

**Return to work after traumatic
brain injury:
A cohort comparison study and
feasibility economic analysis**

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Abstract

Return to Work after Traumatic Brain Injury: A cohort comparison study and feasibility economic analysis

Background

Less than 50% of people return to work after traumatic brain injury. Despite this, specialist traumatic brain injury (TBI) vocational rehabilitation (VR) in the UK is scarce with outcomes, interventions or costs rarely reported.

This study aimed to compare the work outcomes and costs of participants receiving specialist TBI VR (specialist group) to those receiving usual care (usual care group) and to describe the content of the specialist intervention.

Method

People with TBI requiring hospitalisation ≥ 48 hours in work or education prior to their injury, were followed up by postal questionnaire at 3, 6 & 12 months post hospital discharge. Primary outcomes were work/education. Secondary outcomes were functional ability, mood and quality of life. Specialist intervention was recorded on a proforma specifically developed for the study. Health resource use was by self-report.

Results

Fifty-four usual care and 40 specialist participants were recruited. At 12 months, 15% more specialist group participants were in work/education than usual care group participants (27/36, 75% v 27/45, 60%). For those with moderate/severe TBI, the difference was 27% (16/23, 70% v 9/21, 43%). Secondary outcomes showed no significant differences between groups at one year. The proforma showed that the specialist intervention was primarily focussed at preparing participants to return to work. It cost £501.53 more in health and social care costs (UK£2007) to return a specialist group participant to work at one year than a usual care participant.

Discussion

More specialist group participants were working at one year with an extra cost of only £500 per person. This suggests specialist TBI VR may be cost effective. The ability to describe the intervention aids replication and implementation.

Conclusion

As returning to work is a cost effective outcome for individuals and society, this study justifies the need for further investigation of this TBI VR intervention.

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Abbreviations

ASHE	Annual Survey of Household Earnings
BICRO	Brain Injury Community Rehabilitation Outcome scale
CEA	Cost Effectiveness Analysis
CUA	Cost Utility Analysis
DEA	Disability Employment Advisor
DWP	Department of Work and Pensions
EQ5D	Euroqol
GP	General Practitioner
GSC	Glasgow Outcome Score
HADS	Hospital Anxiety and Depression Scale
ICER	Incremental cost effectiveness ratio
ICF	International Classification of Functioning, Disability and Health
LOCF	Last observed value carried forward
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NTBIS	Nottingham Traumatic Brain Injury Service
OH	Occupational Health service
OT	Occupational Therapy
OTs	Occupational Therapists
QALY	Quality Adjusted Life Years
RCT	Randomised Control Trial
ABI /TBI	Acquired brain injury/Traumatic Brain Injury
UK	United Kingdom
USA	United States of America
VR	Vocational Rehabilitation

Outline of Thesis

Chapter 1: Introduction

This chapter gives a brief overview of the topic and details the research questions.

Chapter 2: Literature review and background

The literature review describes the sequelae of traumatic brain injury (TBI), how TBI impacts on the ability to work, TBI vocational rehabilitation (VR) and Occupational Therapy (OT) related TBI VR.

Chapter 3: Cohort Comparison study

The main focus of this thesis was the cohort comparison study which compared return to work rates and associated factors between two cohorts of participants. Results were self-reported by participants. An intention to treat analysis was used.

Chapter 4: Content analysis study

This chapter details the use of the proforma, which was developed specifically for recording the OT delivered in this study. It describes the intervention provided, as recorded by the research OT, to participants who received two or more sessions of OT.

Chapter 5: Feasibility Economic analysis

This chapter reports on the feasibility of collecting economic information from TBI participants and details the economic analysis conducted.

Chapter 6: Discussion and conclusion

The overall strengths, limitations and conclusions of the cohort comparison study, content analysis and economic analysis are discussed.

Chapter 1: Introduction

1.1. Importance of work

Work is important as it contributes to adult identity, provides an income, gives structure to the day, increases social contact and has positive health benefits (Waddell et al. 2005; Frank et al. 2006; Chamberlain 2007). Return to work or education is a major goal for many people who sustain a traumatic brain injury (TBI), but less than 50% are in work at one and two years post injury (Wagner et al. 2002; Franulic et al. 2004; Johansson et al. 2006; Walker et al. 2006; van Velzen et al. 2009b). People with TBI who return to work report a better quality of life, less depression and less anxiety compared to those who do not return to work (Pierce et al. 2006; Andelic et al. 2009; van Velzen et al. 2009b).

1.2. Traumatic Brain Injury (TBI)

Traumatic brain injury (TBI) is defined as ‘trauma to the head including the effects of direct complications of trauma notably hypoxaemia, hypotension, intracranial haemorrhage and raised intracranial pressure’ (British Society of Rehabilitation Medicine 1998). Road traffic accidents, acts of violence, falls and sporting injuries are the most frequent causes of TBI (Maconochie et al. 2007; Brown et al. 2008; Cameron et al. 2008). Approximately three times more men than women are affected (Fleminger et al. 2005; Maconochie et al. 2007; Cameron et al. 2008). The most commonly affected age group is 15-35 years, a period which for most people encompasses the conclusion of their education and the beginning of their working lives (Fleminger et al. 2005; Novack 2006; Maconochie et al. 2007; Cameron et al. 2008).

1.2.1. Incidence and prevalence of TBI

In the UK, approximately 1.4 million people, of whom 50% are children, attend Accident and Emergency Departments (A&E) with a TBI every year, representing 10-11% of all patients attending A&E (Maconochie et al. 2007; Morris et al. 2008). Approximately 229 per 100,000 people are hospitalized due to TBI (Tennant 2005). Of those admitted, it is estimated that 70% stay in hospital for less than 48 hours (Beecham et al. 2009). People hospitalised due

to TBI are those most likely to have problems and thus find working problematic (Turner-Stokes et al. 2005).

1.3. Vocational Rehabilitation (VR)

Vocational rehabilitation (VR) is defined as ‘whatever helps someone with a health problem to stay at, return to or remain in work’ (Waddell et al. 2008).

In the UK, the provision of specialist VR for people with TBI is poor (Deshpande et al. 2004; Department of Health 2005; Nyein et al. 2007).

Despite reported success of specialist TBI VR programmes, there is little consensus about what VR should consist of, who should deliver it or how and when it should be provided (Hart et al. 2006). As the UK government wants to encourage as many people as possible to return to work after an injury, VR after TBI warrants further investigation (Department for Work and Pensions and Department for Health 2008c).

1.4. Occupational Therapy (OT), TBI and VR

Occupational therapists (OTs) help people engage, as independently as possible, in activities (occupations) which enhance their health and wellbeing (College of Occupational Therapists 2010). Although VR is not profession specific, the role of OT is well recognised in TBI VR (Holzberg 2001; Bootes et al. 2002; Chappell et al. 2003; British Society of Rehabilitation Medicine et al. 2004; Holmes 2007; Coetzer 2008; Barnes et al. 2009). In the UK, TBI VR is frequently delivered by OTs as part of a TBI community rehabilitation programme, but rarely is the actual content of the intervention described (Coetzer 2008; Phillips et al. 2010). This lack of detail has hindered comparison of VR interventions in brain injury research (Kendall et al. 2006)

1.5. Cost of TBI

TBI is costly to the individual and the economy. For example, Johnstone et al (2003) examined the personal and societal costs of 35 patients one year post-TBI. They extrapolated the costs and applied them to the estimated 70,000 people with TBI in the USA. They concluded that the costs translated to \$642 million p.a. in lost wages, \$96 million p.a. in lost income taxes and \$353

million p.a. in increased public assistance. (As information was from the 2002 Traumatic Brain Injury Model System (TBIMS) database, it was assumed costs were from 2002). UK information about the cost of TBI is scarce. Prior to 1997, a review of UK TBI economic studies was unable to identify even one economic study (McGregor et al. 1997). However, as there have been very few UK studies since then, there is need to determine whether providing TBI VR by an OT is cost effective.

1.6. Research Aims

TBI affects people of a working age, many of whom then have a reduced chance of returning to work. Even when specialist VR is provided, it is unclear whether it is effective, cost effective or indeed, what it consists of. Thus, this pilot study consisted of three parts:-

1. A cohort comparison study:

to ascertain whether it was possible to compare the return to work rates of participants who received intervention from an OT specialising in VR working independently or as part of a specialist TBI community team (specialist group) with participants who did not receive an equivalent service, in order to ascertain any differences in return to work rates (usual care group).

2. A content analysis study:

to find a method of recording and measuring the content of the OT delivered in the study that would enable the specialist OT intervention to be described.

3. An economic evaluation:

to ascertain the feasibility of conducting a prospective cost effectiveness analysis alongside the cohort comparison study. This was to determine from both a health and social care perspective and a societal perspective, whether over a 12 month period, the provision of specialist provision was likely to be more cost effective than the provision of usual care.

The following chapters report the literature search and the three parts of the study separately.

Chapter 2: Literature review and background

The literature review focused on the consequences of traumatic brain injury (TBI), and the impact of these on the ability to work, TBI focused vocational rehabilitation (VR) for people with TBI and three key components of TBI VR, namely the timing of returning to work, returning to the same employer and provision of work modifications.

2.1. International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) is a widely respected international framework established to facilitate a universal language amongst clinicians and researchers and enable comparison between studies and between health conditions (Bernabeu et al. 2009; Escorpizo et al. 2010; World Health Organisation 2011). The ICF model recognises that impairments resulting from a TBI impact on a person's activity and participation levels. Activity and participation are also influenced by environmental and personal factors and these are affected by contextual factors (personal and environmental)– see Figure 1 (World Health Organisation 2011). Thus, environmental and personal factors such as resuming driving, feeling recovered and enjoying work will be examined in this study.

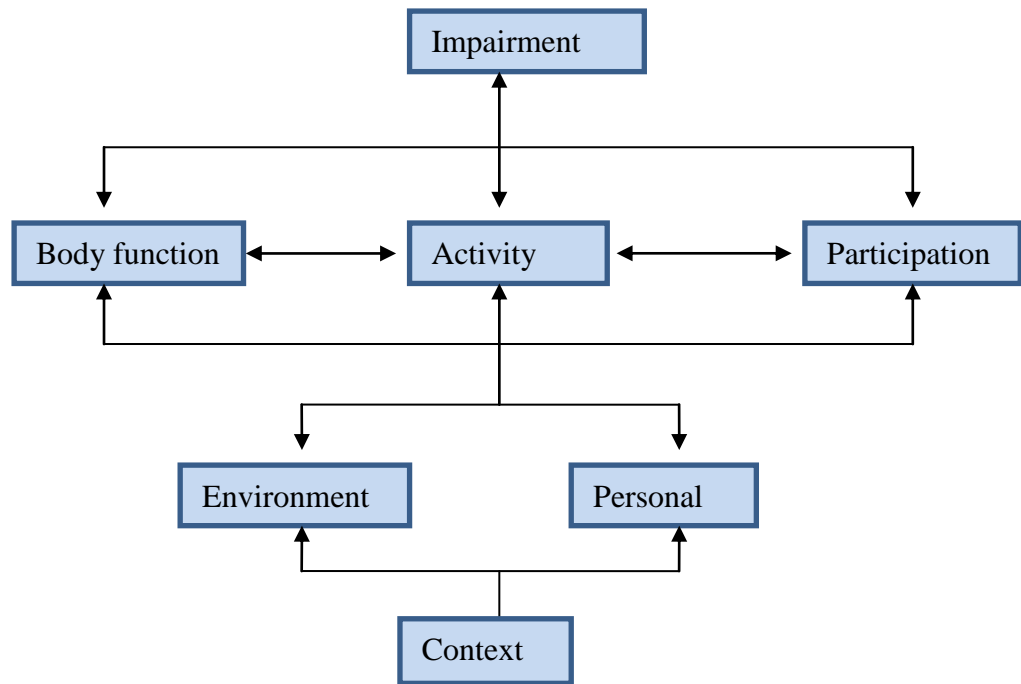


Figure 1: Diagrammatic representation of the International Classification of Functioning, Disability and Health

2.2. Literature review

A literature search was conducted study in October 2006 and repeated in October 2010. This informed a narrative review of the literature regarding TBI VR and return to work after TBI. Search terms used were: - (brain injur\$ or head injur\$), (therap\$ or rehabilitation\$), (work or employment), (economic\$ or cost\$) and dates, 1980 - 2010. Data bases used were Ovid 1950– present, Allied and Complementary Medicine (AMED), Cumulative Index to Nursing and Allied Health Literature (CINHAL), Cochrane Library, Web of Knowledge, Clinical Evidence, Medline (Medical Literature Retrieval System online), Psych info and OT seeker.

2.3. Impairment: Sequelae of TBI

2.3.1. Classification of TBI

For this study, TBI was measured using the Glasgow coma score (GCS) as it is frequently used to indicate injury severity (Ghajar 2000; British Society of Rehabilitation Medicine et al. 2003). The GCS score denotes the depth of loss of consciousness. It classifies brain injury into three categories: minor (GCS

15-13), moderate (GCS 12-9) and severe (GCS 8-3) (Maconochie et al. 2007; Teasell et al. 2007). Approximately 80-85% of people have a minor TBI, with the remainder sustaining a moderate or severe TBI (Maconochie et al. 2007; Maas et al. 2008; Morris et al. 2008; Rickels et al. 2010). Of the 25/100,000 people per year who sustain a moderate or severe brain injury, approximately 2-4 (10-20%) are likely to have a severe disability or prolonged coma and 18 – 22 (65-85%) will make a good physical recovery but are likely to experience cognitive or psychosocial problems that affect their ability to work (British Society of Rehabilitation Medicine et al. 2003).

Although, lower GCS scores are assumed to be associated with worse outcomes (Brown et al. 2008), a systematic review of factors predicting return to work after TBI found GCS was not predictive (van Velzen et al. 2009a). The term ‘mild brain injury’ can be misleading, as up to 20% of people with this classification may continue to experience symptoms which affect their ability to function at their pre-injury capacity at six months post injury or longer (Thornhill et al. 2000; British Society of Rehabilitation Medicine et al. 2003).

2.3.2. Sequelae of TBI

The sequelae of TBI can be classified as: Physical/Sensory, Communication, Cognitive, Behavioural/Emotional, Financial and Social – see Table 1. All potentially cause problems which may impact on a person’s ability to work (British Society of Rehabilitation Medicine et al. 2003; Maas et al. 2008). However, the effect is highly individualised and varied.

Although many people with TBI appear not to have physical injuries, a prospective cohort study of 549 people with all levels of TBI severity, admitted to five Scottish hospitals, found that 45% reported physical problems one year later (Thornhill et al. 2000). Even mild problems with balance have been found to interfere with a person’s ability to return to manual work (Walker et al. 2006; McNamee et al. 2009).

Increased fatigue and epilepsy are both common problems after brain injury and are described under physical effects for ease of reporting. Fatigue has been reported as a long-lasting limiting factor on a person's ability to return to work (Johnson et al. 2009; McNamee et al. 2009). For example, a study comparing 20 people with TBI who were employed with 13 people who were not employed found significantly higher levels of post injury fatigue in the unemployed group (McCrimmon et al. 2006). Additionally, the increased risk of seizures precludes people from driving and working in certain jobs (Annegers et al. 2000; Radford et al. 2004; Rapport et al. 2008; McNamee et al. 2009).

Cognitive and executive problems are the commonest sequelae post TBI and significantly affect a person's ability to work (McNamee et al. 2009; Cicerone et al. 2011). In a study recording problems post TBI, 562 people with TBI and their carers cited memory as the most frequent difficulty (Stilwell et al. 1999). Cognitive problems are seen by OTs as a major problem in returning to work following TBI (Bootes et al. 2002). Additionally, reduced insight, which is the inability to accurately self-monitor and adjust performance, is generally regarded as a poor indicator for returning to employment even though a person may be fully independent in all activities of daily living (Franulic et al. 2004; Shames et al. 2007; McNamee et al. 2009; Bjorkdahl 2010). As these problems are not immediately obvious to other people, TBI is often referred to as a 'hidden disability' (Stilwell et al. 1999; British Society of Rehabilitation Medicine et al. 2003; Rubenson et al. 2007; Headway 2011).

Table 1: Potential Traumatic Brain Injury sequelae

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

Adapted from: Rehabilitation following Acquired Brain Injury (British Society of Rehabilitation Medicine et al. 2003)

High levels of anxiety, depression and low levels of quality of life are commonly reported after TBI (Kersel et al. 2001; Simpson et al. 2007). Some TBI studies have suggested that depression and anxiety are associated with lower levels of post injury employment (Corrigan et al. 2001; Franulic et al. 2004; Catalano et al. 2006; Ponsford et al. 2008). However, it is uncertain whether depression and anxiety interfere with the ability to work (Wehman et al. 2005; Walker et al. 2006). Interestingly, a study of 317 people with TBI approximately ten years post TBI found increased levels of depression in those not working, but only if work was perceived as important to the individual (Tsaosides et al. 2008). Thus, further investigation into the relationship between mood and employment is required to gain a clearer understanding of the relationship.

2.3.3. Pattern of recovery after TBI

For those surviving the initial TBI, approximately 85% of physical and neurological recovery occurs in the first six months post injury (Maas et al. 2008). Problems of social integration, mood and quality of life become more apparent approximately six months post TBI, often when most physical problems have resolved (van Baalen et al. 2003; Reistetter et al. 2005; Rubenson et al. 2007; Maas et al. 2008). The fact that most improvement after TBI occurs in the first year post injury is illustrated in a Dutch study of 119 people with moderate to severe TBI (Willemse-van Son et al. 2009). The authors found Community Integration scores (CIQ) were lowest at three months post injury with maximum improvement occurring in the first year post injury and only small improvements in years two and three.

Only a few studies have examined the longer-term consequences of TBI. A UK study followed up 475 people with TBI for one year (70% with mild TBI) (Whitnall et al. 2006). Of these, 219 were contactable five to seven years post injury. Of these, 53% had the same Glasgow Outcome Scale (GOS) score as they had at one-year post injury, 29% (63) had improved compared to their first year GOS score whilst 25% (55) had deteriorated. They found the development of a new disability was strongly associated with psychological

functioning. As people who survive the initial six months after TBI have the same ten-year life span when compared to the general population, the consequences of TBI can be lifelong (Brown et al. 2008). Interestingly, a Finnish study, followed up 210 people with TBI approximately 24 -30 years from their initial neuropsychological assessment (Himanen et al. 2011), found a reduced ability to work was related to long-term reduced survival rates. They were unclear whether this was due to the TBI or other factors that may have also contributed to the initial injury such as high alcohol intake.

2.3.4. Summary of the effects of TBI

The myriad of problems resulting from TBI (physical, sensory, communication, cognitive, executive, behavioural, emotional, personal and environmental) combine and can have a major long-term impact on a person's life and ability to work.

2.4. Participation: Return to work after TBI

Definitions of work, post TBI employment rates, predictive factors, sustainability of work and personal and environmental factors influencing post TBI employment will now be explored.

2.4.1. Definitions of return to work in TBI studies

In both VR studies (Pransky et al. 2005; Vogel et al. 2011) and TBI studies, there is little consensus about the definition of the term 'work'. Table 2 shows that definitions of 'work' vary widely in TBI studies. Definitions ranged from very specific such as 'on full wages for 8 hours or more for 13 weeks' (O'Brien 2007) to 'being a homemaker' (Gamble et al. 2003). In the USA, vocational agencies have to report whether cases are successfully rehabilitated using the Rehabilitation Services System (RSA 911) categories, which includes the category 'homemaker' (Gamble et al. 2003). The heterogeneity of terms used to describe and measure work as an outcome measure is a major limiting factor when comparing TBI studies of return to work.

The UK guidelines on VR for people with long term neurological conditions, define the term 'work' as: - full and part time employment, self-employment, voluntary work, vocational training, permitted work and full time adult education (British Society of Rehabilitation Medicine 2010). This definition is used throughout this thesis; it does not include 'home maker'.

Table 2: Definitions of return to work

Author	Definition/Outcome criteria	Comments
(Bell et al. 2009) UK	Paid employment = an individual undertaking paid work in the week prior to the interview or has not done paid work but has a job from which they were absent	Based on the British Household panel survey and used for measuring rate of unemployment in disabled people
(O'Brien 2007) Australia	On full wages for 8 hours or more per week for a minimum of 13 weeks.	Commonwealth Rehabilitation Service (CRS) services have 170 centres throughout Australia.
(Malec et al. 2006)	Vocational Independence Scale Level 5 = Competitive. Community based work without external support for more than 15 hours/week. Level 4 = Transitional: Community-based work with temporary supports e.g. job coach, less than 15 hours or in training or school Level 3 = Supported: Community based work with permanent supports or less than 15 hours, volunteer work. Level 2 = Sheltered: Work in a sheltered workshop Level 1 = Unemployed.	Appears only to be used by the author
(Kendall et al. 2006) Australia	Had 2 definitions: <ul style="list-style-type: none"> • Restricted definition = full-time competitive work • Inclusive definition = any competitive work or productive activity 	No time limits given
(Johnstone et al. 2003)	Employed, unemployed, student, retired and other	Used by the Traumatic Brain Injury Model system (TBMIS)
(Cifu et al. 1997) USA	Competitively employed in a part or full time job paying minimum wage	Did not include education or other work schemes

Table 2: Definitions of return to work (continued)

Author	Definition/Outcome criteria	Comments
(Murphy et al. 2006) UK	<p>Paid competitive employment i.e. takes up paid employment with verified named employer.</p> <p>Education or training i.e. takes up a place on a recognised training course, recognised refresher course or degree course.</p> <p>Voluntary work : engages in regular unpaid , voluntary work with named agency</p> <p>Discharge to other services e.g. other specialist rehab programmes, mental health services, social services, referral to disability employment advisor</p> <p>Client withdrew from programme at their own behest.</p> <p>Discharged for other reasons e.g. did not proceed with programme and were not referred to other services.</p>	<p>From Rehab UK – a UK charity</p> <p>No time limits given</p>
(Deutsch et al. 2006) USA	<p>Return to work coding scale:</p> <p>1 = Permanent and total disability – 24 hour care required</p> <p>2 = Supported work (a unique employment opportunity for individuals who require on-going support services while placed with employers in the competitive labour market)</p> <p>3 = Supported/Transitional employment (client has to had moved through level 2 and transitioned into competitive employment without the need for a job coach)</p> <p>4 = Return to School or training with limitations (return to a full time elementary high school or vocational school programme)</p> <p>5 = Return to work without loss of earning capacity (a return to the competitive labour marker without support on the job)</p>	<p>Was used as an outcome measure following a Life care programme.</p> <p>No time limits given for time in work.</p>
(Cifu et al. 1997) USA	<p>Competitively employed in a part or full time job paying minimum wage</p>	<p>Did not include education or other work schemes</p>

Table 2: Definition of return to work (continued)

Author	Definition/Outcome criteria	Comments
(British Society of Rehabilitation Medicine et al. 2004) UK	<ul style="list-style-type: none"> - Previous post:- full time normal duties; graded return = normal duties; graded return = restricted duties; graded return with support/equipment - Alternative post:- same employer = new post; new employer = new post; new post = Work step - Vocational retraining for new post - Work Preparation:-to open employment; vocation re training; supported placement; permitted work; voluntary work - Pre vocational educational course - Occupational provision:- voluntary work, sheltered workshop, Headway/Occupational activity 	Was designed as a list of whom was responsible – not a definitive outcomes list
(Leung et al. 2005) Hong Kong	<p>Same = A return to full time employment with the same occupational title, pre-morbid job nature and demands.</p> <p>Change = A change to another job title with a different job nature and demands</p> <p>Unemployed= being unemployed or unable to resume work after discharge</p>	Did not include students or homemakers or time frame

Table 2: Definition of return to work (continued)

Definitions which included home making		
Author	Definition/Outcome criteria	Comments
(Sherer et al. 2007) USA	Returned to work, school (making progress towards a degree) or independent functioning as a homemaker were classed as a productive, all others were classed as non-productive.	Assessed at time of discharge from post-acute brain injury rehabilitation
(Kendall et al. 2006) Australia	Had 2 definitions: <ul style="list-style-type: none"> - Restricted definition = full-time competitive work only - Inclusive definition = any competitive work or productive activity 	No time limits given
(Gamble et al. 2003)	An individual had to maintain employment for a minimum of 90 days for the case to be classed as rehabilitated, based on the Rehabilitation Services System (RSA 911) Rehabilitated categories include:- <ul style="list-style-type: none"> - competitive employment - sheltered employment - business enterprise programme - unpaid family worker - homemaker Non-rehabilitated closure indicated client was unemployed and not in above groups.	Education not mentioned. This study divided rehabilitated people into competitive employment and not working
(Klonoff et al. 2001) USA	Productive defined as: involved in either full time or part time paid work, school, volunteer work or working as a homemaker	No time limits given but did detail how many people were working in each category pre and post injury

2.4.2. Rates of return to work after TBI

TBI studies show a range of return to work rates from 39% (Walker et al. 2006) to 94% (Salazar et al. 2000) – see Table 3. The heterogeneity of study designs, study populations and differences in service provision may account for some of the reported variation and hinder the possibility of a meta-analysis (Cifu et al. 1997; Catalano et al. 2006). Only a few studies acknowledge additional factors, such as local unemployment rates or work disincentives (Avesani et al. 2005; Catalano et al. 2006).

