time as PWTBI. The term 'employer' was used to refer to line managers and or other employer departments or organisations such as, human resources or occupational health, for people who were in work at the time of injury and to teaching staff for those people who were in fulltime education.

Sampling

Up to 15 employers, five from each site. PWTBI provided permission to contact their employer and it was anticipated that up to 10 employers would be recruited. This necessitated a convenience sampling strategy, which is an accepted method in qualitative design (Carter et al., 2011). If a PWTBI had lost or left employment it was still considered valuable to speak to their employer, if permitted.

Eligibility

An eligibility criteria for all PWTBI recruited to FRESH was being employed or in fulltime education. To meet this study's aims and objectives, only employers of those PWTBI recruited to the FRESH RCT were eligible.

5.4.5.4. NHS Staff

NHS staff included those at each site, who, in their usual role, were involved in managing, commissioning or delivering TBI rehabilitation.

Sampling

The author aimed to recruit 15 NHS Staff, five from each site. A convenience sampling strategy was: this is an accepted method in qualitative design (Carter et al., 2011). Fifteen NHS staff across three sites was considered sufficient to yield diverse experiences and viewpoints to allow a variety of phenomena to emerge that cut across the cases (Ritchie and Lewis 2009).

Eligibility

To meet this study's aims and objectives, only NHS staff within the local vicinity FRESH RCT sites were eligible.

5.4.6. Recruitment

All trial therapists were recruited by the researcher via email and then a follow-up telephone call. Recruitment of PWTBI to this study required contact details to be provided by the FRESH Clinical Trials Units of all participants recruited to FRESH whom had consented to be interviewed at a later date. Verbal consent

from those PWTBI who had been interviewed was provided prior to recruiting employers. Therefore recruitment was restricted to this sample. NHS staff were identified by the FRESH research team and trial therapists in each site and were recruited by the researcher via email and then a follow-up telephone call.

5.4.7. Informed consent

The process for obtaining participant (trial occupational therapist, PWTBI, employer, NHS staff) informed consent was in accordance with Research Ethics Committee guidance, and Good Clinical Practice. All trial occupational therapists had the study explained by the researcher, a written information sheet provided and consent form. All eligible participants (trial occupational therapist, PWTBI, employer, NHS staff) were sent a FRESH study covering letter, information sheet, consent form and stamped addressed envelope. Consent was provided verbally and by completing and returning the consent form to the researcher in a pre-paid envelope.

5.4.8. Data collection

Data were collected whilst the intervention was delivered (January 2014-January 2016). Multiple data collection tools were used at different time points (Table 5-2).

Table 5-2 Data Collection Tools and Timeframes

Tool	Timeframe	Theoretical Framework		Data Type
			Construct	
Content form	Continuous	CFIF	Adherence	Quantitative
Clinical record	Continuous	CFIF	Adherence Moderating Factors	Mixed methods
		CFIR	Intervention characteristics, outer and inner settings	Qualitative
Fidelity Visit Checklist	Every 3 months	CFIF	Adherence Moderating Factors	Mixed methods
Mentoring Record	Monthly	CFIR	Intervention characteristics, outer and inner settings, characteristics of individuals involved	Qualitative
		CFIF	Adherence	Quantitative
Interview Schedule for trial occupational therapists	Early after commencing delivery and late at the end of intervention delivery	CFIR	Intervention characteristics, outer and inner settings, characteristics of individuals involved	Qualitative
		CFIF	Moderating factors	Qualitative
Interview Schedule for PWTBI and Employers	late at the end of intervention delivery	CFIR	Intervention characteristics, outer and inner settings, characteristics of individuals involved	Qualitative
		CFIF	Moderating factors	Qualitative
	late at the end of	CFIR	Intervention characteristics, outer and inner	Qualitative

5.4.9. Data collection tools

5.4.9.1. Content form

Adherence (content, frequency, duration) to ETSVR was measured using an content form that had previously been developed for describing VR components delivered to PWTBI (Phillips, J. et al 2010) (Appendix 11). One content form was completed for each intervention session. Therapists' indicated how many blocks of 10-minutes were spent delivering the intervention against a list of intervention components. Trial occupational therapists recorded face-to-face (direct) activity, travel and indirect activity (participant related activity that was not directly face-to-face contact, such as communications). The content form included a descriptive guide for the trial occupational therapists (Appendix 12). Content forms were anonymised and collected during 3-monthly site monitoring visits by a member of the study team.

5.4.9.2. Clinical records

Trial occupational therapists were asked to document treatment sessions in the same way as they did in usual clinical practice. The style was not prescribed but the expectation was that therapists would record the date and time of an intervention, mode of intervention i.e. face-to-face, describe treatment activities, provide an analysis for the session and provide a plan of tasks that the therapist, participant and any other person involved would undertake. Hand written or electronic word documents were anonymised and collected during monitoring visits.

5.4.9.3. Fidelity Visit Checklist

The Fidelity Visit Checklist (Appendix 13) was used during monitoring visits to guide discussion with trial occupational therapists about fidelity to core processes, timeframes and components and to explore positive and negative moderating factors. The checklist was developed based on an observational checklist used by Hasson et al. (2012) using the theoretical constructs of CFIF (Carroll et al., 2007). It was adapted to include the core components of the intervention (Table 5-1) and additional guidance notes. The level of fidelity for each intervention component was rated on a 1-5 scale (1-always carried out, 2-often carried out, 3-sometimes carried out, 4-seldom carried out, 5-never carried out). Barriers and facilitators to delivery were also documented on the Fidelity Visit Checklist to provide contextual details.

5.4.9.4. Mentoring record

The purpose of mentoring was to support therapists to deliver the intervention. Mentoring was part of their training package and mentoring sessions were captured on a Mentoring form (Appendix 9) completed by the mentor and agreed by both parties. A one-page mentoring record was developed to capture information required to report adverse events related to PWTBI who were receiving ESTVR, address fidelity and implementation issues. It was planned that any adverse events identified in mentoring would be immediately communicated Chief Investigator, Dr Kate Radford, of FRESH as part of the trial safety assessment of potential side effects of the intervention. Outcome data potentially related to the intervention included:

- Accidental injury from noncompliance with equipment or work place adaptations recommended by trial occupational therapists.
- Work accidents resulting in injury requiring hospital treatment.*
- Incidents of aggression[+] of the participant towards the trial occupational or others (e.g. work colleagues).
- Attempted suicide.*

[+] Defined as excessive verbal or physical aggression against objects, physical aggression against self and or others.

* Hospitalisation due to attempted suicide or a work related injury were classified as Serious Adverse Outcomes.

The mentoring form was given to mentors and therapists in soft copy to complete as an electronic document, providing a summary of the mentoring session.

5.4.9.5. Interview schedule

A topic guide (Appendix 15) was developed based on theoretical constructs of fidelity and implementation as described in chapter 2 (2.8). The main topic areas included:

- An introductory conversation about the participant's perception of the need for VR with PWTBI.
- Knowledge about the current local provision.
- For PWTBI and employers their experience of receiving the intervention and any barriers.

- For trial occupational therapists their experience of delivering the intervention and any barriers.
- For NHS staff their experience of the intervention and any barriers or facilitators relating to perceived longer term sustainability.
- Recommendations regarding facilitators and barriers related to future sustainability of the intervention.

5.4.10. Data collection methods

5.4.10.1. Content forms, clinical records and fidelity visit checklist

Monitoring visits to each site were carried out by an experienced post-doctoral research occupational therapist (JP) to check the fidelity of the intervention delivered by trial occupational therapists. Prior to the visit, trial occupational therapists mailed their anonymised clinical records and content forms. These were read ahead of the site visits. Based on the content forms and clinical case notes, the researcher and trial occupational therapists discussed the intervention delivered, using the Fidelity Visit Checklist. Following the visit, treatment components from the content forms and clinical notes were recorded on an Excel document by a member of the study team.

5.4.10.2. Mentoring Records

Mentoring record forms were collected from mentors by the researcher. Supplementary mentoring data was gathered from emails, texts, and written summaries of phone calls during the study period.

5.4.10.3. Interviews

Interviews lasting approximately 45 minutes, took place by telephone. They were digitally recorded, transcribed, cleaned and stored securely.

5.4.11. Data analysis

5.4.11.1. Analysis of fidelity

It was important to measure all constructs of fidelity to avoid gaps in reporting. Fidelity was analysed using the CFIF framework and constructs (Figure 2-4) and data compared to:

- the expected content delivered,
- the proportion of components delivered,
- required components,
- required frequency and,
- intervention duration.

Carroll et al. (2007) suggests using a benchmark to measure the quality of intervention delivery. A benchmark is typically representative of quality improvement processes and determined using multiple best practice evidence (Royal College of Nursing, 2014). However, for this study 'benchmark' means, "a point of reference against which things may be compared." (Oxford Dictionaries, 2017) and refers to the only description of ESTVR that has been published to date by (Phillips, J. 2013) and provides the only best practice comparator available. The same content form, on which therapists recorded each treatment session, was used in this study as in Phillips' and permitted

benchmarking to establish whether the expected content of ESTVR had been delivered.

Data from the clinical records and content form was triangulated in order to identify any missing data, check variations in fidelity and disagreement between data sources. Where there was disagreement e.g. the content of a session, the clinical record was considered more likely to represent what had occurred because therapists were more familiar with this form of documentation. Descriptive statistics (central tendency and spread) were used to describe the quantity and content of the intervention delivered.

The content of the intervention was analysed by triangulating each content form with the description of the intervention session in clinical records. The proportion of time spent on each intervention component was calculated from the content forms, queries were triangulated with relevant text from clinical records. "Intervention" refers to all face-to-face contact and contact that is indirect for example, communications with and relating to the PWTBI. "Supportive activity" refers to time spent travelling or administration such as clinical record keeping and supports the delivery of the intervention.

The frequency and duration of the intervention was calculated using calendar dates on each content forms and further analysed for both direct and indirect contact with PWTBI. The intervention required trial occupational therapists to

have contact with PWTBI at particular time points and data were compared to these requirements:

1. After referral, the trial occupational therapist visits weekly on ward or within 10 days if the participant is at home.
2. Following the initial visit, the trial occupational therapist will contact the participant every 1-2 weeks and the case manager every 6-8 weeks except in cases where more frequent contact is needed.
3. During a graded RTW the trial occupational therapist will contact the participant at least weekly in the 1st 1-2 weeks then weekly for the next 4 weeks then every 2 weeks for the next 8 weeks, then every 6-8 weeks unless decided otherwise by the PWTBI.
4. Once the graded RTW plan is complete, the trial occupational therapist will contact the participant every 4-8 weeks.

5.4.11.2. Analysis of moderating factors

Transcribed audio files were analysed with framework methods. Transcripts were analysed systematically over six stages as recommended (Ritchie and Spencer, 2002, Gale et al., 2013).

1. Familiarisation.

   At this stage notes made by the researcher about themes and emergent issues are important. This was achieved by listening to recordings and through several readings of interview transcripts (trial occupational therapists', PWTBI and their employers and NHS staff) and multiple

records (fidelity visit checklist, content forms, clinical records and mentoring records).

2. Coding.

   The aim of coding was to categorise data to enable comparisons. It is recommended that at least two researchers code a few transcripts to ensure no data is missed and there are representative viewpoints (Gale et al 2013). In this study inductive (open) coding was initially used including values i.e. perceptions of the intervention. However, as the study is also underpinned by implementation research deductive (pre-defined codes) codes relating to the two frameworks, CFIF and CFIR were also used. The study team, comprising the author, who coded all transcripts and all records, post-doctoral researchers (JP and BR), research assistant (RM) and TBI expert (TJ) who coded up to 50% of the interview transcripts. Coding was managed utilising the computer assisted qualitative data analysis software (CAQDAS) Nvivo 10 by QSR International for interview transcripts. Other records detailed above were hand-coded. It is recommended that once coding has been conducted for a few transcripts analysts meet and agree on a set of codes. The study team met on three occasions for this purpose.

3. Developing a working analytical framework.

   The author grouped codes together into categories, based on the CFIF and CFIR constructs.

4. Applying the analytical framework.

   The framework (of codes and categories) was applied to the remaining transcripts and records.

5. Charting the data into the framework matrix.

   Data were charted onto a matrix to provide a visual representation of the data.

6. Interpreting the data.

   Documenting impressions of the data is recommended to assist the interpretation (Gale et al., 2013). Interpretation looked for connections, characteristics and differences between data and lead to an understanding of how the participants perceived and experienced the intervention revealing the issues (barriers and facilitators) surrounding its implementation in the NHS.

Text relating to factors moderating implementation fidelity (participant responsiveness, intervention complexity, facilitation strategies and quality of delivery) were extracted and triangulated across multiple records (fidelity visit checklist, content forms, clinical records and mentoring records) and interview data (trial occupational therapists', PWTBI and their employers and NHS staff). Interview data was analysed using the framework method described above. The frameworks CFIR and CFIF allowed mapping of the barriers and facilitators and provided the relevant structure to interpret the moderating factors.

5.4.12. Ethical Approval

Ethical approval was gained HTA FRESH, REC Ref 13/EM/0353 and University of Nottingham ethics ref No. D14112013 FRESH SoM Rehab & Ageing. Further approval for the unique element of comparing anonymised data was not required following consultation with the University of Nottingham Research Governance

team. The author had a Research Passport and letters of Access for each of the three study sites in FRESH, from where interview participants were recruited.

5.5. Results

5.5.1. Participants

5.5.1.1. Trial occupational therapists

Details of the trial occupational therapists are previously described (4.5.1.3). In summary, four occupational therapists were recruited as trial occupational therapists; one in sites 1 and 3 and two in site 2. Trial occupational therapists in two centres worked for the NHS (one in a community role and the other in an acute role). The third centre was unable to recruit a NHS therapist and therefore two independent occupational therapists were recruited. Trial occupational therapists were trained to deliver both the Occupational Therapy and the case manager roles of the intervention because two separate therapists could not be recruited in two centres. The third centre did recruit two therapists but due to the local geography and difficulty with travel, they also delivered both roles.

Trial occupational therapists hereafter are referred to in the feminine to prevent distinguishing the single male trial occupational therapist and individuals are identified as; OTA, OTB, OTC and OTD.

5.5.1.2. Participants with TBI

Of the 38 PWTBI who received ESTVR, 15 were interviewed. They had a mean age of 39.4 years (±12.64 (range 25-61) and 80% (n=12) were male (Table 5-3).

Table 5-3 Demographics of PWTBI interview participants

		Site 1	Site 2	Site 3	Total
Number of participants		5	5	5	15
Age	Mean (range) SD	44.8 (27-61) ±15.67	33 (25-54) ±11.90	40.4 (26-48) ±9.10	39.4 (25-61) ±12.64
Gender N (%)	Male	4 (75%)	3 (60%)	5 (100%)	12 (80%)
	Female	1	2	0	3
TBI Injury severity	Mild (GCS: 13-15)	3	2	1	5
	Moderate (GCS: 9-12)	1	0	3	4
	Severe (GCS: 3-8)	1	3	2	6
Cause of injury	RTA	2	2	1	5
	Fall	2	2	3	7
	Assault		1	1	2
	Other	1	0	0	1
Other rehab involved		2	2	2	6
OT no consent to visit workplace		0	2	5	7
Consent given to communicate with employer		5	5	5	15
Work roles		Electrician. Care work. Abattoir work. Rigging. Window fitting.	Waiting staff. Teaching. Administra-tion. Business owner.	IT. Warehouse work. Estates man-agement. Doctor.	
Active OH involved		2	0	3	5

Key: SD – standard deviation, GCS – Glasgow Coma Scale, RTA – road traffic accident, other = participant unsure if fell or assaulted, OH – occupational health

A single adverse event related to participants with TBI was captured by the mentoring record. This was verbal (not physical) aggression from a participant in response to being told by one trial occupational therapist that he couldn't drive and needed to inform the DVLA.

5.5.1.3. Employers

Of the 15 PWTBI interviewed, 13 consented to their employer being contacted for interview, one was self-employed and one declined. Of the 13 employers, six consented (Table 5-4).

Table 5-4 Demographics of employer participants

	Site 1		Site 2		Site 3	
Number of participants	2		2		2	
Role	Service manager	Manager	Teacher	Manager	Occupational Health Physician	Assistant Director
Relationship to PWTBI	Human Resources	Line manager	Line manager	Line manager	Occupational Health provider	Line manager
Business Type	National third sector organ-isation	Third sector organisation	School	Restaurant	Higher Education	NHS Trust
Size	Medium	Small	Medium	Small	Large	Large

Key: small enterprises have 10-49; medium enterprises have 50-249; large enterprises have >250 (ec.europa.eu., 2017)

5.5.1.4. NHS Staff

Across the three sites 13 NHS staff with varying roles consented to be interviewed as detailed in Table 5-5.

Table 5-5 Demographics of NHS staff participants

		Site 1	Site 2	Site 3
Number of participants		6	3	4
Organisation	Community NHS Trusts	1	0	1
	Acute NHS Trusts	1	1	1
	NHS England	1	0	0
	Clinical Commissioning Group	0	1	1
Role	R&D	1	1	1
	Network Manager, Strategic Clinical Network	1	0	0
	Commissioner		1	1
	Community Occupational Therapist	1		1
	Lead Occupational Therapist	1	0	0
	Clinical Services Manager	1	0	0
	Local clinical Principal Investigator	1	1	1

Key: CCG – Clinical Commissioning Group; PI – Principal Investigator for FRESH; R&D – esearch and Development

5.5.2. Mixed methods integration: overall fidelity

After concurrently analysing the quantitative and qualitative data, they were integrated to explore complementarity (Table 5-6) and to explain why trial occupational therapists delivered the intervention in the way they did. Comparison of the tabulated data illustrated fidelity findings from multiple quantitative data sources and explained the variation from the qualitative data sources.

There was convergence in the fidelity measurement and in the exploration of the moderating factors; different methods tended to show high levels of agreement and complementarity i.e. when trial occupational therapists talked about frustrations in maintaining contact with PWTBI, this was reflected in PWTBI attrition.

Analysis did not highlight disagreements in data, but missing quantitative data was identified and classified as 'silence' because it was a surprise that a therapist did not document discharge dates with almost an entire caseload.

Quantitative data consisted of thirty eight sets (one per PWTBI) of trial occupational therapists' clinical notes and 699 (42-248 per therapist) content forms and 12 fidelity visit checklists. Some data was duplicated and some missing from both clinical notes and content forms when cross referenced:

- letter writing was not always recorded on the content form,

- session activity in a content form was not always recorded in the clinical record,
- session dates were not always recorded.

Qualitative data consisted of 38 sets (one per PWTBI) of trial occupational therapists' clinical notes, 12 fidelity visit checklists, 183 mentoring records (136 email, 40 phone call, 7 face to face records) and 38 (four trial occupational therapists, 15 PWTBI, six employers, 13 NHS staff) interview transcripts.

Using the Conceptual Framework for Implementation Fidelity (CFIF) originally by (Carroll et al., 2007) and modified by (Hasson, 2010), the integrated and overall results suggest that trial occupational therapists delivered the intervention with high levels of fidelity (Table 5-6). However, there were some instances of non-adherence to duration and frequency. Factors that moderated the implementation of the intervention explain non-adherence and variations in delivery between trial occupational therapists.

The following results section provides a detailed account of fidelity measurement using the CFIF constructs (coverage, content, duration, quality of delivery and dose) and provides case examples for non-adherence. This is then followed by a detailed description of the moderating factors using the CFIF constructs (participant responsiveness, facilitation strategies, complexity and context) mapped to CFIR to illustrate the range of implementation issues.

Table 5-6 Fidelity to ESTVR and moderating factors involved

			Trial OTs				Moderating Factors	Comments
			OT A	OT B	OT C	OT D		
Fidelity measurement (adherence)	Coverage		✓	✓	✓	✓	Participant responsiveness, Complexity.	Fidelity met in all cases. Trial OTs should actively engage with harder to reach PWTBI, preventing attrition.
	Content		✓	✓	✓	✓	Participant responsiveness, Quality of delivery, Facilitation strategies, Complexity and Context.	Fidelity met in all cases. Content tailored to meet.
	Duration		✓*[1]	✓*[1]	✓*[1]	✓*[1]	Participant responsiveness, Comprehensiveness of description, Complexity and Context.	Fidelity met in most cases. Further clarity is required about discharge.
	Frequency of	1 ≤10 days	✓*[3]	✓*[1]	✓*[3]	**	Participant responsiveness, Comprehensiveness of description.	Fidelity met in most cases. Missing recorded session dates. Further clarity required.
		2 1-8 weeks	✓	✓	✓	✓	Quality of delivery, Facilitation strategies and Context.	Fidelity met in all cases. Trial OTs saw PWTBI when they most needed it.
		3 ≤8 weeks	✓	✓	✓	✓	Comprehensiveness of description and Context.	Fidelity met in all cases. Not all PWTBI return to work. Change of wording required in fidelity visit checklist.
		4 4-8 weeks	✓	✓	✓	✓	Comprehensiveness of description and Context.	

Key: OT – occupational therapist, ✓ - fidelity met; ✓* - fidelity met except for n= x cases; ** - missing data; time point 1 within 10 days of referral; time point 2 OT contact every 1-2 weeks, case manager 6-8 weeks; time point 3 On graded RTW, weekly for 4 weeks, then fortnightly for 8 weeks, then checks ≤8 weeks; time point 4 On full RTW contact is 4-8 weeks; RTW – return to work

5.5.3. Adherence

5.5.3.1. Coverage

Thirty nine PWTBI participants were randomised to receive the intervention. One PWTBI did not respond to communication attempts, therefore 38 participants received ESTVR from the trial occupational therapists (in the occupational therapist and case manager roles) (Table 5-7). Of the 38 PWTBI receiving the intervention, four withdrew. In these four participants attrition was reported by trial occupational therapists as occurring after:

1. Participant 1 - 17 working days.
2. Participant 2 - 33 working days.
3. Participant 3 - 57 working days.
4. Participant 4 - 59 working days.

These individuals did not consent to further interview and therefore reasons for withdrawing from the intervention were surmised by the trial occupational OT. Reasons included:

- Disagreement with the therapist regarding safety to drive.
- Back at work.
- Retired and coping.
- Moved away and no contact details.

Numbers of PWTBI participants per therapist varied from four to 17. Variation was attributable to local site recruitment and randomisation. Fifty per cent (n=19) of PWTBI treated were reported as having a mild TBI, using the Glasgow coma scale (GCS), 18% (n=7) a moderate TBI and 26% (n=10) a severe TBI.

Two participants did not have their TBI severity recorded. In contrast Phillips, J. (2013) reported just under half of participants had a severe TBI.

Table 5-7 Numbers of participants per therapist

	Severe TBI (GCS: 3-8)	**Moderate TBI (GCS: 9-12)**	**Mild TBI (GCS: 13-15)**	**No GCS recorded**
Benchmark (N=29)	**14 (48.3%)**	**7 (24.1%)**	**8 (27.6%)**	**0**
Therapist A (N=11)	2 (18%)	1(9%)	7(64%)	1 (9%)
Therapist B (N=6)	2 (33%)	1(17%)	3 (50%)	0 (0%)
Therapist C (N=4)	1 (25%)	1 (25%)	2 (50%)	0 (0%)
Therapist D (N=17)	5 (29%)	4 (24%)	7 (41%)	1 (6%)
Total (N=38)	10 (26.3%)	7 (18.4%)	19 (50%)	2 (5.3%)
Key: GCS: Glasgow Coma Scale.				