A systematic review of return to work rates post TBI identified 35 studies and estimated an average return to work rate of 40.7% one year post injury (van Velzen et al. 2009b). This was based on six studies with a combined total of 4,709 participants, all of whom were in work prior to the TBI. The authors also found a 40.8% two year post injury return to work rate based on three studies and 276 participants (van Velzen et al. 2009b). These rates are similar to those published in the USA Traumatic Brain Injury Model Systems (NTBIMS) database 2010 (Traumatic Brain Injury Model Systems 2010). This is a large prospective longitudinal cohort study examining the course of recovery and outcomes following a coordinated system of acute neuro trauma and inpatient rehabilitation. Of the 10,200 recorded patient's outcomes, 62% were employed pre-injury and 7% were students. One year post injury, 28% were employed and 7% were students. At two years post injury 32% were employed and 6% were students. Thus, it appears that less than half the people who were working prior to their TBI return to work.

It has also been found that if people have not returned to work within one or two years post injury, they are unlikely to do so at all (Johnson 1987; 1998; Kendall et al. 2006; van Velzen et al. 2009b).

Table 3: TBI Return to work (RTW) studies: **Randomised control trials (RCT)**

Title	Study design	Population	RTW rates	VR details	Findings	Comments
(Trexler et al. 2010) USA	RCT examining effectiveness of additional resource facilitation (RF).	22 people with ABI employed pre-injury were recruited either as in or out patients: - 11 in RF group (3 with TBI), 52 days from injury - 11 in control group (4 with TBI), 85 days from injury Mean age = 43 years	RTW rates at 6 months from recruitment:- RF group = 7/11, (64%) employed Control group = (4/11), 36% employed	RF group received a median of 8 hours of RF. Aim of RF was to actively engage persons previous employer	Those receiving RF were more likely to be referred onto state funded VR services and/or specialised brain injury services.	Resource facilitation may be another name for case management. The study did not report how many people returned to previous employers.
(Vander ploeg et al. 2008) USA	Multi-centred RCT intention to treat trial examining the effectiveness of cognitive-didactic v functional experimental approaches	360 veterans or active duty military personnel. Moderate to severe TBI acquired within previous 6 months. Mean age =32 years Mean GCS 7	At one year, no significant differences between groups employment rates:- Cognitive group = 65/167 (39%) Functional group = 58/164 (35%)	Cognitive-didactic group received an extra 1.5 – 2.5 hours daily of cognitive/executive 1:1 exercises based on trial and effort theory conducted in an office. Functional group received mainly group treatments in real life situations based on errorless learning theory	Cognitive group reported lower rates of memory problems at one year. Suggests different approaches may be useful for different sub groups of patients	Recruitment took 7 years over 4 sites. Of 897 people eligible, only 360 (40%) consented. No discussion in the paper about the low uptake especially as patients were military personnel.

Table 3: TBI return to work studies: **Randomised control trials** (continued)

Title	Design	Population	RTW rates	VR details	Findings	Comments
(Sorbo et al. 2005) Sweden	A cross sectional descriptive study comparing two groups	26 people with severe TBI or non-traumatic sub arachnoid haematoma (SDH) recruited from hospital -Group A = 14 people (7 = TBI), mean age 48 years. Started rehab mean 27 days post injury i.e. early -Group B = 12 people (TBI = 7), mean age 46. Started rehab mean 107 days post injury i.e. later	RTW rates at 2 years post TBI Group A: pre-injury = 73% were in work, post injury 43% were working. Group B: pre-injury 83% in work, post injury no-one was in work.	Group A = 6/11 had outpatient rehabilitation (rehab) for 28 days (mean) and 8/14 had an outreach brain injury rehab for 18 months (mean). Group B = 7/12 had outpatient day rehab for a mean of 65 days. No outreach programme	Study felt early formalized intervention contributed to the improved outcomes although did acknowledge the outreach intervention may have contributed	Study acknowledged ethical difficulties in conducting RCT's and used pragmatic design. Classified injury severity via CT scans
(Salazar et al. 2000) USA	Single centre RCT from 1992-1997	120 military personal who sustained TBI on active duty. All moderate/severe TBI Both groups treated immediately following injury, Both groups received initial TBI rehabilitation	RTW rates at 1 year:- Home group = 50/53 (94%) Hospital group = 60/67 (90%) Of these, fitness for military duty = Home group 35/53 (66%) Hospital group 49 (67) 73%	Had 8 week inpatient cognitive rehab or home programme with weekly phone call from psychiatric nurse	No difference was found between the groups Both groups had a 11% drop out rate	Took 5 years to recruit 120 people. Military personnel slightly different to general population. No other study has recorded such high RTW rates.

Table 3: TBI return to work studies: **Prospective cohort studies** (continued)

Title	Design	Population	RTW rates	VR details	Findings	Comments
(Walker et al. 2006) USA	Prospective cohort study one year. From TBIMS data base	1342 employed people, 18-62 years old. TBI: Mean GCS = 8 Did not exclude those with previous TBI, mental health or substance problems	39% competitively employed (full or part time) at one year 50% unemployed. 9% students, homemakers, retired or volunteers 2% other (This is not explained)	All had access to a full rehabilitation team as an inpatient and all were referred for VR on discharge	People in professional jobs were 2x as likely to RTW compared to manual labourers. More likely to return to pre-injury profession.	Did not state what, VR consisted of or effect of VR. Did not state if people returned to pre-injury jobs. Found severity of injury was not a predictor of success
(Wagner et al. 2002) USA	Prospective one year study between 1997/1998	105/378 people with TBI who were not retired pre-injury and had known pre-injury activity level and had one year follow up data TBI: 32% severe, 63% minor/moderate, 5% unknown. 82% under 50 years old	66/105 (63%) RTW at one year (88/105 (84%) employed pre-injury).	Only 12/105 people used VR services. Did not show any statistical difference in RTW rates if used VR services.	Subscales of Disability Rating scale (DRS) and Community Integration Questionnaire (CIQ) were associated with RTW	Numbers in tables and text in paper did not correspond numbers of people who RTW.

Table 3: TBI return to work studies: Retrospective cohort studies (continued)

Title	Design	Population	RTW rates	VR details	Findings	Comments
(Shigaki et al. 2009)	Retrospective cohort study. Part of TBIMS	49 people with TBI Mean age = 49 years Mean GCS = 11.5	2 years post TBI = - Pre-injury 33 people worked (68%), 12 worked post injury (38%) - Pre-injury 6 were unemployed (12%), 11 were unemployed post injury (34%) - Pre-injury 4 were students (8%), post injury 1 was a student (3%) - Pre-injury 6 (12%) were retired/homemaker, post injury 8 (25%) were.	Mean days spent in inpatient rehabilitation was 36 (+/- 41 days)	Participants reported earning less income post injury compared to pre-injury. Those who dropped out after 1 year had higher levels of employment and private income and less need for public assistance compared to those assessed at year 2	No details of any specific VR received were recorded.
(Deutsch et al. 2006) USA	Retrospective cohort study 5-84 months post injury	44 people. All TBI: 31 males, 13 females Mean age 31 years All employed prior to injury.	23/44 (52%) in vocational jobs or school at 23 months (range 5 -84 months)	Had a Life Care Plan programme No details but included detailed VR outcome scale All involved in litigation	Found compensation had no effect on RTW outcomes	Programme was not specifically targeted at work but concluded it needed to be

Table 3: TBI return to work studies: Retrospective cohort studies (continued)

	Design	Population	RTW rates	VR details	Findings	Comments
(Avesani et al. 2005) Italy	Retrospective study over 2-10 years	353 patients consecutively admitted to one intensive rehab unit. TBI: Mean GCS = 6.7	125/230 (53%) of those previously working had returned to work). 76.5% of students resumed study	45/125 patients had VR.	GCS, PTA with LOS and GOS-E predicted social and vocational re-integration. Found main obstacles to RTW were cognitive-behavioural disabilities and/or severe motor disability	Study concluded VR seemed key element but no supporting evidence presented
(Leung et al. 2005) Hong Kong	Retrospective study between 1999-2002	79 previously employed TBI people admitted to hospital 45% cerebral haemorrhage, 23% head injury, 24% tumours 18-65 years old. Referred to OT whilst an inpatient	One year post discharge 37/79 (47%) RTW = 29/79 (37%) had same job, = 8/79 (10%) had different job, = 42/79 (53%) were unemployed	Unknown	Discharge score on DRS, low pre-morbid occupation limited post injury work. Poor attention score on Neurobehavioral cognitive status examination (NCSE) predicted vocational success	Authors said Hong Kong had limited scope to accommodate employees with disabilities. 5% of sample had total dependency at one year.

Table 3: TBI return to work studies: Retrospective cohort studies (continued)

	Design	Population	RTW rates	VR details	Findings	Comments
(Klonoff et al. 2001) USA	Retrospective study 1-7 years post injury	93 patients attended a comprehensive milieu – orientated neuro-rehabilitation, Mean time to access unit = 3 months 54% were TBI of which 79% were moderate/severe. 97% patients had the goal to return to work/study.	Numbers in work/study/volunteering Pre-injury: 89/93 (96%) Post injury: 77/93 (59%) (Mean time post injury = 47 months)	80 patients had a work or school re-entry programme- these patients had higher levels of RTW (79%)	Gender, post injury marital status, admission functional status and litigation status were not associated with RTW but younger age, higher education and driving were	Only half of patients were TBI. No detail of what VR consisted of, Acknowledged higher than average RTW may be due to admission criteria of unit
(Cifu et al. 1997) USA	Retrospective study – one year. From TBIMS data base	132 previously employed TBI people selected from 245 acute inpatient units had 1 year follow up data. Did not exclude those with previous TBI, mental health or substance problems Mean admission GCS for those employed at 1 year = 8.9, for those unemployed at one year = 7.6	49/132 (37%) of those competitively employed pre-injury were working at one year	All had access to a full rehabilitation team as an inpatient and all were referred for VR on discharge	Found low GCS scores and longer PTA, decreased function at admission and at one year and behaviour problems correlated with no RTW Neuropsychological testing did not predict RTW	Older study, advances in acute care may have improved outcome

Table 3: TBI return to work studies: **Retrospective cohort studies** (continued)

	Design	Population	RTW rates	VR details	Findings	Comments
(Johnson 1987) UK	Retrospective study of authors patients	47 people with severe TBI who were previously employed pre injury	Followed up people a mean of 3.5 years post injury. Found overall:- 38% RTW, 34% did not return at all 28% tried but failed to RTW	Did offer help to patients to RTW including working with employers. Arranged part time work, easier work, work train, training, work place support and liaison with employers.	Found 3 types of outcome:- Group 1 = Successful return to work. n = 18, mean age = 27 years, mean PTA = 5 weeks Group 2 = Returned but failed n = 13, mean age 31years, mean PTA = 6 weeks, Group 3 = no attempt to return, n = 16, mean age = 35 years, mean PTA 7 weeks	One of the very few UK studies. He followed these patients up ten years later and found most patients had stayed in their original work category i.e. if unemployed at 3 years, a person was highly likely to be unemployed at 10 years (Johnson 1998)

2.4.3. Predicting employment after TBI

Four systematic reviews of predictive factors relating to return to work following TBI were identified— see Table 4. (Ownsworth et al. 2004; Schonbrun et al. 2004; Willemse-van Son et al. 2007; van Velzen et al. 2009a). The evidence for most factors examined was inconclusive. Moreover, the lack of RCTs and cohort comparison studies make it difficult to tease out whether any increase in employment rates were due to natural recovery, intervention received or other factors such as publication bias (Johnson 1998; Dickinson et al. 2000; Wehman et al. 2003; Sorbo et al. 2005; Catalano et al. 2006; Malec et al. 2006; Murphy et al. 2006; Teasell et al. 2007). For example, the provision of VR as a predictor of employment post TBI had moderate support in a systematic review of 50 studies of prognostic factors (of return to work after TBI) (Ownsworth 2004) but two subsequent systematic reviews found inconsistent evidence for this (Willemse-van Son et al. 2007; van Velzen et al. 2009a). The fourth review did not refer to VR at all (Schonbrun et al. 2004).

One systematic review of RTW after TBI, and some individual studies, suggest people with TBI who work have reduced levels of depression and anxiety, and that emotional state is related to employment (Corrigan et al. 2001; Franulic et al. 2004; Ownsworth et al. 2004). However, another systematic review found depression and anxiety were not predictive of employment (van Velzen et al. 2009a). In that review, only three out the 22 studies examined anxiety and depression. The conclusions were based on only three studies, two of which only included people with mild TBI. Therefore, the author's conclusion may not be relevant for people with moderate or severe TBI. This suggests the need for further research into the relationship between depression and anxiety and work.

Evidence from the systematic reviews as to whether neuro psychological tests accurately predict a return to work found that different tests were used so no consensus was reached (Schonbrun et al. 2004; Willemse-van Son et al. 2007; van Velzen et al. 2009a). Ownsworth et al (2004) found that measures of executive functioning were a more reliable indicator of work ability compared

to neuropsychological tests of memory and attention. They also acknowledged difficulties in the ecological validity of current executive measures to transfer meaningfully from the clinic to the natural world.

Other factors cited in the reviews as predictive of a return to work were length of hospital stay, under 40 years old, married and a higher educational status – see Table 4. Again, these assertions were based on only a few studies and the results were equivocal. Overall, these findings along with other individual studies suggest that work status is determined by a complex mix of factors (Possl et al. 2001; Bootes et al. 2002; Keyser-Marcus et al. 2002; Catalano et al. 2006; Stergiou-Kita et al. 2010). However, the most consistent findings predicting successful post injury employment were being employed pre-injury and having a higher functional status on hospital discharge.

Table 4: Predictive factors for return to work after TBI

Potential Predictive Factors	Schonbrun et al. (2004) Reviewed 21 articles 1991-2003 of TBI predicting RTW	Ownsworth et al. (2004) Reviewed 50 studies 1980 –2003 of TBI predicting RTW	Willemse-van Son et al. (2007) Reviewed 14 cohort studies 1995-2005. Predicted RTW	van Velzen et al. (2009a) Reviewed 13 studies – 1992-2008 predicting RTW in TBI
Glasgow Coma Score (GCS)	Inconclusive	Inconclusive	Inconclusive	Strongly not predictive
Post Traumatic Amnesia (PTA)	Not assessed	Inconclusive	Longer PTA predicted post injury unemployment	Inconclusive
Loss of consciousness	Longer coma = less likely to work	Inconclusive	Inconclusive	Inconclusive
Length of hospital stay	Longer stay = less likely to work	Inconclusive	Inconclusive	Strongly negatively predictive
Age at time of injury	11/12 studies said age was not related to RTW. 1/12 study said those over 40 years old less likely to RTW	Inconclusive	Inconclusive	Inconclusive
Gender	6 studies said this was not a significant factor	Low support for gender not being predictive	Strong support for gender not being predictive	Inconclusive
Hospital discharge status	Those more severely injured were less likely to return to work	Strong support for RTW if higher functional status on discharge	Severe disability at admission predicted post injury unemployment	ADL – inconsistent findings. Residual physical deficits – weakly negatively predictive
Education level	6 studies said higher education levels were predictive of RTW but 7 said it was not predictive	Inconclusive	Low educational level not predictive of unemployment	Inconclusive

Table 4: Predictive factors for return to work after TBI (continued)

Potential Predictive Factors	Schonbrun et al. (2004) Reviewed 21 articles 1991-2003 of TBI predicting RTW	Owensworth et al. (2004) Reviewed 50 studies 1980–2003 of TBI predicting RTW	Willemse-van Son et al. (2007) Reviewed 14 cohort studies 1995-2005. Predicted RTW	van Velzen et al. (2009a) Reviewed 13 studies – 1992-2008 predicting RTW in TBI
Pre-injury employment	Pre-injury employment was predictive of post injury employment	Pre-injury employment moderately predicts post injury employment	Pre-injury unemployment strongly predicted post injury unemployment	Pre-injury job stability was not predictive
Occupation	1 study found those in lower levels jobs less likely to be employed	Moderate support for a link between pre and post injury employment	Not assessed	Inconclusive
Married	2 studies found married people more likely to be in work 2 studies found unmarried people more likely to be unemployed	Inconclusive	Not assessed	Family – weakly positive predictive
Cognitive functioning	Some neuropsychological tests did differentiate between those employed and not employed but different tests were used in different studies.	Mixed findings for memory and attention but strong support for executive functioning i.e. those without problems more likely to be in work	Inconclusive	Inconclusive
Cause of TBI	Not reported	Inconclusive	Violent aetiology not predictive	Inconclusive
Pre-injury substance abuse	Pre-injury substance abuse predicted post injury unemployment	Inconclusive	Pre-injury substance abuse predicted post injury unemployed	Inconclusive

Table 4: Predictive factors for return to work after TBI (continued)

Potential Predictive Factors	Schonbrun et al. (2004) Reviewed 21 articles 1991-2003 of TBI predicting RTW	Owensworth et al. (2004) Reviewed 50 studies 1980–2003 of TBI predicting RTW	Willemse-van Son et al. (2007) Reviewed 14 cohort studies 1995-2005. Predicted RTW	van Velzen et al. (2009a) Reviewed 13 studies – 1992-2008 predicting RTW in TBI
Vocational rehab	Not reported	Moderate support that VR indicates post injury employment	Inconclusive	Inconclusive
Other	Examined race and found those in minority groups had lower levels of post injury employment 1 study said ability to drive was a predictor of post injury employment	Found pre-injury occupational status, function at discharge, global cognitive functioning, executive functioning and use of VR services and emotional status associated with employment.	Found older age, unemployed at time of injury, pre-injury substance abuse and worse functioning at discharge strongly predictive of unemployment post TBI.	Found depression and anxiety were not associated with RTW. However, many variables were only examined in one study

2.4.4. Sustaining employment post-TBI

Remaining in employment is difficult for some people following TBI due to cognitive disabilities (Johnson 1998; Fraser et al. 2006). Johnson (1987; 1998) followed up patients with severe TBI, at three and ten years post injury. At three years post injury, he found that 18/62 (28%) participants had failed to stay at work with the average duration of the first job just 3.5 months. Participants then had a series of short-term jobs. Johnson (1998) also found that these participants, (14/18, 83%) continued to hold down a series of short-term jobs at the ten year follow up. It is unclear whether any of these participants had received VR or whether VR might help people sustain employment. Predicting which people will have problems returning to and sustaining employment has proved difficult and as such it is not possible to identify which individuals will benefit most from VR (Possl et al. 2001; Franulic et al. 2004).

2.4.5. Personal factors affecting post-TBI employment

Factors such as motivation, self-efficacy and empowerment have been explored in employment studies of people with musculo-skeletal problems, but are rarely addressed in TBI work studies (Dekkers-Sanchez et al.; Varekamp et al. 2008; Brouwer et al. 2009). This may be an important omission. One retrospective qualitative study of 425 people with TBI concluded that increasing a person's confidence in their ability to work through vocational training may have improved both self-esteem and confidence to work, which then led to a higher reported quality of life (Tsaousides et al. 2009). Tsaoudies et al. did add the caveat that a higher self-perception of employability should not be misconstrued for actual employability in the TBI population due to potential problems with insight. In a review of best practice for post TBI employment, Holzberg (2001) felt poor psychosocial adjustment and maladaptive family functioning impacted negatively on the ability to work, but did not discuss exactly how these personal factors impacted on working for people with TBI. A qualitative study interviewed four people with ABI who did not return to work, four who did return to work and included information from family, work colleagues and therapists (Macaden et al. 2010).

They concluded that motivation and coping skills were ‘super functions’ that could override cognitive and other disabilities. They also found that these factors helped people with ABI to be good employees. Conversely, being unable to cope at work has been highlighted as a problem after TBI. For example, a UK qualitative study of 33 people with minor and moderate TBI found eight people were still off work or had lost their job four to six months post injury. These people all reported anxiety about work (Gilworth et al. 2008). Thus, factors, such as self-esteem, confidence and poor psychosocial adjustment, appear to be important in successfully regaining and sustaining work after TBI. Unsurprisingly, Walker et al. (2006) found that people with TBI who enjoyed their job were more likely to return to work than those who did not.

2.4.6. Environmental factors affecting post-TBI employment

Environmental factors in this context are aspects outside the influence of the individual that may affect return to work after TBI, such as employment rights, availability of jobs, welfare benefits, driving and claiming compensation. In the UK, an individual can only claim compensation under very specific circumstances, for example, if they have a road traffic accident. As individuals cannot influence these criteria, claiming compensation is included under environmental factors in this study. These will now be discussed.

Employment rights

Government legislation on employing people with disabilities varies across countries. For example, Avesani et al. (2005) suggested the Italian law made re-employment for people with disabilities easier and felt this may have been a factor in achieving higher than average return to work rates in their retrospective study of work reintegration after TBI patients. Conversely, Leung et al. (2005) attributed the low levels of post TBI employment in Hong Kong to the limited provision for the accommodation of employees with disabilities. During the study period, the Disability Discrimination Act (DDA) was in place in the UK, making it unlawful for employers to discriminate against people with disabilities (The National Archives 1995). However,

analysis of the data from the British Household Panel Survey and the Family Resource Survey suggests that the DDA had no impact and possibly worsened the employment rights of disabled people due to increased uncertainty about litigation costs, a low level of general awareness and a lack of financial support (Bell et al. 2009). Clearly, differences in national legislation influence post TBI employment rates and make comparisons of international studies TBI VR problematic.

Employment rates

The impact of local unemployment on post injury employment rates and social security systems were acknowledged in a study of major trauma (Holtslag et al. 2007). However, they are rarely mentioned in reviews of post injury TBI rehabilitation studies despite the fact the availability of local jobs is crucial in post TBI employment (Semlyen et al. 1998; Chesnut et al. 1999; Ownsworth et al. 2004; Cullen et al. 2007; Willemse-van Son et al. 2007; van Velzen et al. 2009a). Interestingly, Sale et al. (1991) found economic layoff was reported as the primary factor in 5/38 TBI people studied who had lost their jobs. Unfortunately, that study did not discuss whether people with TBI were more at risk of being made redundant compared to those without TBI.

Welfare benefits

Catalano et al. (2006) found people with financial disincentives were less likely to return to work. In the UK there is a perception that the provision of state benefits acts as a disincentive to returning to work. Groswasser et al (1999) suggested that part of the VR process was helping patients access benefit advice. However, no studies were found stating this had occurred or was beneficial. Additionally in the UK, the benefit system has tight regulations about hours of work and earnings whilst claiming benefits. These make undertaking a graded return to work financially problematic.

Driving

Being able to resume driving has been found to be important for return to work after TBI (Catalano et al. 2006; Rapport et al. 2008; Macaden et al. 2010). Unsurprisingly, people who have no problems with transport have been found

to have higher employment chances than those with transport problems (Klonoff et al. 2006; Klonoff et al. 2007).

Compensation

Finally, there is mixed evidence to support a common belief that claiming compensation gives people a disincentive to return to work. A USA retrospective cohort study of 44 people with TBI, all involved with litigation, found this did not affect involvement in the rehabilitation process or achievement of employment or education (Deutsch et al. 2006). In contrast, a smaller UK retrospective study of 33 people with TBI found that a higher number of unemployed people (n=8) were seeking compensation compared to those employed (n=5) (McCrimmon et al. 2006). Therefore, it remains unclear whether claiming compensation affects a person's desire, need or ability to return to work.

2.4.7. Summary of TBI and return to work

In summary, post-TBI employment is consistently lower than pre-injury employment. Post-TBI employment appears to depend on a complex combination of pre-injury factors such as employment levels, marital status, TBI sequelae such as injury severity, personal and environmental factors such as feeling able to cope and the ability to resume driving (Shames et al. 2007). What is not known is whether targeted specialist VR affects return to work rates after TBI, if so, how and whether working is influenced by factors such as depression, anxiety and quality of life.

2.5. Vocational Rehabilitation

There is wide variation in the availability and provision of TBI vocational rehabilitation (VR) services, both between and within individual countries (Hart et al. 2006; Malec et al. 2006; Murphy et al. 2006; O'Brien 2007; Vocational Rehabilitation Society 2007). Waisak et al. (2007) suggested a person may require VR at any one of the following phases:- whilst off work, when reintegrating into work, with work maintenance and with career advancement. After the initial TBI, the majority of people with moderate and severe TBI require time off work due to problems resulting from their TBI. VR is focused on reintegration into work. This phase is the focus of this study.

2.5.1. Provision of VR

UK national clinical guidelines and a systematic Cochrane review recommended that specialist TBI rehabilitation should be provided after leaving hospital to maximise function, including returning to work (British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine 2003a; British Society of Rehabilitation Medicine et al. 2004; Turner-Stokes et al. 2005; British Society of Rehabilitation Medicine 2010). Quality requirement six of the National Service Framework for People with Long Term Conditions, which includes people with TBI, states people should have access to appropriate vocational assessment and on-going support to enable them to find, regain or remain in work (Department of Health 2005).

Despite these recommendations, many people in the UK do not receive any form of rehabilitation, vocational or otherwise, following their TBI (Rusconi et al. 2003; Pickard et al. 2004; Gladman et al. 2007; McCartan et al. 2008). A study mapping services providing VR for people with long term neurological conditions (LTNC) in England showed very little VR was provided for this group of patients– see Figure 2 (Playford et al. 2011). The main providers were generic community neuro-rehabilitation teams who tended to see less than 25 people per year for VR – see Figure 2. Within the mapping study, only 32

services were identified that were TBI/ABI specific and provided vocational interventions.

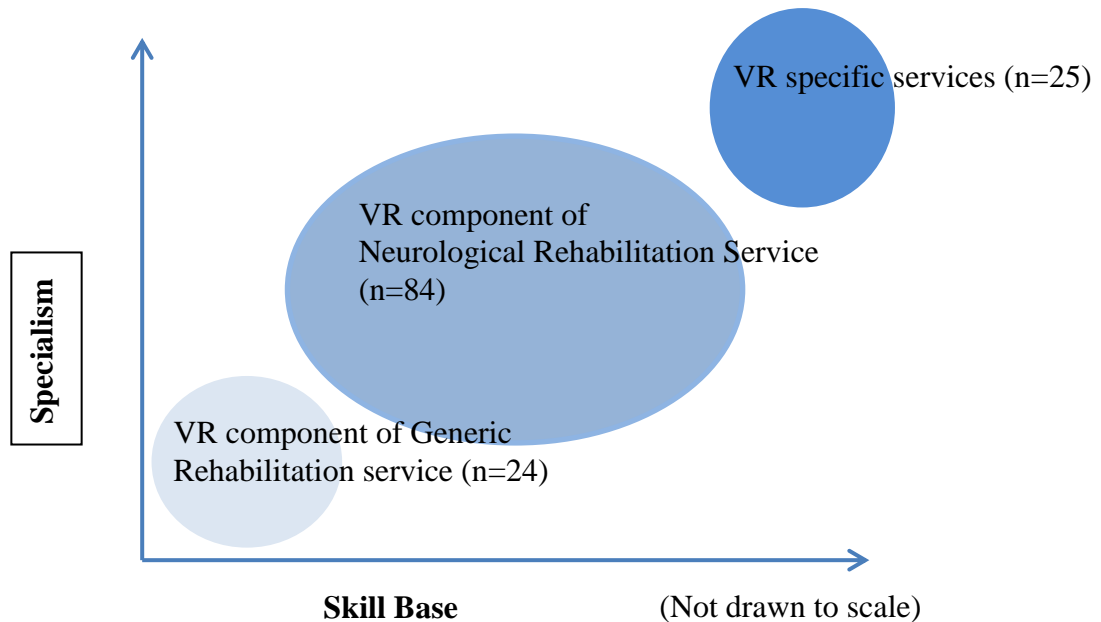


Figure 2: Model of VR services for people with LTNC in England

These were similar findings to an earlier survey of British Society of Rehabilitation Medicine consultants which identified 97 services that saw between 15 – 40 ABI patients per year (Deshpande et al. 2004). Of those identified, 62% stated they addressed vocational issues and only eight (8%) provided specialist ABI VR services. Of those, two were outside the NHS. The authors concluded that the UK appeared to cater for less than 10% of the estimated total need for TBI VR (Deshpande et al. 2004). Thus, it appears only a minority of people with TBI receive specialist VR in the UK.

2.5.2. The need for specialist TBI vocational rehabilitation

As provision of specialist TBI VR appears sparse, the question that needs to be asked is whether specialist TBI VR is required (Deshpande et al. 2004; Nyein et al. 2007). A UK pan-disability specialist vocational programme, run by health professionals, undertook a retrospective audit of employment outcomes of 107 people of different disabilities (DeSouza et al. 2007). The service was

only offered to potential clients if it was felt they would benefit from it. They found brain injury was the most common diagnosis referred to the service. Compared to people with other diagnoses (n=66), people with TBI (n=41) did less well in returning to work. At the end of the 24 week programme, only 34% of the people with TBI were employed whereas employment rates for the other diagnostic groups were: back injury 80%, musculo-skeletal injury 64% and amputees 62%. DeSouza et al suggested these results were not surprising as cognitive, awareness and behavioural problems were particular issues for people with TBI with regard to work. These results suggest that generic VR alone is not enough regardless of the VR expertise of the provider.

Clearly returning to work is problematic for people following TBI. However, two studies of specialist community TBI teams have both concluded that providing specialist TBI rehabilitation without specialist targeted VR is not enough to increase post-TBI employment rates (Powell et al. 2002; Ponsford et al. 2006). It appears both factors are required.

Powell's study (2002) may be the only RCT of TBI community rehabilitation conducted in the UK. Outcomes from 48 participants (intervention group) who received individualised goal directed treatment from a specialist community TBI team were compared to 46 participants (information group) who received one session in which written information was provided (Powell et al. 2002). The specialist team consisted of a half time social worker, two OT's and a physiotherapist. The intervention group received a mean of two sessions per week. Data was collected 18 – 40 months after group allocation. The intervention group showed significant improvements on the self-organisation and psychological wellbeing sub scales of the Brain Injury Community Rehabilitation Outcome Scales (BICRO) and modest improvement on the personal care and mobility subscales compared to the information group. This was impressive given that the mean time since injury was four years and no further natural recovery would be expected (Worthington et al. 2006). However, no significant gains were made on the socialising or productive activity subscales. This was surprising given that the intervention group received treatment aimed at these domains, such as assistance to return to pre-

existing employment. Only 10% (5/48) of participants in the intervention group and 17% (8/46) in the information group were employed at discharge. The authors concluded that there was a need for specialist VR in addition to specialist TBI rehabilitation. However, as the mean time post-TBI was four years (median 1.3 years), only a few patients had pre-existing jobs available to them. It is not known if earlier intervention would have made any difference.

Similar findings were found in a retrospective Australian study which matched TBI patients who were treated as outpatients (n=77) to those treated in the community (n=77) by the same TBI specialist team (Ponsford et al. 2006). Patients were treated as soon as they left hospital so received early intervention. The community group received fewer OT, speech therapy and social work sessions but this was not statistically significant. Both groups received the same amount of physiotherapy. They found that approximately 50% of both groups were employed two years post-TBI (Ponsford et al. 2006). The authors concluded that TBI focused VR was required in addition to standard TBI rehabilitation to improve return to work rates.

2.5.3. Specialist TBI vocational rehabilitation

Despite the need for specialist TBI VR, there is no consensus concerning what this involves. Hart et al. (2006) studied 16 established TBI VR programmes in the USA, and found a wider- than- anticipated variation in what VR consisted of in practice. They concluded that a more in-depth analysis of the programs was required to ascertain whether these differences affected employment outcomes. The variation appeared related to funding differences and how the services had evolved, as opposed to any evidence based rationale.

Both Fadyl et al. (2009) and Hart et al. (2006) separately reviewed TBI VR and concluded that three broad models of TBI VR service delivery existed – see Table 5. Although they used different terms to describe them, the models share similar characteristics. Hart et al. refer to services that provide rehabilitation prior to returning to work as ‘train and place’ whereas Fadyl et al. call these ‘programme based’. Next, Hart et al. refer to ‘place and train’. The underlying

concept for this model is teaching patients to recognize problems and use strategies to overcome them whilst working in situ, with the support of a job coach. Fadyl et al. (2009) refers to this as ‘supported employment’. Finally, Hart et al. refer to a ‘combined model’, which involves a number of different strategies and are co-ordinated by a case manager. Fadyl et al. (2009) refer to this as ‘care co-ordinated’ and suggest the combined model is the most frequently used. However, there is no consensus as to which model is most effective.

Table 5: Models of TBI Vocational Rehabilitation

Type of programme			
Fadyl et al. (2009)	Model 1 Programme based ('milieu approach')	Model 2 Supported employment	Model 3 Case co-ordination
Hart et al. (2006)	Train and Place	Place and Train	Combined
Concept	Teaches patient to recognize problems and use strategies before going in to work.	Teaches patient to recognize problems and use strategies whilst working. Helps with job searching, applications and work place support whilst on placement.	A case manager supports and advocates so relevant help is accessed as required. May involve job coaching and outpatient groups for education re strategies.
Where takes place	In a centre with a multi-disciplinary team as an in or out patient.	In work place with 1:1 job coach, decreasing support as necessary. The job coach educates co-workers about TBI.	Varies e.g. outpatient centres or community based.
Client group	Can be any time post-injury.	Can be any time post-injury.	Any but most frequently delivered soon after injury.
Advantages	Patient learns with other patients in a 'safe environment'. Provides intensive rehabilitation e.g. Klonoff et al. (2006) reported mean length of intervention was 5.7 months (0.8 – 15.4 months)	Negates need for transfer of training to take place. Patient learning in a real situation. Patients get immediate, direct, relevant feedback	Combines medical and vocational needs of patients. Usually delivered locally, so opportunity for return to pre-injury employer and family involvement. Cheaper than models 1 or 2 Appears to be most widely used model

Table 5: Models of TBI VR (continued)

Fadyl et al. (2009)	Model 1 Programme based (milieu approach')	Model 2 Supported employment	Model 3 Case co-ordination
Hart et al. (2006)	Train and Place	Place and Train	Combined
Disadvantages	<p>Waiting time to access programme e.g. Klonoff et al. (2006) reported mean time to access centre was 3 – 408 months (mean 22 months) post-TBI.</p> <p>Units tend to be regional so less family involvement.</p> <p>Costly if it requires an in-patient stay.</p> <p>Admission criteria can be restrictive</p>	<p>Can be costly and time consuming as 1:1 support is provided almost full time initially.</p> <p>Requires a sympathetic employer.</p> <p>Not used widely (Catalano et al. 2006).</p>	<p>Can be less intensive and structured than models 1 and 2.</p> <p>Relies on medical and vocational services working together.</p> <p>Dependent on locally available resources (Fadyl et al. 2009).</p>
Exponents	<p>Pioneered in Israel by Ben-Yishay et al. (Israel) (1987) and continued by Klonoff et al. (USA) (2007).</p> <p>Klonoff et al. (2006) reported that 74% of participants (n=93) returned to work or education post-TBI compared to 95.7% in work pre-injury.</p>	<p>Championed by Wehman (USA) (2003). Wehman et al. (2003) reported the average intervention time per client was 246 hours with average costs per client estimated at \$7789. Reported 77% of clients competitively employed.</p>	<p>Malec et al. (2006) used a Vocational Case Co-ordinator model. Reported 81% of people working in the community at 1 year post- discharge with 53% in independent work (n=114).</p> <p>A review of evidence concluded the case manager approach was effective (Chesnut et al. 1999).</p>

Table 5: Models of TBI VR (continued)

Fadyl et al. (2009)	Model 1 Programme based (milieu approach')	Model 2 Supported employment	Model 3 Case co-ordination
Hart et al. (2006)	Train and Place	Place and Train	Combined
UK example	<p>Rehab UK is a charity funded non-residential center based program aimed specifically at VR for people with TBI in the UK (Murphy et al. 2006). Mean time to access the program 5.5 years from injury, length of program 1 week to 4.5 years (mean 50 weeks)</p> <p>Other units: Stepping Out program, Aylesbury UK, which is a jointly funded by NHS and Jobcentreplus (Tyerman. et al. 2008).</p>	<p>Rarely available in the UK. The nearest equivalent was the WORSTEP scheme administered by Jobcentreplus which was only available if there were 'significant obstacles' to working. The scheme supported people in work but the support given was limited, often just 6 month reviews. It was provided by generic workers who did not have any specific TBI knowledge. Places were limited.</p>	<p>This case manager approach is advocated for use with people with long term complex conditions by the Department of Health (Department of Health 2008). Used by Nottingham Traumatic Brain injury service (Phillips et al. 2010). The case manager co-ordinates all aspects of the patients and family's needs whether medical or not. They act as an advisor; provide support and information as required.</p>
Comments	<p>Length of time to access and complete courses can mean patients lose possibility of returning to pre-injury employment.</p> <p>Literature does not report if there is support when at work or specifically refer to pre-injury employment. Not widely available.</p>	<p>Unclear whether existing jobs or new jobs are created as pre-employment jobs are not referred to.</p> <p>Has been pioneered when there has been relatively full employment. It is not known how acceptable this approach is in a recession.</p>	<p>There appears to be a wide variation in the practice of case management. This approach depends on the case manager being able to accurately identify the patient's needs.</p> <p>This approach is the only one which clearly states it focuses on maintaining pre-injury employment</p>

Very few studies have compared different models of intervention. A secondary analysis of a USA specialised vocational service found no significant differences when they examined the employment outcomes from three different TBI VR pathways (Malec et al. 2002). The study examined 141 people: 64% with TBI (63% moderate/severe, 21% mild, 16% unclassified) and 36% with ABI. Prior to their injury, 9% were unemployed. The three VR pathways were:

- Specialised vocational service (SVS). A vocational case co-ordinator provided individual vocational counselling, liaised with employers and referrers and co-ordinated medical and vocational services. The one year employment rate (n=43) was 77 % (50% with previous employers). This is similar to model three, see Table 5.
- Community reintegration outpatient group (CROG). People in this group received SVS plus three one hour sessions led by an OT, speech therapist or neuropsychologist. The group was aimed at reducing cognitive problems, increasing social skills, communication skills, adjustment issues and goal setting. The one year employment rate (n=20) was 85% (32% with previous employers).
- Comprehensive day treatment (CDT) - similar to model one, see Table 5. Participants attended for six hours a day, five days a week, duration not specified. Group work aimed at improving self-awareness, cognitive skills, adjustment, behavioural and emotional self-management. The one year employment rate was (n=44) 84% (32% with previous employers).

Importantly, the authors found that people were allocated to different pathways according to their needs, as defined by the outpatient team. The reasoning behind these decisions were not explained in the paper. This suggests that different types of VR may be required for different types of patient.

Another RCT compared different types of TBI intervention (Salazar et al. 2000). This single centre study compared the efficacy of an intensive eight week inpatient cognitive rehabilitation programme with an OT co-ordinating the work placements (hospital group, n=67), to a limited home rehabilitation programme with weekly telephone support from a psychiatric nurse (home

group, n=53) for US active duty military personnel with moderate or severe TBI. At one year, there was no significant difference in employment rates. Ninety percent of the hospital group had returned to employment, with 73% fit for military duty. Ninety four percent of the home group, 94% had returned to some form of employment, with 66% returning to military duty. No other TBI VR study has reported such a high employment outcome. There were no significant differences between groups on cognitive, behavioural or quality of life measures. The study did not state what VR or community intervention, if any, was provided.

Although three broad models of TBI VR have been described, this may not be enough. Catalano et al. (2006) identified 29 different types of people with TBI, all with different rates of return to work. This suggests that different models of VR may be required for different types of patient. However, questions remain unanswered about which model is effective for whom, what the key components are, and whether who delivers it and how makes any difference. In summary, further research into the most effective model of TBI VR is required (Shames et al. 2007; Geurtsen et al. 2010).

2.5.4. UK TBI Vocational rehabilitation guidelines

Specialist TBI VR in the UK is based on best practice guidelines which have been produced based on expert consensus of clinical opinion (British Society of Rehabilitation Medicine et al. 2004) - see Table 6. These are consistent with findings from other countries. The guidelines state that TBI VR should include assessment of readiness for return to work, liaison with other professionals, employers and disability employment advisors (DEA's) when required and a return to previous employer with work modifications if there is a job to return to. However, evidence to support these guidelines is scarce and the extent to which they are implemented in practice is unclear. This is partly due to scarcity of provision and the lack of research.

Table 6: Summary of UK TBI VR guidelines
(British Society of Rehabilitation Medicine et al. 2004)

Guideline statement	How to achieve it
Ask questions about occupational status, vocational aspirations	Should be undertaken as a standard part of a health assessment
Respond to questions about return to work, education or training	If necessary, refer to relevant person or agency e.g. medical consultant, neuropsychologist, OT, DEA, occupational health (OH).
Provide those with identified VR needs with interventions to promote optimal recovery and management of difficulties	Could include: <ul style="list-style-type: none"> - education about difficulties likely to affect work - development of skills and behaviors required for work e.g. building up attention, use of strategies - restore work related routines i.e. fatigue management - practice strategies to be used in the workplace
Consultation with people relevant to the clients work or study situation	Seek clients consent prior to any contact with others e.g. employer, DEA, tutor etc. Recommends doing this while patient present
Agree with the patient, others involved in the persons care and family the optimal way to return to work or education.	Consider: <ul style="list-style-type: none"> - the level of ability required to start the process and anticipated length of time to reach it, - individual and social circumstances, - cognitive, behavioral, motor, sensory, and emotional skills - buildup of hours, duties - practical considerations e.g. getting to work, financial implications including effect on benefits. - what information to disclose to others - liaise with others for advice if any queries
Agree and carry out the actual return to work or return to study plan	Consider: <ul style="list-style-type: none"> - graded return, voluntary trial, restricted hours/duties, advice/support in the workplace, job coaching, support from work colleagues, off site support. - when returning to study consider adjustments to course, learning support equipment, individual learning support, extra time in exam
Progress review with patient and employer	Consider: <ul style="list-style-type: none"> - provision of ongoing advice, support and feedback for client and employer as appropriate - feedback from family about the impact of work on personal and family life.
Liaison with DEA if long term or major support is required	e.g. Major adjustments to work duties, specialist equipment in the workplace or help with travel to work.

2.5.5. Usual care

In the UK, people with TBI who do not receive specialist VR, may not even access general or specialist rehabilitation. For example, a UK cohort study of 219 people at 5-7 years post-TBI found that only 16 (7.3%) reported using any rehabilitation services following hospital discharge (Whitnall et al. 2006). Rusconi et al (2003) studied 53 patients discharged from an UK inpatient neuro-rehabilitation unit i.e. a specialist unit, and found that only four of the patients discharged received input from a multi-disciplinary neuro community team. The researchers commented on the lack of brain injury expertise available in the community. Allanson et al (2011) undertook a retrospective audit of services provided for TBI patients in an area without a specialist TBI team (UK). Of 86 patients admitted to their regional neurosurgical unit over a two-year period, only 30 patients had been referred to their neuro trauma clinic. Additionally, 46 local residents with TBI, 15 (35%) of whom had not been an inpatient, were referred with problems to the neuro trauma clinic three years after injury. Furthermore, two patients were accessing daily neuropsychological rehabilitation but this had started between 18 and 30 months post injury. These studies illustrate that rehabilitation for people with TBI appears to be infrequent and varied due to the disparity in service provision, with many patients appearing not to receive any services or access them late when sequelae become problematic. There is not a standard pathway for people with TBI to access rehabilitation with or without VR.

2.5.6. OTs and vocational rehabilitation

OT's deliver VR for people following TBI because of their skills in activity analysis, problem solving, goal setting, an understanding of the medical consequences of TBI and ability to relate this to a work situation (Bootes et al. 2002; Barnes et al. 2006; 2009). The mapping study of vocational services for people with long term neurological conditions in England found OTs delivered the VR in 77% of services (Playford et al. 2011). For example, Johansson et al. (2001) found OTs undertook assessments (Rivermead Behavioural Memory test, activity limitations in personal and instrumental activities of daily living as measured by the Functional Independence Measure and the Assessment of

Motor Processing Skills) which accurately predicted failure to return to work but did not reliably predict success for people with TBI.

The specialist medical knowledge of an OT is an important factor in TBI VR. The lack of appropriate information and advice has been reported as the biggest barrier for any employer once a person has gone off sick (Black 2008). A survey on working with cancer by the Institute of Personnel and Development and Cancerbackup (2006; 2006a), found 'being nice was not enough'. They found both patients and employers wanted hard facts and often got conflicting advice from everyone involved. Also, it has been noted that 'providing realistic information to the employer without inordinately raising his or her concerns, requires substantial finesse' in the case of returning someone with TBI to work (Kowalske et al. 2000). The 'hidden' aspects of TBI, such as cognitive, executive and behavioural problems, along with other non-obvious difficulties, such as fatigue and the risk of seizures after TBI, requires specialist knowledge in addition to VR skills.

'Job coaching' and 'follow along' post-placement were identified by USA VR specialists as the two most crucial 'make or break interventions' in helping a TBI person obtain work (Hart et al. 2006). Job coaching was defined as "treatment involving a staff member accompanying the client to his/her work place or working with the client off site with a focus on job training, trouble shooting and problem-solving, development and application of strategies on-the-job. It may also include intervention or education with employer and co-workers, work place modifications (physical or scheduling modifications), or other interventions as needed to assist the client in performing a job". 'Follow along' was described as continuing to see the client after work had commenced to provide on-going support. These are the roles an OT in a UK specialist community TBI undertakes to assist a person in returning to work (Coetzer 2008; Phillips et al. 2010). However, there appears to be no published research into the effectiveness of these interventions.