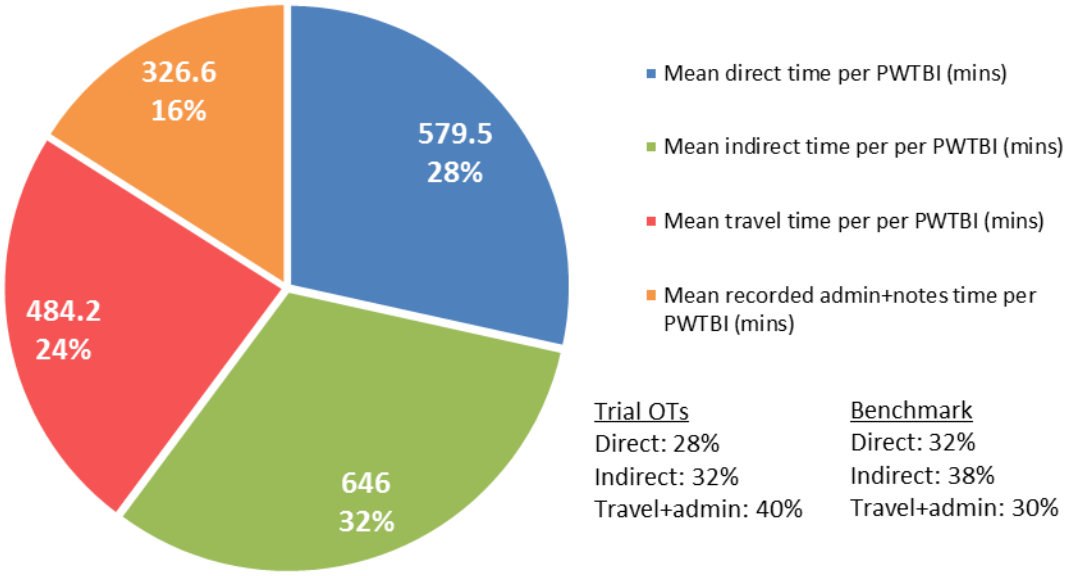
Participants had a mean age of 40.4 years (range 16-62), 87% (n=33) were male, and 71% (n=27) were in full time work prior to injury. In comparison, Phillips (2013) reported cohort study participants (N=29) were five years younger having a mean age of 35 years (range 19-66), fewer were men 82.8% (n=24), and 100% (n=29) were in full time work prior to injury.

5.5.3.2. Content

Content relates to the components of the intervention that were delivered. Overall, 60% of trial occupational therapists' time was spent delivering the intervention and 40% of time spent in supportive activity. This is similar to the benchmark (70% intervention delivery and 30% supportive activity) (Figure 5-

2). The proportion of time spent in direct intervention was similar for each trial occupational therapist (OTA=65%, OTB= 58%, OTC=54% and OTD = 59%).

Figure 5-2 Time spent on direct and supportive components



Travel time differed between therapists ranging from 14%-34%. OTB and OTC spent almost 15% more of their total intervention time travelling. This was due to city congestion and reliance on public transport.

5. Contact with employers

Trial occupational therapists had direct contact with 14 (37%) employers (range 0-6) and indirect contact (where the PWTBI, after discussions with the trial occupational therapist, relays advice to the employer) with 24 (63%) employers (range 2-9). The benchmark had similar findings; direct contact with 28.5% (N=8) employers and indirect contact with 55% (N=16). OTA and OTB had

direct contact with their PWTBI's employers for more than half of their caseload (67% (n=6) and 55% (n=4), respectively). OTD had direct contact with 4 (24%, n=17) employers and OTC did not have any direct contact with employers.

6. Proportion of intervention components delivered

The intervention components delivered are presented in three formats to illustrate the quality of delivery:

1. Two pie charts (Figure 5-3 and 5-4) compare the proportion of components delivered by all trial occupational therapists (Figure 5-3) and benchmark (Figure 5-4).
2. The percentage of each intervention component delivered by each trial occupational therapist is compared to the benchmark (Table 5-8).
3. A comparative histogram (Figure 5-5) illustrates the variation.

Trial occupational therapists delivered the intervention components in a similar proportion to the benchmark. Figure 5-3 indicates that the five intervention components most frequently delivered across trial occupational therapists, in descending order, were work preparation, return to work, assessment, family support and cognitive (Figure 5-3). In comparison, the five intervention components most frequently delivered in the benchmark were work preparation, assessment, return to work, current issues and psychological (Figure 5-4). 'Family support' did not feature as a component in the benchmark and was subsumed under current issues. Current issues included discussing medical

issues such as medication side effects, financial issues such as discussing welfare benefits, family issues, current work issues and discussing intervention from other rehabilitation providers (Phillips, J. 2013).

In vocational rehabilitation, it would be expected that non work-related components would be delivered less or not at all i.e. personal ADLs, mobility or specific physical issues. These findings reflected this. Little time was spent on these components, which compared favourably to the benchmark (Table 5-8 and Figure 5-3).

Whilst it is useful to show the combined proportions of the intervention components delivered, this doesn't illustrate individual variation in delivery. This is most apparent being "family support" where the mean indicates that this component was delivered the fourth most frequent. However, OTB delivered this 37% of the time whilst the others did not record delivering the component at all.

Figure 5-3 Intervention components delivered face-to-face (all therapists)

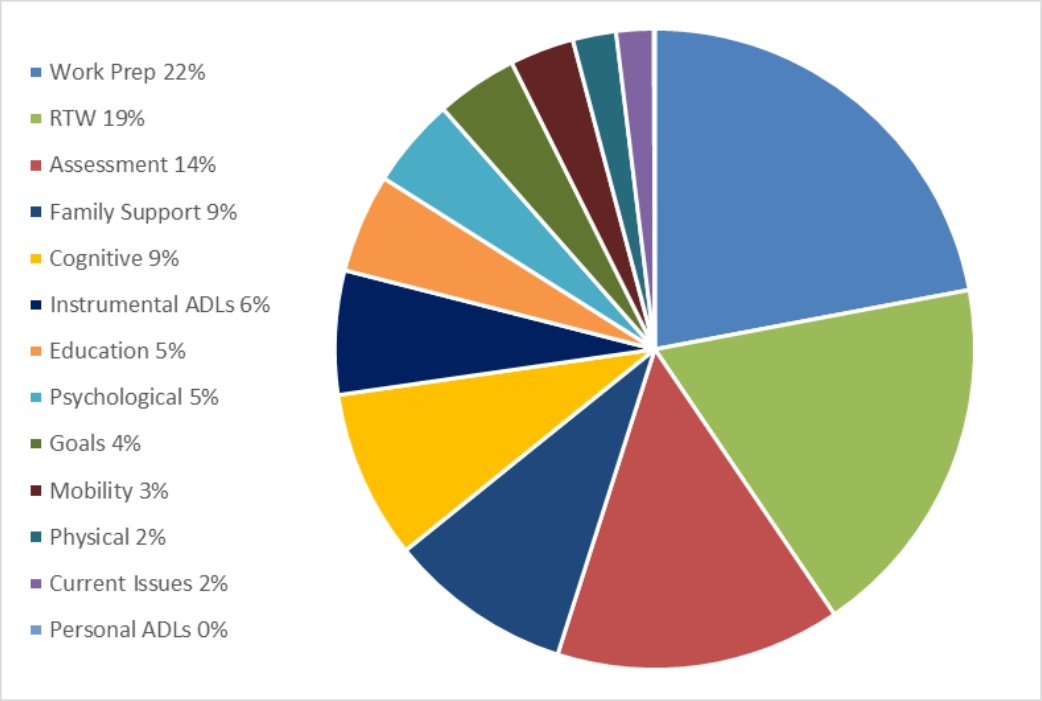
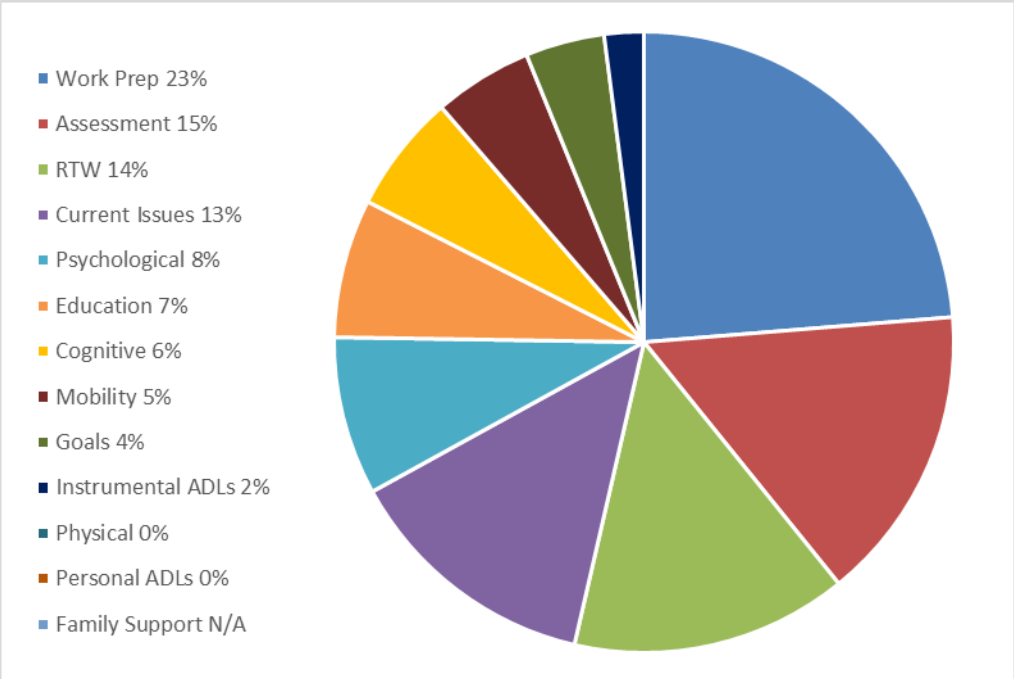


Figure 5-4 Intervention components delivered face-to-face (benchmark)



To demonstrate individual variations, the amounts of each component delivered by each trial occupational therapist are shown in Table 5-8. This shows greater variation between trial occupational therapists and the benchmark for 'current issues', 'rehabilitation goal setting', 'instrumental ADLs' and 'psychological issues' (Table 5-8 and Figure 5-5). Variability can in part be explained by clinical and mentoring records but also by differences in the way the intervention components were categorised by the trial occupational therapists.

Table 5-8 Intervention components delivered compared to benchmark

	OT A	OT B	OT C	OT D	Benchmark
Work Prep	20%	15%	39%	15%	23%
RTW	9%	8%	13%	44%	14%
Assessment	13%	10%	12%	23%	15%
Family Support	0%	37%	0%	0%	N/A
Cognitive	9%	10%	11%	4%	6%
Instrumental ADLs	8%	6%	10%	2%	2%
Education	9%	3%	1%	6%	7%
Psychological	14%	0%	2%	2%	8%
Goals	14%	1%	0%	2%	4%
Mobility	1%	4%	7%	1%	5%
Physical	1%	4%	3%	1%	0%
Current Issues	1%	2%	3%	1%	13%
Personal ADLs	0%	0%	0%	0%	0%

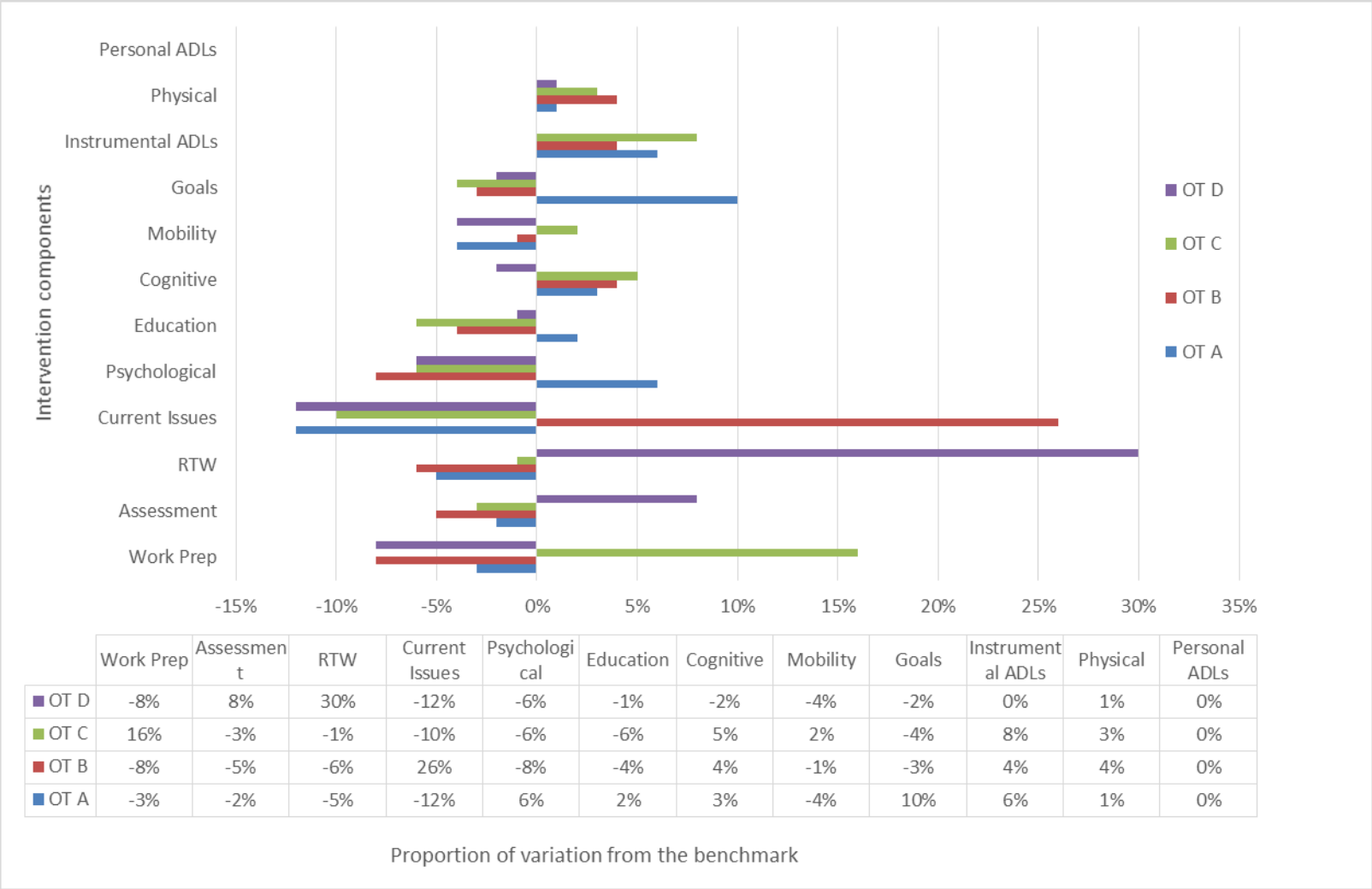
Key: ADL- activities of daily living; Prep – preparation; RTW – return to work; N/A – not applicable as this data was not represented in the original study by Phillips (2013).

A histogram (Figure 5-5), using the benchmark as zero shows how much of each ESTVR component the trial occupational therapists delivered. Even though "family support" did not have a benchmark comparison, it was important to include this to demonstrate variation across the trial occupational therapists for transparency. Whilst most components were delivered with a variation close to 10%, three (family support, RTW and work preparation) varied more. Clinical records and reported moderators explained that this was due to participant

need. Even if "family support" were combined with "current issues", the delivery of this component would exceed the benchmark by 26%.

Proportionately, OTC delivered more work preparation than the other trial occupational therapists and the benchmark. This trial occupational therapist only had four cases, two PWTBI, one with long-term addiction and one who had complex neuropsychological symptoms, and delivered this component more than any of the other components. OTD delivered more intervention categorised as 'return to work'. This was due to a single PWTBI who successfully returned to work but then experienced additional workplace relationship issues requiring the trial occupational therapists' support. Similarly OTB delivered more family support component where one PWTBI required additional education and family support due to the effects of the TBI and other trauma-related sequelae. OTD also spent nearly twice as much time in 'assessment' and OTA spent more time in 'goal setting'. In both cases clinical and mentoring records provided explanations.

Figure 5-5 Variation of components delivered compared to benchmark



	Work Prep	Assessment	RTW	Current Issues	Psychological	Education	Cognitive	Mobility	Goals	Instrumental ADLs	Physical	Personal ADLs
OT D	-8%	8%	30%	-12%	-6%	-1%	-2%	-4%	-2%	0%	1%	0%
OT C	16%	-3%	-1%	-10%	-6%	-6%	5%	2%	-4%	8%	3%	0%
OT B	-8%	-5%	-6%	26%	-8%	-4%	4%	-1%	-3%	4%	4%	0%
OT A	-3%	-2%	-5%	-12%	6%	2%	3%	-4%	10%	6%	1%	0%

Proportion of variation from the benchmark

5.5.3.3. Duration

Trial occupational therapists demonstrated high fidelity to the duration of the ESTVR intervention. However, there was considerable difference in the duration of intervention between therapists and between participants. Nearly three months difference was measured between the participants seen for the shortest (9 days) and the longest (456 days) durations. Each trial occupational therapist exceeded the 12 month duration with a single participant (Table 5-9), one with severe TBI and three with mild TBI.

Table 5-9 Duration of intervention per therapist

	Duration of intervention (days between referral and discharge)	Duration of intervention (with single case excluded)	Injury severity of single case
Therapist A	9-372	9-365	Severe TBI
Therapist B	82-456	82-365	Mild TBI
Therapist C	174-391	174-328	Mild TBI
Therapist D	22-382	22-361	Mild TBI
Duration of intervention: From documented date of referral or first entry in clinical records to date of last contact with patient in clinical records.			

Moderating factors were related to individual participant' needs, which varied considerably as documented in the clinical records as described below:

- The first PWTBI, (severe TBI) returned to the same job, same employer. The PWTBI remained on the therapist's caseload for 11 months but without receiving intervention. The therapist used the maximum 12-

month allowable duration as a follow up period in case any problems occurred (with job retention). Clinical records and content forms indicated this occurred across therapists with multiple participants but clinical reasoning is not clearly documented.

- The second PWTBI (mild TBI) did not return to work. The therapist made referrals to 10 further services to meet ongoing needs due to trauma-related symptoms, but the long local NHS waiting times meant the therapist monitored the PWTBI beyond 12 months until these services were in place.
- The third PWTBI (mild TBI) did not return to work and had not been in work prior to recruitment. Regular intervention was recorded over eight months and discharge is recorded close to 12-months but contact was made again at the 16 month point but without clearly documented reasons.
- The fourth PWTBI (mild TBI) returned to studying. Documentation does not provide a clear reason for discharging after 12 months.

5.5.3.4. Frequency

'Frequency' refers to the how often the trial occupational therapist had contact with the PWTBI. 'Key time points' refers to important timeframes by which trial occupational therapists were expected to see the PWTBI and described in the fidelity visit checklist (Appendix 13) and the intervention components (Table 5-1). The four key time points are described below. Analysis of sources (content forms, clinical records and fidelity visits) providing quantitative data revealed inconsistencies. Key dates were not consistently documented by trial

occupational therapists. Findings indicated high levels of fidelity to key time points. Variations in delivery were explained by clinical and mentoring records.

Time point one – (within 10 days of referral) - The intervention required that the PWTBI was seen early after injury. This could start whilst an inpatient in hospital. Triangulated data sources indicated that the some visits did occur when intended. Three trial occupational therapists met the time point with some participants, whilst the fourth (OTD) had not recorded this data with all cases except one. OTD had been employed as a trial occupational therapist later than the other therapists, having replaced one who left. OTD was trained differently to the other trial occupational therapists but did have the same access to ongoing mentoring.

OTA did not meet this time point with three participants (out of a total caseload of 11 (27%), OTB with one participant out of a caseload of 6 (17%) and OTC with three participants out of a caseload of 4 (75%). Clinical and fidelity records indicated moderating factors were a lack of participant responsiveness and a participant temporarily staying with relatives while recuperating. Although trial occupational therapists did not consistently meet this aspect of the intervention fidelity records indicated that they made contact with or attempted to contact participants within the stated period.

Three trial occupational therapists were based outside of the acute hospital setting and this affected the feasibility of seeing participants whilst an inpatient.

Referral to the trial occupational therapist occurred only after recruitment and randomisation and even the trial occupational therapist based on the acute trauma ward did not manage to see participants before discharge because of the high turnover of patients. An exception to this was recorded but the trial occupational therapist failed to see the individual on the ward within the stipulated timeframe because the participant declined a visit as further surgery related to trauma injuries was imminent.

Time point two – (OT every 1-2 weeks, case manager every 6-8 weeks) - The fidelity visit checklist indicated this marker was achieved with high fidelity all of the time by two trial occupational therapists and with moderate fidelity the majority of the time by the other trial occupational therapists. Clinical and mentoring records explain the variation. Moderating factors were related to trial occupational therapists determining the frequency of input based on the complexity of participants' needs and circumstances.

Based on Phillips (2013) study, it was anticipated that participants would receive an average of 11 occupational therapy and case manager face-to-face (direct) sessions. ESTVR was delivered a mean of 6.3 sessions per participant (mean range between therapists 5-9.5). The overall range of the number of times a trial occupational therapist provided ESTVR to PWTBI was wide (0-40), (Table 5-10). Clinical and mentoring records explained the variation. Moderating factors for the participant who received no visits had wanted to retire and felt ESTVR would not meet his needs. Moderating factors for the participant who received 40 visits were related to the complexity of the participant's injuries and the lack

of response from the local NHS that necessitated more visits from trial occupational therapist B. The trial occupational therapist accompanied the participant to some of the 21 services involved in his post injury care.

Table 5-10 Number of face-to-face visits per therapist per whole caseload

	Mean number of face-to-face to face sessions per participant
Benchmark	5.9 (range 1-23)
OTA (n=11)	6.7 (range 1 to 19)
OTB (n=6)	9.5 (range 2 to 40)
OTC (n=4)	5.75 (range 2 to 13)
OTD (n=17)	5.00 (range 0 to 26)
Total (n=38)	6.3 (range 0-40)

The number of visits per participant was highest in the first month and then declined in frequency. The mean number of face-to-face visits per participant in the first month was 1.5, (range 1.27 – 1.72). The average number of visits per participant in month 12 was 0.21 (0-0.31).

Time point three – (On graded RTW, once per week) - The Fidelity Visit Checklist indicated this marker was achieved with high fidelity by all trial occupational therapists.

Time point four – (On full RTW, 4-8 weeks) - The Fidelity Checklist indicated this marker was achieved with high levels of fidelity by three trial occupational

therapists and with moderate fidelity by one trial occupational OT, where there was variation, clinical and mentoring records offered an explanation for the variation.

5.5.4. Moderating Factors

Analysis of clinical, mentoring and fidelity visit records revealed the moderating factors emanating from individual and organisational origins and helped to explain variation in intervention delivery. Interviews with trial occupational therapists, recipients of the intervention, their employers and NHS staff provided additional perspectives on the moderating factors. Data was in accordance with four of the six moderating factor constructs described by Carroll et al. (2007) and Hasson (2010) and 14 factors were identified (Figure 5-6). These factors mapped to 21 of the 26 implementation constructs of CFIR. Moderating factors were considered as barriers or facilitators in terms of their negative or positive effect on the delivery of the intervention. Most moderators were mapped to more than one implementation construct. Twelve barriers and 36 facilitators were identified with a further 11 identified as both barriers and facilitators. Constructs without any mapped barriers or facilitators were:

- Trialability, design quality, packaging and cost of the intervention in domain one.
- Organisational culture to support implementation in domain three.
- Process of planning the implementation of the intervention in domain five.

Figure 5-6 Summary of moderating factors mapped to CFIR constructs

CFIF Moderating Factors	1. Intervention source	2. Evidence strength & quality	3. Relative advantage	4. Adaptability	5. Trialability	6. Complexity	7. Design quality & packaging	8. Cost	9. Structural characteristics	10. Networks and communications	11. Culture	12. Implementation climate	13. Readiness for implementation	14. Patient needs & resources	15. Cosmopolitanism	16. Peer pressure	17. External policy & incentives	18. Knowledge & beliefs of Rx	19. Self-efficacy	20. Individual stage of change	21. Individual identification with org	22. Other personal attributes	23. Planning	24. Engaging	25. Executing	26. Reflecting and evaluating
Participant Responsiveness																										
Communication with PWTBI and employer														✓✓												✓
Collaboration from PWTBI and employer														✓✓			✓									
Intervention acceptability														✓✓												
Context																										
Access to NHS systems										✓			✓													
Local geography									✓				✓				✓									
Inter-agency providers	✓	✓	✓											✓	✓		✓✓									
Limited backfill & manager support									✓			✓	✓													
Intervention complexity																										
Individual needs of PWTBI & employer				✓										✓✓	✓✓	✓✓	✓✓									
Changing needs of PWTBIs				✓										✓✓												
Tailoring of the intervention				✓										✓												
Facilitation Strategies																										
Training package (mentoring)													✓					✓	✓		✓					
Monitoring visits	✓	✓	✓	✓		✓								✓									✓	✓	✓	
Specialist therapists						✓			✓	✓			✓					✓	✓✓	✓	✓	✓✓				
Resources from the provider organisation	✓	✓	✓	✓					✓	✓		✓	✓										✓			

Key: ✓ = facilitator to implementation, ✓ = barrier to implementation, ✓✓ = barrier and facilitator to implementation

5.5.4.1. Participant Responsiveness

Communication with the PWTBI and employer

Regular contact with the participant was a required intervention component. Trial occupational therapists explained that this was difficult in some cases, especially when people had returned to work: *"With these guys, … they just switched off from responding and to dealing with sort of the hassle of having to deal with us as therapists … So how long do we keep on trying for?"* (OTC). Some PWTBI reflected that they had busy lives and found it difficult to make time for the intervention: *"I just felt bad because there were a lot of times that she wanted to call me or meet me, but I just couldn't because I was so busy all the time."* (02002).