2.6. Key components of TBI vocational rehabilitation

Van Velzen et al. (2009a) suggested that TBI VR should target factors that can be ameliorated through rehabilitation. Early intervention, liaison with employers and the implementation of work modifications are recommended as key components of the VR process so evidence of these in relation to TBI will now be explored (British Society of Rehabilitation Medicine 2003a; British Society of Rehabilitation Medicine et al. 2004; Department of Health 2005; Stergiou-Kita et al. 2009; British Society of Rehabilitation Medicine 2010).

2.6.1. Early intervention and return to work after TBI

A systematic review of work disability associated with musculoskeletal conditions was conducted on the effectiveness of workplace based return to work interventions (Franche et al. 2007a). Based on ten high quality studies they found strong evidence that early contact by a health care professional with the work place helps to maintain post- injury employment. No similarly robust evidence is available for TBI. A quantitative synthesis of 26 studies of VR after TBI suggests early, more intensive intervention is more likely to help people with TBI, particularly those with severe TBI to return to work and retain their jobs (Kendall et al. 2006). Additionally, a scoping review of community integration after ABI identified 25 studies, of which five examined early vocational intervention, and suggested that the optimum time to return to work was between six and eighteen months post-injury (McColl 2007). Therefore, there appears to be consensus that people with TBI were more likely to return to work if they received specialised VR early, ideally within the first one or two years of injury (Kendall et al. 2006; McColl 2007).

A closer look at the studies cited as evidence for early VR suggests that the evidence pre-2007 is based mainly on two studies by Johnson (1987; 1998). Johnson followed up 47 patients with moderate to severe TBI, a mean of 3.5 years post-TBI, all of whom were employed prior to their TBI. All patients were treated by the author in a UK rehabilitation unit immediately after their injury. Johnson found that no one returned to work before four months post-TBI and those who made a successful return did not do so until five months

post-TBI. Johnson followed these patients up ten years later (along with another study sample). At the ten year follow up, he found that 82% of people at follow up (n=62) had not changed their employment status. Of those unemployed at the first follow up (21/47), 90% were still unemployed at ten years. Additionally, those who initially failed to maintain a job (mean time for length of first job was 3.5 months), subsequently continued to have unstable employment. On the basis of these findings, Johnson recommended that a return to work after TBI should commence between six and eighteen months after TBI. Even though the original study was relatively small, conducted 24 years ago and medical, rehabilitation and employment practices will have changed; these studies remain among the very few examining the effect of initial rehabilitation on long term outcome. It also appears from Johnson's studies that the initial employment outcome from vocational intervention is important as it may influence future employment.

The need for VR to take place in the first year after TBI is supported in a referral cohort study that compared the effects of receiving early or late intervention (Malec et al. 2006). Malec et al. found that participants who entered the USA vocational case coordinated VR programme within a year of their TBI had a 75% chance of being employed, whereas those who entered later than this only had a 25% chance of resuming employment. No explanation was given to why participants received early or late intervention. On entering the programme, 60/120 (50%) participants with TBI were placed in employment within three months and 116/120 (94%) were placed in employment within a year. The mean time from injury to accessing the project was 3.5 years, but the median time since injury was 0.6 years. Therefore, the majority of people returned to work approximately nine months after their TBI.

A small cross-sectional study also aimed to compare the effect of early and late intervention for people with severe TBI, starting with rehabilitation in hospital as different hospitals had differing treatment regimes (Sorbo et al. 2005). The early rehabilitation group commenced specialist intervention a mean of 27 days from injury (n=14) whereas the late group commenced rehabilitation a mean of 107 days from injury (n=12). Both groups had similar levels of injury severity.

At two years post-TBI, 43% of the early intervention group had returned to work (pre-injury employment rate was 73%) compared to no patients returning to work in the late intervention group (pre-injury employment rate was 83%). Unfortunately, this study was confounded by the fact the early intervention group also received community outreach service for up to 18 months, whereas the late rehabilitation group did not receive the community intervention.

In contrast, a few studies have shown that some people with TBI have achieved employment two or more years after TBI when they received specialist VR (Johnstone et al. 2003a; Malec et al. 2006; Murphy et al. 2006). As the focus of this study is work within 18 months post injury, this aspect will not be discussed further.

As judgements about a person's fitness to work can be made in the initial months post-injury, there is a need for early specialist intervention to help inform decision-making. For example, military personnel with a TBI were recruited consecutively from hospital admission to a RCT of inpatient cognitive rehabilitation versus limited home rehabilitation (Salazar et al. 2000). The decision whether to return to these participants to the military was made at six months for the inpatient group (n=63), and five months for the home group (n=570). As over 90% of people in both groups were in some form of employment at one year, we do not know if the timing of this decision was correct. We also do not know when civilian employers decide to terminate a person's pre-injury job or whether intervention from rehabilitation professionals can influence this decision. Neither do we know what is the optimal time to make this decision, or what other factors, for example, financial matters, are taken into consideration.

The timing of when to return to work is important. Returning to work too soon after any injury may have negative consequences, cause a relapse and increase resistance to future working for both the employee and employer if problems then occur (Franche et al. 2005). Returning to work too early after TBI is a particular problem. Participants in a qualitative study of 33 people with minor to moderate TBI reported that, with the benefit of hindsight, they felt they had

returned to work too soon due to the on-going problems resulting from their TBI (Gilworth et al. 2008). It has been suggested that initial failure at work after TBI may lead to long term difficulties with adjustment, mood and development of maladaptive strategies over time, all of which may negatively impact on future employment (Ownsworth et al. 2004; Stergiou-Kita et al. 2010).

2.6.1.2. The possible value of early TBI specialist intervention

If early VR does increase return to work rates, this raises the question about how this is achieved. There is very little discussion in the TBI VR literature regarding this point. It is known that the first three months following hospital discharge is a particularly challenging time for both TBI patients and their carers (Turner et al. 2007; Turner et al. 2009). During this period depression and emotional distress may develop as people become aware of TBI sequelae. Early intervention may increase patients and families awareness of these problems, facilitate the acquisition of positive coping strategies and prevent the emergence of maladaptive behaviour (Wade et al. 1998; Turner et al. 2007; Bay et al. 2008; Berendsen et al. 2009). This increased ability to cope may positively impact on the ability to work.

Additionally it has also been suggested that activity may impact on the neuroplasticity of the brain during the recovery phase thus aiding recovery (Castellanos et al.; Sorbo et al. 2005; Wilson 2010). Furthermore, it has also been suggested that satisfaction with the care received and working on patients goals may improve the therapeutic alliance which in turn has been shown to optimise employment rates (Schonberger et al. 2006; Klonoff et al. 2007; Sherer et al. 2007; Kissinger 2008). A questionnaire survey of 389 patients who were off sick with a health condition found that patients who perceived the therapist to be competent, had better outcomes following rehabilitation (Rasmussen et al. 2005).

In summary, optimum employment appear to be achieved within one to two years of injury. Commencing VR within the first few months post-TBI appears to facilitate improved employment outcomes (Chesnut et al. 1999; Kendall et

al. 2006; Wehman et al. 2009). However, for some people with TBI, returning to work too soon can be a negative experience (Gilworth et al. 2008).

2.6.2. Returning to the same employer

Only a few TBI studies report whether participants return to their pre-injury employer (Johnson 1987; Buffington et al. 1997; Malec et al. 2002). Many TBI studies report overall numbers of people 'in work', as opposed to how many people return to pre-injury employers (Groswasser et al. 1999; Kendall et al. 2006; Cullen et al. 2007; Shames et al. 2007; Willemse-van Son et al. 2007). A study of 1,221 TBI participants reported that returning to the same job was perceived to be the easiest option, but did not report how many people returned to their pre-injury employer (Walker et al. 2006). The lack of detail regarding how many participants return to the same employer or job or why previous jobs were not maintained does not further our understanding of the issues involved in returning to work after TBI. This absence of detail has also been highlighted as an issue in VR studies of other health conditions (Vogel et al. 2011).

For people with TBI, returning to the pre-injury employers appears advantageous. Adapting to a new employer, new role and new people entails new learning which is known to be difficult after TBI and may increase anxiety (Holzberg 2001; Walker et al. 2006). Also, some TBI studies have reported that pre-injury employers have provided alternate jobs when required (Macaden et al. 2010). For example, Buffington et al (1997) found that 37% of people with TBI (n=80) returned to work with their previous employer but not necessarily to the same job. McCrimmon et al. (2006) found of the 14/20 people with TBI who had returned to their pre-injury employer, four people had changed roles. Additionally, Malec et al. (2000) found that participants who returned to their pre-injury employment (40 /102) were placed in work within three months of entering a TBI medical/vocational case co-ordinated programme in the USA compared to seven months for the 62/102 participants that did not return to their pre-injury employer. Fabiano et al. (1995) also found that those who returned to the same employer had significantly higher

wages. Finally, Yasuda et al. (2001) suggested returning to a pre-injury work place with familiar colleagues has the potential to counteract the social isolation which is common post-TBI.

A person's relationship with their pre-injury employer and work colleagues may be influential. The importance of a good employer/employee relationship was found to be the key variable influencing the effort made to return to work in a study examining the outcomes of 415 Dutch disabled workers (cause of disability unspecified) up to two years post-injury (Muijzer et al. 2011). In a qualitative study of four people in work with ABI, (which also included the persons co-worker, job coach and family member), Macaden et al. (2010) stressed the importance of supportive employers for sustaining employment post-TBI. They also found that employers were more supportive if the employer had some experience of disability themselves. Similarly, Gilworth (2008) found that some employers were more supportive than others and cited lack of understanding of TBI to be an issue, partly due to the invisibility of the effects of TBI. A Norwegian qualitative study of eight people with ABI who had been working for at least four months post-ABI, found that workplace managers and colleagues who understood TBI and its consequences were helpful in their return to work (Rubenson et al. 2007). These qualitative studies suggest interpersonal relationships are major factors affecting employment rates after TBI (Sale 1991; Rubenson et al. 2007; Gilworth et al. 2008). Conversely, the effects of TBI can be negatively highlighted in the workplace if employers do not fully understand and expected the person with TBI to function as before. In an older study, Sale (1991) interviewed 38 people with TBI who had experienced failure at work. They cited interpersonal relationship issues as one of the main causes for stopping work.

There appears to scant literature examining whether TBI VR influences return to pre-injury employers. One North American RCT explicitly targeted pre-injury employers (Trexler et al. 2010). The study compared nine TBI participants who received specialist intervention with eleven TBI participants who received usual care. The specialist intervention aimed to engage the subject's former employer in a return to work plan. The specialist group

achieved a higher rate of post-injury employment at six months post-injury (6/9 v 4/11). However, the authors omitted to record how many people returned to the same employer or job or what intervention they carried out. Johnson's study (1987) remains one of the few studies that explicitly stated that they liaised in person and by phone with patients' pre-injury employers. Johnson studied 47 people with moderate or severe TBI, all of whom were previously employed. He found 22/47 (47%) patients initially returned to the same job, but he did not state whether this was with the same employer or whether the intervention with the employers was instrumental in helping patients keep their jobs. He found that both employers and employees required education about the effects of TBI. He also provided an example of what he termed 'employer tolerance' over the erratic way a person with TBI fed the pigs and kept records. A qualitative study of eight people returning to work after TBI reported the outreach brain injury team had approached employers' (Rubenson et al. 2007). This was viewed as both positive and negative; positive, because it aided the employers understanding of brain injury, and negative because a person felt labelled, for example, with 'memory problems' and felt others became overly protective in the workplace. This illustrates the complexity of the interaction required between patients, employers and therapists.

Effect of occupation

TBI research has focused on the predictive nature of the person's pre-injury occupation on return to work. Walker et al. (2006) followed up 1,341 people with TBI who were previously employed. At one year post-TBI, 56% were in professional occupations, 40% were in less skilled occupations and 32% were manual workers. Thirty nine percent of manual workers had to change occupational category compared to approximately 30% of people in other categories. Walker et al. concluded that those in professional jobs may have had greater financial incentive to return to work, more supportive employers, and more flexibility in employment options. They also surmised that manual workers were the group most likely to have to change jobs, least likely to return to work and were the group most in need of VR. Walker et al did not report whether VR was provided, so it was not possible to conclude what other factors may have influenced the final occupational outcome.

In summary, although maintaining links with pre-injury employers is advocated in TBI VR, the evidence is weak (British Society of Rehabilitation Medicine et al. 2004; Wehman et al. 2009). For TBI, it is not clear how many people return to pre-injury employers or whether intervention with employers influences return to work.

2.6.3. Provision of work modifications

Grading a return to work and implementing work modifications, such as reduced hours and more breaks, is advocated as good practice in TBI VR (Groswasser et al. 1999; British Society of Rehabilitation Medicine et al. 2004; Ownsworth et al. 2004; McColl 2007). However, there is very little discussion in the literature to why they are needed, how to implement them and how they improve work ability. Evidence from a systematic review on workplace interventions for people with musculo-skeletal problems suggests there is strong evidence that work modifications reduce the length of sick leave, but similar studies do not appear to have been conducted for TBI (Franche et al. 2005). Johnson (1987; 1998) is one of the very few authors to detail what work modifications were used. He reported using reduced hours, easier work, unpaid work trials, training for work specific problems and workplace support. At the ten year follow up, Johnson found those who had received these work modifications were more likely to be successfully employed compared to those who did not receive these. He also found that 85% of those who returned to stable employment had returned with work modifications in place or undertaken some structured activity first. The work modifications lasted for an average of eight months but some lasted longer than 12 months. Support with job maintenance was required for many months after injury. He did not specify how participants who had work support or modifications differed from those who did not have them. He concluded that the opportunity to undertake a graded return and modify the workplace was more important for a successful outcome than age or severity of post-traumatic amnesia. However this was not an RCT, so this cannot be concluded with any certainty.

A supported, graded return to work, together with the implementation of work modifications may contribute to a successful return by helping a person manage fatigue. A qualitative study of return to work after TBI (n=12) found fatigue to be the main factor limiting a person's ability to work (van Velzen et al. 2011). Fatigue is very common post-TBI. It negatively impacts on cognitive ability, behaviour, and mood (McCrimmon et al. 2006; Johansson et al. 2009). Being able to manage fatigue may reduce errors, decrease irritability and improve attention, thus increasing the chance of a successful return to work (McCrimmon et al. 2006; Johansson et al. 2009). A graded return to work, when managed well, also allows the person to test out skills in manageable chunks and gain feedback on performance. If problems occur, they can be dealt with individually and quickly. No studies were identified that investigated the optimum timing and structure of a graded return to work for someone with a TBI.

A qualitative study conducted with people with low back pain showed that the instigation and implementation of work modifications relied on the knowledge and beliefs of the individual with back pain and relied on the goodwill of employers (Coole et al. 2010a). This may be difficult for some people with TBI. Following a newly acquired TBI, many people do not expect to have problems and so return to work too soon (Johnson 1998; Catalano et al. 2006; Gilworth et al. 2008). For example, in a RCT offering specialist TBI intervention to people with minor, moderate and severe TBI (although not specifically work focused) 7 - 10 days after injury, participants in the trial group were given advice by phone or in person once (n=137) (Wade et al. 1998). Only 62/137 requested a follow up phone call and only 21/184 of patients identified a need for further face-to-face follow up at that early stage. At six months, the trial group reported significantly less social disability and significantly less severe post-concussion symptoms compared to the control group, who received usual care (n=860). This suggests that although patients do not initially expect problems, symptoms do persist that respond to early intervention. Therefore, people with TBI may have difficulty recognising the need for and instigating their own work modifications when they first return to work. Also, problems resulting from TBI are potentially long term. An

employer's goodwill and tolerance may reduce over time (Johnson 1998; Gilworth et al. 2008).

Again, evidence for the use of a graded return to work and work modifications for people with TBI is limited despite being recommended as good practice (British Society of Rehabilitation Medicine et al. 2004).

2.7. UK Government policy and vocational rehabilitation

In the UK, Government policy directly influences the provision of VR through the Department of Health (DOH) and/or the Department of Work and Pensions (DWP). In 2007, 2.6 million people in the UK claimed illness-related unemployment benefits at an estimated total cost of over £100 billion to the UK government (Department for Work and Pensions and Department for Health 2008c). Supporting people with health conditions to stay in or return to work became a government priority in an effort to reduce this state dependency (Department of Health 2005; Department for Work and Pensions and Department for Health 2008c). This was in line with government's vision that by 2025, disabled people in Britain should have full opportunities and choices to improve their quality of life (Prime Minister's Strategy Unit 2005). This aim was reiterated in the 2010 National Health Service (NHS) White paper which stated, 'success should not be measured by speedy services but by the true outcome – whether the person gets back to optimal function – whether they are back at work. This means placing greater trust in the judgement of allied health professionals and empowering them' (National Health Service 2010). The government implies that returning people to work should be part of NHS provision. Importantly, OTs, as allied health professionals, have an important role to play in helping people do this (Barnes et al. 2009).

Prior to this, the British Society for Rehabilitation Medicine (BSRM) had commented that the NHS had largely lost the culture and skills of facilitating employment as a key element of effective health care (British Society of Rehabilitation Medicine 2003a). Possible reasons for that statement could be because NHS OTs predominately focus on facilitating hospital discharge, not

providing rehabilitation. Heavy workshops and hospital-based outpatient services have been lost, which was where VR was once delivered (Gladman et al. 2006). As a result, OTs have gradually become deskilled in delivering VR and lost potential training opportunities despite the fact that VR was once a founding principle of the profession (Barnes et al. 2006; 2007). However, TBI rehabilitation is an area where OTs continue to conduct VR (Coetzer 2008; Phillips et al. 2010; Playford et al. 2011).

As money for implementation did not follow the National Service Framework for Long Term Conditions, the number of services for people with TBI has not increased even though people with long term conditions remain a priority area for the NHS (Department of Health 2005; Darizi 2007; Nyein et al. 2007; Playford et al. 2011). However, contrary to their statements, the government is investing resources into the Department of Work and Pensions (DWP), rather than the NHS, to support people back to work due to sickness or disability. Subsequently, the DWP may be perceived by NHS commissioners to be the main provider of return to work services for people with disabilities and returning people with TBI to work is not considered a current NHS priority. Additionally, providing NHS based VR and helping people return to work, pay taxes and stop claiming benefits translate into savings for the DWP, not the NHS. Of the 600,000 new incapacity claimants per year, those with long term neurological conditions (including TBI) make up less than 10%, further supporting the assumption that work is not a 'health service' problem (Black 2008). As the majority of services and staff employed by the DWP are not specialist health professionals, they are unlikely to have the necessary knowledge to deal with the complexity of the few TBI people they see.

In summary, although the NHS White Paper states the NHS wants to support people in returning to work, the current practice does not appear to facilitate this.

2.8. Summary of TBI vocational rehabilitation

There is a consensus that TBI VR is beneficial and that it needs to be delivered by people with specialist knowledge, both of TBI and of VR. However, scarcity of provision in the UK, and a lack of robust evidence about its effectiveness suggest research is required before more services can be commissioned. Therefore, the purpose of this study was to determine whether specialist TBI VR delivers a higher rate of return to work compared to usual care, describe what specialist TBI VR consists of and ascertain whether it is cost effective to provide.

Chapter 3: Cohort Comparison Study

3.1. Introduction

The cohort comparison study compared the return to work rates of participants who received traumatic brain injury (TBI) vocational rehabilitation (VR) from an occupational therapist (OT), working independently or as part of a specialist TBI community team (specialist group), with participants who received usual care (usual care group), to ascertain any differences in return to work rates.

This chapter will describe usual and specialist intervention, the study method, results and discussion.

3.1.1. Usual Care pathway

As there is no standard pathway or routine access to rehabilitation following TBI in the UK, there is wide variation in provision of TBI interventions within both hospital and community services. Some areas provide little or no intervention. TBI patients are reliant on GP support and the voluntary sector such as Headway, if available. Others may have a variety of services including community rehabilitation services, which may or may not be a specialist neurological service and may or not include VR support. The advice given to patients can vary from simple signposting to detailed vocational interventions including re-training for those unable to return to an existing job (Tyerman. et al. 2008; Gibson et al. 2011; Playford et al. 2011).



3.1.2. Specialist pathway

There is little consensus regarding the content of specialist TBI rehabilitation. Wilson (2010) suggests due to the complexity of TBI, no one theoretical model or framework is sufficient to address all the problems encountered by people with TBI. Specifically, Wilson (2010) suggested that successful TBI rehabilitation depends on a combination of partnership working between patients, families and health professionals. She also states that it requires individualised goal setting, the recognition that cognition, emotional and social functioning are interlinked thereby requiring a holistic approach incorporating a wide variety of theories and models. In addition, for TBI VR, the use of: education, exploration of the barriers and enablers related to returning to work

and follow up when at work have been recommended (Wade et al. 1998; Paniak et al. 2000; Comper et al. 2005; Rasmussen et al. 2005; Turner-Stokes et al. 2005; Hart et al. 2006; Schonberger et al. 2006; Rubenson et al. 2007; Kissinger 2008; Varekamp et al. 2009). The few UK TBI multi-disciplinary teams who provide specialist VR appear to use a variety of approaches depending on patient need and the professional skill set available, and deliver it as a continuum of an overall rehabilitation programme (Powell et al. 2002; Coetzer 2008; Tyerman. et al. 2008; Phillips et al. 2010; Playford et al. 2011).

The aims, interventions and the role of the specialist OT in TBI rehabilitation and underpinning principles and theories at each stage are outlined in Table 7. This pathway is in line with findings from the literature review, the UK best practice guidelines on TBI, Cochrane recommendations and the National Service Framework (NSF) for Long Term Conditions (British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine et al. 2004; Department of Health 2005; Turner-Stokes et al. 2005; British Society of Rehabilitation Medicine 2010; Wilson 2010).