Communication was also stilted when a newly referred individual temporarily stayed out of area and due to the effects of a pre-existing health condition. Communication also halted when a PWTBI moved and did not provide forwarding contact details.

Even when PWTBI provided permission for trial occupational therapists to contact their employers about RTW, some employers did not reciprocate, which was perceived as a barrier to intervention delivery.

Collaboration from PWTBI and employer

Mentoring and clinical records indicated that some PWTBI were unhappy with the intervention or part of it and ceased engagement but did not formally withdraw

from the FRESH RCT. In one case this was due to advice provided about refraining from driving for a time specified in published guidance by the DVLA. Records also indicated that some PWTBI felt the intervention was not appropriate at that time because of impending surgery related to other trauma injuries or where was no intention to work in the future.

In order to facilitate RTW, the trial occupational therapists ideally worked directly with employers and most PWTBI provided consent. Mentoring records revealed that not all PWTBI allowed contact with their employer, a decision respected by the trial occupational therapist. This was anticipated and working around this issue perceived as tailoring the intervention. Reasons for not providing access were not routinely recorded and those that were, varied. These included the PWTBI asserting their independence in negotiating RTW planning with guidance from the trial occupational therapist to those who did not perceive any need or simply did not want this aspect of the intervention.

As expected records showed that employers were not always able to accommodate PWTBI in work roles but this was infrequent and related to safety-critical roles e.g. driving. In these situations then the trial occupational therapist continued to communicate with the employer to seek a resolution. This could involve organising medical evidence to reassure the employer about the employee's capacity to carry out specific duties e.g. machine handling or driving. The trial occupational therapist continued to deliver other components of the intervention whilst negotiations lasted. Reassuring the employer about capacity to drive was frequently raised as an issue by trial occupational therapists, PWTBI

and employers. The Driver Vehicle Licensing Authority (DVLA) is the primary organisation that reinstates a driver's licence (for private and commercial vehicles) after it has been relinquished. DVLA were slow returning paperwork even when participant PWTBI had no reported limitations following an assessment at a NHS Driving and Mobility Assessment Centre. This situation resulted in some dissatisfaction reported with the intervention because it could not be resolved by the therapist.

Acceptability of the intervention

The majority of PWTBI interviewed reported that they found the intervention helpful in achieving their goals and delivered in an acceptable manner: *"Well, it was helpful because she went to my employer and she explained everything to them as well about breaks at work. So from that side it was helpful. "* Similarly, employers interviewed also had positive views of the intervention: *"I think it was very important for [participant] as well because she wanted to come back to work very quickly, she was very eager, and I think [trial occupational therapist] was holding her back, in a positive way, like telling her, "No, you cannot do this yet. You have to wait." I think in the end it was a success."* (Employer 0200b).

Employers valued the OT's expertise: *"I think because [trial occupational therapist] had such an in-depth knowledge of [participant]'s case, I think occupational health wouldn't have been able to give anything extra because we already had it so in-depth."* (Employer 0100b). Employers also valued clear

communications from trial occupational therapists, which helped to gain the trust and engagement of the employer.

Some PWTBIs felt information sharing about their injury caused employers to limit RTW opportunities. One example involved a participant who explained their employer had not allowed a return to work due to information the trial occupational therapist had provided about the injury. Specifically this related to the risk of potential seizures when conducting safety critical job tasks such as driving or operating machinery.

All the trial occupational therapists were enthusiastic about the intervention and its positive effect on recipients: *"I think everyone values the vocational rehab and … we have done some good work and we've got people back to work. So I guess the results speak for themselves."* (OTD). Some trial occupational therapists worried about the ethics of providing one group of people a higher intensity programme compared to the usual caseload whereas others found the flexibility to provide the intensity without restrictions liberating. NHS colleagues of the trial occupational therapists within the same hospital and outside it also agreed that ESTVR was an appropriate intervention: *"understanding how people get back into work, stay in work is absolutely vital both to help the patients and to help our nation"* (Neurologist 0300c).

5.5.4.2. Context

Access to NHS systems

The trial occupational therapist's organisation had to have the IT infrastructure to support electronic transfer of referrals, using an NHS.net email account and a secure space for clinical records away from colleagues that might otherwise cause contamination. Records show that while these issues did not directly affect intervention delivery, mentoring helped to provide solutions.

Trial occupational therapists who usually worked independently found that they could liaise more effectively with NHS colleagues when they had an NHS.net email account. They reported that without this, NHS colleagues refused to communicate due to perceived confidentiality restrictions: *"you definitely have to have an NHS.net to put patient information across and email through."* (OTD) *"… that NHS.net email gives you the stamp of approval."* (OTB).

The trial occupational therapists reflected on the process of receiving a referral and how adaptations were made to improve the time taken and the accuracy of information received. Trial occupational OTD initially had to rely on the internal postal service between the acute and community hospital, which extended the period between consent to first contact. This was considered an unnecessary delay to start the intervention and the trial occupational therapist suggested that electronic referrals should be instigated, which was successfully implemented by the local trial site team providing the trial recruiter with an NHS.net email. These referral process issues were identified in mentoring and improved early across the sites and no further timing problems arose later on.

The information provided in the referral was felt to be inadequate on occasions. For example, inaccurate contact details resulted in the trial occupational therapist being unable to make early contact with the PWTBI. In this situation, the trial occupational therapist reported that the NHS IT systems were able to provide correct details. After this, and because memory recall can be problematic post TBI, it was considered important that trial recruiters had permission to access NHS IT systems in order to check current contact details. Another example included inadequate information about the cause of the injury that led the trial occupational therapist to feel unprepared on the initial face-to-face session. It was commented that more detailed information about the traumatic circumstances would have caused the trial occupational therapist to consider the safety and mental health of the PWTBI. In a contrasting example, a recruiter did pass on information regarding the reported inappropriate behaviour of a PWTBI whilst an inpatient and this afforded the trial occupational therapist the opportunity to locate a 'safe' initial meeting venue in a local GP surgery. Recruiters did not necessarily have experience of TBI or rehabilitation to be able to ascertain what would be useful to convey to the trial occupational therapist. Whilst recruiters did have the opportunity to receive some additional training, this could only change knowledge not experience.

Trial occupational therapist OTD did not record the date that a referral was received and therefore it was not possible to check the fidelity of time point 1 (participant to be seen within 10 working days). On further questioning, the trial occupational therapist reported that she had responded to incoming referrals on the same day or the next work day and it is likely therefore that she did meet the required timeframe but this cannot be confirmed from the records.

Local geography

Content forms indicated that some trial occupational therapists spent more time travelling due to delivering the intervention in London where using public transport was more feasible than driving to visit PWTBIs. Mentoring records indicated that most journeys typically took an hour.

Inter-agency providers

Mentoring records and interviews with both trial occupational therapists and community teams indicated that working together cooperatively for the benefit of the PWTBI was variable. Sometimes trial occupational therapists experienced positive team practices where there was open negotiation about the role each would take and sometimes the trial occupational therapist felt less confident to be able to negotiate her role: *"trying to establish good rapport and relations really without stepping on toes and role, you know, role boundaries really. And to me that was a little bit daunting."* (OTA).

One of the aims of the intervention was to provide intervention earlier than local community rehabilitation provision. However, in a minority of cases the local community rehabilitation team saw the PWTBI before the trial occupational therapist. Interview data from one such team indicated that they had the operational flexibility to triage referrals in such a way that an initial visit could be arranged within a week of a patient being discharged from hospital. Mentoring records demonstrated that the trial occupational therapist was supported to manage this situation, encouraging her to clearly communicate her role and to

negotiate with the community therapist who would be responsible for which aspects of rehabilitation.

Community rehabilitation services are limited by geographical boundaries and services determined by their funders (Clinical Commissioning Group (CCG)). Community rehabilitation services would refuse participants' access to rehabilitation because of these limitations, which the trial occupational therapist found as frustrating as the PWTBI. One participant voiced his frustration about this situation: "*But what happened was, this occupational therapist came round to see me and she basically told me she couldn't help me with the things that I really felt I needed help with… then this woman [another rehabilitation provider] came out to see me …, to find out how her department could help me. … She saw me making myself a cup of tea and she said, "Well, there's nothing I can do for you." … they basically wrote me off.*" (02020). This situation was not helped because the participant was not able to describe his needs in detail due to his TBI. His trial occupational therapist spent more than the expected amount of time advocating on the participant's behalf to get these decisions reversed.

Getting access to specialist services such as a Neurologist was slow in some cases and local health services lacked a coordinated patient-centred approach. Improving the coordination of more than 20 health services for the benefit of one PWTBI was led by the trial occupational therapist in her case management role. The importance of the case management role was emphasised by the PWTBI who felt that, without the ESTVR, he would not have received the

appropriate specialist treatment in the NHS or from the community ABI team to meet longer term needs.

Communication with community rehabilitation teams was sometimes perceived as lacking responsiveness and reported to affect delivery of ESTVR in terms of making decisions collaboratively or in providing feedback to participants. However, the trial occupational therapist adapted their intervention to this situation and fidelity was not affected. Community therapists reported that they found the additional support of the trial occupational therapist as helpful in dealing with their own heavy caseloads, though for some the differentiation in roles was not clear.

Limited backfill and manager support

Despite securing excess treatment costs for the intervention delivery, no backfill was arranged for the trial occupational therapists' usual caseload, which affected the proposed flexibility in intervention delivery. Trial occupational therapists worked, on average, one day per week delivering the ESTVR intervention with the rest of their week spent in their usual role. The intention was that time spent delivering ESTVR would be compensated by NHS Excess Treatment Costs[3] (NHS England, 2015), allowing senior managers to backfill the time therapists spent working in the trial. Mentoring records and interviews showed this situation affected fidelity indirectly by causing less flexibility in working patterns

[3] Excess treatment costs are treatment costs in excess of normal care that occur as a result of non-commercial research, funded by the Government and research charities. Costs are funded through normal commissioning arrangements for patient care NHS England (2015) NHS ENGLAND 2015. Guidance on Excess Treatment Costs. *In:* ENGLAND, N. (ed.). NHS England, London.

and increased pressure on the trial occupational therapist to attend to her usual caseload.

This situation was further complicated by some managers' lack of knowledge about research and the effect a local trial would have on usual practice. NHS service restructuring resulted in a smaller pool of experienced therapists in one site and limited options to backfill therapists' usual clinical caseloads. Perceived lack of management support meant therapists felt over-worked when pressures increased in their usual NHS role. Line managers were not fully cognisant of the operational impact of staffing requirements over the life of the trial and believed that existing services were expected to absorb this commitment to the study within existing resource: *"the service has grown since she started and the staffing has reduced since she started… I think we were unclear of the commitment"* NHS manager 0100e. All sites recognised the difficulties in finding staff to backfill the trial occupational therapist due to restructuring: *"we had lost probably perhaps some of our skilled longstanding workforce of OTs and physios through the integration. So we didn't have a huge skill base there that we perhaps would have had before really."* (NHS manager 0100d). They suggested increasing the number of hours allocated to the trial occupational therapist role, would be both more attractive to Occupational Therapy staff and force senior managers to ensure adequate cover for existing and new service demands.

Mentoring records identify difficulty with flexible working for an occupational therapist on an acute ward setting where workloads need to be conducted quickly to manage the fast turnover of patients. The tension between demands

from their usual role and research role resulted in the mentors and trial team becoming involved to resolve issues. In one site additional administrative support was organised for a trial occupational therapist when the caseloads on both her research and NHS roles were highest. In another site, the mentor both coached the trial occupational therapist to effectively communicate her needs to her line manager and communicated directly with the line manager to reiterate the details of the trial and the usual Occupational Therapy role. Both actions helped to diffuse the situation and allow the trial occupational therapist to feel less stressed.

5.5.4.3. Intervention complexity

Individual needs of PWTBI & employer

ESTVR is a complex intervention that supports PWTBI to RTW. The needs of PWTBI are often complex, the work and employer organisations are often complex and the healthcare system in which this is conducted is complex. Trial occupational therapists recognised these complexities in delivering the intervention: *"You might think, "Okay, I can do just the same as the first one" but, no, it might look the same, it's a TBI going back to a bank but the boss might be different, the relationships are different. Everything is completely different. And, it's not as simple as saying, right, "I'll pull this tool out and I'll use the same thing." Every single one has to be different, doesn't it?"* (OTA). Part of the complexity were the broad needs of the PWTBI that resulted in a wide range of variability in ESTVR delivery. PWTBI's needs were individually determined through assessment and collaboration and frequency of contact from the trial occupational therapist was negotiated.

Some PWTBI had atypical employment arrangements, worked in family businesses or were themselves business owners. These different employment contexts required adaptations to the intervention in terms of the communications and negotiation about RTW.

Clinical and mentoring records confirmed that employers were bound by their in-house procedures and policies for RTW and other related issues such as ill-health retirement or for managing bullying that risked the sustainability of one PWTBI's RTW. Whilst UK legislation and regulations applied to all employers, therapists had to find out about employers' individual policies in order to support PWTBI. Employers reported that they found it helpful when the trial occupational therapist demonstrated knowledge of the workplace in this way: *"So we did sit down, two of us, and then with [PWTBI] afterwards. And we've discussed – she did ask me what's the nature of the job. And you know, after asking all those questions, you know, she advised what she thinks would be good for [participant]. I think she was very good because she understood… that certain things are possible to be adjusted but certain things are impossible."* (Employer 0200a).

Changing needs of PWTBI

PWTBI's needs were not static and as such the intervention required tailoring using information from assessments and collaborative goal setting. Multiple sources indicated that PWTBI's condition-related symptoms e.g. cognition, balance, emotions changed over time and this required tailoring of the intervention. Some PWTBI had concurrent or pre-existing health conditions,

which affected their capacity to participate. This affected people differently. One example was an individual who was unable to communicate with the trial occupational therapist because mental ill-health and associated behaviours interfered. Some PWTBI experienced normal life events such as bereavement or relationship changes that interrupted participation in the intervention. This required an adjusted approach and hiatus by the trial occupational therapist for a few weeks before resuming the intervention, as described by an employer: *"And I think one of the problems is that when he [PWTBI] had a slight hiccup, he had a tragedy unfortunately and therefore his cognition went backwards, she [trial occupational therapist] managed very well to get him back up to where he was. But we'd lost four months."* (Employer 0300a). Needs also related to the context of the workplace where a change or loss of job or education required an adjustment in the intervention. For example, workplace bullying experienced by one PWTBI resulted in additional workplace visits and education sessions for managers and colleagues.

Tailoring the intervention

Data indicated that the intervention was adapted successfully by trial occupational therapists i.e. without detracting from fidelity and that this could accommodate most of the needs presented by the PWTBI and their employer. Trial occupational therapists valued the ability to adapt the intervention in terms of the breadth of components and dose to meet the PWTBI's RTW needs.

5.5.4.4. Facilitation Strategies

Training package

Trial occupational therapists were provided with a training package that included an intervention manual with additional resources, direct teaching about the intervention and ongoing mentoring. The details of this are described in detail in chapter four (4.5.3). Interview data indicated that trial occupational therapists felt the training package had prepared them to deliver the intervention. The intervention manual was useful for some early after training but used less in the later stages as the trial occupational therapists' confidence grew.

All trial occupational therapists reported that mentoring helped them to implement the intervention. Feedback and advice from mentors who were viewed as experts was highly valued. Mentoring with feedback on performance in relation to individual cases helped the trial occupational therapists develop confidence and expertise.

Monitoring visits

In addition to mentoring, trial occupational therapists' interventions were scrutinised on monitoring visits. These provided an opportunity to check intervention fidelity and to provide feedback to trial occupational therapists regarding fidelity. The trial occupational therapists said they expected that they might be required to adapt their behaviour following monitoring visits if fidelity was not being met. Trial occupational therapists did not always distinguish

between fidelity visits and mentoring discussions and valued the feedback they received.

Specialist therapists

Trial occupational therapists with a number of years of relevant clinical experience of neurological rehabilitation were considered specialists in TBI or neurorehabilitation. Three out four had experience of community rehabilitation and TBI and some knowledge and experience of VR. Even with this experience therapists reported that they recognised the complexity of the intervention but felt that with mentoring support they were able to deliver it as trained. Data indicated that their experience to make complex clinical decisions helped in overcoming complexity such as working to meet both the needs of the PWTBI and the employers.

The trial occupational therapists with experience of delivering rehabilitation in the community required less mentoring than those who had only worked in secondary care. This person lacked confidence in asserting the VR role with other community therapists, which occasionally resulted in taking a less active role in RTW. Mentoring data indicated that writing letters and reports to non-clinicians also required significant support as this was not a familiar part of an acute therapist role. Mentoring records explain the support and guidance provided to maintain fidelity in these situations.

Trial occupational therapists reported that in order to meet some needs of the PWTBI, they referred to other services. However, because they were unfamiliar with these outside their usual geographical patch, they found them difficult to locate. Mentoring records indicate that guidance was provided to ensure that appropriate referrals were made for participants. Those who worked independently showed more confidence in working in new locations and demonstrated skills in researching new service providers.

Resources from the provider organisation

The specific context of the research environment meant that trial occupational therapists had to prevent contamination and were not permitted to discuss the details of interventions provided. For the two independent trial occupational therapists this was not problematic but the two NHS trial occupational therapists felt compromised and somewhat disloyal to their existing team because they perceived as withholding useful information.

Telephone calls had to be conducted away from their usual colleagues and only limited communications could be offered about participants that a colleague might be also be seeing. To assist this in one site, the local research team offered the trial occupational therapist a desk and use of their office.

Trial occupational therapists reported that controlling their own diary throughout the week allowed them to work flexibly across their usual and research roles. One trial occupational therapist had less autonomous working practices working

on an acute ward and this caused tension with the line manager and reduced flexibility in delivering ESTVR i.e. she was not able to attend a workplace meeting with a PWTBI on a day typically allocated to her usual role. The other trial occupational therapists were autonomous and mentoring records and interviews indicated that they valued this and being accessible to PWTBI and their employers.

Although workload tension did occur, it was on the whole managed by rearranging commitments. However, a pinch point occurred for one trial occupational therapist when her usual caseload increased and her research caseload peaked: *"there was a point in [research trial] where I wasn't in control of the discharges, so it felt that they were all coming in the front door...in an ideal world I would have shut the door for a bit, but you can't do that with [research trial]. And the minute after December we stopped recruiting it just felt a whole lot better... That was a really difficult time."* (OTD). The situation was highlighted through mentoring and extra personnel sourced and paid for by the research project to assist with administration tasks. This then allowed the trial occupational therapist to concentrate on delivering the intervention. In order to facilitate autonomous working, caseload management, team dynamics and workplace stress levels, trial occupational therapists valued a supportive line manager who had knowledge of research demands as well as managing an ongoing caseload.

5.6. Discussion

5.6.1. Summary of findings

This study found that for most of the time trial occupational therapists delivered ESTVR with high levels of fidelity. There were some instances of variation. With one participant the dose was exceeded and one where discharge from the intervention dates were not recorded that meant the frequency of intervention delivery could not be calculated. Trial occupational therapists delivered most intervention components with small variations (close to 10%) when compared to the ESTVR benchmark. There were three exceptions to this that were explained by clinical records. These were the ESTVR components; current issues, return to work and work preparation. Fidelity was determined using multiple data sources associated with delivering, receiving, managing and monitoring the intervention.

Factors which positively influenced fidelity of the intervention included the Occupational Therapists' community rehabilitation experience, the expert mentoring and the ability of the intervention to be individually tailored to participants' needs. Factors which were a barrier to delivery included a lack of access to NHS systems such as the NHS.net email, the lack of backfill and limited support from local managers. Factors that both helped and hindered delivery were communication with study participants, whether the intervention was seen as acceptable by participants and the individual's changing needs and interagency working. These findings are discussed below and recommendations for future studies made.

5.6.1.1. Measuring implementation fidelity

The importance of monitoring

It is agreed that monitoring fidelity is important where complex interventions are delivered (Chesworth et al., 2015) and that this occurs throughout delivery, not just at the end of a study (Bellg et al., 2004). The 16 visits (four each) to trial occupational therapists provided important data that contributed to measuring fidelity but each monitoring visit was resource-heavy and involved an entire day. In this study, one of the mentors' role was also to monitor fidelity, which could be viewed as duplication of resources. In order to maintain the important role of fidelity monitoring whilst optimising resources in future studies, mentors could collect fidelity data, using the fidelity monitoring checklist at set intervals. In this way a larger study with more therapists need not require additional meetings specifically related to fidelity monitoring. The quality control of fidelity data collection could be managed by a single researcher who could support mentors and oversee the collection of content forms, fidelity checklists and clinical records.

The process of measuring fidelity also revealed where improvements could be made in training trial occupational therapists. For instance, measuring duration revealed that trial occupational therapists had not been given concrete instructions about how to decide when best to discharge a PWTBI or how to record this part of the intervention process in the therapy records.

Multiple data collection tools

Therapists' usual clinical records would not have provided all the required data to adequately measure fidelity because they tended to provide an overview of a session rather than detail the individual components that were listed on the content form lacked specific details such as consistent recording of dates. However, recording intervention sessions on two forms resulted in some duplication of data and placed additional demands on the trial occupational therapists, which in a larger trial it would be unreasonable and result in an unfeasible amount of data. In order to address this workload issue whilst maintaining high quality data, the content form and clinical record should be combined. This would still allow triangulation with mentoring and fidelity monitoring records.

Adequate trial occupational therapists training

Some key data, when trial occupational therapists made their initial contact with PWTBI, were missing from both the clinical record and the content form and not picked up in mentoring or monitoring. For one trial occupational therapist, this meant it was not possible to measure how 'early' the intervention had started, an important component of ESTVR. In a larger study, preventing missing implementation fidelity data such as this, would be of great importance when examining the intervention's effectiveness (Dusenbury et al., 2003). In addition, all trial occupational therapists were inconsistent in how they documented the end of the intervention and triangulation of clinical records and content forms was essential. Triangulation in this case meant finding these details in the clinical record, which added to the researcher's workload. A future study would

require well-defined instructions for therapists as part of the training and closer monitoring that therapists were recording data accurately, by those monitoring the intervention process.

Whilst therapists were introduced to the content form during their training, they did not practice interpreting the terms used on the form or completing it and were not tested on their skill in accurately and consistently coding each 10-minute period. There is currently no standardised language in everyday use to represent specific treatment activities in rehabilitation, which leads to a wide range of terms and increases the potential for different interpretations. It is suspected that there was not consistent use of the same terms on the content form by trial occupational therapists that may have been a cause of variation in the content of the intervention. For example a therapist may have delivered multiple components at once, such as psychological support, work preparation and education but chose to classify it as just one component. Therapists may also have favoured one component category to represent their treatment activity and if so this would reflect the need to specify component definitions. The new International Classification of Health Interventions would be a potential source of standardised terminology in the future but lacks sufficient detail in its present alpha form. Providing therapists the time to acquire skill and experience to deliver a new intervention in a trial has shown benefits in building the competence of therapists (Döpp et al., 2013). Future studies that include a period to allow trial therapists to practice delivering the interventions, completing documentation and receiving feedback on performance, may improve fidelity data for analysis.