Table 7: TBI pathway (for specialist participants aiming to return to work)

Stage	Aim	Intervention	Role of OT	Principle or theory
Pre-injury variables e.g. age, occupation	n/a	n/a	Be aware of impact of pre-TBI situation on post-TBI situation	Evidence of predictors of RTW are inconclusive
Hospital treatment	Maximise medical recovery. Treatment aimed at ICF impairment and activity levels.	Stabilise medically Optimise recovery Assessment of physical, cognitive, emotional, behavioural related to home situation. For eligible patients, see NTBIS case manager	Assess and ensure safe discharge Advise not to return to work too early	Restoration - neuroplasticity (Kimberley et al. 2010)
 Post-hospital discharge – community intervention aimed at preparing for work	Maximise functional recovery. Treatment aimed at ICF activity and participation	Continued assessment and treatment of above factors by NTBIS for patient’s eligible for a service. Assess and treat impact of TBI on function and potential impact on work.	Make patient, family, employers and others aware of the potential impact of TBI on work ability and ways to cope. Explore barriers and facilitators that will assist with RTW Assess readiness for work. Liaison with others (Trexler et al. 2010)	Education Goal focused treatment Motivation Cognitive retraining (Cicerone et al. 2011) Task analysis Grading activity Compensatory strategies Fatigue management Anxiety management Self-awareness Adjustment Empowerment
 Work or alternative activity	Maximise participation	Assess work situation so employer aware of potential impact. Assist patient to cope at work and maintain life/work balance Continued support by NTBIS for eligible patients	Liaise with patient, employer and family about RTW Explore alternatives occupation if work is not an option	Education Self-awareness Self-efficacy Compensatory techniques Graded return to work Work modifications Acceptance and use of feedback

VR=VR, RTW= Return to work, ICF= International Classification of Functioning, QOL=quality of life, NTBIS=Nottingham Injury Service

3.1.3. TBI Return to work model

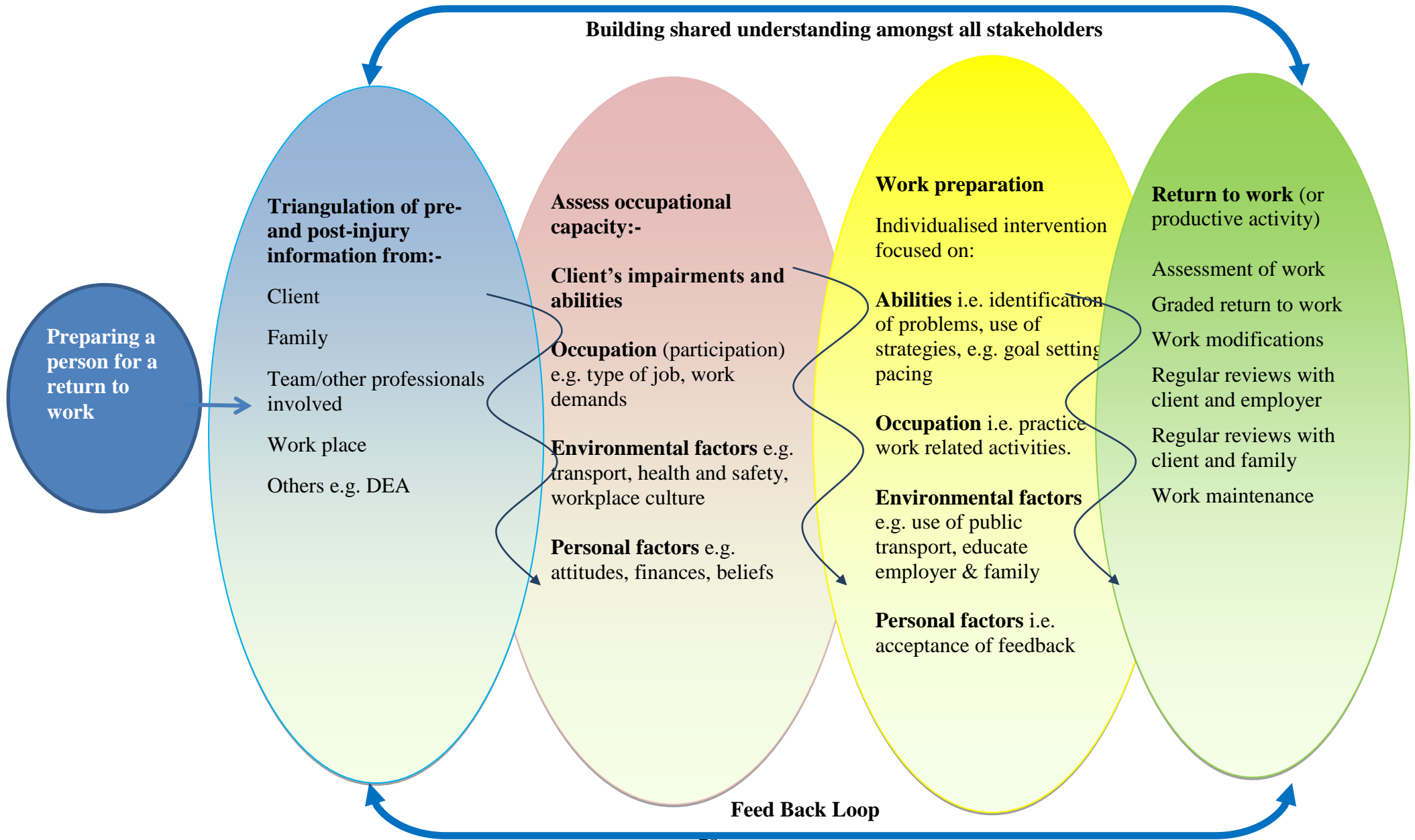
The aim of the study was to optimise return to work. Therefore, Table 7 was also informed by a conceptual model of factors specifically related to TBI employment (Ownsworth et al. 2004) and the TBI work readiness evaluation model (Stergiou-Kita et al. 2010) – see Appendix 1 and 2 for diagrams of the original models. Findings from the literature review suggest the work readiness model could be refined further for use with people with TBI who are returning to work and not just becoming work ready. This adapted model has been renamed ‘The TBI Return to work model’ - see Figure 3. The adaptations include:

- Re-naming the first section ‘triangulation of information’. A qualitative study of 20 OT’s involved in return to work after TBI, found that OT’s used information from a wide variety of sources such as patients, families, the work place, other team members, formal assessments and functional activities to construct an accurate picture of a person’s work capacity. They called this information gathering ‘triangulation’ (Bootes et al. 2002).
- Adding personal, environment and contextual factors to the ‘assessing occupational capacity’ section.
- Changing the conceptualisation phase to a return to work phase.
- Finally, as information from a variety of sources such as family and employers is utilised on an on-going basis to assist with job maintenance, a feedback loop was added.

The TBI Return to work model sums up diagrammatically the specialist intervention provided in this study.

Figure 3: The TBI Return to Work model

Adapted from the work readiness evaluation model (Stergiou-Kita et al. 2010)



The pathway described in Table 7 and the TBI Return to work model describe the intervention provided by the Nottingham Traumatic Brain Injury Service (NTBIS). The NTBIS was a NHS TBI multi-disciplinary community team that included an OT specialising in VR for people with moderate and severe TBI. The majority of people with TBI outside the NTBIS catchment area did not have access to such a team. Despite being concordant with best practice guidelines and being delivered in the NHS, no evidence was found in the literature review that examined the effectiveness of specialist OT VR intervention delivered as part of a NHS community team (or individually) or whether it was more effective compared to any other care. This regional variation enabled a cohort comparison study that would facilitate comparison of return to work rates between people who had access to this specialist service and those who did not.

3.2. Method

3.2.1. Research design

A pilot cohort comparison study design was chosen for two main reasons: the documented difficulties in conducting TBI RCTs (Semlyen et al. 1998; Dickinson et al. 2000; Whyte 2002; Teasell et al. 2007) and regional differences in service provision which facilitated the comparison of specialist intervention with usual care.

A systematic review of 275 rehabilitation based intervention studies of ABI found only 76 (28%) were RCTs (Teasell et al. 2007). This suggests conducting RCTs in a TBI population is possible, but problematic. Problems include difficulty randomising patients where well established patterns of provision exist. As there are usually no alternatives to existing services, removing the opportunity to be treated would be considered unethical (Powell et al. 2002a; Turner-Stokes et al. 2005). Secondly, delaying treatment for research purposes when it is assumed that early intervention may affect the outcome could also be considered unethical especially in younger patients who may have the ability to resume a productive life (McCull 2007; Teasell et al. 2007). Finally, many services do not have the large numbers of patients required for an adequately powered RCT within research funding time limits (Vanderploeg et al. 2008). These problems have resulted in very few UK based RCTs of TBI interventions (Wade et al. 1998; Powell et al. 2002).

Whilst there is some evidence that factors such as more severe injury, less than 40 years old, receiving VR, lower educational level and married are predictive of employment post TBI, the evidence is equivocal (See 2.4.3. Predicting employment after TBI). This ambivalent evidence is insufficient to justify using these factors as the basis for matching cases in a controlled trial (Ownsworth et al. 2004; Willemse-van Son et al. 2007; van Velzen et al. 2009a). Thus, studies of rehabilitation following TBI frequently use alternative research designs, such as: single centre studies (Franulic et al. 2004); single cohort pre-post- intervention evaluations (Wehman et al. 2003; Malec et al. 2006; Murphy et al. 2006; Walker et al. 2006) It has been suggested that

observational studies are a good substitute when RCTs are not possible or there may be differences in treatment but not large numbers of patients (Black 1996; Whyte 2002; McColl 2007).

As it is acceptable to use ‘usual treatment’ as opposed to ‘placebo’ in trials, the regional differences in services available to people with TBI in Nottinghamshire and surrounding areas enabled a cohort comparison study to be undertaken (Medical Research Council 2006). People with a TBI living within the city and south Nottinghamshire, with a Nottingham GP were eligible for treatment from the Nottingham Traumatic Brain Injury Service (NTBIS), which had dedicated VR OT input. Whereas the majority of people with TBI living in other parts of the region had no access to a specialist TBI team with dedicated VR OT input.

Thus due to the above considerations, a cohort comparison design was chosen.

3.2.1.1. Ethics and Research & Development approval

Ethical approval was obtained from the Nottingham Research Ethics Committee 2 on 27.11.2006 (REC reference number 06/Q24004/138). Research and Development approval was obtained from the following trusts: Sherwood Forest Hospital Trust on 13.12.2006 (Reference R&D 98), Nottingham University Hospitals Trust on 3.1.2006 (Reference 06OT002), Nottinghamshire County PCT on 28.3.2006 (no reference number given), United Lincolnshire Hospitals on 20.1.2006 (Reference number 020407Radford).

3.2.2. Participants

3.2.2.1. Identification of participants

People admitted to the following medical centres between January 07 and October 08 were asked to participate in the study (a 22 month period):-

- The neurology, neurosurgical and the emergency admission ward (D10, D11, C25) at Queens Medical Centre, Nottingham (QMC). QMC was a regional neurosurgical centre that treated the majority of moderate and

severe TBI patients from the East Midlands. It covered a regional population of 2.25 million and the local Nottingham population of 630,000 (Deanery 2008).

- Linden Lodge, City Hospital, Nottingham, was an inpatient neuro-rehabilitation unit. It covered a population of 630,000 (Deanery 2008).
- Two emergency wards (D8 and D9) and the neurology ward at Kings Mill Hospital, Sutton in Ashfield (a District General Hospital) and Chatsworth Unit, Mansfield (an inpatient rehabilitation unit). Together, they covered a population of approximately 300,000 (Deanery 2008).
- Ashby ward, Lincoln County Hospital, an inpatient neurological rehabilitation ward, population covered approximately 680,000 (ULH.NHS.Trust 2008).

3.2.2.2. Inclusion and exclusion criteria

Participants were included if:

- The reason for the current hospital admission was a documented TBI (For definition of TBI –see 1.2.)
- They required ≥ 48 hours hospitalization due to their TBI.
This was intended to exclude patients with alcohol/drug induced confusion and is in line with recommendations which state that any TBI patient still in hospital after 48 hours with impaired consciousness or mobility should be assessed by a specialist rehabilitation team (British Society of Rehabilitation Medicine et al. 2003).
- They were aged 16 or over
(the age when people can start work).
- Were in or intending to be in paid or voluntary work or education immediately prior to their injury.
Students and voluntary workers were included as Johnson et al. (2006) suggested that it was not necessary to treat work or education as separate entities as they represented the same broad functional dimension. Wagner et al. (2002) also suggested that return to productive activities was a broad outcome involving both work and education. Voluntary work was included as this was deemed to be as

important to many people as paid work and has an indirect social cost to the economy.

- Able to give informed consent

People were excluded if there was documented evidence in the medical notes of:

- Current mental health problems or due to receive mental health services.
- Current drug or alcohol problems or due to receive drug or alcohol services.

Both factors are known to negatively affect a person's ability to work pre-injury and are frequently cited as exclusion criterion in return to work studies following TBI (McCrimmon et al. 2006; Walker et al. 2006).

People were excluded if they:

- Lived more than one hour travelling time from Nottingham due to practical considerations of time and cost involved in carrying out the initial visit.
- Were deemed unable to give consent by ward staff who knew them.
- Did not intend to return to any form of productive activity

3.2.3. Procedure

3.2.3.1 Recruitment

To facilitate recruitment at the start of the study, presentations were given in each centre explaining the purpose of the study. As no TBI registers existed in any of the medical centres, twice weekly telephone or personal contact was maintained with recruiting centres to ensure comprehensive identification of eligible participants. Additionally, weekly emails were sent to staff who had access to potential participants.

Whilst in hospital, potential participants were identified by ward staff and given information about the study and a letter inviting them to participate. Where possible, those expressing an interest were seen on the ward by the research OT (JP) who explained the study, answered any questions and

arranged further contact if the participant expressed an interest in taking part. A home visit was arranged to obtain baseline data four weeks post-hospital discharge (+/- 5 days). The home visit was arranged at the convenience of the participant and confirmed both in writing and by telephone nearer the date of the visit. Potential participants discharged home before being seen by the research OT on the ward were sent written information about the study and an invitation to participate.

3.2.3.2. Collecting demographic, baseline and follow up data

The research OT visited potential participants at home four weeks after hospital discharge. This time point had been used as a baseline point in another TBI study (Johnston et al. 2005). This was considered enough time to allow participants to recover sufficiently, especially cognitively, to be able to make an informed decision about whether or not to participate. It was also felt to be more appropriate to start discussing work when a person was at home rather than at a set time point as TBI patients may be in post-traumatic confusion whilst in hospital. This time point was deemed early enough to see most people before they returned to work. It was also consistent with existing clinical practice, the point at which the NTBIS OT could become involved. During the home visit, the study was explained, written consent obtained and baseline data collected - see Appendix 3: Participant pre-injury form, Appendix 4: Participant questionnaire. Data collected included injury severity, cause of injury, length of hospital stay, age, educational level, marital status, pre-injury functioning including type of job and driving status as these were factors identified in the literature associated with return to work (Ownsworth et al. 2004)– see 2.4.3. The secondary outcome measures were also completed –see 3.2.4. The Carers version of the Brain Injury Outcome Scales (BICRO) was completed during the visit if the participant agreed and named a person to complete it. The form was left for the participant's carer to complete and return if they were not present at the visit. A stamped addressed envelope was provided. Participants' general practitioners were informed by letter.

3.2.3.3. Intervention

The Nottingham Traumatic Brain Injury Service (NTBIS) was a specialist TBI case management community team (NTBIS) funded by the National Health Service (NHS). It treated people who had a moderate or severe TBI (Glasgow Coma Score [GCS] score ≤ 12 for 30 minutes or more) and who were under the care of a Nottingham based GP. The team consisted of three case managers (two whole time equivalents [w.t.e]), with professional backgrounds in OT, Social Work and intensive care nursing. The social work case manager post was jointly funded with Social Services. When possible, case managers aimed to see the client and family within ten days of referral. This meant patients and family were seen in hospital and/or at home within ten days of hospital discharge, if possible. Case managers co-ordinated the patient's care and involved other team members as appropriate. They also provided support, education and advice to the client, the family and others who may be involved with the patient's care. In addition, case managers offered individual support to the family/carers. The remaining NTBIS team members were:

- a Cognitive Behavioural Therapist (0.75 w.t.e) who saw clients on an individual basis for cognitive behavioural therapy, anger management, adjustment issues and psychiatric problems
- a Neuro-Psychologist (0.5 w.t.e) who saw clients on an individual basis for neuropsychological assessment and treatment
- an OT (0.6 w.t.e). who specialised in VR
- a full time administrator

Most of the team members were experienced, having been in the team for more than ten years. The post of the neuro-psychologist was vacant for the first year of the study. Clients were seen by individual team members as often as necessary within the limitations of staffing levels and varied depending on patients' individual needs. For example, if there was a specific goal, contact could be weekly for a set number of sessions or every eight weeks or longer if the situation was stable. The team members worked closely together to provide co-ordinated treatment, which was focused around the patients (and families) own goals, return to work was just one possible aspect. All team members shared the same office and clients received regular progress reviews.

Groups were run for clients when needed, but were not a routine part of the service.

The NTBIS remained in contact with patients and families whilst there were achievable rehabilitation goals. This ranged from a minimum of one appointment (if no goals were identified or client declined the service) to several years. Appointments from team members generally lasted one hour and patients and/or family were seen in the most appropriate place to meet their needs, such as the hospital, home, work or community. Most of the treatment occurred in participant's homes so family were frequently present. Once discharged, clients could refer themselves back to the service within a year. After that, a GP referral was required.

Inclusion in this study did not alter the content or amount of treatment participants received by the NTBIS. In order to reduce bias, the research OT, (who was also the treating OT), or NTBIS staff did not take part in collecting data, remind clients to send back questionnaires, help clients fill in questionnaires or refer to the study whilst treating participants. Information was sent out in the name of the principal investigator who was unknown to the clients and collected by independent assessors.

Participants with minor TBI (GCS 13 or more) were not eligible for treatment by the specialist team due to NHS funding criteria. They were offered OT targeted at returning to work, in addition to any other services received. They received intervention from the research OT in the community at a location of their choice. No other NHS treatments were routinely offered.

All specialist group participants were treated by the same OT. Treatment was provided through interview, discussion, exploration of options with participant and family and structured planning of activities so they could be carried out in the home, community or at work. Activities were reviewed and altered as necessary.

The specific role of the OT was based on current guidelines and best evidence (British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine et al. 2004; Department of Health 2005; Turner-Stokes et al. 2005). The role consisted of:

- Assessing the impact of TBI on the participant, family and their roles such as a worker or student.
- Educating participants and families about the effects of TBI and how this affects work or education. Exploring and practising acceptable strategies to lessen the impact of the effects of TBI, for example, use of memory aids, pacing techniques.
- Community reintegration training, for example, in the use of transport, increasing confidence to leisure activities.
- Planning and grading a vocational targeted programme. This could include helping participants get a structured routine that gradually increased activity and included opportunity for practicing specific skills in preparation for work such as the use of computers to increase concentration, cooking to practice multi-tasking.
- Liaison with employers, tutors or disability employment advisors (DEAs) to advise about the effects of TBI, find out what the participant needed to do to prepare for work, to plan, monitor and adapt a graded return to work as necessary. Once a participant had achieved their maximum ability at work, the work situation was monitored for as long as the participant and employer felt necessary.
- Find an alternative activity if work was not possible, available or desirable.

Participants who felt no treatment was required were given advice in the presence of a partner/family member where possible. Participants were given:-

- An information leaflet about minor brain injury produced by Headway, the national brain injury association (Headway: the brain injury association 2010)
- Verbal information about common problems experienced after TBI and how these might impact on their job.

- Advice to mimic the work they needed to do before returning to work so they could self-assess their abilities.
- Advice to contact their General Practitioner (GP) and Department Vehicle Licensing Authority for guidance on work and driving.
- Advice to inform their employers about their injury. They were also recommended to return part time and build up hours and tasks gradually.
- An open appointment to refer themselves back to OT.

Participants outside the NTBIS catchment area continued to receive usual care. Local differences in TBI service provision meant intervention for people with TBI varied throughout the region. Based on information obtained from telephone contact with the recruiting sites prior to the study commencing, it was anticipated that usual care participants would be discharged from hospital without rehabilitation follow up and would not routinely access general or specialist community rehabilitation services. Participants would have access to support from their GP.

The exception was for usual care participants living in Derby and Leicester. In Derby, TBI services existed but adopted a different model of service delivery. The Derby team had a TBI case manager, an OT and a physiotherapist but no cognitive behavioural therapist. They ran more groups compared to NTBIS. Derby TBI service wrote to clients admitted to Derby hospitals and invited them to contact the Derby Head Injury team if they required support. It was not known whether participants admitted to the regional neuro-surgical unit in Nottingham would be identified by the team. In Leicester, Headway house, provided support with limited input from an OT and physiotherapist. Clients either self-referred or were referred by their GP.

3.2.4. Outcome Measurement

A lack of consensus about which standardised tools to use to capture the effect of specialist vocational focused OT for people with TBI made selecting appropriate measures problematic (Salter et al. 2008; Bernabeu et al. 2009; Fadyl et al. 2009; van Velzen et al. 2009a). For example, a systematic review of 14 cohort studies examining activity or participation between 1995 - 2005 identified 20 different outcome measures (Willemse-van Son et al. 2007). Thus, specific questions had to be developed for the purpose of this study even though it was recognised that this would limit comparison of the findings to other research.

Therefore, outcomes chosen for this study were:

Primary outcome

- Return to paid or voluntary employment or full time education.

Secondary outcomes

- Function measured by the Brain Injury Community Rehabilitation Outcomes Scale, including the Carers BICRO (BICRO) (Powell et al. 1998)
- Mood measured by the Hospital and Depression Scale (HADS) (Zigmond et al. 1983)
- Quality of life measured by the EQ5D (Kind et al. 1999)

Factors which may affect return to work

- Such as injury severity, type of work; returning to same employer
- Rehabilitation factors such as services received, work place modifications
- Personal and environmental factors such as reasons for returning to work, supportive employers, claiming compensation.

These outcomes will now be discussed separately.

3.2.4.1. Primary outcomes: Return to work, education and voluntary work

The primary outcome of a return to paid or voluntary employment or full time education was operationalised as:

- A return to paid or voluntary work of at least one hour a week or more. This was defined as a participant stating they did more than one hour paid work on the BICRO scale – see 3.2.4.2.
- A return to full time education of more than five hours a week. Five to ten hours was chosen as many UK final year courses have low contact time, meaning participants could have five to ten hours a week contact time but still be classed as full time. Time spent in education was recorded on the BICRO scale.
- Voluntary work was ascertained by the participant ticking they did voluntary work and/or stating they did more than one hour a week voluntary work on the BICRO scale.

Participants were asked to tick ‘yes’ or no’ to the question ‘are you now in work or education?’ - see Appendix 4: Participant Questionnaire. As it was recognised that the questionnaire needed to be brief because of potential cognitive impairment, these definitions were not included in the participant questionnaire (van Baalen et al. 2006).

3.2.4.2. Secondary outcomes:

The secondary outcomes were: function, mood and quality of life.

Function: Brain Injury Community Rehabilitation Outcome (BICRO) scales

The BICRO scale is a self-report measure of function and participation (Powell et al. 1998). This 39 item questionnaire seeks to determine the level of help required in six domains: personal care, mobility, self-organisation, socialising, productive employment and psychological well-being. The six response categories are: ‘don’t do at all’, ‘constant help’, ‘a lot of help’, ‘some help’, ‘prompts only’ and ‘no help’ - See Appendix 3.

The BICRO scales were used in an RCT of community rehabilitation for TBI in the UK (Powell et al. 2002). In that study, two subscales (comprising a total

of five questions) from the original 39 questions were omitted. These were frequency of contact with parents/siblings and frequency of contact with partner and own children. These were omitted because the scale was not unidimensional; changes in both directions could be positive or negative. For example, seeing less of a partner could be positive if it meant the person was safe to be left alone and the partner could return to work. Equally, it could be perceived as negative if both patient and carer chose to be in separate rooms due to increased irritability. These questions were omitted for this study for the same reason. Therefore, six sections were used covering 34 items.

The BICRO scales were chosen because they were one of the recommended outcome measures of community rehabilitation for TBI in a systematic review of community integration measures (Reistetter et al. 2005). They were also recommended in the British Society of Rehabilitation Medicine (BRSM) ‘basket of measures’ for use in rehabilitation as an extended measure of activities of daily living (British Society of Rehabilitation Medicine 2000a). Additionally, Powell et al (2002), found them to be sensitive to change produced by the intervention. The BICRO scales were designed specifically for people with neurological problems, their carers and measure productive activity (as ‘paid work, unpaid or voluntary work, studying and childcare’). The BICRO also captured functional ability and some aspects of instrumental activities of daily living (ADL) negating the need for a separate measure. Additionally, they enabled comparisons to be made between a person’s pre and post-injury ability and carers’ perspective which are important in measures of TBI community outcomes (Hall et al. 2001). In the Carers version, the questions are identical to the participants questions but the wording is directed to the carer – see Appendix 3: Participant pre-injury form for copy of the BICRO.

The BICRO scales were validated on 235 patients (TBI n =127, stroke n=72, multiple sclerosis n=15, acquired brain injury n=21) for reliability and validity (Powell et al. 1998). The reliability tests showed statistically significant test–retest reliability for all sub scales pre-injury (except personal care), post-injury and carer post- injury. There were highly significant correlations ($p<0.001$) of

scores between patient and carers except on the socialising and productive employment sub scales where agreement levels were $\leq r_s=0.60$. The internal consistency for the sub scales of personal care, mobility, self-organisation and psychological well-being were high with Cronbach's alpha $\geq \alpha =0.88$. However the internal consistency for the sub scales of socialising ($\alpha =0.67$) and productive employment ($\alpha =0.30$) were low, suggesting that these sub scales were not reliable. As there was a participant-reported measure of employment in the study and socialising was not the focus of the study, the BICRO was still believed to be the most appropriate. A fuller description of this measure and justification for use is detailed in Appendix 5.

The literature review undertaken for this study and a systematic review (Reistetter et al. 2005) also highlighted the Community Integration Questionnaire (CIQ) (Willer et al. 1994), the Craig Handicap Assessment and Reporting Technique (CHART) (Whiteneck et al. 1992) and the European Brain injury Questionnaire (EBIQ) (Teasdale et al. 1997; Avesani et al. 2005) as potential measures of participation for TBI studies –see Appendix 5 for a comparison of these measures including details of their psychometric properties. These measures were not chosen for the following reasons:-

- The BICRO captured a broader range of activities compared to the CIQ. For example, the BICRO included a self-care and psychological well-being section which the CIQ does not (Reistetter et al. 2005).
- The CHART was originally designed for the people with spinal injuries. Some of the questions are lengthy, potentially making it difficult for people with cognitive problems to understand. As this study used a postal questionnaire, this was an important consideration.
- The CIQ and CHART do not have pre-injury comparisons or allow for the carers perspective to be considered. Additionally, both the CIQ and the CHART have been shown to have ceiling effects (Hall et al. 2001; Salter et al. 2008).
- The EBIQ consists of 68 items compared with 34 items in the BICRO. As the study questionnaire booklet was already lengthy, brevity was an important consideration.

Mood: Hospital and Anxiety Depression Scale (HADS)

A link between depression, anxiety and employment for people with other health conditions such as stroke and back pain has been established (Glozier et al. 2008; Waddell et al. 2008), but for people with TBI the relationship is unclear. Therefore, a tool to capture mood was included to ascertain if there was an association between depression, anxiety and work after TBI. The Hospital and Anxiety Depression Scale (HADS) is a self-report measure of seven symptoms of depression and anxiety (Zigmond et al. 1983) – see Appendix 4: Participant questionnaire, section 3.

The reliability and validity of the HADS as a screening tool for depression and anxiety has been well established for a variety of different medical conditions (Bjelland et al. 2002). The HADS is also quick and simple to complete and can be administered by post. Studies have also recommended its use in a brain injured English speaking population but recommend caution when interpreting some responses (Dawkins et al. 2006; Whelan-Goodinson et al. 2009). For example, Dawkins et al. (2006) found that the question ‘I have lost interest in my appearance’ did not load on to a depression factor in a principle component analysis. They suggested that reduced loss of interest could be due to frontal lobe damage in TBI patients as opposed to depression.

Despite the need for caution in interpretation, the HADS is widely used for people with TBI and thus offered the opportunity for comparison with other TBI studies. It was used in the only RCT study of community TBI rehabilitation in the UK (Powell et al. 2002). It is also recommended for use in rehabilitation studies by the British Society of Rehabilitation Medicine (British Society of Rehabilitation Medicine 2000a), in the Cochrane report on rehabilitation for brain injury (Turner-Stokes et al. 2005) and has been used in many other studies of TBI rehabilitation (Ownsworth et al. 2006; Skinner et al. 2006; Svendsen et al. 2006).

Each item on the HADs is rated 0 to 3, where 0 = No symptoms and three indicates a higher symptom frequency or distress. In this study, scores on HADS of seven or below were considered within the normal range, scores

between eight and ten borderline and scores 11 or above indicated caseness. These cut-off scores are the most frequently recommended for both depression and anxiety to obtain the optimal balance for sensitivity and specificity (Zigmond et al. 1983; Wade 1995; Bjelland et al. 2002; Bowling 2002).

Health Related Quality of Life: EQ5D

The EQ5D is a standardized, non-disease specific instrument for describing and valuing health states. It is widely used across Europe and commonly used in economic evaluation (Brazier et al. 2004). Respondents are required to tick whether they have ‘no problems’, ‘some problems’ or ‘severe problems’ or ‘unable to’ on a given day, in five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. These combine to form 243 health states. Dolan et al. (1995) valued 45 of these states using time-trade off and visual analogue techniques in a representative sample of 3,395 people in the UK. Using regression models they were able to attach utility weights to all health states, this set of values is known as the York A1 Tariff which allows comparison with other economic evaluation studies. In part two of the EQ5D, participants are required to mark on a visual analogue scale (VAS) their state of health with 0 being the worst state imaginable and 100 the best state imaginable. The SF-6D is an alternative, but longer measure (Brazier et al. 2004).

The EQ5D (Kind et al. 1999) was selected for use in this study as it is the health-related quality of life instrument recommended by National Institute for Health and Clinical Excellence (NICE) (National Institute for Health and Clinical Excellence 2007). It enables a cost utility analysis to be undertaken and compared to other cost utility analyses for other health interventions so that value for money assessments can be made. It is short, simple and can be administered by post.

3.2.4.3. Factors which may affect return to work

Additional questions were developed to capture potential changes in employment status and services received. These questions were based on unpublished work by Hart (2006) in a study of treatment and service models

across 16 TBI medical centres in the US delivering VR, advice from an VR expert advisor to the study (AT) and a critical review of 50 studies which examined the effect of various factors on employment outcome (Ownsworth et al. 2004). Whether someone had returned to the same employer or same job was asked because improved return to work rates have been associated with people returning to the same employer or job category (Ownsworth et al. 2004; Walker et al. 2006). Also, activity status other than work was requested as it was hypothesised that treatment from the OT may increase a participant's participation in other activities if return to work was not achieved.

For this study, job categories were based on the Standard Occupational Classification 2000 (SOCv2000), a coding index for 26,000 jobs (Office for National Statistics 2008). Although the SOCv2000 code classifies jobs into nine categories, it also describes four skill levels (SOC2000 vol 1, v5 page 6). The four skill levels were felt to be more appropriate for the numbers involved in this study. They were:

- Level 1: elementary trades such as plant and storage occupations, elementary administration and service occupations.
- Level 2: administrative, secretarial, personal caring, sales, leisure, customer services, process, plant and machine operatives
- Level 3: health and social welfare professions, managers and proprietors in agriculture and services, science and technology associated professionals, cultural, media and sport occupations
- Level 4: Corporate managers, science, technology, health professionals, teaching and research professions

When using SOC, students were classified according to what they would be when they completed their studies (SOC2000v2 section 3 p xiii). Therefore in this study, students on a course with a clear vocational outcome were classified according to the SOC codes. If there was no clear vocational outcome, students were classified as level 3.

Questions to capture the effects of the intervention included asking whether a participant undertook a graded return to work and whether any work

modifications were undertaken as these are recommended as good practice in TBI VR (British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine et al. 2004) . For example, any reduced work load or responsibility, increased frequency of breaks, more supervision, availability of home working and involvement of other agencies such as occupational health (OH), Disability Employment Advisors (DEAs). As there was no formal definition of what constituted a ‘graded return’, this was defined as how long a participant worked part time hours before resuming their previous hours.

Frequencies of visits to solicitors were included as they can be closely involved with patients who claim compensation.

Personal and Environmental factors

Personal factors included asking about relationship status as the evidence is inconclusive as to whether being married is predictive of employment and how supportive they felt their employers were as employer support has been suggested as worthy of further investigation (Ownsworth et al. 2004; van Velzen et al. 2009a). Also, willingness to publicly own up to problems is believed to be part of acceptance and been found to correlate to successful employment outcomes (Holzberg 2001). Therefore, participants were asked if they had informed their employer about their TBI. Additionally, participants’ perceptions of whether or not they had received adequate care since hospital discharge were examined as it was not known what treatment the usual care would receive or how useful participants would find the specialist intervention.

Environmental factors included driving status as studies suggest people who resume driving were more likely to return to work (Catalano et al. 2006; Klonoff et al. 2006). Participants were also asked whether they were pursuing a compensation claim as this has been investigated in relation to employment outcomes (Deutsch et al. 2006).

3.2.5. Data collection

In total, 32 questions were used to capture the primary and economic outcomes. Participants were asked to reply yes, no or not applicable. The secondary measures: BICRO, HADS and EQ5D, were incorporated into the study questionnaire booklet which was posted to participants at 3, 6, 12 and 18 months after baseline - see Appendix 4.

Given the documented difficulty with loss to follow up in TBI research (Corrigan et al. 2003; Willemse-van Son et al. 2007), postal reminders were sent two weeks after the initial questionnaires were sent out. Non-respondents were telephoned by a researcher blind to the group allocation. The researcher offered assistance to complete questionnaires over the phone. In these cases, the primary outcome was obtained with as much additional data as the participant was willing to give during a phone call. The questionnaire was too long to be fully completed by phone by the majority of participants. If the questionnaire was returned with incomplete or missing information, the participant was telephoned by the independent researcher to obtain the missing information where possible. To ensure equity of information collected between groups, information entered onto SPSS was from the questionnaires and phone calls, not from NHS records as these were only available for participants in the specialist group.

The use of postal questionnaires and telephone follow up was dictated by cost and time available. They have been used in other studies to collect similar information (Thornhill et al. 2000; Wagner et al. 2002; Walker et al. 2006). To facilitate blinding, participants' questionnaires were identified by a unique study number when entered onto SPSS. At each time point (pre-injury, baseline, 3,6,12 and 18 months), all of the primary outcome (return to work) and a random selection of 20% of questionnaires were checked by an independent assessor.

3.2.4. Data Analysis

Participants in each group were analysed as a whole regardless of severity of injury. For primary outcomes and factors related to returning to work, namely time taken to return to work, undertaking a graded return to work, work place modifications and feeling recovered, the groups were sub-divided based on injury severity (minor TBI and moderate/severe TBI) to determine whether injury severity impacted on return to work. This is in line with other studies where people with minor TBI and those with moderate/severe TBI are treated as separate groups. It was assumed those with minor TBI would be less likely to have problems compared to those with moderate/severe TBI and therefore less likely to require intervention (Turner-Stokes et al. 2005). An intention to treat analysis was conducted.

Primary outcomes, secondary outcomes and factors associated with work were compared at 3, 6 12 and 18 months. Frequencies were used to compare the two groups for:

- Primary outcome: returned to work or not
- Secondary outcomes: BICRO, HADS and EQ5D
- Factors related to return to work

For categorical and nominal data, odds ratios with 95% confidence intervals (CI) were used. A 95% confidence interval states that 95% of a sample mean (\bar{x}) would lie within 1.96 standard errors above or below the population mean, since 1.96 is the two-sided point of the standard normal distribution.

Confidence intervals were deemed statistically significant at $p \leq 0.05$ if the null hypothesis value of zero was not included in the range. For example, a 95% confidence interval of (CI 1.2, 4.5) was deemed statistically significant as the figures are both positive, but a CI of (-0.5, 0.5) was not considered statistically significant as the value of zero is included (Kirkwood et al. 2003).

As secondary outcome measures were standardised, they were tested for statistically significant differences. For parametric data, means with paired t tests were used when data were normally distributed. Levene's test of equality

of variances was observed. When data was not normally distributed, or non-parametric, Mann-Whitney U tests were used. For categorical data, Chi squared (χ^2) was used, applied to numbers, not percentages and deemed valid when:

- The overall total numbers in the table was ≥ 40 regardless of the expected value
- The overall total was between 20 and 40 provided all the expected values were at least five.
- For 2x2 tables, Fischer's exact test was used when the overall total of the table was < 20 or the overall total of the table was between 20 and 40 and the smallest of the four expected numbers was less than five.
- For tables greater than 2x2, Chi squared was deemed valid when less than 20% of the expected numbers were less than five and none less than one. Fischer's exact test was used as above.

(Kirkwood et al. 2003).

BICRO scores were analysed by summing responses in each category and dividing by the number of responses in each sub scale. This gave a mean score for each category.

Logistic regression was used to determine the association between the binary outcome of return to work (yes or no) and exposure variables associated with predicting return to work. Variables identified as predictors of return to work in the literature review were considered for the model.

Intra class correlation coefficients (ICC) were used to measure the level of agreement between the participants and carers scores on the BICRO. A two way random effects model was used where both people effects and the measures effects were random. The average measure was recorded.

Missing data was examined using SPSS. As data was missing at random, no missing values were replaced Data was analysed using SPSS version 16.

3.2.4.1. Number of participants required

An estimate of how many people could be recruited was undertaken. NTBIS treats 35-40 people per year of whom 28 were anticipated to fit the inclusion criteria. It was estimated that 42 people would be available for recruitment over an 18 months period. Allowing 25% for non-consent and attrition, we aimed to recruit 32 people per group over 18 months, 64 participants. It was not known how many controls would be recruited, as there were no TBI registers at any of the medical centres involved in the study. Contact with hospitals outside the NTBIS catchment area suggested they did receive many TBI patients, but they could not even supply estimated numbers.

3.3. Results

The results are presented in three parts: 1) feasibility of undertaking the cohort comparison study, 2) baseline demographics and 3) group comparisons.

3.3.1. Practical considerations found when conducting the study

3.3.1.1 Recruitment

Recruitment was planned from January 2007 to April 2008 (18 months), but due to higher than anticipated non-consent and attrition rates, recruitment was extended to October 2008 (22 months). Overall, 382 potential participants were identified of whom 130 (34.03%) met the inclusion criteria.

The most frequent reason for exclusion was that the person was not working – see Table 8. Consent was not obtainable for 31 patients who were either too confused and/or transferred to outlying hospitals or where ward staff reported the patient was unable to consent.

Table 8: Reasons for exclusion

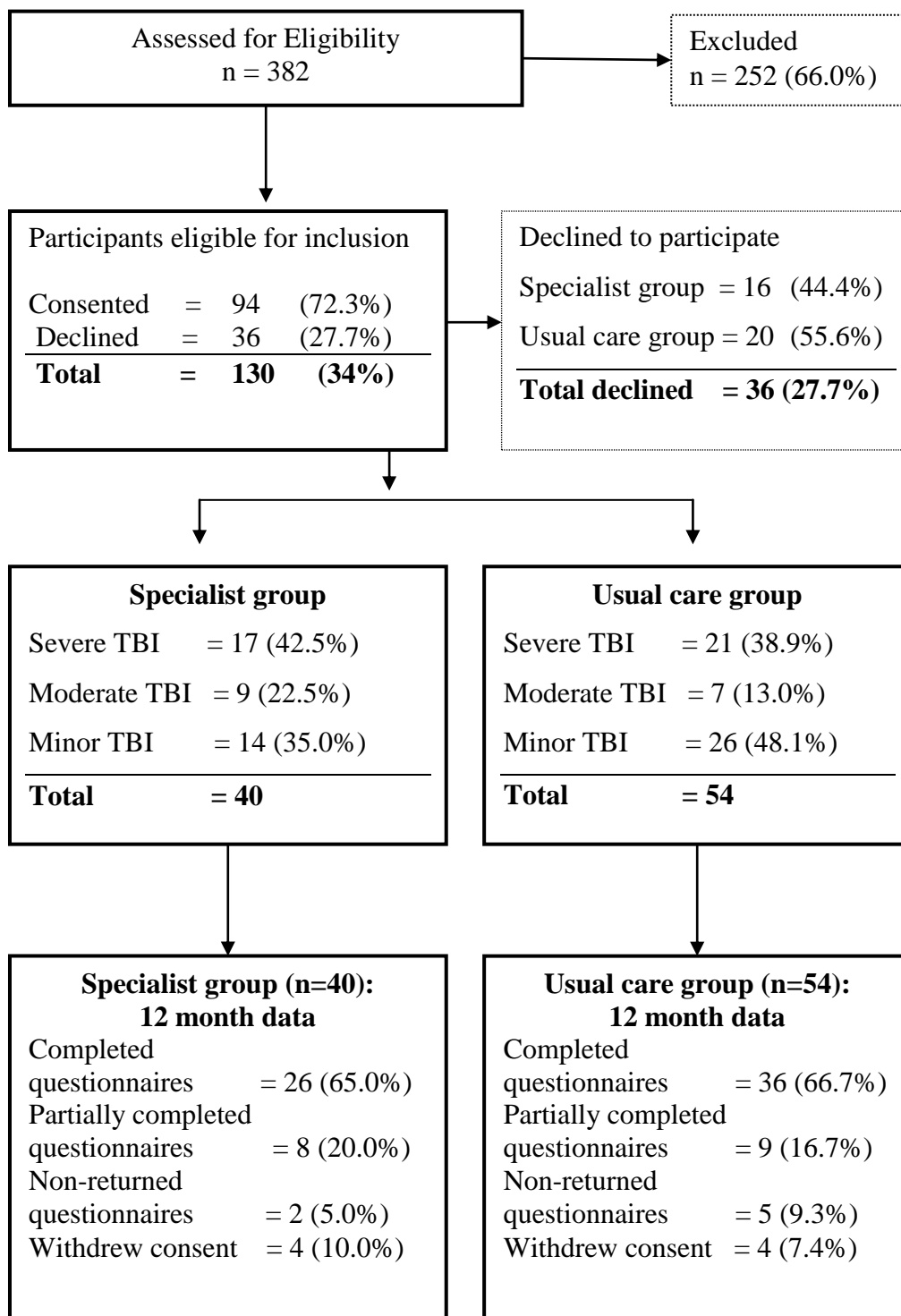
Reason for exclusion	Numbers
Not in paid or voluntary work or education prior to injury (includes 39 who were retired)	83
Admitted for less than 48 hours	43
Unable to consent	31
Lived more than one hours traveling time from Nottingham	25
Current alcohol or drug problems	23
Admission not due to traumatic or new brain injury ¹	11
Current mental health problems	9
Died	5
Did not want to return to productive activity	1
Unable to recruit ²	21
Total	252

¹ Reasons for admission included: anoxia (1), tumour (1), sub arachnoid haemorrhage (1), no clear documented TBI (4), suicide attempt (1), current admission not related to a new TBI (3)

² Of these 21 participants, 12 were discharged before their eligibility could be ascertained, 5 were in outlying hospitals and discharged whilst waiting R&D approval which took 4 months to obtain for all outlying areas, 2 participants self-discharged and 2 were still in patients when recruitment ended.

Of those eligible for inclusion, 94 consented to participate: 40 in the specialist group and 54 in the usual care group—see Figure 4.

Figure 4: Flow Chart of Participants



Reasons for non-participation

Of the 130 people who met the inclusion criteria, 36 (27.7%) did not participate in the study –see Table 9. Of these 36 people, 10 could not be contacted after hospital discharge. Of the remaining 26 people, reasons for declining included being back at work (n=6), feeling too unwell to participate (n=6), no reason given (n=5) and refusing consent (n=9). Some reasons for refusing consent included, people with multiple injuries who felt they did not have problems related to a TBI (n=4) and wanting to forget the accident had happened (n=1). Approximately equal proportions declined who were eligible for the specialist group 20 (56%) and the usual care group 16 (44%).

Eleven potential participants were not seen by the research OT whilst in hospital. Of these, nine declined to participate.

Table 9: Reasons for declining to participate

Reasons for non-consent	Specialist group		Usual care group	
	n=16	%	n=20	%
Unable to contact after discharge	5	31.3	5	25.0
Refused consent*	7	43.8	2	10.0
Had returned to work and did not wish to participate	2	12.5	4	20.0
Felt too unwell	1	6.3	5	25.0
No reason given	1	6.3	4	20.0
Total	16/36	44.4	20/36	55.6

*Five people in this category also declined services from the specialist community service.

Acceptance of intervention

Two of the 26 participants treated by the NTBIS and five of the 14 people with minor TBI had one session with the OT. These participants felt no further intervention was required and received advice only- see 3.2.3.3 for advice given. Therefore, 33/40 (82.5%) of the specialist group participants received two or more treatment sessions from the research OT. All participants with available data were analysed.

3.3.1.2. Data collection and analysis

As planned, 83% of baseline assessments (78/94) were conducted within four weeks of hospital discharge +/- five days. Participant's holidays were the main reasons for data collection outside this period.

The 24 participants recruited due to the recruitment extension, increased the numbers of participants available for analysis at 12 months post-baseline to 94. These 24 participants did not have 18 months data collected due to the time constraints of the study therefore only data from 70 participants was available for analysis at 18 months post-baseline.

People either returned the questionnaires fully completed, returned the questionnaires with questions missed out, did not return the questionnaire but were happy to undertake a telephone interview, did not return the questionnaire or declined to participate.

In total, 62/94 (66.0%) fully completed questionnaires were returned for analysis at 12 months and 38/70 (54.3%) returned at 18 months. Combined completed and partially completed questionnaires increased the 12 month data set to 34/40 (85.0%) in the specialist group and 45/54 (83.3%) in the usual care group – see Table 10. When the full and partially completed questionnaires were combined, both the specialist and usual care group had similar response rates at three months and at 12 months post-baseline. Inclusion of partially completed questionnaires meant the numbers of respondents in different sections of the analysis varied according to which questions were answered.

Table 10: Fully and partially completed questionnaires

Time		Full data		Partial data		Full + partial data combined	
		Specialist group (n=40)	Usual care (n=54)	Specialist Group (n=40)	Usual care (n=54)	Specialist Group (n=40)	Usual care (n=54)
3/12	no's	27	47	80	1	35	48
	%	67.5	87.0	20.0	1.9	87.5	88.8
6/12	no's	29	39	7	4	36	43
	%	72.5	72.2	17.5	7.4	90.0	9.6
12/12	no's	26	36	8	9	34	45
	%	65	66.7	20.0	16.7	85.0	83.3
		Specialist group (n=27)	Usual care (n=43)	Specialist Group (n=27)	Usual care (n=43)	Specialist Group (n=27)	Usual care (n=43)
18/12	no's	15	23	7	6	22	29
	%	55.6	53.5	25.9	14.0	81.5	67.4

Loss to follow up

Data from participants who did not return questionnaires and could not be contacted by phone was coded as missing. Participants were classified as having withdrawn consent if they requested it in writing on their questionnaires or verbally requested to withdraw when telephoned. Missing and withdrawn participants (non-respondents) were combined to form 'loss to follow up'.

Total loss to follow up for whole cohort was 16%. Both groups had a similar loss to follow up at 12 months (15.0% [6/40]) in the specialist group and 16.7% (9/54) in the usual care group) - see Table 11. Proportionally at 18 months twice as many usual care participants withdrew consent (2/27 [7.4%] v 6/43 [14%]), but when those who withdrew were combined with the non-responders, the difference between the groups was not statistically significant.

Reasons given for withdrawal from the study were: being back at work (n=2), no time to participate (n=1), too much effort involved (n=1), imminent prison sentence (n=1), readmission to hospital (n=1), one participant felt she did not have a brain injury as she had been told 'I had a bleed on the brain and not a

brain injury' and one did not want to be reminded of the accident. No participant was withdrawn by the research team.

Table 11: Loss to follow up

Time		Questionnaires not returned		+	Participants who withdrew consent		=	Total loss to follow up	
		Specialist group (n=40)	Usual care (n=54)		Specialist group (n=40)	Usual care (n=54)		Specialist group (n=40)	Usual care (n=54)
3/12	no's	2	5		2	1		4	6
	%	5.0	9.3		5.0	1.9		10.0	11.1
6/12	no's	2	8		2	3		4	11
	%	5.0	14.8		5.0	5.6		10.0	20.4
12/12	no's	2	5		4	4		6	9
	%	5.0	9.3		10.0	7.4		15.0	16.7
		Specialist group (n=27)	Usual care (n=43)		Specialist group (n=27)	Usual care (n=43)		Specialist group (n=27)	Usual care (n=43)
18/12	no's	3	8		2	6		5	14
	%	11.1	18.6		7.4	14.0		18.5	32.6

Comparison of non-respondents with the total cohort showed similar gender ratios, age, cause of injury and job levels. The greatest difference between the total cohort and non-respondents was in length of stay and injury severity. Non-respondents stayed in hospital approximately 7 days less and were more likely to be categorised as a severe TBI –see Table 12.