5.6.1.2. Measuring moderating factors

Pre-implementation evaluation

Aspects that make interventions complex include the context in which it is delivered (Hawe, 2015), tailoring permitted, if it is delivered to multiple recipients and skills required to deliver it (Craig et al., 2008). Measuring whether an intervention was delivered as intended and exploring reasons for variations can provide contextual detail and reveal what affected implementation (Carroll et al., 2007, Damschroder et al., 2009, Hasson, 2010, Hasson et al., 2012). Utilising two complementary theoretical frameworks, has facilitated comprehensive identification of root causes to implementing ESTVR across the three NHS sites in England. By revealing implementation issues in this study, researchers studying ESTVR, or similar interventions in the future, will be able to make use of this information to inform the study design. Implementation researchers advocate study designs that specifically address the potential barriers and facilitators that may moderate an intervention's (Carroll et al., 2007, Durlak and DuPre, 2008, Fixsen et al., 2005, Moore G. et al., 2014). One way of achieving this is to evaluate implementation issues prior to participant recruitment, pre-empting the barriers and facilitators and designing implementation strategies to optimise successful intervention delivery (Moore et al., 2014, Allen JD. et al., 2012, Mittman BS., 2012). By ensuring barriers to implementation are minimised, researchers can be more assured that interventions are delivered as planned, outcomes are attributable to effectiveness and Type III errors averted (Dusenbury et al., 2003).

Using existing findings

Moderating factors identified in this study were similar to other complex intervention and rehabilitation studies (Chesworth et al., 2015, Hasson et al., 2012, Masterson-Algar et al., 2014, Siemonsma et al., 2014). Most studies report barriers and facilitators related to adherence, intervention acceptability and reasons for attrition these are required as indicators of high quality reporting (Hoffmann et al., 2013) and more recent guidance such as TIDieR (Template for intervention description and replication) (Hoffmann et al., 2014) and SQUIRE (Standards for quality improvement reporting excellence) (Ogrinc et al., 2016). However, few studies report issues comprehensively. One reason for this may be that when study participants are asked to consider why an intervention was not implemented as expected, they provide superficial causes and are not able to identify the underlying, fundamental (root) cause. For example, when, exploring why therapists felt over-worked, several reasons were provided including, one therapist had little flexibility to manage her own time, one line manger did not understand how to access excess treatment costs to backfill the trial occupational therapist's time away from usual duties and needed the trial occupational therapist to deliver her usual duties at particular times, a service restructuring had resulted in a smaller pool of therapists in the therapy department to manage waiting lists, which placed further demands on the trial occupational therapist in her usual role. It would be untenable to understand implementation from numerous individually reported reasons, so similar characteristics amongst them are examined. Similar characteristics provide a way to aggregate the findings, categorise them and understand relationships and differences. Implementation research frameworks describe these categories

and provide a way to understand the root causes of barriers and facilitators to implementing interventions, therefore the example above, using CFIR, show characteristics associated with the preparedness of the organisation to deliver the intervention, which CFIR classifies within the 'inner setting' (the organisation delivering the intervention) domain and the construct 'readiness for implementation'.

Mapping the reasons (moderating factors) has revealed that the root causes are wide ranging and rehabilitation trialists would be advised to make themselves aware of these as early in the process as possible. It may not be practical to carry out a pre-implementation assessment during the initial design phase and before funding is granted, so utilising existing study findings reporting implementation issues would be a cost-effective alternative. Pre-implementation assessment is important to trouble-shoot potential barriers and build facilitation strategies and is particularly recommended by Damschroder and colleagues who have developed tools and resources online since this study commenced (CFIR Research Team, 2016, Damschroder et al., 2009).

Importance of disengagement

Variation in intervention delivery was shown to be partly determined by how well the PWTBI and their employer collaborated in the intervention. Some PWTBI did not collaborate as much as others indicated by trial occupational therapists' difficulties maintaining contact. In order to understand what recipients thought about ESTVR, if it was the right intervention for them, we planned to question PWTBI and their employers. As ethical procedures dictate, interviews were only

held with those who were consented and these people were the ones who engaged with the intervention and were motivated to tell their story. Some PWTBI and their employers did not consent to be interviewed and it was not possible to contact those who dropped out, arguably the very people who could have held the most useful information to help understand coverage (Moore G. et al., 2014).

Study participants who drop out may highlight potentially important barriers related to the intervention or study processes (Prescott et al., 1999), and especially within the TBI population where this is a well-documented problem (Langley et al., 2010, Vikane et al., 2014, Jourdan et al., 2016, Krellman et al., 2014, Wade et al., 1997). One participant in this study reported she felt too busy to talk with the therapist, which may indicate the intervention was not required and one therapist queried how many attempts should be made before ceasing contact. One solution to examining this issue would be to invite participants and employers for interview early after recruitment and at staggered points throughout a study to offer insight into attrition or acceptability of the intervention (Grant et al., 2013). In future, trial therapists identifying those they consider less responsive to communication and disengaging with the intervention would record this as part of their clinical records, allowing analysis.

An added dimension with this intervention is that it is delivered to the employer and at the workplace; known as a dyad. Some PWTBI did not permitted the trial occupational therapists to access their employer but reasons for this decision were not routinely recorded. As this was a predictable barrier, being

experienced before (Phillips, J. 2013), it indicates a gap in the training package. In future, trial therapists should be made aware of the reported range of barriers associated with delivering an intervention to a dyad (Bentley et al., 2014, Johannessen et al., 2014, Mackenzie et al., 2014, Mahoney et al., 2006, Prick et al., 2014, Veenhuizen et al., 2011, Voigt-Radloff et al., 2011, Wesson et al., 2013). In particular, the importance of discussing and documenting decisions where access to one half of a dyad is denied.

The important effect of the external setting

In this study, the external setting refers to all those agencies that may provide ongoing support to the PWTBI in relation to their recovery and RTW. As part of their rehabilitation, PWTBI were sometimes engaged with or referred by their trial occupational therapist to other relevant agencies and sometimes this interagency working was not successful. Reasons for this are only understood from the OT's perspective as documented in clinical records, mentoring records and some interviews. Rehabilitation is often provided by multiple agencies post TBI and to optimise patient outcomes, it is important to understand why this might fail. Future studies should engage these teams, such as community rehabilitation teams prior to implementing the intervention in order to gain their collaboration and also instruct trial therapists to document reasons when a service does not accept a referral or stops delivering a service sooner than expected.

Some factors that moderated the implementation were coded "inter-agency providers", which included both barriers and a facilitator that were mapped to

five CFIR constructs across two domains. The first domain was *intervention characteristics*. Whilst interviewees believed the intervention would be beneficial to PWTBI, the community rehabilitation providers said they did not understand the intervention especially its source, evidence strength or the relative advantage of delivering it. This was believed to have caused confusion when some community therapists had similar roles to the trial occupational therapist and hindered the implementation of ESTVR i.e. the community therapist lead the VR intervention instead of the trial occupational therapist. In order to address this type of issue, NHS staff recommended that during the set up phase of future studies, communications between the research team and other rehabilitation providers would be beneficial in promoting collaboration. Mentors supported the trial occupational therapists to clearly communicate their role across agencies in this study and this approach should be retained in future studies.

The second was the *outer setting* domain. In some instances the collaborative working practices and networking facilitated intervention delivery and NHS staff remarked that collaborative work helped to share the workload of an already busy caseload. External policies, especially related to referral criteria, sometimes presented barriers and sometimes facilitated implementation. Whilst little can be done by researchers to change referral criteria of external organisations during the life a study, being aware of potential problems can highlight that clinicians may have to adapt an intervention to meet the needs of participants that would otherwise have been met through a community rehabilitation team. It was this situation that was partly responsible for one therapist, in her case management role, providing significantly more of the component 'current issues' than other trial occupational therapists. One case

was responsible for this finding. The PWTBI experienced multiple trauma injuries and complex neuropsychological symptoms post TBI and as such required ongoing consultations and treatment from different specialists in the NHS. It could be argued that the GP should take the role of managing care once a person is home from hospital, but the reality is GPs do not have the time allocated in their day to dedicate to one patient. Waiting lists to see some NHS specialists reached almost 12 months and two community rehabilitation services indicated that the PWTBI's needs did not meet their referral criteria. The trial occupational therapist addressed these external organisation barriers together with the PWTBI's lack of capacity to explain his problems. The trial occupational therapist's understanding of the individual, through detailed assessment meant she advocated on his behalf, ensuring appropriate referrals were made and liaising between different specialists in order that his needs were met. In order to pre-empt these potential issues, future studies should include a pre-implementation evaluation to investigate barriers and facilitators as recommended by (Damschroder et al., 2009, Kirk et al., 2016).

Lack of implementation framework sensitivity

Some moderating factors were less straightforward to map and in particular these included issues related to the dyad of PWTBI and employer. There was little sensitivity in CFIR "patient needs and resources" that resulted in all participant responsiveness moderators being mapped to this broad ranging construct. It would have been helpful to be able to separately map PWTBI and employer issues and to understand more detail. CFIR may benefit from extending this construct to include theoretical understanding of patient

behaviour and engagement in interventions. Additionally, rehabilitation is often provided as a team often across organisational borders and the implementation issues associated with this are not apparent. In future studies, implementation issues related to recipients and collaborators in intervention delivery could be augmented with an additional theoretical framework such as the Theoretical Domains Framework (Cane et al., 2012). However, including yet another framework needs to be balanced with duplications and unnecessary complexities in data analysis (Birken et al., 2017).

5.6.1.3. Fidelity and variation in intervention delivery

There is no specific guidance to answer, "How much variation is allowed in fidelity measurement?" but Durlak and DuPre (2008) indicated, in their meta-analysis of 542 interventions between 1976 and 2006, that outcomes were effective when interventions were delivered with 60-80% fidelity. They advised researchers not to expect 100% fidelity and recommended that the variation in fidelity across sites should be reported rather than only presented as a mean, because this can mask expected variation. Phillips (2013) description of ESTVR and the proportions of intervention components provided a benchmark against which to compare. This study's findings indicated a maximum variation of 30% (RTW component) but tended to be within 12%, well within what was advised by (Durlak and DuPre, 2008).

However, while some may identify these variations as modifications that support fidelity by improving the fit of the intervention (Damschroder et al., 2009, Greenhalgh et al., 2004, Moore G. et al., 2014, Hawe et al., 2004) others

identify variation as non-adherence that negatively impacts patient outcomes (Dane and Schneider, 1998, Mihalic, 2004).

For the stage of development, of ESTVR, it was important to be able to contribute to understanding why it was implemented in the way it was revealing more detail about its complexity. This was successfully achieved firstly identifying variation and secondly explaining variations by examining what helped and hindered delivery. Stirman et al. (2013) developed a coding system to help describe different types of variations to intervention delivery and in this study tailoring was the most frequent type. Trial occupational therapists also lengthened the intervention for a few PWTBI but both types of modifications were made intentionally to retain the spirit of the intervention (Stirman et al., 2013).

ESTVR has a loose structure where therapists can deliver a wide range of components without a prescribed order but with the expectation that the underlying function, of supporting a RTW that is safe for the both the PWTBI and the employer, is retained. Measuring fidelity revealed one component (personal ADLs) was never delivered by trial occupational therapists or by the benchmark and would suggest this redundant component should be removed as a core component and from associated data collection tools. This recommendation would be supported by Moore G. et al. (2014) where components are not delivered and do not negatively affect patient outcomes. Refining the intervention description in this way moves its development forward and helps to distinguish it from other similar types of interventions. In turn, refinement of

the description will also assist in fidelity measurement and should a future therapist deliver a personal ADL component, then this would be considered tailoring.

5.6.2. Strengths

A strength of this study was that it involved analysing and triangulating data from multiple sources (content forms, fidelity visit data, and clinical records). This was useful in that it revealed information about the complexity of the intervention and therapists' training needs and the measurement process, which others have found (Hasson et al., 2012).

A strength of this study was that mentors continued to support trial occupational therapists on a regular basis throughout intervention delivery. The mentors provided an implicit dual role in providing clinical support and monitoring the delivery of the intervention. They were able to make enquiries about intervention delivery and suggest how the trial occupational therapist could make adjustments to realign any drift as recommended by (Moore et al., 2014).

A strength of the study design was that trial occupational therapists completed the content form in addition to clinical records, allowing triangulation of data such as session components and dates that would otherwise have been missing.

CFIF guided the determination of fidelity measurement. The framework has been used by a number of researchers since its inception (Hasson, 2010,

Hasson, 2015, Hasson et al., 2012, Hasson et al., 2014, von Thiele Schwarz et al., 2013). Descriptions of how CFIF has been utilised to measure fidelity of complex interventions proved useful in providing the method and tools for this study.

5.6.3. Limitations

A limitation of this study was that fidelity monitoring visits were conducted by a member of the research team who also took the role of a trainer and a mentor meaning that the trial occupational therapists might not have been honest in their reporting about how they delivered the intervention. On the other hand, a strength was the rapport that allowed in-depth enquiry, which may not have been possible without the close relationship. In a future study, the responsibility of maintaining intervention fidelity across multiple sites could be jointly held by mentors and an overseeing monitor.

Even though findings report on the experiences of only four occupational therapists who implemented a new complex intervention and are therefore unlikely to be representative of all therapists, they highlight important points for consideration by those developing rehabilitation interventions.

Data collection relied on treatments recorded by therapists and did not involve observations that may have provided further objectivity. However, each therapist's account was questioned repeatedly in site monitoring visits and by

mentors. This was felt to be a strength and more acceptable where observations were considered potentially intrusive for the PWTBI.

Triangulating findings provided a robust method to measure implementation fidelity. However, it created a large quantity of data that required careful management and many hours to analyse. In order to address this resource issue in a future trial, implementation fidelity would have to be measured in only a proportion of trial therapists.

5.6.4. Implications for practice and research

Measuring the fidelity of ESTVR has highlighted some of its complexities, the complex contexts into which it was implemented and the heterogeneous and complex PWTBI and their employers it is delivered to. The method of measuring fidelity and detailed reporting of findings should stand as a good example to be used not only by other researchers but also by practitioners and managers. Measuring fidelity in practice would reveal useful complexities that could be used to highlight service-user needs and develop services. Demonstrating variance between therapists might prove useful data for managers when addressing productivity and performance.

Examining therapists' delivery of ESTVR in detail revealed adaptations, which were mostly expected. Some components were not delivered at all and therefore begs the questions whether these should be part of it (Moore G. et al., 2014). In the development of new interventions it is important to be able to

articulate what is core and this study suggests that the component of "personal activities of daily living" is not a core component of ESTVR. Further work is required to clearly articulate the core components of ESTVR as recommended by Hart (2009).

It could be argued that those components, delivered in excess of what was expected, were a type of adaptation called lengthening (Stirman et al., 2013), rather than non-adherence because each trial occupational therapist was able to provide a legitimate clinical reason. The excess was also within the recommended tolerance of variation (Durlak and DuPre, 2008). Testing this in a future study would add to the understanding of permissible variations to ESTVR and theoretical debate.

Through the process of measuring fidelity additional learning objectives have been identified to add into future therapists' training. These were specifically around the detail required in clinical records of treatment sessions, standardised terminology and coding of treatment activities. At this stage we cannot be sure that these changes would make a difference and a future study testing the training package as an implementation strategy may help to reveal which parts are effective in preparing trial occupational therapists to deliver ESTVR with fidelity.

5.7. Conclusion

This, the final study of this research showed that NHS occupational therapists, after training and mentoring, can deliver ESTVR in a trial as intended and that PWTBI and their employers valued the intervention. The Conceptual Framework for Implementation Fidelity provided a structure for measuring adherence to the intervention. Barriers and facilitators that moderated implementation fidelity were identified from multiple perspectives and understood using the Consolidated Framework for Implementation Research. Individual participants' needs, employer access, mentoring, local rehabilitation service provision, the deployment of experienced occupational therapists, administrative support and access to NHS systems all affected delivery. Researchers should utilise suitable frameworks such as CFIF to report fidelity comprehensively and CFIR to report detailed implementation factors. Further testing of fidelity measurement tools is required. Future studies should explore potential barriers and facilitators across sites using a pre-implementation assessment.

Chapter six, provides an overall discussion of this programme of research. Key findings from each study will be combined and summarised to present a synthesised description of the barriers and facilitators to delivering a complex rehabilitation intervention within a research context as well as discussing the wider implications arising from the findings together with strengths and limitations of the research overall and methodological approaches. Implications and recommendations for researchers and clinicians will be suggested.

CHAPTER SIX

6. Final Discussion

6.1. Introduction

Chapters three, four and five described three studies; Study One, a systematic review, investigated the reported barriers and facilitators to the implementation of complex rehabilitation interventions delivered in clinical trials and other research to people with long term neurological conditions. Barriers and facilitators were described and mapped to implementation research frameworks (chapter three); Study Two described the development of a training package, used as an implementation strategy, to train NHS occupational therapists to deliver Early Specialist Traumatic brain injury Vocational Rehabilitation (ESTVR) in three English NHS sites in the context of a rehabilitation trial. Confidence of the occupational therapists to deliver the intervention was measured, its usefulness examined and implementation issues mapped (chapter Four); in Study Three the extent to which the intervention was delivered as intended was measured and barriers and facilitators were explored and mapped (chapter five). The three studies relate to each other and are logical in their sequence. The strengths and limitations of each study have already been presented in chapters three, four and five along with interpretations of their results.

This chapter therefore provides an overall discussion of this programme of research. Key findings from each study will be combined and summarised for studies One, Two and Three in order to present a synthesised description of the barriers and facilitators to delivering a complex rehabilitation intervention within a research context (6.2). The wider implications arising from the findings will be presented and discussed (6.3). The strengths and limitations of the project as a

whole and the methodological approach taken will be considered (6.4). Implications for researchers, vocational rehabilitation for people with TBI and clinicians will be posited and recommendations for future research made (6.5). Finally, the project findings will be concluded (6.6).

6.2. Overall findings

The aim of this project was to understand factors that affect the delivery of complex rehabilitation interventions for people with long term neurological conditions (LTNCs), specifically which of vocational rehabilitation for people with traumatic brain injury (TBI) within a in research context. To accomplish this, three studies were executed.

Study One found it was possible to identify barriers and facilitators affecting the implementation of complex interventions in rehabilitation trials. However, this was complicated by the lack of standardised terminology for implementation research and that researchers had not set out to report these. Treatment adherence, its acceptability and causes of attrition were the most frequently reported barriers and facilitators. The quality of intervention delivery, the preparedness of organisations to implement an intervention as part of a trial and the readiness of interventions were reported rarely. Findings may be reflective of the lack of appropriate language and reporting guides to comprehensively convey barriers and facilitators. Study One highlighted the potential types of barriers that trial occupational therapists might encounter delivering complex interventions such as ESTVR and therefore where training packages should offer support.

The second study found that experienced occupational therapists can be trained to deliver a complex intervention in a rehabilitation trial with individual and organisational level barriers and facilitators affecting the process. Soon after being trained, occupational therapists identified direct instruction and the training manual were important to help implement the intervention. However, after becoming experienced in intervention delivery, occupational therapists reported not using the manual. Mentoring was identified as the most useful element of the training package in both early and late interviews. The final study determined that ESTVR was delivered with fidelity by trial occupational therapists. Facilitators included ongoing expert mentoring, trial occupational therapists having community rehabilitation experience and an intervention that could be tailored to individual need. Barriers included a lack of access to NHS systems, lack of backfill to the trial occupational therapists' usual role and a lack of management support and research knowledge. Communication with trial participants and their acceptability of the intervention, individual and changing needs of participants and interagency working all helped and hindered delivery dependant on the individual situation.

The complex intervention being examined in Studies Two and Three was Early Specialist Traumatic brain injury Vocational Rehabilitation (ESTVR) that supported people with traumatic brain injury (PWTBI) to return to work or study.

This overview brings together findings of the three studies in relation to the project aim, which was to explore and understand the barriers and facilitators affecting the delivery and implementation of ESTVR within a trial. Key findings suggested that in order to implement a vocational rehabilitation intervention in a

randomised controlled trial; the therapists delivering it need specialist training, mentoring and feedback on intervention adherence, the contexts from which and into which the vocational rehabilitation intervention is delivered need to be clearly understood in terms of barriers and facilitators that affect its implementation fidelity. Implementation research frameworks help to understand these contexts and provide a mechanism to explain what affects fidelity. Each key finding and the consequences for implementation will be discussed and recommendations made for further research.

6.2.1. Improvements to reporting implementation required

The barriers and facilitators affecting implementation fidelity of rehabilitation interventions explored in this thesis emanate from wide ranging individual and organisational origins (3.6.4, 4.5.4, 5.5.4). They were described in varying ways by the authors of studies included in the systematic review in this thesis. However, descriptions of barriers and facilitators tended to be incidental and lacked richness and breadth in the descriptions.

The reporting focus for most of the studies in the review was not implementation but rather other aspects, such as the intervention effectiveness, which is not uncommon (Damschroder and Hagedorn, 2011). Implementation barriers and facilitators in the included studies were probably reported as components of standardised reporting guidelines such as; CONSORT (CONsolidated Standards Of Reporting Trials) extension for Trials Assessing Nonpharmacological Treatments (Boutron et al., 2008) and TIDieR (Template for Intervention Description and Replication) (Hoffmann et al., 2014). Where such guidelines

were used, barriers and facilitators focused on the providers and recipients of complex interventions in terms of:

- Acceptance of the intervention.
- Attrition from studies.
- Adherence to intervention protocols.

Conversely, in studies that used implementation frameworks to organise their findings, a broader range of barriers and facilitators were identified and described.

In the review (Study One), barriers and facilitators from each included study were extracted and mapped to the conceptual framework for implementation fidelity (CFIF) and the consolidated framework for implementation research (CFIR). These two frameworks are based on a published body of work described in chapter two (2.8.2, 2.8.3) and as such suggest the origins of individual and organisational barriers and facilitators that researchers may encounter when implementing the intervention and constructs in the frameworks articulate this. However, it is acknowledged that both frameworks were designed to reflect intervention implementation into clinical practice rather than within a research context. As such findings from this programme of work should be used with some caution.

The review highlighted that study authors did not explicitly report a wide range of barriers and facilitators and tended to only report on a few issues; namely

acceptance of the intervention, attrition and intervention protocol adherence. The frameworks therefore aided identification of implementation issues that were less obvious, being described more subtly in varying nomenclatures. The narrow focus of reporting could be attributed to a combination of researchers' lack of knowledge about implementation research theories and frameworks and the requirement to adhere to reporting guides such as CONSORT and TIDieR. These guides are essential to improve the quality of reporting and allow comparisons across studies. However, in and of themselves reporting guides are not designed to lead researchers to identify wide ranging implementation issues.

Implementation barriers and facilitators were described in different ways across the studies in the review, regardless of whether implementation theory was used or not as recognised by others (Brownson et al., 2012, Damschroder et al., 2009, Graham et al., 2006, Greenhalgh et al., 2004, Proctor et al., 2013). One pragmatic aspect to this was the time required to identify barriers and facilitators in published rehabilitation intervention studies, which may result in missing important information (Pinnock et al., 2017). A lack of agreed terminology related to implementation research also made drawing comparisons across studies in this review difficult. In future studies the lack of standardised terminology may delay advances in implementation science (Proctor et al., 2013).

Individual implementation research frameworks such as CFIR promote the use of their own standard terminology (CFIR Research Team, 2016) and Nilsen (2015) has proposed an implementation science taxonomy. However, there remains a

lack of consensus among implementation scientists (Pinnock et al., 2017). A parallel situation in healthcare has been addressed through the World Health Organisation's (WHO) family of international classifications (FIC) (World Health Organisation, 2017b). These classifications provide standard terminology for describing health conditions and are developed and disseminated at an international level to support health information systems (World Health Organisation, 2017b). This allows international comparisons of studies through a common language. A similar programme of work could be developed by the international body of implementation scientists, using FIC as an example.

Whilst CFIF and CFIR have been shown to have utility in all three studies of this research, they are not specifically designed to aid standardised reporting of findings. A reporting guide focussed on implementation findings would ameliorate some of the language issues (Proctor et al., 2013). However, would have to compete with over 300 guides already published, which some journals require authors to adopt and that aim to provide minimum standards for reporting research. The Equator (Enhancing the QUAlity and Transparency Of health Research) Network describe their international initiative as seeking, *"to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines."* (Equator-network.org., 2017). Some guides, such as CONSORT, are used routinely and have been modified with CONSORT extensions, for different types of trials, for example Trials Assessing Nonpharmacological Treatments (Boutron et al., 2008) and randomised pilot and feasibility trials (Eldridge et al., 2016).