Table 12: Comparison of total cohort to non-respondents

			Participants (n=94)	Non-respondents (n= 19)
Number of males	Mean		77	16
	%		82	84
Age	Mean		34.8	33.0
	SD		13.9	14.9
	Range		16-66	16-68
Length of hospital stay (days)	Mean		20.4	13.5
	SD		20.9	12.5
	Range		2-104	2 - 45
GCS	Mean		9.9.	8.8.
	SD		4.4	4.7
	Range		3-15	3 - 15
GCS categories	Severe	no's	37	11
		%	39.4	57.6
	Moderate	no's	18	6
		%	19.1	31.6
		%	36.2	31.6
	Minor	no's	39	2
		%	41.4	10.5
		%	36.2	31.6
	RTA	no's	36	7
		%	38.3	36.8
	Assault	no's	21	5
		%	22.3	26.5
Other	no's	3	1	
	%	3.2	5.3	
Job level¹	1 (Low skill)	no's	22	4
		%	23.4	21.1
	2	no's	32	8
		%	34.0	42.1
	3	no's	30	7
		%	31.9	36.8
	4 (High skill)	no's	10	0
		%	10.6	0.0

¹(Office for National Statistics 2008)

Problem with wording questions

Participants gave different responses at different time points when answering 'how long it had taken them to return to work on a part time basis'. Only 15/49 (30.62%) of participants responded consistently. The question for returning to previous hours invoked a similar response and 30/41 (73.17%) participants gave more than one answer. When these discrepancies occurred, the initial

responses were entered on the assumption that they were more likely to be more accurate.

Analysis

Fewer participants and loss to follow up combined with the fact that not all questions were applicable to all participants meant some questions received a small number of replies at 18 months. Therefore, the Carer's BICRO and factors that may affect return to work were analysed up to 12 months.

Questions regarding undertaking a graded return to work and work modifications were analysed at 18 months to determine any relevance to the primary outcome. Data was checked for distribution to determine whether parametric or non-parametric statistics were required.

Missing data occurred when entire questionnaires were not returned, when primary outcomes were obtained from follow up phone calls and when there was missing data on the forms that could not be obtained through follow up telephone calls. As there was no pattern to the missing data, it was judged to random and therefore it was not adjusted for in the analysis.

3.3.2. Baseline demographic information

Characteristics of participants were compared to ascertain baseline differences between the groups in terms of demographic information, work characteristics, length of hospital stay and secondary outcome measures.

As shown in Table 13, the proportions of men to women, mean age and cause of injury were similar in both groups. Mean Glasgow Coma scores (GCS) between the groups did not differ significantly but the specialist group had proportionately more people with moderate or severe TBI (65.0%) compared to the usual care group (51.9%).

Table 13: Gender, age and injury severity characteristics

		Specialist group (n=40)	Usual care group (n=54)	Statistic ¹
Men	no's	32	45	$\chi^2=0.17$ df=1, p=0.68
	%	80.0	83.3	
Women	no's	8	9	
	%	20.0	16.7	
Age				
Age	Mean	35.4	34.3	U=1010.0 Z=-0.54 P=0.59
	SD	13.49	14.30	
	Range	18 -66	16-68	
GCS				
GCS	Mean	9.48	10.2	U=964.0 Z=-0.90 P=0.371
	SD	4.31	4.53	
	Range	3-15	3-15	
Minor (13- 15)	no's	14	26	$\chi^2=2.24$, df=2, p=0.33
	%	35.0	48.1	
Moderate (12 -9)	no's	9	7	
	%	22.5	13.0	
Severe (8 - 3)	no's	17	21	
	%	42.5	38.9	

¹ χ^2 = Chi², Mann Whitney U tests

Marital status, ethnicity and the total number of people reporting a past medical history were similar in both groups – see Table 14.

Table 14: Pre-injury demographic characteristics

Total number (n =94)	Specialist group (n=40)		Usual care group (n=54)		Statistic¹
Cause of injury	No's	%	No's	%	
Fall ²	16	40.0	18	33.3	Expected cell frequency too low
RTA	12	30.0	24	44.4	
Assault	10	25.0	11	20.4	
Other ³	2	5.0	1	1.9	
Driver pre-injury					
Yes	23	57.5	40	74.1	OR 0.48, (0.20, 1.14)
Marital status					
Married or with a long term partner	17	42.5	26	48.1	OR 0.80 (0.35,1.81)
Past Medical History					
Previous brain injury	4	10.0	4	7.4	OR 1.39, (0.33, 5.93)
Other neurological conditions ⁴	1	2.5	4	7.4	OR 0.32, (0.34, 2.99)
Mental health problems ^{5,6}	3	7.5	2	3.7	OR 2.11, (0.34, 13.25)
Drug problems ⁶	0	0.0	1	1.9	OR 1.76 (1.47-2.10)
Alcohol problems ⁶	1	2.5	3	5.6	OR 0.44, (0.04, 4.35)
Total numbers with previous medical history	9/40	22.5	14/54	25.9	
Ethnicity					
White UK	37	92.5	51	94.4	OR 0.73 (0.14, 3.80)
Other nationalities	3	7.5	3	5.6	

¹ Odds ratio (OR) and 95% confidence intervals, $\chi^2 = \chi^2$

² Falls include falls from ladders, buildings, downstairs

³ Other = object falling on person, being hit whilst cycling, industrial accident

⁵ Epilepsy (n=3), long-term neurological conditions (n=2)

⁶ Depression but coping with medication

⁵ Past history but no longer using drugs, alcohol or receiving treatment.

3.3.2.1. Pre-injury work and education status

Table 15 shows that almost all participants reported being in work or education at the time of injury (specialist group 38/40 [95.0%] v usual care group 52/54 [96.3%]) - see Table 15. No-one in either group reported being on a Government programme to help with work. Overall, there was no significant difference between the groups in the numbers in work at the time of injury.

Three students were coded as level 3 as recommended by the Social Occupational Codes (SOC) (Office for National Statistics 2008) – see 3.2.4.2. A participant who was in the process of leaving school aged 16 was coded as level 1. The groups were almost identical if SOC categories one and two were added together (specialist group 24/40 [60.0%] v usual care group 30/54 [55.50%]) - see Table 15.

Almost identical proportions in both groups left school before or at age 16 years old (specialist group 25 [62.5%] v 35/54 [64.9%]) - see Table 15.

At baseline, the majority of participants in both groups reported enjoying their job (specialist group 92.50% v usual care group 85.20%) - see Table 15.

Table 15: Pre-injury injury work and education status

Total number (n =94)	Specialist group (n=40)		Usual care group (n=54)		Statistic ¹
	No's	%	No's	%	
Total no's in work or education	38	95	52	96.3	OR 0.73 (0.01, 5.42)
Work status					
Working	35	87.5	48	88.9	OR 0.88 (0.25, 3.10)
Not working	5	12.5	6	11.1	
In education					
Yes	6	15.0	4	7.4	OR 1.73 (0.49, 6.13)
No	34	85.0	50	92.6	
In voluntary work					
In voluntary work	0	0.0	3	5.6	Expected cell frequency too low
Unemployed (u/e) + seeking work					
U/e + seeking work	1	2.5	3	3.7	OR 0.67 (0.06, 7.62)
Looking after children					
Looking after children	3	7.5	3	5.6	OR 1.38 (0.26, 7.22)
Job category					
1 Unskilled	12	30.0	10	18.5	$\chi^2=2.28,$ df=3, p=0.52
2 Semi skilled	12	30.0	20	37.0	
3 Semi professional	11	27.5	19	35.2	
4 Professional	5	12.5	5	9.3	
Educational Level					
Left school before 16	5	12.5	7	13.0	$\chi^2=3.68,$ df=4, p=0.45
Left school at 16	20	50.0	28	51.9	
Left school at 18	4	10.0	7	13.0	
Had higher education	11	27.5	9	16.7	
Other ²	0	0.0	3	5.6	
Enjoyed their job					
Yes	37	92.5	46	85.2	Expected cell frequency too low
No	0	0.0	2	3.7	
Sometimes	3	7.5	6	11.1	

¹ OR =Odds ratio (OR), $\chi^2 = \text{Chi}^2$

² Time at college extended due to personal reasons

3.3.2.2. Baseline differences

Length of hospital stay and number of participants' in work were statistically significant baseline differences between the groups, Logistic regression was used to adjust for both factors – see 3.3.3.5. Logistic regression.

Length of hospital stay

Three participants stayed in hospital markedly longer than other participants did. These were classed as outliers. (An outlier is a value that is distinct from the main body of the data and thus incompatible (Petrie et al. 2007)). Two outliers in the specialist group: 56 and 104 days, were not removed as a large variation in length of hospital stay in people with TBI is expected. However, one usual care participant stayed in hospital 289 days due to additional injuries. This was 12 times longer than other usual care group participants. Removing this person from the analysis reduced the median length of stay in people with moderate/severe TBI by 12 days.

Participants of all injury severity in the usual care group stayed in hospital 10.5 days longer (median) than participants in the specialist group—see Table 16. This was statistically significant. The difference was more pronounced when examined by injury severity. Participants in the specialist group with moderate/severe TBI stayed in hospital 14.5 days less (median) than those in the usual care group. Specialist group participants with a minor TBI stayed in hospital 7.5 days less (median) than those in the usual care group. These were statistically significant.

Despite the decreased length of stay, three quarters (25/34 [73.5%]) of the specialist group reported being satisfied with the treatment they had received at four weeks post-discharge compared with less than half of usual care group (25/52 (48.1%). This was also statistically significant (OR 3.00 [1.176 – 7.651], χ^2 5.472, df 1, p=0.019).

Table 16: Length of hospital stay (LOS)

Length of Hospital Stay (Days)¹	Specialist group	Usual care group	Mann-Whitney U
Whole cohort	n= 40	n= 54	
Median	6.5	17.00	U= 689.0, ² z=-2.89, p=0.004
Range	2-104	3-75	
IQR	20	35.50	
Moderate/Severe TBI	n= 26	n=28	
Median (range)	13.5	28.0	U= 240.00, z=-1.98, p=0.05
Range	3-104	3-75	
IQR	26.75	41.0	
Minor TBI	n=14	n=26	
Median (range)	3.0	10.5	U=54.00, z=-3.67, p=0.001
Range	2-23	3-63	
IQR	2.00	14.75	

¹One outlier omitted due to LOS of 289

²Red text = statistically significant

Baseline return to work rates

The numbers of participants who reported being in work at baseline were: specialist group 8/40 (20.0%) v usual care group 3/54 (5.6%), OR 4.25 (1.05, 17.21), Fischer's exact test= p=0.05 (statistically significant). This was 11.7% of the total cohort.

The characteristics of the 11 participants who reported working at baseline were examined to explore potential reasons for the difference in numbers working between the groups at baseline – see Table 17. Seven out of the eleven people who reported working at baseline stated they were self-employed. Only one person in the specialist group and two people in the usual care group reported working any hours at baseline.

Table 17: People in work at baseline

	Specialist group (n=8)	Usual care group (n=3)
Gender	7 male, 1 female	2 male, 1 female
Age	5 = under 40 years 3 = over 40 years	1 = under 40 years 2 = over 40 years
GCS	2 = Minor TBI 3 = Moderate TBI 3 = Severe TBI	2 = Minor TBI 1 = Moderate TBI
Length of stay	7 = Less than 14 days 1 = Over 14 days	3 = Less than 14 days
Job Characteristics	5 = Self-employed 2 = Employed 1 = Student	2 = Self –employed 1 = Voluntary worker at charity
Reported hours worked at baseline	7 = 0 hours 1 = 45 hours	1 = 0 hours 1 = 30 hours 1 = 40 hours

None of the participants responses to the question ‘are you now working or in education?’ were queried. This highlighted differences in participant’s perceptions of what constituted being in work or in education. For example, some respondents classified themselves ‘at work’ whilst on sick leave because they had a job to return to. A student on study leave classified themselves as being in education even though they were not studying. A specialist group participant who had returned to work on the day of the assessment, ticked they were at work, but then temporarily stopped work on the advice of the OT. One participant accompanied his partner to their jointly owned business, because the alternative was staying home alone. The partner reported that the participant did not do any work even though the participant had ticked they were working. Therefore, as similar numbers in each group reported hours in work, the difference in work rates appears to be due to how participants defined working.

3.3.2.3. Baseline: Secondary outcome measures

Brain Injury Community Rehabilitation Outcome Scales (BICRO)

There was less than half a point difference in either direction between both groups in BICRO scores in any of the six domains, suggesting both groups had similar levels of functioning –see Table 18.

Table 18: Baseline: Median BICRO scores

Baseline BICRO scores ¹		Specialist group (n=40)	Usual care group (n=54)	Mann Whitney U
Personal care	Median	0.0	0.0	U = 961.00,
	Range	0.0, 1.33	0.0, 2.67	Z = -1.35,
	IQR	0.00	0.00	P = 0.18
Mobility	Median	2.08	2.5	U = 898.00,
	Range	0.0, 5.00	0.0, 5.00	Z = -1.39,
	IQR	2.50	3.21	P = 0.16
Self-organisation	Median	1.75	1.92	U = 927.00,
	Range	0.0, 4.17	0.0, 5.00	Z = -1.18,
	IQR	3.33	3.58	P = 0.238
Socialising	Median	2.42	2.25	U=1025,
	Range	0.83, 4.17	1.00, 4.33	Z = 0.42,
	IQR	1.29	1.17	P = 0.68
Productive employment	Median	5.00	5.00	U= 910.00,
	Range	2.75, 5.00	1.25, 5.00	Z = -1.58,
	IQR	1.25	0.12	P = 0.11
Psychological well being	Median	2.08	2.00	U = 1006.50,
	Range	0.50, 4.33	0.17, 4.67	Z = -0.56,
	IQR	1.62	1.33	P = 0.57

¹BICRO scores:- 0 = no problem, 1 = prompts only, 2 = some help, 3 = a lot of help, 5 = constant help, 6 = don't do at all. Lower scores = less problems

There was less than 0.6 points difference in either direction between participants' and carers' median scores on the BICRO -see Table 19. The intra class correlation coefficients (ICC) showed that there was a statistically significant level of agreement between participants and carers in all categories.

Table 19: Baseline BICRO scores: Agreement between participants and carers

BICRO:Baseline scores		Specialist group					Usual care group				
		Participants n=40	Carer n=27	ICC	95% CI	p value	Participants n=54	Carers n=41	ICC	95% CI	p value
Self-care	Median	0.0	0.0	0.62	0.17, 0.83	0.008	0.0	0.0	0.97	0.94, 0.98	0.001
	Range	0.0, 1.33	0.0, 1.00				0.0, 2.67	0.0, 2.66			
	IQR	0.0	0.33				0.0	0.33			
Mobility	Median	2.08	1.83	0.76	0.47, 0.90	0.001	2.50	2.67	0.90	0.82, 0.95	0.001
	Range	0.0, 5.00	0.0-5.00				0.0, 5.0	0.0, 5.00			
	IQR	2.50	2.67				3.21	3.42			
Self-organisation	Median	1.75	1.83	0.84	0.64, 0.93	0.001	1.92	2.67	0.87	0.75, 0.93	0.001
	Range	0.0, 4.17	0.0, 4.17				0.0, 5.00	0.0, 5.00			
	IQR	3.33	2.50				3.58	3.25			
Socialising	Median	2.42	2.67	0.85	0.67, 0.93	0.001	2.25	2.83	0.76	0.54, 0.87	0.001
	Range	0.83, 4.17	1.6, 4.83				1.00, 4.33	1.67, 5.83			
	IQR	1.29	1.17				1.17	1.33			
Productive employment	Median	5.00	5.00	0.90	0.78, 0.96	0.001	5.00	5.00	0.60	0.24, 0.79	0.003
	Range	2.75, 5.00	3.75, 5.00				1.25, 00	2.50, 5.00			
	IQR	1.25	0.50				0.12	0.50			
Psychological well being	Median	2.08	2.50	0.68	0.29, 0.85	0.003	2.00	2.33	0.82	0.66, 0.90	0.001
	Range	0.50, 4.33	0.0, 4.50				0.17, 4.67	0.1, 4.83			
	IQR	1.62	2.17				1.33	1.33			

Red text = statistically significant

Baseline Hospital Anxiety and Depression Scale (HADS)

There were no significant differences between the groups at baseline on either HADS depression or anxiety scores with the median scores in both groups falling within the normal range (0-7) – see Tables 20 and 21. When divided into categories, approximately one third of participants' scores fell within the borderline or abnormal ranges for both depression and anxiety (Bowling 1997).

Table 20: Baseline HADS – Depression

HADS:-Baseline score Depression ¹		Specialist group (n=40)		Usual care group (n=54)		Statistic
Median	Median	4.0		5.0		U =1045.00 Z=-0.07 p=0.94
	IQR	7.0		7.0		
	Range	0-17		0-15		
		n	%	n	%	
Categories	Normal	26	66.7	35	64.8	$\chi^2 = 0.31$ df=2 p=0.86
	Borderline	7	17.9	12	22.2	
	Abnormal	6	15.4	7	13.0	

¹HADS scores: 0-7 normal range, 8-10 =borderline, 11-21 = abnormal

Table 21: Baseline HADS - Anxiety

HADS:-Baseline score Anxiety ¹		Specialist group (n=40)		Usual care group (n=54)		Statistic
Median score	Median	6.0		6.0		U= 1018.00 Z=-0.55 p=0.58
	IQR	8.0		7.0		
	Range	0-16		0-19		
		n	%	n	%	
Category scores	Normal	26	65.0	32	59.2	$\chi^2 = 0.32$ df = 2 p = 0.85
	Borderline	7	17.5	11	20.4	
	Abnormal	7	17.5	11	20.4	

¹HADS scores: 0-7 normal range, 8-10 =borderline, 11-21 = abnormal

Quality of life: Euroqol 5D (EQ5D)

Most participants reported a lower quality of life at baseline than prior to their injury, but 15 -20% of participants reported feeling much the same. There were no significant differences between the groups. The mean scores were similar between groups– see Table 22.

Table 22: Quality of life: EQ5D

Baseline EQ5D		Specialist group n=40		Usual care group n=54		Statistic
Overall	Mean	5.45		5.69		t = -0.59 df = 92 p = 0.56
	SD	1.70		2.21		
	Range	2-9		1-10		
		no	%	no	%	
Categories	Better	1	2.5	0	0.0	Cell frequency too low
	Much the same	6	15.0	11	20.4	
	Worse	33	82.5	43	79.6	

3.3.2.4. Summary of practical considerations and baseline data

There were no statistically significant pre-injury or baseline differences with regard to demographic information, pre-injury work status or on any of the secondary outcome measures of function, mood and quality of life.

However, length of hospital stay and baseline return to work rates showed statistically significant differences between the groups. The usual care group had a median length of hospital stay 10.5 days longer than the specialist group. Five more specialist group participants (14.4%) classed themselves as working at baseline compared to usual care participants.

3.3.3. Findings from the cohort comparison study

This section reports the return to work rates between the groups, the results from the secondary outcomes, and then factors that may affect work. These include rehabilitation, environmental and personal factors.

3.3.3.1. Primary outcome: Return to work rates between groups: All injury severity

More specialist group participants returned to work at all time points compared to usual care group participants: 15% more specialist group participants reported being in work at 12 months post- baseline – see Figure 5 and Table 23. This was not significant.

Return to work - All injury severity

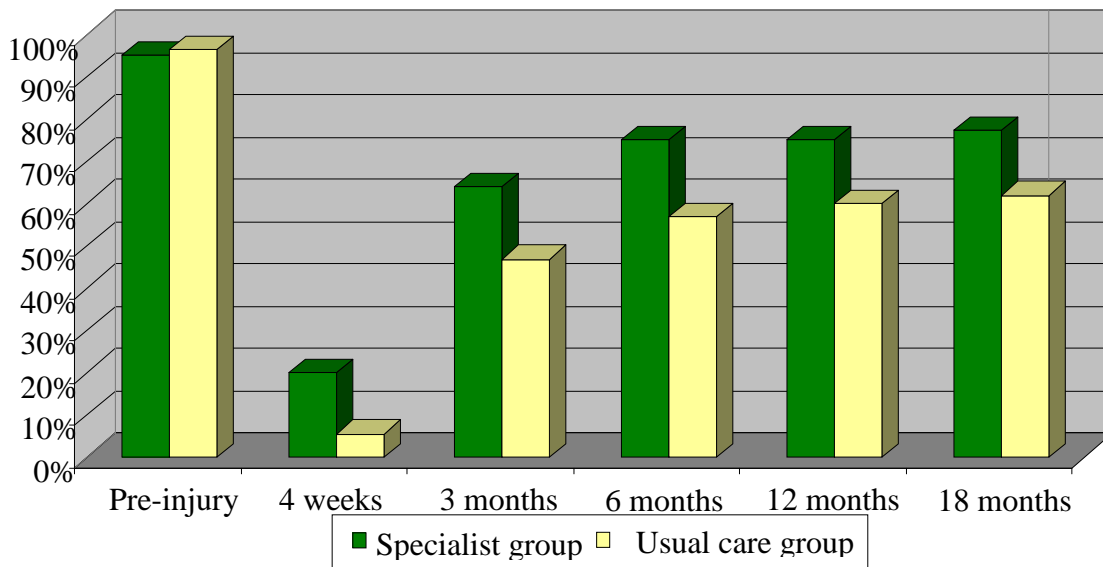


Figure 5: Participants in work: Total Cohort

Table 23: Return to work rates between groups: All injury severity

All GCS severity		Specialist group	Usual care group	Difference	Odds (95% CI)
Pre-injury	no's	38/40	52/54	-1.3% ¹	0.73 (0.10, 5.42)
	%	95.0	96.3		
4 weeks (Baseline)	no's	8/40	3/54	14.4%	4.25 (1.05, 17.21)
	%	20.0	5.6		
3 months	no's	23/36	23/49	17.0%	2.00 (0.83, 4.83)
	%	63.9	46.9		
6 months	no's	27/36	25/44	18.2%	2.28 (0.87, 5.97)
	%	75.0	56.8		
12 months	no's	27/36	27/45	15.0%	2.00 (0.77, 5.23)
	%	75.0	60.0		
18 months	no's	17/22	18/29	15.2%	2.08 (0.60, 7.24)
	%	77.3	62.1		

¹ Minus difference reflects specialist group participant's were in work compared to usual care group participants.

3.3.3.2. Return to work rates between groups: Moderate or severe TBI

When the groups were divided by injury severity, 27.5% more specialist group participants with moderate and severe GCS reported being in work at 12 months, this was not statistically significant – see Figure 6, Table 24. Between three months and 12 months, the proportion of usual care participants in work increased by 5.4% (37.5% – 42.9%) compared to an increase of 24.1% in the specialist group over the same period (45.5% - 69.6%) - see Table 24.