CONSORT extensions require authors to report generally on implementation of the intervention, but do not provide any further guidance. TIDiER (Hoffmann et al., 2014) includes sections that prompt authors to report some aspects of implementation (sections 8 (when and how?) 9 (tailoring), 10 (modifications), 11-12 (how well?)), but lacks specific guidance about identifying and describing implementation barriers and facilitators. TIDiER is focussed on describing interventions delivered in research rather than their implementation. Hoffman (2014) encourages researchers to use TIDiER in conjunction with other guides to assure comprehensive reporting.

Another similar reporting guide that has relevance to implementing complex interventions is the Standards for QUality Improvement Reporting Excellence (SQUIRE) (Ogrinc et al., 2016). This guide is, *"intended for reports that describe system level work to improve the quality, safety, and value of healthcare."* (Squire-statement.org., 2017, homepage). SQUIRE implies that reporting on intervention implementation is required in sections 10 (measures) and 11 (analysis) and it is specifically mentioned in section 12 (ethical considerations). However, it also lacks detail related specifically to implementation research.

While some argue these guidelines, alone or in conjunction with others may be sufficient for reporting implementation findings (Davies et al., 2017), others advise using a particular guide (Pinnock et al., 2017, Pinnock et al., 2015). Standards for Reporting Implementation studies (StaRI) provides a guide to describe two strands simultaneously in one paper; that of the implementation strategy being used and the intervention itself (Pinnock et al., 2015). The

premise of StaRI is to support researchers reporting phase IV (testing the implementation of an intervention once phase III effectiveness studies are complete) of the MRC's framework for developing complex interventions. However, the updated 2008 MRC framework, implies that implementation research should happen earlier in intervention development and whilst STaRI may be useful in the former stages of rehabilitation trials e.g. during a feasibility trial such as FRESH, it remains untested.

Whilst reporting guides continue to be revised and new ones created, none to date provide every element required nor is there the standardised language that is called for when reporting intervention implementation within a research context. Researchers may need to continue to use implementation framework-specific language and multiple reporting guides to enable comprehensive reporting. The findings in this thesis suggest that to ensure comprehensive reporting of barriers and facilitators the following should occur:

- A suitable implementation framework is chosen with clear reasons for selection.
- The implementation framework is used to organise data i.e. by mapping barriers and facilitators to the framework constructs.
- Positive solutions (facilitators) as well as barriers to implementation with descriptions of how facilitators worked (the mechanism) to overcome barriers and the relationship between the two.
- Findings reported in simple language (Proctor et al., 2013) and in a format that allows others to quickly locate and interpret them. A grid format was used in all three studies of this research to provide a visual overview, which others may find helpful.

6.2.2. Training and mentoring essential for implementation fidelity

Study Two pertained to training the trial occupational therapists to deliver the intervention ESTVR. Whilst training is an important facilitator to implementing complex interventions (Brady et al., 2011, Gage et al., 2014, Johannessen et al., 2014, Richardson et al., 2015, Speelman et al., 2014, Sturkenboom et al., 2013, Thomas et al., 2014, Veenhuizen et al., 2011, Voigt-Radloff et al., 2011) and trial occupational therapists reflected that the absence of training would have created an implementation barrier, a single episode of training alone is insufficient for ensuring implementation fidelity. The findings from studies two and three highlighted the need for additional mechanisms to support fidelity such as ongoing mentoring.

Training packages for trial therapists delivering complex interventions are rarely described in sufficient detail for replication (Albrecht L et al., 2013). To overcome this the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations were used to provide a detailed account of the training delivery in FRESH. Additionally, the perceptions of trial occupational therapists were sought to understand the most useful aspects for implementation in future vocational rehabilitation studies. In particular, trial occupational therapists were asked to list changes they would recommend for future training and these are listed in Study Two (4.5.7). Recommendations included:

- Helping the occupational therapists understand their different role within a research context. Trial occupational therapists were worried that their actions or inactions would jeopardise the trial findings and reflected that

more time spent on understanding the trial design, completion of Case Report Forms such as the intervention content form (Appendix 11 and 12) for robust data collection and reducing the time between training and commencing delivery of the intervention were required in future.

- Being able to understand the trial intervention early on to be able to distinguish its uniqueness from usual care and to become familiar with the intervention manual. This recommendation was followed up in "refresher training" where trial occupational therapists came together after having delivered the intervention with some trial participants. This allowed the trial occupational therapists time to discuss ESTVR and compare it to usual care provided in their sites, discussing their anonymised cases together and with the mentors.

- The importance of face-to-face training, discussions about cases to work through clinical decisions and the use of service-users' experiences of being supported back into work through the intervention. Although there was reticence to engage with role play together with service users, the trial occupational therapists valued the experience and the pressure they felt to "perform" as expected. They used reflective practice to consider their own learning in this process.

- The ability of the training package and the trainers to provide a flexible learning environment that would take account of and support the occupational therapists' clinical experience or lack of. One way of providing support could be to offer additional online materials as the occupational therapists also recommended this resource, but some also found difficulties accessing online materials from their NHS Trust.

Additionally there was a lack of recognition by the occupational therapists' manager that time should be provided to watch online materials such as videoed teaching sessions and feedback reflected the need to ensure that managers would provide time.

The FRESH trial occupational therapists valued the whole training package they received and reported that it improved their confidence and knowledge to deliver ESTVR. However, their perceptions about which part of the package was most useful changed over time. Early on therapists reported on the utility of the training manual for reminding them about the intervention components and a process for delivery. However, manuals alone are not sufficient for changing practice, which has been reported elsewhere (Farmer et al., 2012, LaRocca et al., 2012). This was evidenced in later interviews where trial occupational therapists indicated they did not use the manual because they had become sufficiently confident to deliver the intervention without reference to it. From a training perspective, the manual should be recognised as a reminder and information repository but its capacity to change behaviour alone is negligible (Grimshaw et al., 2006).

This showed a distinct change in the opinions of trial occupational therapists soon after commencing delivery of ESTVR and later, once their experience had developed. Using a single point in time to gain insight into the experiences of participants is usual practice in qualitative methods. However, with regards to understanding how participants experience training, seeking perceptions over time to capture any changes in the way training is perceived, is recommended (Murray et al., 2009)

All therapists emphasised the importance of mentoring in supporting the intervention delivery and tailoring to individual participants with TBI, the opportunity to discuss cases and obtain feedback on how best to maintain adherence to the intervention. Mentoring built confidence in intervention implementation. Implementation strategies have been described as, "methods or techniques used to enhance adoption, implementation, and sustainability of a clinical program or practice." (Proctor et al., 2013 p40). Mentoring could be described as a supportive strategy to aid implementation of an intervention and although this research did not define mentoring, it has provided a detailed description of what was delivered, when, how and by whom.

The Expert Recommendations for Implementing Change (ERIC) project refined a collection of implementation strategy terms and definitions previously published by Powell et al. (2012) via systematically compiling views of expert implementation science stakeholders (Powell et al., 2015). The method involved three rounds of a modified Delphi process to produce consensus on implementation strategies and resulted in 73. The term mentoring is not among the 73 strategies, but the concept of supporting clinicians and providing ongoing training does feature. ERIC was only conducted with stakeholders from North America and 34 of the 35 were from the USA. As such, it is possible that had the process been done with international experts representative of more countries, then mentoring may have featured.

As identified by Powell et al. (2015), mechanisms by which an implementation strategy such as mentoring might work to support clinicians requires further investigation. This may also help define mentoring and determine its

effectiveness as a single component of, or in combination with the other training package components. Thereby improving the understanding about which aspects of a training package, that includes mentoring, have the greatest effect on sustaining behaviour change to elicit intervention fidelity, an implementation strategy outcome (Proctor et al., 2009).

Mentoring was valued when it took the form of open and honest discussions about how the therapist was adhering to the intervention, building their confidence to implement it. In a grounded theory study, the preferences from 54 Canadian researchers and research users from different professions were sought, through interviews, to determine the design, infrastructure and capacity required to deliver of a knowledge transfer mentorship programme (Gagliardi et al., 2015). Participants' preferences were similar to the mentoring described in studies two and three of this thesis; for an individualised approach with mentors who were experts and perceived as high calibre practitioners. Although Gagliardi's study in 2015 focussed on knowledge translation into clinical practice there are some commonalities with implementation research that make the findings relevant. Additionally there is a body of knowledge that supports the use of mentoring and describes components of and mechanisms by which mentoring may be effective (Gagliardi et al., 2009, Gagliardi et al., 2014, Gagliardi et al., 2015, Moran et al., 2014). This study identified that, although the manual and direct teaching were useful initial strategies to upskill trial occupational therapists in knowledge, future studies should focus on providing expert mentoring, by a clinician experienced in the intervention and research, throughout the intervention delivery period.

Future vocational rehabilitation trials may have limited resources to provide mentoring and will need to design mentoring programmes that are not only effective, but efficient. Peer discussions about real world implementation of the intervention was reported as important by trial occupational therapists in this research. The value of group-delivered mentoring has been recognised elsewhere (Abdullah et al., 2014) and therefore both strategies warrant evaluation in future trials.

An important finding of triangulating data was that trial occupational therapists did not complete paperwork with consistent accuracy, which was not picked up during mentoring or fidelity visits. Future recommendations to improve data recording involve providing trial occupational therapists, those monitoring fidelity and mentors the opportunities to practice using trial paperwork and receive feedback on accuracy. This would provide the following benefits:

- Trial occupational therapists would improve consistently and accurately record key data e.g. dates (referral, return to work, discharge etc.) and intervention components, that aid fidelity data collection.
- Fidelity monitors would be able to identify relevant fidelity data within trial occupational therapists' records.
- Mentors would be able to identify needs and support trial occupational therapists with intervention implementation fidelity issues.

6.2.3. Measuring implementation fidelity is fundamental

Study Three focussed on measuring whether the trial occupational therapists delivered ESTVR as planned. A lack of understanding about implementation successes and failures in rehabilitation research may result in misinterpretation

of findings (Dusenbury et al., 2003, Spillane et al., 2007) and in ineffective or harmful interventions being delivered to people with LTNCs and therefore the measurement of implementation fidelity is fundamental to intervention development. The complex nature of rehabilitation and the complexity of the systems in which it is delivered including healthcare, the patient context and in the case of VR, the employment context could lead to errors in interpreting rehabilitation research (Wade, 2001).

Behavioural science is adept at identifying factors associated with Type I and II errors, which focus on the 'evaluation' aspect and often involve statistical tests to disprove a null hypothesis (Tate, 2015). A Type I error is where an intervention is concluded to have effect where none exists and Type II where it is concluded that an intervention has no effect (Lamb and Douglas, 2015, Tate, 2015, Wade, 2001) when in fact it may. However, a third type of error has been described and popularised by the eminent statistician, Charles Frederick Mosteller (1916-2006). Mosteller described an error of reasoning or logical conclusions about the underpinning theory or how variables are operationalised (Tate, 2015, Wade, 2001, Dobson and Cook, 1980), whereby effectiveness (positive, neutral or negative) is erroneously attributed to an intervention that has not been delivered as planned (Dobson and Cook, 1980, Hasson, 2010, Birken et al., 2017, Dusenbury et al., 2003).

This research has shown that a detailed understanding of implementation fidelity regarding the delivery of a complex vocational rehabilitation intervention (ESTVR), can be gained in a feasibility RCT (FRESH) rather than waiting until phase IV; translation into clinical practice. Study Three measured whether trial

occupational therapists delivered the complex intervention, ESTVR, as intended (with fidelity) (1.4) when they had been trained. By using CFIF it was possible to demonstrate when the trial occupational therapists provided ESTVR as intended and when they did not. Taking into consideration the CFIF constructs (content, coverage, frequency and duration), trial occupational therapists adhered to the key components of ESTVR and therefore delivered the intervention with fidelity.

This knowledge is important and could be used by trialists to design future research that takes account of reported barriers and facilitators to implementing a vocational rehabilitation intervention. Using this information for example to select optimal sites and prepare site for trial participation (Luker et al., 2016). This is especially important for UK rehabilitation, which is a small, threatened service (Wade, 2015a) and which need well designed research to advance scientific knowledge of rehabilitation. To ignore the importance of examining, measuring and describing implementation fidelity accurately may result in difficulties translating an intervention into clinical practice (Proctor and Brownson, 2012).

There is a paucity of evidence to guide implementation in trials (Luker et al., 2016). A recent qualitative process evaluation carried out in an international phase III trial of an early mobilisation study in stroke rehabilitation explored implementation fidelity and concluded that adherence was challenging (Luker et al., 2016). It was only by tracking implementation fidelity to the intervention and monitoring usual care, that researchers were confident that the between-group differences were maintained despite usual care changing to look similar to

the very early mobilisation intervention over the course of the trial (The AVERT Trial Collaboration group, 2015). The more studies that report findings related to implementing a rehabilitation intervention within a trial context, the more this data can be utilised by others to understand factors that could affect the delivery of other complex rehabilitation interventions in the context of research and start to inform the eventual implementation into clinical practice.

6.2.4. Describing and understanding barriers and facilitators

As well as measuring fidelity, Study Three also identified factors that affected implementation fidelity from the perspective of the trial occupational therapist, PWTBI, their employers and the wider group of NHS staff involved (1.4).

When mapped to CFIR, barriers and facilitators to implementation of ESTVR in Study Three were wide ranging across its five domains. The domains are concerned with:

- the characteristics of the intervention,
- aspects of the organisation providing the intervention (inner setting),
- aspects of the people and environment outside the NHS Trust (outer setting),
- the trial occupational therapists delivering the intervention (individuals involved) and,
- the process of implementing ESTVR.

The process of mapping each barrier and facilitator revealed five constructs that were not mapped, which Kirk et al. (2016) identified as a gap that limits the contribution to knowledge about implementation science. This could indicate

that these constructs (trialability of the intervention i.e. can the intervention be started and then modified in response to the context, its cost and design, the organisational culture and the process of planning the intervention's implementation) did not have any relevance. However, these were not sufficiently scrutinised in the interviews to come to a conclusion. A broader range of gaps were also identified in the systematic review in Study One (quality of the intervention delivery, trialability of the intervention and its design, the provider organisation's characteristics, networks and culture, the organisations external to the provider that may exert peer pressure and finally the process of planning, engaging and executing implementation). These gaps would arguably be expected in this case because the studies did not set out to explore implementation. However, in order to reduce gaps in knowledge studies using CFIR should record and report reasons for including and excluding constructs in any exploration of barriers and facilitators Kirk (2016).

Although the barriers and facilitators to implementing ESTVR have parallels with other studies (Chesworth et al., 2015, Hasson et al., 2012, Masterson-Algar et al., 2014), each study arguably presents a unique combination. The detailed descriptions of barriers and facilitators in all three studies in this thesis could inform future vocational rehabilitation trial design. In particular the findings of Studies Two (4.5.5.4) and Three (5.5.1.7) describe the barriers and facilitators to learning how to deliver a complex vocational rehabilitation intervention in the NHS, which may be applicable to similar future studies and may have relevance for implementation of these specific vocational rehabilitation interventions in clinical practice.

For instance, findings showed that NHS trial occupational therapists, who worked 1-day per week on the trial and the rest of the week in their usual role, felt under increasing workload pressure from their usual role. Mentoring records indicated this pressure resulted in a reduced ability to respond flexibly to the needs of PWTBI or their employers. For example, visiting workplaces had to be done on certain days, which did not always fit with the employers' schedule and did not fit with the flexible nature of the intervention. A combination of barriers contributed to this situation; a lack of awareness by line managers of the research processes to secure backfill for occupational therapists' time in their usual role and an organisational perception that one day a week should be absorbed by the usual service resulting in a lack of management support or available staff to backfill time.

This detail contributes to the theoretical debate about implementation fidelity and the adaptation of complex interventions by enabling comparisons across studies (Moore et al., 2013, Stirman et al., 2013, Sundell et al., 2016). Although the context in this study was the English NHS research environment, the detailed description allows others to draw some comparisons with their own rehabilitation contexts.

Identifying the moderating factors (barriers and facilitators) affecting implementation fidelity from studies two and three indicated that:

- Trial occupational therapists required support from:
    - The research team (specialist training in the complex intervention plus ongoing mentoring and feedback on performance) to facilitate fidelity to the intervention.

    - NHS managers and the NHS organisation to allow flexibility in the delivery of the intervention during the trial period.
- PWTBI and their employers require:
    - Trial occupational therapists to be flexible in their delivery of the intervention as their needs changed over time.
    - Trial occupational therapists to provide frequent, clear communications about the impact of the condition on work, in order to engage with the intervention.
- NHS managers require support from:
    - The research team to understand the practical implications of deploying therapists for research.
    - The NHS organisation to provide training regarding involvement in research in the NHS and support for staff seconded to research trials, even if for small proportions each week

Understanding these barriers and facilitators did not, in this programme of work, lead to a new framework for analysis. However, in future this could be addressed using a logic model. This future work to develop a logic model could also address how the implementation findings related to patient outcomes in receipt of the VR intervention. This distinction is considered important and is described by Proctor (2011) because patient outcomes are impacted by implementation outcomes. This programme of work was not able to make this relationship because the design of FRESH was a feasibility RCT. As such it was never designed to measure patient outcomes. However, similar future studies of complex rehabilitation interventions should look to analyse patient and implementation outcomes to understand the relationship thoroughly.

6.3. Wider study implications

Through synthesis of the three studies' findings, two key overlapping issues have arisen; using implementation data in developing complex rehabilitation interventions and the use of implementation research theory in vocational rehabilitation trials to reduce research waste. These are discussed.

The first iteration of the Medical Research Council's (MRC) framework for developing complex interventions (Medical Research Council, 2000) positioned implementation at the end of the process (stage IV), implying that only when an intervention is adopted into clinical practice, should implementation be addressed. This positioning persuaded researchers that implementation need not be addressed earlier in research and assumed that implementing an intervention during research is straightforward and doesn't meet with any problems. The exploratory phase II trial was described as being important in testing and examining methodological aspects, including outcome measures, before the main RCT in phase III (Medical Research Council, 2000). Researchers were advised to deliver the intervention in the same setting in which it would be implemented to assure generalisability.

In updated guidance published by the MRC in 2008, implementation is threaded throughout the process of complex intervention development. Factors associated with the intervention's complexity and the complex social systems in which people (delivering and receiving the intervention) and services sit can negatively or positively affect its implementation (Eccles et al., 2005). The guidance posed questions to researchers about whether the intervention could,

"be implemented in a research setting", and whether it was, "likely to be widely implemented" if effectiveness findings were favourable (MRC 2008, p4).

Researchers are asked to consider what affected implementation fidelity before adopting an intervention into clinical practice. This implies that implementation research should be carried out at stages before and during a main phase III trial in order to learn as much as possible to inform the intervention's transition into everyday clinical use. The MRC guidance on process evaluations of complex interventions reinforces that rehabilitation researchers should embed implementation fidelity, examining and reporting barriers and facilitators throughout intervention development (Moore G. et al., 2014) and not leave this until translating interventions for clinical use. There are differences between implementing complex interventions into clinical practice and in a trial but little is known about the context of the research setting (Luker et al., 2016, Brady et al., 2011).

Even though the MRC guidance on developing complex interventions and process evaluations has been widely cited over the past nine years, the rehabilitation research community has been slow to respond. This has been demonstrated in this thesis by the paucity of studies explaining the implementation failures and successes experienced during intervention testing. The systematic review reported in this thesis identified only 28 rehabilitation studies reporting implementation issues since 2008. However, it is acknowledged that this review did not set out to identify the proportion of all studies reporting rehabilitation for long term conditions, within its timeframe.

Researchers have ethical responsibilities to faithfully report what has occurred in studies and not doing so can harm patients and prevent clinicians from making evidence-based decisions (Goldacre, 2015). Findings from studies of ineffective interventions that investigate their implementation can reveal important details about the contexts, processes and people involved for future researchers to learn from (Moore G. et al., 2014). Publication bias, where researchers are reluctant to expose unfavourable results, was highlighted 30 years ago when Simes (1986) revealed the difference between the larger number of registered trials contained in a cancer trials registry compared to published findings. When less than half of health-related studies are reported (Song et al., 2010) this inaccessibility of research wastes the US$240 billion annual worldwide spend on health research (Røttingen et al., 2013). Publication bias and inaccessibility of research findings remains problematic (Moore G. et al., 2014) and there are calls for researchers to follow an international reporting process by the WHO International Clinical Trials Registry Platform (World Health Organization, 2017) to prevent this.

Highly competitive and scarce research funding opportunities may fuel this behaviour and researchers have problems publishing findings that are considered negative (Goldacre, 2015). However, publishing implementation studies has been limited to final reporting stages with limited opportunity to describe important contextual findings that would allow better interpretation of results (Eccles and Mittman, 2006). Reporting of implementation studies has been scattered across a wide range of journals and has meant that studies have not been easy to locate and the field has been not easily understood (Eccles and Mittman, 2006). This has been overcome in part with the relatively recent

addition of the journal Implementation Science in 2006, which publishes studies about the implementation of evidence-based interventions and includes developing interventions (Implementation Science, 2017).

Whilst Implementation Science is the primary location for implementation studies, the MRC guidance on process evaluations would support wide publication (Moore G. et al., 2014). Implementation may not be recognised by some editors as an important aspect to include in their publication and the scientific literature is recognised as incomplete and a biased subset of research findings (Chan et al., 2014). This perpetuates the impression that implementation should be considered separately to the reporting of effectiveness. Publishers may benefit from understanding how readership could widen and citations improve by publishing the implementation research aspects, even if these do not equate to positive results (Chan et al., 2014). The aim of any solution would be to promote the research of implementation fidelity as guided by the most recent MRC framework and process evaluation guidance (Medical Research Council, 2008, Moore G. et al., 2014).

Translating rehabilitation research into clinical services to gain patient improvements is not straightforward (Grimshaw et al., 2012). Those responsible for developing healthcare and rehabilitation policy and commissioners of these services require information about how an intervention is likely to work in different contexts and different populations whilst maintaining optimum outcomes (Bonell et al., 2006, Shiel-Davis, 2015). Researchers can help to provide this assurance by clearly demonstrating that an intervention has been implemented as planned, preventing errors in explanation of study findings

(Dusenbury et al., 2003, Spillane et al., 2007) and before implementation in the NHS.

By not addressing implementation of complex interventions early on in their development, the price paid by commissioners of research is unnecessary repetition of similar research (Ioannidis et al., 2014). Similar financial waste can be experienced by policy makers and healthcare commissioners where interventions:

- Reach clinical practice that are wrongly labelled as effective when in fact the intervention was not implemented as planned and not evaluated at the trial stage (Type III error) (Dusenbury et al., 2003).
- That may be effective do not progress further because they have been evaluated as neutral or ineffective when in fact they have been incorrectly implemented.

The ultimate beneficiaries of this system are patients who do not achieve the potential outcomes of rehabilitation (Colditz, 2012, Bosch et al., 2006). This wastes scarce resources, such as those in vocational rehabilitation and potentially causes harm to recipients and a drain on health services.

Avoidable waste in research can also be reduced by utilising published findings and conducting a systematic assessment of existing research (Chalmers et al., 2014). A systematic review was helpful in this research (chapter 3) to synthesise previously published findings in order to learn from what other researchers had already published about the facilitators and barriers affecting implementation in trials of complex rehabilitation interventions for adults with long term neurological conditions. The barriers and facilitators identified in this

review helped to inform trainers and mentors in supporting the FRESH occupational therapists (Holmes et al., 2016). Other researchers can use this information to inform study design and understand, for instance, what support might be required by clinicians delivering an intervention.

6.4. Project critique

In critiquing this programme of research, it is important to consider two main aspects; the former is the unique contribution it makes to knowledge in the field of rehabilitation research and implementation research (6.4.1) whilst acknowledging the limitations that exist (6.4.2); the latter is to discuss the methodological choices (6.4.3).

6.4.1. Unique contribution

One purpose of a PhD is to provide a unique contribution to research in a given field of work. The studies in this thesis span the fields of both implementation science, rehabilitation (specifically vocational rehabilitation) and traumatic brain injury. This thesis presents contemporary evidence relating to the implementation of a complex vocational rehabilitation intervention delivered in a research (RCT) environment. Previous studies have described barriers and facilitators to implementing complex interventions in a research context. However, none have explored it in relation to implementing vocational rehabilitation for PWTBI in a trial, demonstrated by the lack of studies identified in the systematic review. Furthermore, none have provided detailed descriptions necessary to understand the contexts in which the intervention was delivered.

The comprehensive measurement of fidelity of a vocational rehabilitation intervention delivered by trial occupational therapists within a research environment and its detailed description is unique. The transparency of the fidelity measurement and use of the CFIF theoretical framework should prove useful to researchers developing similar interventions in the future. Finally, whilst the use of two complementary implementation theories is not unique, neither is it commonplace. This programme of research is unique in the use of CFIF and CFIR to guide the exploration of and describe the implementation of a complex vocational rehabilitation intervention (ESTVR) delivered to PWTBI and their employers in a rehabilitation research environment.

6.4.2. Limitations

The limitations with each study have been described in (3.6.3, 4.6.1 and 5.6.3). However, it is important to recognise the limitations across the programme of research.

The three studies were conducted as part of a PhD project which imposed certain limitations. In particular timescales were set by both the structure of the PhD framework itself and the reporting requirements of the funders. Most importantly though were the limitations associated with using data from the feasibility RCT FRESH. FRESH had its own timescales and milestones, which required the author to be flexible about when and how data was collected and analysed.

Qualitative methods were used to explore opinions of the intervention. But some key voices were absent. These included participants who may have had negative experiences and chose not to participate. TBI is a group that is known

to be hard to reach in research that may be related to memory problems they experience, being a young and mobile group who move home and change their contact details, being a group who do not want to be traced due to the nature of their accident or socioeconomically disadvantaged (Bonevski et al., 2014). Very few employers participated in interviews, even though more expressed agreement to be interviewed, they too were difficult to reach. In a future study, a range of methods may be needed to capture different viewpoints whilst also respecting total anonymity and the constraints on participants' available time to engage with interviews.

The author's lack of implementation research experience may have introduced limitations of subjectivity. However, this was minimised by seeking expertise from other researchers locally and nationally. In particular, from those more experienced using implementation research frameworks and who may have different experiences of mapping data. In order to go some way toward addressing this issue, the author used triangulation methods to ensure findings agreed and made use of existing literature. These sources sought to explain terminology and provided illustrations of how to interpret constructs and how to interpret data to understand which construct was the best fit within CFIR (Breimaier et al., 2015, CFIR Research Team, 2016, Connell, 2014, Connell et al., 2014, Damschroder et al., 2009, Damschroder et al., 2015, Damschroder et al., 2012, Damschroder et al., 2011, Kirk et al., 2016, Sorensen and Kosten, 2011) and CFIF (Augustsson et al., 2015, Booth, 2008, Carroll et al., 2007, Hasson, 2010, Hasson, 2015, Hasson et al., 2012, Hasson et al., 2014, Pérez et al., 2016, Slaughter et al., 2015, Sundell et al., 2016). The validity of mapping,

in particular, would have been improved by having additional experts checking the findings.

The choice of CFIR and CFIF has been explained in chapter two and some limitations associated with the frameworks have been discussed such as the differences in semantics causing potential misunderstandings and reducing the ability to compare data across studies. Critically for this programme of work however, is the lack of evidence to support or refute their use in such an early phase of intervention development and within a feasibility trial. Therefore the findings should be interpreted with some caution. Future research could include a detailed analysis to understand if these frameworks require modifications in order to be used with rigour in feasibility trials of complex rehabilitation interventions such as VR.

The term mentoring can be confused with other mechanisms that infer support, such as supervision and advice but (Sambunjak and Marušić, 2009) warn that scientific rigour is at risk if the term is not used appropriately. They suggest that the conceptual variation creates the potential for errors to occur and limits analysis of findings and estimations of the effects of mentoring (Sambunjak and Marušić, 2009). However, others have deliberately combined several concepts of support including mentoring, peer discussions and supervision when looking at potential mechanisms for successful outcomes (Moran et al., 2014).

6.4.3. Strengths

Adopting theoretical implementation research frameworks, such as CFIF and CFIR, helps identify and measure implementation fidelity in trials (Masterson-

Algar et al., 2016). Frameworks facilitate reporting and use of defined terms, helping others to make comparisons (Chambers, 2012). In order to widely examine what affected the implementation fidelity of ESTVR retrospectively, a combination of CFIF and CFIR were used to ensure that a broad spectrum of implementation concepts were covered. In determining the barriers and facilitators from multiple data sources, the author created an illustration of how both frameworks related to each other (Figure 6-1), which aided data analysis.

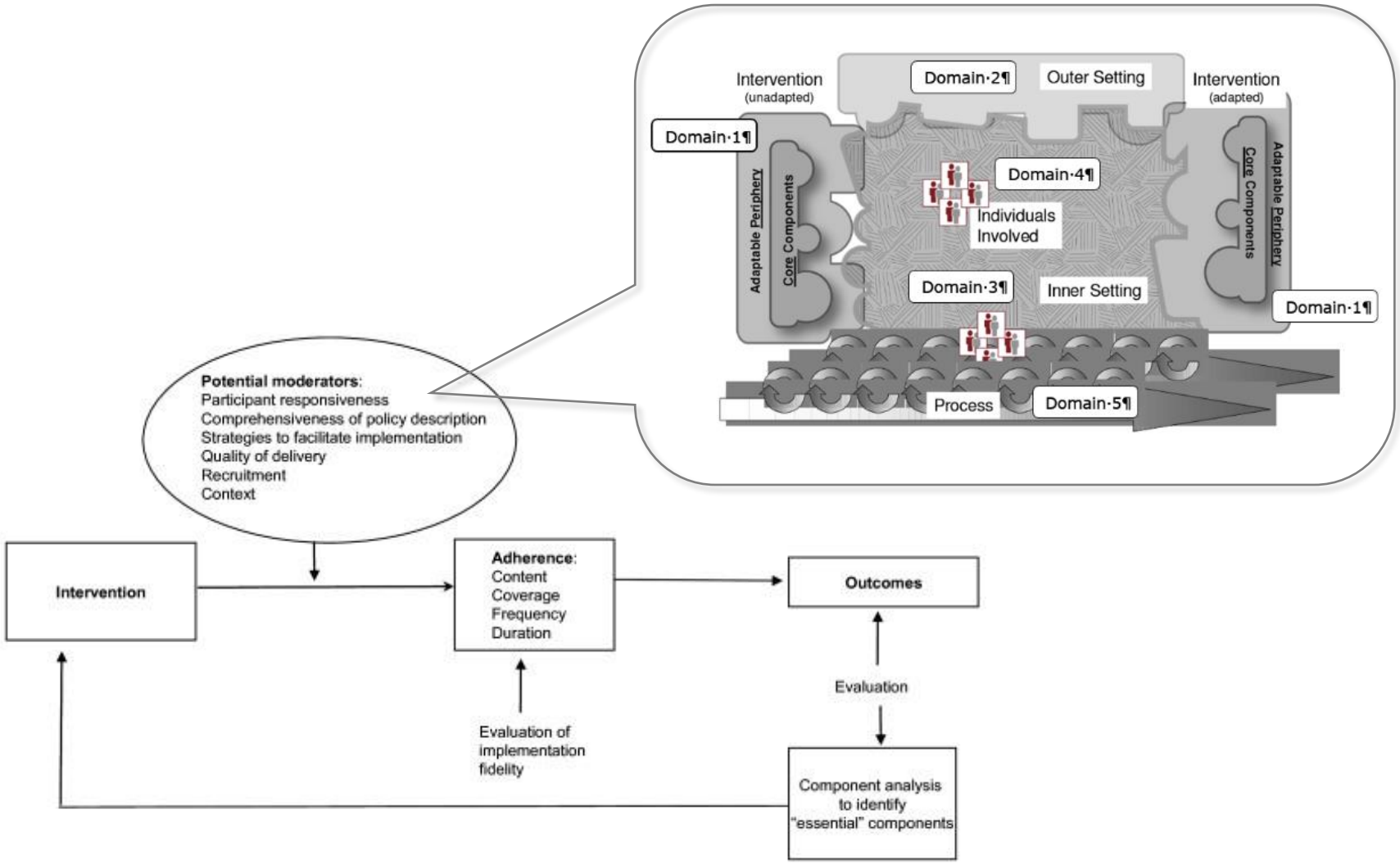
Even though others have previously used CFIF and CFIR together (Connell, 2014, Masterson-Algar et al., 2014), the relationship between them has not been described. Whereas CFIF helped to guide measurement of implementation fidelity, identifying what moderates it, CFIR helped to understand the barriers and facilitators to implementation in more detail, thereby shedding light on the moderating factors (CFIF). This mental model could be used to visually communicate how these frameworks function together to provide a deeper understanding of implementation fidelity in future training of trial occupational therapists, fidelity monitors and mentors.

6.4.1. Methodological choices

Mixing methods, using quantitative and qualitative methods in a single study, helps to understand the research problem better than either approach would provide alone (Creswell and Plano Clark, 2007). Creswell (2003) explains that mixed-methods designs are complementary, practical, strengthen trustworthiness and provide a gradual development of knowledge. Knowledge develops by using findings from one method to inform subsequent ones and both

explanatory and exploratory research questions can be addressed (Borglin, 2015).

Figure 6-1 Complementary relationship of CFIF and CFIR



Overall, mixed methods were more helpful than either qualitative or quantitative methods alone. Together they provided a comprehensive understanding of the barriers and facilitators to implementing a complex vocational rehabilitation intervention within an NHS rehabilitation feasibility randomised trial. As expected, the quantitative methods provided appropriate ways to collect and analyse numerical data in the studies using descriptive statistics. This was sufficient detail in this project, which aimed to explore and describe what occurred. Likewise, the qualitative methods provided the voices of the different research participants, revealed details of their experiences and contributed to understanding the contexts over three sites. Both methods were brought together in the triangulation of data sources, which increased the robustness of the analysis. This provided a method to analyse quantitative and qualitative data concurrently, as illustrated in the mapping process carried out in studies one (3.5.3.1 – Table 3-2) and three (5.5.1.7 – Figure 5-6) and the overall fidelity results of Study Three (5.5.1.5 – Table 5-6).

6.5. Overall recommendations

Each study has described the implications arising from them (3.6.4, 4.6.2, 4.6.3 and 5.6.4) but the overall implications for researchers involved with complex vocational rehabilitation interventions (6.5.1), clinicians involved in delivering interventions in a research context (6.5.2) and future research recommendations (6.5.3) are offered.

6.5.1. For researchers

The most important overall recommendations for researchers involve becoming more educated about and adept at including implementation research into trials

of complex interventions and particularly those in vocational rehabilitation for people with traumatic brain injury, although arguably for all rehabilitation trials. Examining implementation of a rehabilitation intervention, such as vocational rehabilitation should occur from the earliest testing and not wait until after effectiveness trials are complete. This examination should be guided by theoretical implementation science underpinnings, choosing a suitable implementation research framework for intervention contexts. Although this choice is not straightforward, there being 60 frameworks to choose from (Martinez et al., 2014, Tabak et al., 2012), the framework should provide sufficient breadth to be able to capture the entire context, yet sufficient depth to be able to describe the detail of the context. The suggestion, extrapolated from this project, is that CFIF and CFIR would be appropriate for most complex rehabilitation interventions being delivered in the NHS.

Trialists should be cognizant of the value of training and mentoring trial occupational therapists to deliver interventions, but training alone will not be sufficient to ensure an intervention is delivered as planned. There should be close examination paid to other parts of the context including potential barriers and facilitators situated within and external to the provider organisation, those that lie within the intervention itself and finally those that are associated with the process of implementation.

Finally, the development of implementation research taxonomies requires the international cooperation of researchers to improve comparisons of findings across studies to continue to develop implementation science. This will be

helped if more researchers become conversant with the developing lexicon of implementation science.

As well as exploring, measuring and analysing implementation fidelity, researchers should make every attempt to make findings available for dissemination. Even though studies two and three in this thesis are restricted to vocational rehabilitation, this thesis argues that researchers should strongly advocate the publication of implementation and effectiveness findings concurrently and if this cannot be done in a single publication that both should be cross referenced. This process could commence with all rehabilitation research funders insisting, as a minimum, that rehabilitation studies include implementation research in the development phases of the intervention to ensure data becomes public. In order to comply with such requirements, universities should provide research students and researchers with adequate leadership and support to be able to address implementation research.

6.5.2. For clinicians delivering interventions in trials

This project involved occupational therapists who worked as trial occupational therapists delivering the complex intervention ESTVR. The findings from this project demonstrated that alongside initial training in a complex vocational rehabilitation intervention, trial occupational therapists should additionally receive mentoring throughout the duration of the trial. Study Two and three demonstrated that this was important when delivering a complex vocational rehabilitation intervention in order to optimise the occupational therapists' confidence and implementation fidelity.

Study Two demonstrated that trial occupational therapists benefit from understanding research processes, especially comprehending contamination issues in real-world, pragmatic trials. As part of their training and mentoring, trial occupational therapists should receive ongoing information and feedback related to minimising contamination and optimising fidelity.

6.5.3. Future research

The ESTVR training package provided in Study Two needs to be developed further for trial occupational therapists delivering the intervention. This involves refining the content and delivery based on the experience of the trial occupational therapists and will facilitate future measurements of the training package's effectiveness. A specific training programme for mentors supporting trial occupational therapists needs to be developed and tested.

Study Three demonstrated that the fidelity measurement tools require refinement and further testing. The impact of this would be to reduce the amount of data required to measure fidelity of the vocational rehabilitation intervention whilst retaining sufficient sensitivity. Finally, the author anticipates that from these studies, the development of a guide to aid the reporting of implementation research specifically for studies of complex rehabilitation interventions conducted at the exploratory phase of intervention development can be extrapolated.

6.6. Conclusion

Identifying, measuring and describing barriers and facilitators can elicit important information to assist researchers in improving rehabilitation trial design, ensuring more robust trial outcomes, reducing the risk of type III errors and expediting translation of research into improved patient outcomes. Using implementation research frameworks, such as CFIF and CFIR can support this, but further guidelines to help researchers without expertise in the lexicon of implementation science are required to address the reporting gaps. Mentoring for therapists, case discussions, training in research processes, support from their own organisation and the research team is essential for delivering a trial intervention with fidelity. Implementation of complex rehabilitation interventions, such as ESTVR, are affected by individual and organisational factors which need to be considered in a definitive trial. Support the trial occupational therapists received from the research team and support from their own organisation was most important.

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8. Appendices

8.1. Appendix 1 - MeSH and non-MeSH Search Terms

Barriers and Facilitators

(Barrier* or Block* or Hurdle* or barricad* or Obstruct* or obstacle* or Facilitat* or enable* or Support* or Encourag* or challeng* or problem* or threat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

(Barrier* or Block OR Hurdle* or barricade* or Obstruct* OR negative* OR Positiv* or Facilitat* or Support* or Cause* or Encourag* or challeng* or problem* or threat*) .mp. [mp=title, abstract, subject headings, heading word, original title, keyword]

AVOID ?

Implementation

(Implement* or Applicat* or adopt* or uptake or Apply or Execut* or Instigat* or Carry out or Employ* or Perform* or Usage or Practice or Enactment or Fulfil*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

implement* or

AVOID rehabilitation/service cessation or de-implementation, policy model being tested, undergraduate training toolkits or strategies, general evidence-based medicine/practice.

Long-term neurological condition

1. Migraine Disorders/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

2. Huntington Disease/ or Neurodegenerative Diseases/

3. Postpoliomyelitis Syndrome/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

4. Muscular Atrophy/ or Charcot-Marie-Tooth Disease/ or Friedreich Ataxia/

5. Myasthenia Gravis/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

6. Neuromuscular Diseases/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

7. Brain Injuries/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

8. Dementia/

9. Cerebral Palsy/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

10. Amyotrophic Lateral Sclerosis/ or Motor Neuron Disease/ or "motor neuron* disease".mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

11. Stroke/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

12. Muscular Dystrophies/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

13. Multiple Sclerosis/ or Nervous System Diseases/ or Spinal Cord Neoplasms/

14. Spinal Cord Injuries/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

15. Parkinson Disease/nu, px, rh, th [Nursing, Psychology, Rehabilitation, Therapy]

16. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

LTC OR long AND term AND (Health AND Physical OR mental) condition* OR dementia OR Stroke OR (Cardiovasc* AND Disease) OR TBI OR (Traumatic AND Brain AND Injury) OR ABI (Acquired AND Brain AND Injury) OR (Older AND Adults) OR MS OR Multiple Sclerosis OR Neurologic* AND Disorder OR Parkinson* OR Cancer OR Rheumatoid AND inflammatory AND OR Arthritis OR Respiratory AND Disease OR Depression OR Anxiety OR Schizophrenia OR Bipolar

Co-morbidities allowed e.g. TBI and mental health

AVOID short term/acute health conditions, maternity, all non-LTNC

Complex intervention

(complex OR complicated AND health AND OR care AND intervention) OR rehabilitat* OR (Ther* AND Occupational OR Physi* OR (Speech AND OR Language AND OR Pathology) OR Psycholog*) OR Nurs* OR (individ* AND treat*) OR multidisciplin* AND team OR MDT

AVOID public health intervention or promotion, professional education interventions, interventions with only employers, specific guideline intervention, robotics studies, telehealth/rehabilitation

INCLUDE specific treatment guidelines or manuals of a specific complex intervention

General Limits

adult (19 plus years) OR adolescent (13-18 years) and research in developed countries. All studies written in any language were included initially and then a final limit of English language was applied. This provided a clear awareness of all relevant studies and allow clear identification of the full breadth of literature.

8.2. Appendix 2 – Screening form

Review Question: What are the barriers and facilitators affecting the implementation of evidence-based complex health interventions with adults with long-term conditions?

Inclusion criteria: (based on PICO):
Population = adults (16 years old and over) who have a long term neurological condition in a developed country (1st world country)
Intervention = any complex health intervention as defined by MRC guidelines, (2008) targeted at the long term neurological condition
No comparator
Outcomes = Identification of barriers and or facilitators associated with implementing the complex intervention to the population group
Study = any published and grey literature (opinion pieces excluded)

SCREENING AND SELECTION TOOL

Reviewer name:			Date:
Author name/study ID:			Year:
Title:			Publication source:
Abstract			
	Include	**Exclude**	**Unclear**
Patient population:	☐ 16 years old and over ☐ long term health condition ☐ study conducted in a developed country ☐ Any sex	☐ 15 years and younger ☐ short term neurological condition ☐ No health condition ☐ in a developing country or undeveloped country ☐ robotics, specific equipment testing or telehealth ☐ not neurological condition	☐ age of population unclear ☐ health condition unclear ☐ the country the study was conducted in is unclear
Intervention:	☐ complex health intervention ☐ targeting the LTNC ☐ Targeted primarily at the individual	☐ health intervention would not likely be considered complex ☐ not a health intervention ☐ only refers to training practitioners/service providers i.e. pre-delivery of intervention ☐ intervention focussed only on a 3rd party e.g. carer ☐ generalised evidence-based practice studies related to professional groups	☐ unclear
Outcome of interest:	☐ barriers and or facilitators associated with implementing the complex intervention to the population group ☐ implementation issues/concepts/perspectives	☐ no mention of barriers and or facilitators associated with implementing the complex intervention to the population group ☐ no implementation issues documented	☐ unclear whether reported barriers and facilitators pertain to the implementation of the intervention ☐ unclear documentation of implementation issues
Study design:	☐ any design – Cluster RCT ☐ published literature ☐ grey literature	☐ opinion piece ☐ protocol only without results	☐ undetermined

Language:	☐ English	☐ not published in English	N/A
Overall decision:	☐ INCLUDED	☐ EXCLUDED	☐ NEED MORE INFO/FULLTEXT
Further comments/describe further action required:	•		
Overall decision:	☐ INCLUDED	☐ EXCLUDED	☐ NEED MORE INFO/FULLTEXT
Decision by			
Agreement by			
Disagreement by			
Adjudication by			

8.3. Appendix 3 – Data Extraction Tool

Study title	Journal	Country	Study design	Study setting	Age of study pop	Number of participants	LTNC	Complex intervention(s)	Implementation by	Intervention outcome measures used	Implementation outcome measures used	how barriers are described	how facilitators are described	Method to ID barrier/facilitator	Implementation model/guideline/framework	Further comments				

ID = identification

LTNC = long term neurological condition

Pop = population

8.4. Appendix 4 – Overview of included studies

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
1	(Allison and Dennett, 2007)	England	Pilot RCT	Stroke	Conventional PT of 45 minutes plus an additional session of standing practice of 45 minutes per PT session. Aim to increase motor recovery and mobility post stroke. Continued through hospital admission.	PT and PT assistant.	Not described specifically but text indicates patient reporting following a specific request to withdraw.	None
2	(Barzel et al., 2015)	Germany	Parallel, cluster-RCT	Stroke	Home-based Constraint Induced Movement Therapy (CIMT). 5 hours of professional therapist contact in 4 weeks. Therapists used the contact time to instruct and supervise patients and (family/carer) coaches in home CIMT. Aim to improve movement in affected limb.	PT or OT with a professional qualification or at least 2 years of experience in treatment of chronic impairment caused by stroke.	Not described. A separate qualitative study to gather information on the experiences of patients and coaches with home CIMT to gain a deeper insight into the strategies of coping with the new therapeutic concept in everyday life.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
3	(Bentley et al., 2014)	Australia	Cross-sectional feasibility study used a one-group pre-test post-test design	Motor Neurone Disease	Dignity therapy (brief psychotherapy) builds a recorded life reflection by a person with terminal disease. Aim to provide the opportunity to discuss significant memories, meaningful events and important accomplishments, as well as leave messages for loved ones.	Researcher trained in dignity therapy by Harvey Max Chochinov who developed the therapy	Three recordings, transcripts, and completed documents (10%) were reviewed by three experienced researchers (two trained in dignity therapy) and deemed to be adherent. Participant acceptability survey.	None
4	(Bovend'Eerdt et al., 2010)	England	Parallel-group, RCT	Stroke, brain injury, multiple	A motor imagery strategy taught (the person imagining himself undertaking the movement without actually doing the movement) in usual therapy time. Aim to improve functional use of an affected limb.	PTs and OTs.	Researcher asked the therapists (immediately after the intervention) and patients (at follow up) about compliance and perceived benefits.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
5	(Brady et al., 2011)	Scotland	Pilot non-randomised before and after evaluation	Stroke	Complex, multidimensional oral care intervention for people in stroke rehabilitation. The intervention included components that targeted three systems of care - (i) patient, (ii) staff and (iii) services. Aim to improve oral health.	All MDT members including nursing staff and clinical support workers. Guided by dental specialists.	Adapted Oral Health Care Knowledge and Attitudes Questionnaire (Frenkel et al., 2002) and semi-structured interviews with staff and patients about the views on the feasibility of the implementation of the intervention.	None
6	(Braun et al., 2010)	Netherlands	Process evaluative [embedded in a multi-centre RCT]	Stroke	A motor imagery treatment frame-work embedded in regular therapy sessions of 30 minutes over six week mental practice (imagining movement patterns) intervention of four phases: explanation of imagery, teaching patients how to use imagery, using imagery as part of therapy, and facilitating the patient in using it alone and for new tasks. Aim to improve motor function.	PTs and OTs. Specialised in stroke rehabilitatio n and most had some awareness of mental practice but did not use it regularly.	Registration forms, pre structured patient files (frequency and content of therapy and also the clinical progress of the patient), patient logs (practicing the intervention plus mood and any other important issues) and self-administered questionnaires for therapists and patients (experiences and opinions)	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
7	(Cup et al., 2011)	Australia	Prospective Cohort Study	Neuromuscular Disorders (NMD)	Specialist multidisciplinary advice provided by NMD experts (in a specialist outpatient unit) regarding management of patients. Provided to OT, PT and SLT or rehabilitation physician in a primary care or rehabilitation setting. Integrated allied health care advice was developed on the basis of these consultations and a multidisciplinary meeting. Aim was to optimise patient outcomes by upskilling local MDT through targeted advice.	NMD specialists at the regional centre in Nijmegen provided advice to local MDT providing ongoing input with patients.	Questionnaires x3; x1 prior to intervention; x1 2 weeks after advice provided; x1 6 months after advice given. Looked at intervention frequency, duration and satisfaction with the intervention and service delivery processes.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
8	(Demers and McKinley, 2015)	Netherlands	Descriptive qualitative study design	Stroke	Biweekly 45-min dance intervention over 4 weeks in a group. The dance intervention followed the structure of a usual dance class, but exercises were modified and progressed to meet each individual's needs. Aim was to improve multiple components of physical functioning.	OT with dance experience	No specific method reported, However, the dance instructor kept a journal containing the feedback of the participants on the dance intervention. Frequency of sessions attended and responsiveness recorded.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
9	(Douglas, 2014)	Canada	Mixed-methods design	Dementia	Non-electronic external memory aids (visual schedules and reminders with large print, memory wallets with pictures or family scrapbooks with important events). Aim is to increase positive communicative interactions and decrease negative behavioural problems.	SLT	Frequency of memory aid use by SLTs collected by estimated percentage overall. Semi structured interview to provide a deeper understanding of the facilitators and barriers to SLP's use of non-electronic external memory aids with residents with dementia in nursing facilities. Interview questions were posed according to components of the PARIHS framework. Organisational variables such as culture, leadership priorities, and resource availability are considered. Used apriori codes derived from PARIHS in analysis.	Promoting Action on Research in Health Services (PARIHS) framework (Kitson et al., 1998)

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
10	(Gage et al., 2014)	USA	Pragmatic three-parallel group RCT	Parkinson's Disease	Specialist domiciliary rehabilitation service for people with Parkinson's and carers. Over a period of 6 weeks. Most patients received one visit from one of the professionals each week. Aim not explicitly specified.	Parkinson's nurse specialists, PTs, OTs, and SLTs	Semi-structured patient and carer questionnaires (acceptability and usefulness). Open comments from MDT and completing a structured feedback form (Likert scale ratings and comments on communication and support within the team, delegation of responsibilities, involvement of patients and carers in care planning, and examples of good practice and challenging situations that they had encountered). Staff exit interview with a semi-structured interview.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
11	(Haines et al., 2007)	UK	RCT subgroup analysis	Included Stroke	Exercise programme sessions, three times per week, for 45 minutes. Content based on tai chi with functional movements (transferring from chair to chair, weight shifting, reaching, stepping) and activity visualization. Aim to prevent falls in the subacute hospital setting.	PTs	Incidence of attendance in sessions and reasons for non-attendance.	None
12	(Halle et al., 2014)	Australia	Qualitative grounded theory	Stroke	Family (significant other) based aphasia rehabilitation. Aim positive changes in significant others' psychosocial well-being, improvements in significant others' skills and behaviours in conversation and also improved communication.	SLTs	Individual semi-structured interviews with patients receiving the intervention. Reflections on the ideal arrangement for treatment and experiences of the intervention.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
13	(Johannessen et al., 2014)	Canada	Qualitative interviews with health professionals within a RCT	Dementia	Psychosocial and educational intervention. Carers had five counselling sessions. The person with dementia was invited to join two meetings, whereas the extended family participated in one meeting. Carers were introduced to cognitive techniques. Aim to provide home-dwelling people with dementia and their families with knowledge and skills to cope with the emerging problems and stresses of everyday life.	15 nurses, OTs, nursing assistant.	Focus groups x3 and interviews x6 with those receiving the intervention. Reflecting on experiences of the intervention and future recommendations.	None

14	(Mackenzie et al., 2014)	Norway	RCT feasibility study	Stroke	Behavioural dysarthria intervention was behavioural, delivered in eight home-based sessions, and included practice of individually appropriate words, sentences and conversation plus non-speech oro-motor exercises. Aim to improve word intelligibility and communication effectiveness.	SLTs	A post-intervention anonymous evaluation (AE) questionnaire was issued to participants following the final intervention session. It comprised (1) 15 statements on therapy sessions and results, for response on a one to five scale (1=strongly disagree; 2=disagree; 3 = neither agree nor disagree; 4 = agree; 5 =strongly agree); (2) 12 suggested programme improvements, using a 'tick all that apply' response, covering session difficulty, pace, length, number, amount of content and of home practice; (3) a question on preferred therapy location; and (4) two open questions requesting further suggestions for programme improvement and 'anything else you would like to tell us'.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
15	(Mahoney et al., 2006)	Scotland	Qualitative descriptive study	Dementia	Home-based bathing intervention involved teaching, role-modelling, and coaching patients and carer dyads over 3 weeks. Aim to improve behavioural symptoms and caregiver self-efficacy to improve the bathing experience at home.	Research nurse.	Mixed qualitative methods to identify implementation issues (experiences of delivery and receipt of the intervention); direct observation, nurse interventionist field notes, case analyses, and caregiver journals, reflecting various perspectives.	Adapted by (Burgio et al., 2001)
16	(Merlo et al., 2013)		A phenomenological approach to qualitative inquiry	Stroke	Intensive mobility training performed 3 hours per day for 10 consecutive weekdays. Aim to stimulate functional recovery of gait, balance, and mobility.	PTs	Participants were interviewed twice regarding their impressions of the therapy (semi structured interviews were held with each participant after the initial 5 days of participation and following completion of the 10 days of therapy), and a focus group was conducted with participants and family members.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
17	(Morrison and Backus, 2007)	USA	Retrospective study analysed data	Spinal cord injury	Locomotor training modalities, such as body weight-supported treadmill training. Aim to improve the recovery of walking in individuals with motor incomplete spinal cord injury.	PT, PT technicians, and volunteer	Cost calculations (expenses and revenue for each individual).	None
18	(Nanninga et al., 2015)	USA	Case Report	Stroke	Combined Clinical and Home Rehabilitation (CCHR) involved task and context-specific training two 45-minute home treatment sessions a week over 2 to 5 weeks. Aim to improve functional independence at home.	PTs, OTs,	Semi-structured individual interviews with 9 therapists and the 4 patients and their caregivers involved in the pilot study. Discussions with members of the Board of Directors of University Medical Center Groningen and with regional health insurance experts.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
19	(Prick et al., 2014)	Netherlands	Mixed methods RCT	Dementia	Exercise and support intervention implemented with both the person with dementia and the caregiver present. The support component, directed at both the person with dementia and the caregiver, included three elements: (a) psycho-education; (b) communication skills training; and (c) pleasant activities training. Aim to motivate dyads to complete 30 minutes of active exercise at least 3 days a week.	Sport coach and psychology	Semi-structured interviews with 11 dyads and interviewer reflection notes made directly after the interviews. Daily exercise and pleasant activities logs of all caregivers (n = 57). Questions included: Could you describe your experiences with regard to the physical exercises? Could you describe your experiences with pleasant activities planning? Could you describe your experiences with regard to the communication skills training?	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
20	(Richardson et al., 2015)	Canada	Case report with a single group before and after design	Stroke	Self-management and task-orientated functional training and allocated 10 visits per patient. Home-based Aim to optimize physical function and self-management skills.	PTs and OTs as dyads.	Eight therapists completed reflective journals. Therapist response was determined from focus groups; patient response was measured by standardized assessments (Patient Satisfaction Questionnaire (modified PSQ-18)).	None
21	(Siemonsma et al., 2014)	Netherlands	Systematic review	Stroke	Home-based rehabilitation involved rehabilitation taking place in the home or habitual environment, task and context-specific training. It replaces inpatient rehabilitation. Aim to increase participation in daily life (e.g. activities of daily living and quality of life).	MDT	Systematic review of 7 studies. Thematic analysis. Identifying determinants influencing implementation of the intervention.	Framework for the Introduction and Evaluation of Innovations (Fleuren et al., 2014)

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
22	(Speelman et al., 2014)	Netherlands	Multi-site RCT	Parkinson's Disease	Multifaceted intervention (PARKFIT). PTs were activity coaches guiding patients towards a more active lifestyle during monthly personal coaching sessions, educated patients about the beneficial effects of physical activity and suitable activities. Group exercise to experience social support. Also included regular PT. Aim to promote physical activity.	PTs	Interviews and questionnaires. Research team contacted therapists every three months by telephone to investigate whether they experienced barriers in delivering the PARKFIT program.	None
23	(Sturkenboom et al., 2013)	Netherlands	Feasibility RCT	Parkinson's Disease	Home-based OT. Delivered for 10 weeks and up to 16 sessions (45–60 minutes). Aim to optimise a person's functional performance and engagement in everyday activities and life roles.	OTs	The qualitative evaluation had a phenomenological design exploring perceptions of the intervention procedures and outcome using individual interactive interviews with participants (patients, caregivers, therapists), and focus group discussion with therapists.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
24	(Thomas et al., 2014)	England	Mixed methods single case study	Stroke	Systematic voiding programme (SVP) for patients with urinary incontinence. Individualised SVPs tailored to the physical and cognitive capabilities of each patient and weekly progress review. Two routes: Bladder training and pelvic floor muscle training for those patients who were cognitively able and prompted voiding for those with cognitive impairment. Aim to improve urinary continence.	MDT	Soft systems methodology provided new insights into the challenge of implementation at the interface of organisational attributes and systems and clinical work. Normalisation Process Theory proved particularly useful in highlighting implications of introducing the SVP for professional practice, including less concrete processes such as negotiating priorities and division of responsibility.	Normalisation Process Theory (May, 2006)

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
25	(Van't Leven et al., 2012)	Netherlands	Qualitative grounded theory	Dementia	Community OT in Dementia (COTiD), psychosocial interventions for dementia patients and carers. Ten 1-hour sessions in a 5-week period. First 4 sessions clients and primary carers learn to choose and prioritise the meaningful activities that they want to improve. Remaining six sessions, client is taught to optimise the strategies learnt. Total time about 18 h for one client carer dyad (Graff et al. 2006b, 2010). Aim to improve functional performance.	OTs	Focus group with 17 OTs and semi structured interviews with 10 physicians and 4 managers. OTs in the focus groups were asked to name three facilitators and three barriers that they had encountered, which were discussed in depth. Questions for physicians asked about familiarity with and about problems when they referred patients to COTiD. Managers were asked about their willingness to contract the intervention.	Combinaties van interventies. (Grol R, 2006)

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
26	(Veenhuizen et al., 2011)	Netherlands	Survey	Huntingdon's Chorea	Outreaching multidisciplinary intervention. Assesses the stage of the disease and formulates, coordinates and implements the individual care and treatment plan in the home situation. Aim to optimise functioning and quality of life.	Institutional physician, a psychologis t, a SLT, a social worker, an OT and a case manager	Questionnaires with a mixture of 10 open and multiple choice questions (satisfaction with and usefulness of the intervention) received from patients, caregivers and health professionals. Five Dutch "experts-in-the-field" and the lay organisation were asked for their opinion on the implementation and usefulness of the intervention.	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
27	(Voigt-Radloff et al., 2011)	Germany	Process evaluation [embedded in a RCT]	Dementia	Community OT in Dementia (COTiD) programme (as above but delivered in a different country). Aim to improve functional performance.	OT's	Semi structured questionnaires. After the treatment period, therapists described inhibiting and facilitating processes at the study site. Focus-group discussion to achieve consensus about the main performance problems. Therapists dichotomously scored the 20 treatment sub processes performed either with or without problems. Therapists rated patient adherence and carer acceptance of innovations. Therapists rated these indicators for adherence on a five-point-Likert scale ranging from 'very facilitating for the treatment performance' (1) to 'very hindering for the treatment performance' (5).	None

Study ID	Author(s)	Country	Study design	LTNC	Complex intervention(s)	Implement-ation by	Method to identify barrier and facilitator	Implement-ation model or framework
28	(Wesson et al., 2013)	Australia	Randomised pilot trial	Dementia	Fall prevention programme with strength and balance training exercises and home hazard reduction. The 12 week intervention program was conducted in participants' homes. Tailored to participant's individual cognitive levels and implemented as a carer-supported intervention. Aim to reduce falls.	OT, PT and carer	Adherence - Staff/field notes documenting adherence/visit by therapist, home safety booklet/logbook, exercise logbook/checklist with staff monitoring and documentation, Adaptability - Individualised home safety booklet (theory-based), individualised home exercises. Acceptability - Field notes/visit by therapist	None

OT – occupational therapist, SLT – speech & language therapist, PT – physiotherapist,

8.5. Appendix 5 – Learning needs analysis

Your Learning needs vs what we can manage to achieve...

	Your current needs:- Please rate the level of your need based on a combination of your existing knowledge and confidence in the following areas. 1= not very confident or knowledgeable to 5= already really confident and knowledgeable	Rate it... 1 to 5
1	To increase my knowledge of traumatic brain injury	
2	To get a *basic* understanding of vocational rehabilitation related to TBI (i.e. I don't have much or any experience to date).	
3	To get an increased knowledge of vocational rehabilitation related to TBI (i.e. I have a little/some experience to date)	
4	How to convince participants and /employers that a graded return to work is a good idea?	
5	To develop my skill in helping a participant become work ready and ways of achieving this.	
6	How to gain support from GP/medical consultants/therapy professionals regarding the approach to RTW	
7	How to know when a client is work ready?	
8	Knowledge of the GP Fit Notes. E.g. how they can be successfully used/how much to rely on or quote Fit Notes to employers	
9	How to use the AHP Fitness for Work Report effectively with employees and employers	
10	How to convince employee/employer that a RTW is a good idea even though I can't give a 100% guarantee there won't be problems?	
11	How to plan graded returns with regard to hours and when to increase them, what tasks and precautions to suggest and how to monitor this.	
12	How to negotiate compromises on RTW plans with employers (and clients). How much influence do I really have?	
13	How to separate employer/employee issues that pre date the current RTW need.	
14	What to do is the return to work/job is not going well	
15	Increase my knowledge of useful resources?	
15	Gain knowledge about the research process and study	

Make a note of any other learning needs that come to mind...

Bear in mind we will be walking you through all the research information and "how to" elements for this as well.

Learning need	Issue to address

You will have been told by which date you need to send this form back to me. We will also discuss needs and the training plan at the first session of day 1 of the training. So if other issues arise, you will have an opportunity to tell us.

8.6. Appendix 6 – Direct teaching timetable

Day 1: Brain injury and return to work

Day 1	
09.00	Intro to the two days and overview of relevant research to date and the FRESH study
09.45	Overview of study
10.00	Case manager and OT roles
10.30	Morning break with refreshments
10.45	TBI and work
11.15	Case studies and video group work
11.45	Vocational rehabilitation framework
13.00	Lunch provided
13.45	Service users and group work
14.45	Afternoon break with refreshments
15.00	Service Users and an employer meeting
16.00	Workplaces and responsibilities
16.45	Final round up and questions. Homework

Homework: Remembering the video case studies – think about and then outline what you would consider an appropriate work preparation program. Please use the FRESH manual as a prompt. Bring this with you on day 2.

Day 2: The FRESH study, your role and return to work after brain injury

Day 2	
09.00	Recap of previous day feedback ideas from homework.
09.30	Case Management role
10.15	Morning break with refreshments

10.30	FRESH study details
11.30	Disclosure and managing difficult situations
11.45	Tailoring RTW plans
12.30	Lunch provided
13.30	Money and RTW
14.00	Study paperwork
15.00	Afternoon break with refreshments
15.15	What if? Problem-solving scenarios
16.30	Close and final questions

Make sure you go away with your manual and resources and know how to contact your mentor.

Thanks for attending!

8.7. Appendix 7 – Interview topic guide

Semi-structured interviews with Occupational Therapists following ESTVR training.

Open ended questions to generate conversation	**Links to implementation framework[4] (CFIR)**
Introductory conversation to include covering demographics and professional life:	Background information Outer setting Inner setting Characteristics of individuals
Introductory conversation about the person and the training: • What was your motivation for getting involved with this study? • What were your expectations of the training • Tell me about the initial training you were involved with. • Tell me the key points of learning that you gained from the training. o Rationale for the ESTVR o Process of the ESTVR	Inner setting Characteristics of individuals Process
Conversation about more details of the training and its effectiveness: • How did the training facilitate you to deliver the ESTVR (the intervention)?	Characteristics of individuals Inner setting

[4] Implementation research framework based on Consolidated Framework for Implementation Research Damschroder L, Aron D, Keith R, et al. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 4: 50.

• What are your views about the VR training programme you attended?
• What did you consider were the most helpful elements for you?
• What were the least helpful elements for you?
• Did your self-efficacy (your self-belief) change between
  o Pre and post initial training – how?
  o Post the update/refresher training in April – how?
• Were your learning needs met (to be able to carry out the ESTVR)? – How?
• Did the training cause you to worry in any way afterwards?
• Have you been on any other courses/training previously that you found really useful in your daily role? What made it memorable?	

Conversation about the practicalities of the training:
• What are your views about the length of the training programme you received?
• How did you find the training was organised ahead of attending?
• How did you find the presentation of the learning materials
  o On the day?
  o After the training?
• Is there any further information you would have liked in this?
• What are your views about the training manual?
	Characteristics of individuals
	Process

Conversation about mentoring: • You were allocated a mentor following the training. What do see the role of the mentor being?	Outer setting Inner setting

○ How can she support you in being able to put the training into practice? • How have you used your mentor to date? • What has been the most useful aspect of mentoring you have experienced so far? • Could you manage without a mentor?	Characteristics of individuals
Conversation about putting the training into practice: • Now you have a few clients/patients under your belt, how did the training prepare you for this? • How confident do you feel now about using the ESTVR? • How have you put the training into practice? • What else have you found supportive? • How much pressure do you feel under to be successful in doing the ESTVR/intervention? • Is it possible to do the intervention in your area? • How do you feel about being able to manage your caseload in the coming weeks/months?	Intervention characteristics Outer setting Inner setting Characteristics of individuals Process
Conversation about the future: • Is mentoring something you'd recommend for OTs in the future doing a trial or learning the ESTVR to carry out in the NHS? • How could the training be altered/improved for future therapists • Is there anything further that should be included in such a training course? • Is there anything which could be omitted? • Where do you see this training take you in the future?	
Ending conversation:	

• Are there any other comments you would like to make about the training and mentoring provided?	

Abbreviations:

TBI – Traumatic brain injury, VR – vocational rehabilitation, OTs – occupational therapists, ESTVR – Early Specialist TBI vocational rehabilitation, NHS – National Health Service

8.8. Appendix 8 – Self-perceived knowledge and confidence questionnaire

Effectiveness of the training programme. <u>Pre-training</u>

We would like to know if the training provided for this study increased your knowledge and confidence in helping a person with traumatic brain injury (TBI) return to work. Therefore, we would like you to complete this form a before you have started the course. We will give you the same forms to complete after the study.

	Poor				Very good
Please rate your current:					
Knowledge of TBI	1	2	3	4	5
Knowledge of how TBI impacts on the ability to work	1	2	3	4	5
Knowledge of vocational rehabilitation in general	1	2	3	4	5
Knowledge of how to prepare someone with TBI to go back to work	1	2	3	4	5
Knowledge of how to do a graded return with an employer and person with TBI	1	2	3	4	5
Knowledge of the research process	1	2	3	4	5
Confidence in helping someone with TBI **prepare** for work	1	2	3	4	5
Confidence in helping someone with TBI **return to** work	1	2	3	4	5
Confidence in dealing with employers	1	2	3	4	5
Confidence in working in a research project	1	2	3	4	5
useful was the pre-training reading pack?	1	2	3	4	5

You do not have to sign your name, but as people come with different experiences, it may help us add context to the answers. For example, we would expect people with no experience of helping a person return to work be less confident compared to someone who has experience.

Name (optional) …… Date ……

Effectiveness of the training programme. <u>Post-training</u>

We would like to know if the training provided by this study increased your knowledge and confidence in helping a person with TBI return to work. Now you have completed the training, we would like you to complete this form and the list of local contacts you know about (we do not need phone numbers).

	Poor				Very good
Please rate your current:					
Knowledge of TBI	1	2	3	4	5
Knowledge of how TBI impacts on the ability to work	1	2	3	4	5
Knowledge of vocational rehabilitation in general	1	2	3	4	5
Knowledge of how to prepare someone with TBI to go back to work	1	2	3	4	5
Knowledge of how to do a graded return with an employer and person with TBI	1	2	3	4	5
Knowledge of the research process	1	2	3	4	5
Confidence in helping someone with TBI **prepare** for work	1	2	3	4	5
Confidence in helping someone with TBI **return to** work	1	2	3	4	5
Confidence in dealing with employers	1	2	3	4	5
Confidence in working in a research project	1	2	3	4	5
useful was the pre-training reading pack?	1	2	3	4	5
How useful do you think the training pack will be?					
How useful was the course overall?	1	2	3	4	5

In order to fully evaluate the course, please could you list 3 things you felt were St

Most useful to you?

1. ……..

2. ……

3. ……

Least useful to you?

1. ……..

2. ……

3. ……

Please give your suggestions on how the training could be improved or any other comments:-

1. ……..

2. ……

3. ……

Any other comments

……
……
…….

You do not have to sign it if you would rather not, but as people come with different experiences, it may help us add context to the answers. For example, we would expect people with no experience of helping a person return to work be less confident compared to someone who has experience.

Name (optional) …… Date ……

8.9. Appendix 9 – Mentoring record form

FRESH Peer/ Mentor Support Form			
Therapist Name:		**Date:**	
Mentor Name:		**Time spent:**	
Method used (delete):			
Organisation (delete):			

Topic/issue notes	**Agreed Action (if applicable) notes (action by whom and date required)**
Recruitment	
Research Documentation	
Research process/Implementation	
ESTVR intervention/ Client-related	
Other including serious adverse events	

Agreed as correct content.		**Next session date and method:**	

8.10. Appendix 10 – PWTBI purposive sampling matrix

	Site 01					Site 02					Site 03				
	1	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Early stage of project (Jan-Apr)		Apr				Jan	Feb				Mar	Apr			
Mid stage of project (May-Aug)	May							Jun		Jul			Aug		
End stage of project (Sep-Jan 15)			Sep	Jan	Oct				Sep					Sep	Jan
Mild TBI				X	X			X	X		X				
Moderate TBI	X	X										X	X	X	
Severe TBI			X			X	X			X					X
Engaged with Rx	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Had a neuro rehab team		X	X					X		X	X	X			
Didn't have a neuro rehab team	X			X	X	X	X		X				X	X	X
Allowed OT to communicate with employer	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Didn't allow OT to see employer						X	X				X	X	X	X	X
Self-employed/own business					X				X						
Male		X	X	X	X	X			X	X	X	X	X	X	X
Female	X						X	X							
Age group ≤ 30				X	X		X			X					X
Age 31-50						X		X			X	X	X	X	
Age 51-65	X	X	X						X						
Private/public/3rd sector employer at interview	3rd	3rd	Priv	Priv	Priv	Uni	Priv	Pub	Priv	3rd	Pub	Priv	Pub	Pub	Priv
Employer size (micro, small, medium, large)	Med	Sm	Large	Micr	Sm	Large	Sm	Med	Micr	Sm	Lrg	Med	Lrg	Lrg	Med
Active OH involvement	Y	N	Y	N	N	N	N	N	N	N	Y	N	Y	Y	N

8.11. Appendix 11 – Content form

Patient number …….. **Intervention session date……** **Intervention session number……..** **F2F 10 min units…….**

Return travel time from base (10 min) …….. **Non F2F 10 min units……**

1. Assessment		**5. Personal ADL**		**9. Cognitive/executive skills**		**15. Liaise by f2f,letter,t/c,Email,Text**	
Medical history		Dressing		Education about cognition		**Please write F,L, T, E or TC+ add time**	
Social situation/roles		Toileting		Strategies for managing cognitive difficulties		Patient	
Pre-morbid lifestyle		Bathing/showering		Use of standardise tests		Family, partner, carer	
Functional ability		Other		Other		Case manager	
Cognitive assessment						GP	
Psychological assessment		**6. Instrumental ADL**				Consultant	
Insight		Meals/drinks		**10. Work preparation**		Employer	
Financial situation		Housework/laundry		Teach pacing/fatigue management		HR	
Work ability		Money/budgeting		Pt contact with employer		Occ health	
Family views		Shopping		Detailed job analysis		DEA	
Other - specify		Organisational skills		Work hardening		DWP Work provider	
		Being left alone		Discuss work options		Physio	
2. Current issues		Socialisation including leisure		Other;-specify		SALT	
Medical		Sleep issues				OT	
Social		Other				Psychologist	
Benefits				**11. RTW process + employer present**		CBT	
Family		**7. Mobility**		RTW planning & Ax meeting + stat issues		Solicitor	
Work		Walking - in and outside		Monitoring/grading meeting		Other	
Other		Safety including road safety		Maintenance meeting			
		Using transport				**16. Admin**	
3. Goals		Route finding		**12. RTW process: no employer present**		Note writing i.e. OT notes	
Goal setting		Driving		RTW planning and assessment meeting		Report/letter writing	
Reviewing/modifying goals		Other		Monitoring/grading meeting			
				Maintenance meeting		**Notes**	
4. Physical		**8. Psychological issues**					
Assistive devices & adaptions		Psychological support		**13. Family/Carer Support**			
Pain inculding headaches		Confidence building					
Communication/speech		Low mood		**14. Education re TBI &/or RTW**			
Visual problems		Motivation		(Please write v =verbal and/or w=written)			
Upper limb		Anxiety		Patient			
Sensory problems		Behavioural problems		Carer			
		Dealing with others		Employer			
		Adjustment/ re-evaluation		Written info given			
				Other			
						TURN OVER PLEASE	

FRESH Fidelity form **Patient ongoing/current status**

Patient number …….. Date……

Pay when returning to work		**How got to work**		**Current Status**	
		Lifts			
RTW on Statutory sick pay (SSP)		Walk		Same employer, same job	
RTW on Employment Support Allowance (ESA)		Public transport		Same employer, different job,	
RTW on full pay but reduced hours		Drive		New employer, same job	
RTW on permitted work (negiotated with Job Centre Plus)		Access to work		New employer, different job,	
No benefits, pay cut for graded return		Cycle		Self employed	
On full pay but reduced hours		Works at home		Voluntary work	
Full pay, usual hours				Home to look after children	
Other		**Supportiveness of employer** (therapists views)		Homemaker/housewife	
		Very helpful		Same college/uni/same course	
Concessions agreed		OK		Same college/uni/different course	
Allowed a phased RTW		Cautious		Different college/same course	
Flexibiilty of extra breaks		**Where seen**		Different college/different course	
Reduced amount of work		Home		Other – please specify	
Reduced responibilites		Work			
Mentor/more supervision		Job centre			
Flexibile start/finish times		Other		**Comments**	
Provision of special conditions		**Use of other services**		(Please detail as much as possible)	
Being supernumery		Jobcentre ESA advisor			
Work at home		Work choice provider			
Permanent decreased hours/days		Work programme			
Other		Permitted work			
		DEA			
GP Fit Note Categories		Work Psychologist			
(if known)		Social services			
a.Phased RTW		Headway			
b. Altered hours		Extra support in education			
c. Amended duties		Compensation provision			
d. Workplace adaptations		Other			

8.12. Appendix 12 – Content form guide

FRESH OT Fidelity Form :Explanatory notes	
Record in 10 min units = 1 The recording of your time is as close an estimation to the purpose of your session – the main focus. Try not to get side tracked by all the aspects you "may have" covered and concentrate instead on the main aspects.	
Early supported TBI vocational rehabilitation (ESTVR)	
Category	**Explanatory notes i.e. factors to consider/details of discrete elements.**
1. Assessment	**This includes initial and on-going assessment (and use of baseline measures) and any current and on-going issues. This is what is discussed or assessed. It does not involve intervention.**
Medical	Past medical history, present medical situation, any new medical issues e.g. development of epilepsy and on-going treatment Patient's knowledge of brain injury and understanding of the recovery and rehab process.
Social situation/roles	Living arrangements, social support. Family, friends and carers views, support, expectations. Change of roles e.g. increased time together etc.
Pre-morbid lifestyle	Include driving, leisure, roles, attitudes and behaviours.
Functional ability	Assess occupational performance in physical, personal and instrumental ADL and mobility,– see subcategories in Fidelity form
Cognitive assessment	Non-standardised/general assessment. Memory, attention, problem solving, dysexecutive skills

Psychological assessment	See subcategories in Fidelity form– General and non-standardised assessment
Insight	A persons awareness of the problems they are having and their ability to subsequently learn from their actions
Financial situation	Benefit claims, sickness entitlement, changes to pay, compensation and insurance claims
Work ability	Assess person's ability to do their job
Family views	Family and friends views, knowledge of brain injury, expectations and understanding of the recovery and rehab process.
Other	If you tick this box then supplement it with notes in the "notes" box on the Fidelity form
Category 2 onwards are the interventions and involve doing things with and providing advice to Pt/family	
2. Current issues	This is discussing, dealing with and problem solving issues that are the pts concerns.
Medical	Present medical situation, any new medical issues of individual and on-going treatment. Knowledge of TBI, rehab and recovery
Social situation	Living arrangements, social support. May change over time
Benefits	Including helping access benefit advice, supporting them filling in forms and completing phone applications
Family	Dealing with any family issues that arise. Family views, support, and expectations. Change of roles e.g. increased time together etc. May change over time
Work	Dealing with any work issues that arise. These are work issues that are separate from work preparation e.g. dealing with pts worries, explaining any work related letters.

Other	E.g. Compensation – advise to consult solicitor. If you tick this box then supplement it with notes in the "notes" box.
3. Goals	
Goal setting	Use SMART goals *(Specific, measurable, achievable, realistic and time specified)
Reviewing and modifying goals	Encourage pt to reflect and judge success of goal. Encourage pt to alter goal if required
4. Physical	
Assistive devices and adaptations	Advice given about personal/home assistive devices and adaptations including splints, wheelchairs. Could involve a referral to specialist services.
Pain management	Advice about managing headaches or other bodily pain
Communication/speech	Dysarthria and use of strategies to overcome communication difficulties (often with advice from SALT). Intervention for social communication difficulties e.g. what to say about their TBI to different people they come into contact with
Visual problems	Intervention for hemianopia, double vision etc.
Upper limb	Working on coordination, dexterity writing etc.
Sensory problems	Loss of smell and taste, sensory loss to affected side. Education regarding precautions e.g. home fire alarms, sell by dates for food.
5. Personal Activities of Daily Living	
Dressing	All aspects Including choosing appropriate clothing for all situations

Toileting	All aspects including managing menstruation, continence, access to toilets, equipment etc.
Bathing/ showering	All aspects including frequency of washing
Other	If you tick this box then supplement it with notes in the "notes" box.
6. Instrumental Activities of Daily Living	
Making drinks/meals	Discussing observation and practicing these tasks
Housework/laundry	Includes all aspects including use of prompts e.g. to change bed linen, clean bathroom
Money/Budgeting	Working on skills including money handling, budgeting and managing Benefits. Could include being aware of pertinent insurance policies and acting on them.
Shopping	Using as intervention activity. Includes all aspects of shopping except budgeting, which is above.
Organisational skills	Managing and teaching strategies for e.g. correspondence by letter, phone or email and managing appointments e.g. use of diary, calendar, mobile phone, other people. Also includes managing home responsibilities generally such as child care.
Being left alone	Working with family and the pt about the spending time on their own safely E.g. being left alone at home for a few hours, days, etc.
Leisure activities and socialising	Encouraging people to restart both new and old activities. Includes use of day centres and community resources. Encouraging people to keep in contact with friends, family
Sleep	Look at sleep routines, hygiene and their impact on lifestyle
Other	If you tick this box then supplement it with notes in the "notes" box.
7. Mobility	

Walking in and outside	Alone or accompanied, indoor, outdoor, up and down stairs.
Safety including road safety	All aspects including crossing roads, consistent use of pedestrian lights, choosing safe places etc. Risk taking and awareness of own limitations
Using transport	All aspects including use of buses, trams, trains etc. e.g. obtain bus pass, route finding, organising lifts
Route finding	Topographical orientation tasks including finding remembering routes, planning routes, planning what to do if he or she gets lost.
Driving	Notification to DVLA, assessment at a mobility driving centre
Other	If you tick this box then supplement it with notes in the "notes" box.
8. Dealing with psychological issues	
Psychological support	Listening, reassuring, positive reinforcement of their personal journey
Confidence Building	Encouraging and affirming the individual (their strengths and engagement in activities)
Mood	Talking about mood and strategies for managing changes in mood
Motivation	All aspects including encouragement to focus on short and longer term goals and strategies for engagement
Anxiety	Talking about anxiety and strategies for managing changes in anxiety levels. Could include teaching anxiety management/relaxation techniques, mindfulness techniques
Behavioural problems	Talking about behavioural issues and managing behavioural problems e.g. increased irritability, identifying warning signs
Dealing with others	Identify specific problems and work out relevant strategies. Discuss disclosure in social situations.

Adjustment/ re-evaluation	Talking about psychological adjustment to the impact of the TBI and re-evaluation of life priorities.
9. Cognition	
Education about cognitive problems	Education and awareness of limitations in memory, attention, information processing, problem solving, executive problems including insight. Factors affecting it e.g. fatigue, food, alcohol, routine.
Strategies for managing cognitive difficulties	Recognition of problem and use of strategies e.g. turn off TV, plan plenty of breaks, do not multi-task if attention is a problem Strategies for memory include use of diary, phones, calendars, other people, notice boards Problem solving – get pts to plan night out Encourage self-monitoring by predicting/evaluating success/failure of activity. Increase insight by asking pts to predict performance, giving them honest feedback
Use of standardised test	Record any time spent on formal standard tests e.g. Rivermead Behaviour Memory Test as we want to record how much time is spent on this specific activity
Other	If you tick this box then supplement it with notes in the "notes" box.
10. Work Preparation	
Teach pacing and fatigue management	Talking about fatigue symptoms and managing the impact including pacing.
Pt contact with employer	Includes encouragement given to the pt to keep in touch with work place e.g. phone calls, visits, visiting work friends,
Detailed job analysis	Detailed analysis of the job and all the skills the person requires to do undertake their job including travel to/from work.

Work hardening	This is intervention and NOT ASSESSMENT. It includes practicing the person's ability to work and sustain work by practicing work routines and activities e.g. .time keeping. Use of work samples. This could be prior to work return and during a phased return.
Discuss and plan work options	Includes all aspects including encouraging pts to think of RTW problems and subsequent solutions about role, tasks, environment etc. This could include discussing possible options that are acceptable to the person and family e.g. specifics of a graded RTW, length of allowed period of time versus what the individual needs/wants, getting to and from work
Other	If you tick this box then supplement it with notes in the "notes" box.
11. Return to work (RTW) process + employer present (face to face meetings)	
Return to work planning and assessment meeting and statutory issues	Includes all aspects of RTW planning including agreeing with pt before the meeting what can be disclosed in the meeting about their TBI and problems. Encouraging honesty and openness. Also includes: - identifying potential problems and subsequent solutions. Working towards the Pt, OT and employer having the same awareness of the employer's sickness policy, RTW policies and procedures, absence policies, performance or productivity and what is expected of both employer and employee. Also includes agreeing a plan of action e.g. patient/OT to notify the employer when the patient is nearly ready to go back to work or set up regular appointments to monitor progress. Inform GP in writing of proposed RTW plan and support mechanisms. This should also cover statutory issues such as employers insurance and welfare benefits if the person is returning under permitted work rules, risk of epilepsy, driving, working at heights, pay
Monitoring/grading meeting –face to face	Worksite meeting to monitor and grade return to work. Includes need to providing honest feedback and that the pt has been primed to accept this feedback positively.

Maintenance meeting	To monitor situation. Includes all aspects such as identifying potential problems and subsequent solutions.
12, Return to work (RTW) process where OT has no direct employer contact	
Return to work planning discussion	Assess job, potential problems and potential solutions RTW procedure and expectations Agree plan of action. Find external people to check ability if possible. Set up regular appointments to monitor progress. Inform GP of proposed intervention This should also cover statuary issues such as employers insurance, benefits, risk of epilepsy, driving, working at heights, pay
Monitoring/grading discussion	Meet to monitor and grade return to work. Visit work place if possible. Stress honest feedback is needed by peers and or managers.
Maintenance discussion	To monitor the situation of RTW, discussing issues that are raised and facilitating independent problem-solving
13. Family/Carer support	
Family and carer support	Seeing family or carers to offer support this could include seeing them with the pt present or individually and where family support is the main focus of the session.
14. Education re TBI &/or RTW – please write v=verbal and/or w=written	
Pt	Time spent explaining the effects of TBI or how to RTW after TBI or discussing written information given to them

Carer	
Employer	
Written info given	Please record if gave out any pre-produced information and name it in the notes section e.g. Headway leaflets,
Other	If you tick this box then supplement it with notes in the “notes” box.

8.13. Appendix 13 – Fidelity visit checklist

ESTVR Intervention Components ***Words in italics are related to frequency of intervention***	**Extent of delivery (always, often, sometimes, seldom, never)** **Also consider content, coverage, frequency, duration**	**Moderators - +ve & -ve** **Also consider participant responsiveness, resources, recruitment, context, comprehensiveness of policy description, strategies to facilitate implementation, quality of delivery**
1. OT and CM interventions are tailored to each participant and explicitly work-focused (content form will capture detail). However, they include the following essential intervention components (numbers 13-19).		
2. Assessing the impact of TBI on function and work role and providing individualized education to PWTBI, family and employer.		
3. Developing strategies for the PWTBI to explain the effects of their TBI to others.		
4. Developing strategies to manage TBI effects in everyday life and work/study.		
5. Assessing the work/study role, work duties/functions, work/job demands.		
6. Supporting the PWTBI in seeking and accepting feedback about their (work) function.		

7. Exploring options for returning to work.		
8. Retraining or practicing work skills/functions.		
9. OT negotiates a graded RTW. The OT then monitors the PWTBI *at least weekly in the first 1-2 weeks; weekly for the next 4 weeks; then every 2 weeks for the following 8 weeks; then every 6-8 weeks unless decided otherwise by PWTBI.*		
10. CM supports PWTBI and family with work-related issues and provides feedback, e.g. by meeting before and after workplace review sessions.		
11. OT and CM support PWTBI to develop and maintain coping skills to help them deal with risks to job retention. *OT monitors this every 4-8 weeks once the graded RTW plan is complete.*		
12. OT formulates vocational rehab plan on the basis of the assessments results.		
13. All planning is done in consultation with the PWTBI.		
14. OT/CM informs other professionals and care providers about the VR plans.		

15. CM ensures that non-work focused activities are coordinated and continue.		
16. OT contacts PWTBI *every 1-2 weeks except in cases where more frequent contact is needed.*		
17. CM reviews participant *every 6-8 weeks except in cases where more frequent contact is needed*.		
18. At the end of the workplace intervention OT/CM writes thank you letter to employer and cc participant's GP.		

Adherence	Moderating factors
Content – was each of the intervention components implemented as planned? Coverage – what proportion of the target group participated in the intervention? Frequency – how often was the intervention provided? Duration – how long was either each intervention session and/or the overall duration of the intervention?	Participant responsiveness – How were the participants engaged with the intervention service? How satisfied were the participants and how did the participants perceive the outcomes and relevance of the intervention? Recruitment – what procedures were used to attract participants? What constituted barriers to maintaining involvement of individuals? Context – what factors at the political, economical (resources, money and time) or organisational level affected the implementation? Comprehensiveness of policy description – How specific is the intervention description? Strategies to facilitate implementation – what strategies were used to support implementation? How were these strategies perceived by staff? Quality of delivery – how was the quality of the intervention components?

8.14. Appendix 14 – Mentoring record

FRESH Peer/ Mentor Support Form			
Therapist Name:		**Date:**	
Mentor Name:		**Time spent:**	
Method used (delete):			
Organisation (delete):			
Topic/issue notes	**Agreed Action** (if applicable) **notes** (action by whom and date required)		
Recruitment			
Research Documentation			
Research process/Implementation			
ESTVR intervention/ Client-related			
Other including serious adverse events			
Agreed as correct content.		**Next session date and method:**	

University Of Nottingham Monday, 13 January 2014, FRESH Mentoring Form v3.0 JH 20140109

8.15. Appendix 15 – Interview topic guides

Early Specialist Traumatic brain injury Vocational Rehabilitation (ESTVR) Training Evaluation – OTs Topic Guide:

Semi-structured interviews with Occupational Therapists following ESTVR training.

Open ended questions to generate conversation	**Links to implementation framework[5]**
Introductory conversation to include covering demographics and professional life: • Name • Age • Place and Date qualified as an OT • Actual qualification (letters) • Years of experience as an OT (may have qualified and then not worked as an OT) • Years of experience in TBI/neuro • Years of experience in vocational rehab (VR) • Previous VR training courses • Experience in previous research	Background information Outer setting Inner setting Characteristics of individuals

[5] Implementation research framework based on Consolidated Framework for Implementation Research Damschroder L, Aron D, Keith R, et al. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 4: 50.

• Currently working at … (NHS, independent work, any other secondments as well as FRESH) • How is your current work arranged? ○ How have you managed to fit working on the FRESH study into your day to day work?	

Introductory conversation about the person and the training:
• What was your motivation for getting involved with this study?
• What were your expectations of the training
• Tell me about the initial training you were involved with.
  ○ Original 2-day
  ○ 1-day plus coming to University of Nottingham plus watching the recorded training materials
  ○ Watching the recorded training materials plus training on NHS site
• Tell me the key points of learning that you gained from the training.
  ○ Rationale for the ESTVR
  ○ Process of the ESTVR
	Inner setting
	Characteristics of individuals
	Process

Conversation about more details of the training and its effectiveness:
• How did the training facilitate you to deliver the ESTVR (the intervention).
• What are your views about the VR training programme you attended?
• What did you consider were the most helpful elements for you?
  ○ General VR elements
  ○ Research elements
	Characteristics of individuals
	Inner setting

○ ESTVR elements ○ Service user involvement ○ Group work ○ Other • What were the least helpful elements for you? ○ General VR elements ○ Research elements ○ ESTVR elements ○ Service user involvement ○ Group work ○ Other • Did your self-efficacy (your self-belief) change between ○ Pre and post initial training – how? ○ Post the update/refresher training in April – how? • Were your learning needs met (to be able to carry out the ESTVR)? – How? ○ What did you see as your knowledge gaps prior to the training? • Did the training cause you to worry in any way afterwards? ○ Initial training ○ Mentoring ○ Refresher/update training	

• Have you been on any other courses/training previously that you found really useful in your daily role? What made it memorable?	

Conversation about the practicalities of the training:
• What are your views about the length of the training programme you received?
• How did you find the training was organised ahead of attending?
• How did you find the presentation of the learning materials
  o On the day?
  o After the training?
• Is there any further information you would have liked in this?
• What are your views about the training manual?
	Characteristics of individuals
	Process

Conversation about mentoring:
• You were allocated a mentor following the training. What do see the role of the mentor being?
  o How can she support you in being able to put the training into practice?
• How have you used your mentor to date?
  o Do you speak often?
  o Do you text, email, call
• What has been the most useful aspect of mentoring you have experienced so far?
• Could you manage without a mentor?
	Outer setting
	Inner setting
	Characteristics of individuals

Conversation about putting the training into practice:	Intervention characteristics

• Now you have a few clients/patients under your belt, how did the training prepare you for this?
• How confident do you feel now about using the ESTVR?
• How have you put the training into practice?
  ○ What resources in the manual have you referred to/used?
  ○ What about the letter templates?
  ○ Something else?
• What else have you found supportive?
  ○ Peer support
  ○ Mentoring
  ○ Calling/contacting Julie?
  ○ Something else?
• How much pressure do you feel under to be successful in doing the ESTVR/intervention?
  ○ Where does this pressure come from?
• Is it possible to do the intervention in your area?
  ○ What if anything is stopping you?
  ○ What is helping you?
  ○ How have you adapted what you've learned so you can put things into practice?
• How do you feel about being able to manage your caseload in the coming weeks/months?
	Outer setting
	Inner setting
	Characteristics of individuals
	Process

○ What if anything might you change to help workload management? ▪ Your time management ▪ Prioritising workloads ▪ Changing the intervention ▪ Something else	
Conversation about the future: • Is mentoring something you'd recommend for OTs in the future doing a trial or learning the ESTVR to carry out in the NHS? • How could the training be altered/improved for future therapists ○ Could it be delivered in a different way/format? ○ Could it be commercialised into a product? ▪ Booklet ▪ Website ▪ Training product face 2 face ▪ other • Is there anything further that should be included in such a training course? • Is there anything which could be omitted? • Where do you see this training take you in the future?	
Ending conversation: • Are there any other comments you would like to make about the training and mentoring provided?	

Abbreviations:

TBI – Traumatic brain injury

VR – vocational rehabilitation

OTs – occupational therapists

ESTVR – Early Specialist TBI Vocational Rehabilitation

NHS – National Health Service





FRESH - Facilitating Return to work through Early Specialist Health-based interventions

FRESH Study

Framework for interviews for employers – Topic Guide

Questions will be asked on the following topics. Some examples of questions are given below.

I am a researcher working on the 'FRESH' project at the University of Nottingham. One of your employees, who sustained a TBI, took part in this project and gave their consent for us to contact you.

The research involved an occupational therapist helping this person return to work. Now the intervention is complete we want the employers' views of the help both you and the employee received and whether employers think is a useful service for the NHS to provide for people who have had a traumatic brain injury.

We are also trying to understand the cost of supporting people who have a TBI in a return to work and the cost of any changes you might have had to make or been advised to make (by the therapist) to support this particular person in returning to work. For example the costs of your time in meetings to plan the return, the cost of any equipment or adaptations you might have had to pay for and the cost of paying for additional staff to help cover their role until they were up to speed.

Your name will not be mentioned on any published documents, and therefore anything you say cannot be identified as coming from you. Any names of individuals or places that you might refer to during the interview will be anonymised when transcribed. All information you provide will be kept confidentially and will only be used for the purpose of the economic analysis and to develop our understanding further.

Would you be willing to answer some questions? They are specific to this one person and this should only take up about 10 minutes of your time.

Mechanism	Question	Prompts
Support	What support was offered to you and your employee? Did you feel it was helpful or unhelpful in helping this person return to work?	How effective was it? Explore expectations and practicalities of this support being offered.
Timely and long-term support *Research shows it is ideal to intervene as early and as rapidly as possible. This would be viewed as timely intervention.*	What do you think about the timing of the support you were offered?	Did you/your employee get help at the right time? Too soon after the TBI? Not soon enough? Too short?
Assessment	How well do you think XXXX understood the job and the employee's overall ability and readiness to do their job? Did they give you enough information about the person's ability?	How well did she understand the needs of employers, what happens in the workplace, the employer's point of view, their readiness to return to employment – travelling to and from work, coping with the day to day of working, getting on with other people, getting around.
Flexibility *Services need to be flexible and responsive to the needs of people with a traumatic brain injury (TBI).*	Do you think the advice the therapist provided was adapted for the individual needs of the employee and the business?	Was the service flexible enough? Did you feel that it was like a set 'package' – or that it was adaptable for individual needs? How much say did you have over what took place, and when?
Working with employers	How well did XXXX work with you and others	Communication Who else was involved?

	involved in the RTW process?	
Planning and preparing for RTW	Was there a return to work plan? If so, how effective was it in preparing you and your employee in their return to work?	What did the plan consist of – what was helpful – what was unhelpful – what else would you have liked? Was it feasible? How was the plan put together?
Providing interventions	Did you provide any modifications or were any suggested to help your employee return to work e.g. graded return to work? What were the costs to this?	e.g. hours, environment, tasks, staged return
Economic evaluation	What do you think are the economic consequences helping an employee come back to work for your workplace?	Time resources in meeting OH/HR/H&S/Union support Economic consequences of a staff member having more support? Income protection insurance policy? Did this encompass RTW support?
	Do you think this is a useful /realistic service for the NHS to provide for people with traumatic brain injury?	Expectations of the employer
Economic evaluation	Use of AtW? Yes/no	If yes then what was your financial contribution to this? What did they provide? Over how long?
What		

Explore employers perceptions of timeliness in relation to VR provided, e.g. was the intervention timely?

Explore responsiveness to the needs of the employee and employer during the course of the vocational rehabilitation. Ask about expectations and perceptions of how they were met in relation to responsiveness.