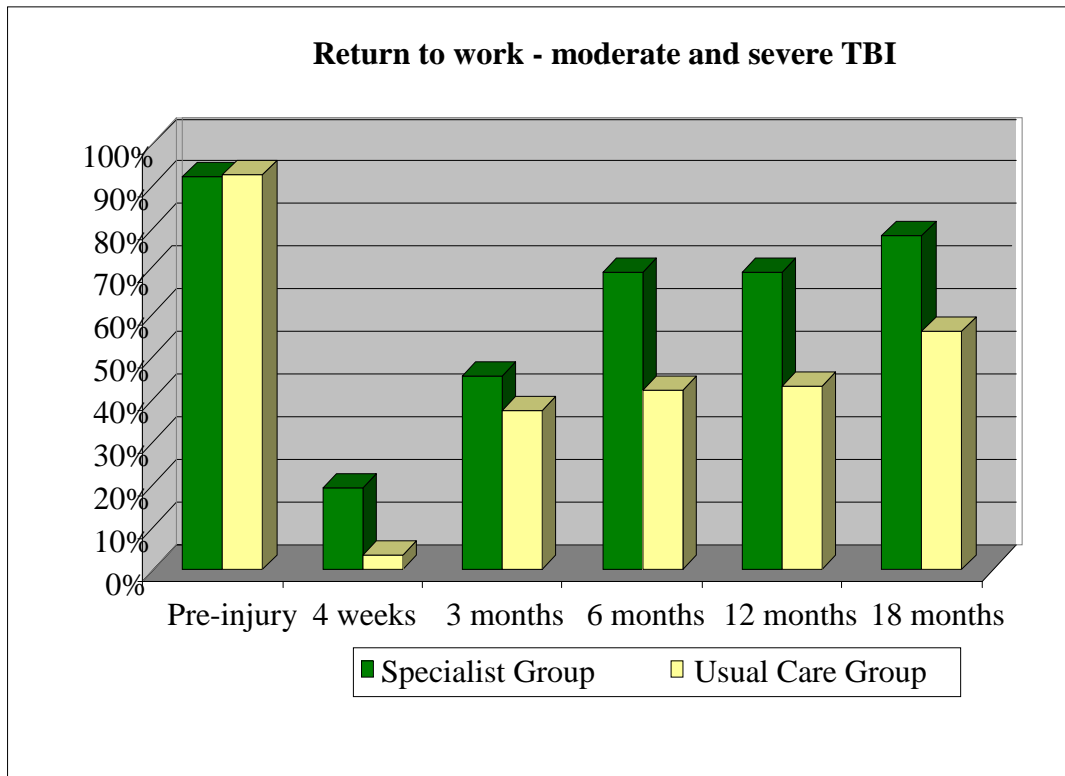


Figure 6: Participants in work: Moderate and severe TBI

Table 24: Return to work rates between groups: Moderate and severe TBI

Moderate/ Severe GCS		Specialist group	Usual care group	Difference	Odds (95% CI)
Pre-injury	no's	24/26	26/28	-0.6% ¹	0.92 (0.12, 7.08)
	%	92.3	92.9		
4 weeks (Baseline)	no's	5/26	1/27	15.6%	6.43 (0.70, 59.77)
	%	19.2	3.6		
3 months	no's	10/22	9/24	8.0%	1.39 (0.43, 4.51)
	%	45.5	37.5		
6 months	no's	16/23	8/19	27.5%	3.14 (0.88, 11.22)
	%	69.6	42.1		
12 months	no's	16/23	9/21	26.7%	3.05 (0.88, 10.52)
	%	69.6	42.9		
18 months	no's	11/14	8/15	25.3%	3.21 (0.63, 16.38)
	%	78.6	53.3		

¹ Minus difference means fewer people in the specialist group were in work compared to the usual care group

3.3.3.3. Return to work rates between groups: Minor TBI

Again, more participants with minor TBI in the specialist group had started to return to work at all time points compared to the usual care group – see Figure 7, Table 25. The main difference between the groups occurred at three months. Compared to the usual care group, 37% more specialist group participants reported being in work at three months. This was statistically significant (Fishers exact test, $p= 0.028$). No other comparisons were statistically significant. At 12 months, 9.6% more specialist group participants were in work compared to usual care participants.

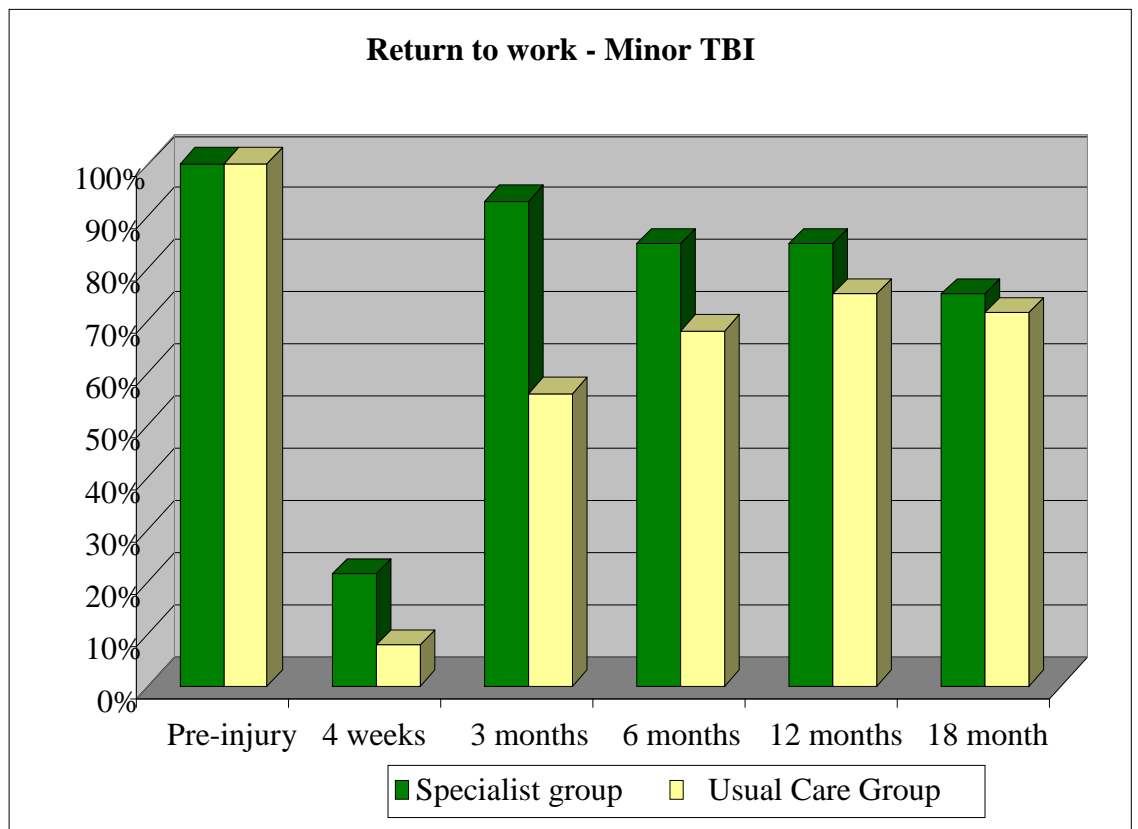


Figure 7: Participants in work or education: Minor TBI

Table 25: Return to work rates between groups: Minor TBI

Minor GCS		Specialist group	Usual care group	Difference	Odds (95% CI)
Pre-injury	no's	14/14	26/26	0%	n/a
	%	100.0	100.0		
4 weeks (Baseline)	no's	3/14	2/26	13.7%	3.27 (0.48, 22.46)
	%	21.4	7.7		
3 months	no's	13/14	14/25	36.9%	10.21* (1.15, 90.53)
	%	92.9	56.0		
6 months	no's	11/13	17/25	16.6%	2.59 (0.46, 14.53)
	%	84.6	68.0		
12 months	no's	11/13	18/24	9.6%	1.83 (0.31, 10.74)
	%	84.6	75.0		
18 months	no's	6/8	10/14	3.6%	1.20 (0.17, 8.66)
	%	75.0	71.4		

* Red text = statistically significant

3.3.3.4. Return to education

Similar proportions of specialist group participants reported being in education at 12 and 18 months post injury compared to pre-injury but fewer were in education at 6 months—see Table 26. The pattern was different in the usual care group. Proportionately more usual care participants reported being in education at 12 and 18 months compared to pre-injury, three and six months – see Table 26,

Table 26: Participants in education in each group

Time point (total number of participants)		Specialist group	Usual care group	Odds (95% CI)
Pre-injury (n=94)	no's	6/40	4/54	0.84
	%	15.0	7.4	(0.19, 3.70)
3 months (n= 75)	no's	3/29	2/46	0.39
	%	10.3	4.3	(0.06, 2.52)
6 months (n= 67)	no's	2/30	2/37	0.80
	%	6.7	5.4	(0.11, 6.04)
12 months (n= 67)	no's	4/31	4/36	0.84
	%	12.9	11.1	(0.19, 3.70)
18 months (n= 39)	no's	2/15	3/24	0.93
	%	13.3	12.5	(0.14, 6.32)

3.3.3.5. Logistic regression

Factors identified in the literature review as having an association with being in work following TBI were used in logistic regression analysis to determine their effect on being in work at 12 months post-baseline, in this study. These were:

- Injury severity: Coded as Minor GCS (= reference group) or Moderate or severe GCS
- Length of hospital stay: in days
- Age: in years
- Intervention: Specialist group (= reference group) v usual care group
- Education: left school at 16 years old or before v had education above 16 years old (= reference group).
- Job level: SOC 1,2 (lower level jobs) v SOC 3,4 (higher level jobs) (= reference group)
- Relationship status : Married/ with partner (= reference group) v not married/ no partner

Baseline working (Coded as working as the reference group) was included as there was a statistical significance between the groups. The outlier with the 289 day length of hospital stay was removed from this analysis – see 3.3.2.2.

Length of hospital stay.

The results of the logistic regression analysis are shown in Table 27. The baseline group differences in length of hospital stay and whether a participant reported working at baseline did not significant predictors being in work at 12 months. The following factors were significantly predictive of being in work at 12 months post-baseline:

- Age: the younger the person, the more likely they were to be in work at 12 months (OR 0.90 [0.84, 0.96])
- GCS: A person with minor TBI had an increased probability of being in work compared to a person with moderate/severe TBI (OR 7.75 [1.64, 36.62])
- Intervention: Participants in the specialist group were more likely to be in work compared to a person in the usual care group (OR 3.75 [1.02, 13.70])

These factors were statistically significant. However, with the exception of age, the 95% confidence intervals were wide - see Table 27.

Table 27: Predictive factors for return to work or education

Variable	β	Significance p	Odds (95% CI)
Age (years)	-0.11	0.01¹	0.90 (0.84, 0.96)
GCS (1) (minor TBI)	2.05	0.01	7.75 (1.64, 36.62)
Group (1) (specialist group)	1.32	0.05	3.75 (1.02, 13.70)

¹ **Red text** – statistically significant

3.3.3.6. Summary of primary outcomes

At all time points more participants in the specialist group reported being in work but there were few statistically significant differences. There was a 15% difference in return to work in favour of the specialist group at 12 months for all injury severities. However, at 12 months, the percentage difference increased to 27% when only those with moderate and/or severe TBI were examined. For those with minor TBI the difference was most marked at three months with a 37% difference in favour of the specialist group. Logistic regression analysis suggested being younger, having a minor TBI and receiving the intervention, were significantly predictive of being in work at 12 months.

3.3.4. Secondary Outcomes

Differences between the groups on the secondary outcomes of function (BICRO), mood (HADS) and quality of life (EQ5D) will now be reported. Mood and quality of life were also examined for differences between participants working and not working.

3.3.4.1. Brain Injury Community Rehabilitation Outcome Scales (BICRO)

The BICRO median scores at 12 months were similar in both groups - see Table 28. There was less than 0.6 point difference between the groups, with the higher scores consistently in the usual care group.

Table 28: 12 month: Median BICRO scores

12 months BICRO scores		Specialist group (24/40)	Usual care group (36/54)	Mann Whitney U
Personal care	Median	0.0	0.0	U=459.00
	Range	0.0, 1.00	0.0, 2.50	Z= -0.46
	IQR	0.00	2.50	p=0.64
Mobility	Median	0.25	0.83	U= 452.50
	Range	0.0, 5.00	0.0, 5.00	Z=-0.42
	IQR	5.00	5.00	p=0.67
Self-organisation	Median	0.67	0.83	U=472.50
	Range	0.0, 5.00	0.0, 4.50	Z=-0.12
	IQR	2.62	2.96	p=0.90
Socialising	Median	2.42	2.75	U=414.00
	Range	0.83, 5.00	0.33, 4.83	Z=-0.70
	IQR	1.71	4.50	p=0.49
Productive employment	Median	2.50	2.50	U=455.00
	Range	1.67, 3.33	1.33, 3.33	Z=-0.19
	IQR	0.50	1.50	p=0.85
Psychological well being	Median	1.83	1.83	U=435.50
	Range	0.0, 4.67	0.0, 4.67	Z=-0.21
	IQR	1.42	1.46	p=0.83

¹BICRO scores:- 0 = no problem, 1 = prompts only, 2 = some help, 3 = a lot of help, 5 = constant help, 6 = don't do at all. Lower scores = less problems

Comparison of carers' and participants' BICRO scores

Participants and carers' scores were compared to ascertain levels of agreement using the BICRO scales. Overall, there was significant agreement between participants' and carers' ratings in both groups at 12 months post-baseline– see Table 29.

Table 29: BICRO 12 months: Agreement between participants and carers

BICRO:12 month scores		Specialist group					Usual Care group				
		Participants n=24	Carer n=18	ICC	95% CI	p value	Participant s n=36	Carers n=32	ICC	95% CI	p value
Self-care	Median	0.00	0.00	0.96	0.90, 0.99	0.01	0.00	0.00	0.99	0.98, 1.00	0.01
	Range	0.00, 1.00	0.0,-6.00				0.00, 2.50	0.00 -2.33			
	IQR	0.00	0.04				0.00	0.00			
Mobility	Median	0.25	0.67	0.67	0.14, 0.87	0.01	0.08	0.33	0.97	0.94, 0.99	0.01
	Range	0.00, 5.00	0.0-6.00				0.00, 5.00	0.00, 5.00			
	IQR	2.04	0.46				2.21	2.42			
Self-organisation	Median	0.67	1.42	0.77	0.40, 0.91	0.03	0.83	4.12	0.94	0.88, 0.97	0.01
	Range	0.00, 5.00	0.00-6.00				0.00, 4.50	0.00, 5.00			
	IQR	2.62	3.38				2.96	2.96			
Socialising	Median	2.42	2.67	0.60	0.01, 0.84	0.01	2.75	2.83	0.78	0.55, 0.89	0.01
	Range	0.83, 5.00	0.83-6.00				0.33, 4.83	0.33, 4.50			
	IQR	1.71	2.08				1.79	0.96			
Productive employment	Median	2.5	3.88	0.73	0.30, 0.90	0.01	2.50	3.75	0.91	0.82, 0.96	0.01
	Range	1.67, 3.33	2.25-6.00				1.33, 3.33	2.00, 5.00			
	IQR	0.50	1.12				1.50	1.81			
Psychological well being	Median	1.83	2.00	0.96	0.90, 0.99	0.01	1.83	2.00	0.92	0.84, 0.96	0.01
	Range	0.00, 4.67	0.00-6.00				0.00, 4.67	0.00, 5.00			
	IQR	1.42	2.29				1.46	2.08			

Red text = statistically significant

3.3.4.2. Hospital and Anxiety Scale (HADS)

Depression

Analysis showed that both groups had similar median scores for depression at 3, 6, 12 and 18 months - see Table 30. Approximately 10% more usual care participants reported scores in the abnormal range at both 6 and 12 months but this was not statistically significant.

Table 30: HADS:Depression scores

HADS score¹: Depression scores			Specialist group(SG)		Usual Care Group(UG)		Statistic
3 month SG n=26 ² UG n=47	Total	Median	4.00		3.00		U=584.50 Z=-0.423 p=0.67
		IQR	5.00		6.50		
		Range	0-15		0-16		
			No	%	No	%	
	Categories	Normal	21	80.8	36	76.6	Fischer's exact test =0.10
		Borderline	2	7.7	4	8.5	
Abnormal		3	11.5	7	14.9		
6 month SG n=27 UG n=39	Total	Median	2.00		3.00		U=472.00 Z=-0.51 p=0.34
		IQR	4.00		8.00		
		Range	0-13		0-16		
			No	%	No	%	
	Categories	Normal	22	81.0	28	71.8	Fischer's exact test =0.64
		Borderline	2	7.4	3	7.7	
Abnormal		3	11.1	8	20.5		
12 month SG n=24 UG n=35	Total	Median	3.00		3.00		U=414.50 Z=-0.33 p=0.74
		IQR	8.00		9.00		
		Range	0-15		0-17		
			No	%	No	%	
	Categories	Normal	17	70.8	25	69.4	Fischer's exact test =0.42
		Borderline	4	16.7	3	8.3	
Abnormal		3	12.5	8	22.2		
18 month SG n=14 UG n=21	Total	Median	4.00		3.00		U=130.00 Z=-0.58 p=0.56
		IQR	7.50		7.50		
		Range	0-18		0-18		
			No	%	No	%	
	Categories	Normal	10	71.4	16	76.2	Fischer's exact test =0.10
		Borderline	2	14.3	2	9.5	
Abnormal		2	14.3	2	14.3		

¹ HADS scores: 0-7 within normal range, 8-10 =borderline, 11-21 = abnormal (Bowling 2002)

² No missing data was replaced

Anxiety

There were no statistically significant differences between the groups on the HADS anxiety mean or category scores - see Table 31. The category scores showed approximately 10% more usual care participants reported abnormal anxiety scores than specialist group participants at 3 months – see Table 31. This pattern was reversed at 18 months, more specialist group participants reported abnormal anxiety category scores compared to usual care participants.

Table 31: HADS: Anxiety scores

HADS score¹: Anxiety			Specialist group (SG)		Usual Care Group (UG)		Mann Whitney U
3 month SG n=26 ² UG n=45	Total	Median	6.00		4.00		U = 540.00 Z = -0.69 p = 0.49
		IQR	5.50		8.50		
		Range	0-18		0-20		
	Categories		No	%	No	%	Fischer's exact test =0.42
		Normal	20	76.9	32	71.1	
		Borderline	3	11.5	3	6.7	
	Abnormal	3	11.5	10	22.5		
6 month SG n=27 UG n=40	Total	Median	5.00		4.00		U=507.00 Z=-0.51 p=0.61
		IQR	8.00		7.00		
		Range	0-17		0-17		
	Categories		No	%	No	%	Fischer's exact test =0.81
		Normal	17	63	28	70	
		Borderline	5	18.5	5	12.5	
	Abnormal	5	18.5	7	17.5		
12 month SG n=24 UG n=35	Total	Median	7.00		5.00		U=402.50 Z=0.30 p=0.76
		IQR	10.5		9.00		
		Range	0-20		0-20		
	Categories		No	%	No	%	Fischer's exact test =0.93
		Normal	13	54.2	20	55.9	
		Borderline	3	12.5	5	14.3	
	Abnormal	8	33.3	10	28.6		
18 month SG n=14 UG n=22	Total	Median	7.00		4.00		U=102.00 Z=-1.70 p= 0.90
		IQR	14.00		7.00		
		Range	0-18		0-13		
	Categories		No	%	No	%	Fischer's exact test =0.36
		Normal	8	57.1	17	77.3	
		Borderline	2	14.3	1	4.5	
	Abnormal	4	28.6	4.	18.2		

¹ HADS scores: 0-7 within normal range, 8-10 =borderline, 11-21 = abnormal (Bowling 2002)

² Missing data was not replaced

3.3.4.3. EQ5D: Differences between groups

There were no statistically significant differences between the groups at any time point on the visual analogue scale (VAS) or the category scores of the EQ5D-see Table 32. At 12 months, proportionately more usual care group participants reported a lower quality of life compared to specialist group participants –see Table 32.

Table 32: EQ5D Visual analogue scale and category scores

EQ5D			Specialist group (SG)		Usual care group (UG)		Statistic
3 months SG ³ =27 UG =47	VAS ¹	Median	7.00		8.00		U= 536.00 Z =-1.11 p= 0.27
		IQR	2.75		2.81		
		Range	4-10		3-10		
			No	%	No	%	
	Categories	Better	3	11.1	7	14.9	$\chi^2=0.25$ df=2 p=0.88
		Much the same	15	55.6	26	55.3	
Worse		9	33.3	14	29.8		
6 month SG=27 UG =40	VAS score	Median	7.00		7.50		U= 486.00 Z =-0.69 p= 0.49
		IQR	3.50		3.40		
		Range	2.8-10		3-10		
			No	%	No	%	
	Categories	Better	8	29.6	6	15.0	$\chi^2=2.19$ df=2 p=0.33
		Much the same	12	44.4	23	57.5	
Worse		7	25.9	11	27.5		
12 month SG = 24 UG =36	VAS	Median	8.00		8.00		U= 391.00 Z =-0.62 p= 0.53
		IQR	1.67		3.20		
		Range	4-10		2-10		
			No	%	No	%	
	Categories	Better	7	29.2	9	25.0	$\chi^2=0.92$ df=2 p=0.63
		Much the same	14	58.3	19	52.8	
Worse		3	12.5	8	22.2		
18 month SG=14 UG =22	VAS	Median	7.0		8.5		U= 121.00 Z =-0.76 p=0.45
		IQR	3.55		2.4		
		Range	5-10		3-10		
			No	%	No	%	
	Categories	Better	3	21.4	10	45.5	Fischer's exact test =0.43
		Much the same	9	64.3	10	45.5	
Worse		2	14.3	2	9.1		

1=VAS= visual analogue scale, 0=low quality of life, 10 = high quality of life,

3.3.4.4. Differences between those working and not working

There were statistically significant differences between those in work or not in work in depression and anxiety HADS scores and EQ5D visual analogue scores. Those in work reported less depression and less anxiety and a higher quality of life - see Tables 33, 34, 35.

For depression, the differences were statistically significant differences at baseline, three, six, twelve months -see Table 33.

Table 33: HADS Depression scores for participants in and out of work

HADS: Depression scores ¹		Working	Not working	Mann Whitney U
Baseline	Participants	11	82	U =167.50²
	Median	2.00	5.50	Z = -3.39
	IQR	2.00	6.25	p = 0.002
	Range	0-4	0-17	
3 months	Participants	38	35	U =293.50
	Median	1.50	7.00	Z = -4.13
	IQR	3.00	7.50	p =0.001
	Range	0-14	0-16	
6 months	Participants	41	25	U =280.50
	Median	2.00	6.00	Z = -3.10
	IQR	4.00	10.00	p = 0.002
	Range	0-15	0-16	
12 months	Participants	38	22	U =255.00
	Median	2.00	8.00	Z = -2.53
	IQR	5.25	10.00	p = 0.01
	Range	0-15	0-17	
18 months	Participants	23	12	U =134.00
	Median	3.00	9.00	Z = -0.51
	IQR	5.00	16.00	p = 0.61
	Range	0-10	0-18	

¹ HADS scores: 0-7 normal range, 8-10 =borderline, 11-21 = abnormal (Bowling 2002)

²red text = statistically significant

For anxiety, there were significant differences at baseline, three, six and twelve months –see Table 34.

Table 34: HADS Anxiety scores for participants in and out of work

HADS: Anxiety scores		Working	Not working	Mann Whitney U
Baseline	Participants	11	83	$U = 167.50^2$
	Median	2.00	7.00	$Z = -3.39$
	IQR	2.00	7.00	$p = 0.002$
	Range	0-12	0-19	
3 months	Participants	37	34	$U = 293.50$
	Median	4.50	5.50	$Z = -4.13$
	IQR	6.00	8.00	$p = 0.001$
	Range	0-15	1-20	
6 months	Participants	41	25	$U = 280.50$
	Median	3.00	8.00	$Z = -3.10$
	IQR	5.00	7.50	$p = 0.002$
	Range	0-17	0-17	
12 months	Participants	38	21	$U = 255.00$
	Median	4.50	9.00	$Z = -2.53$
	IQR	7.50	10.00	$p = 0.01$
	Range	0-20	0-20	
18 months	Participants	23	13	$U = 134.00$
	Median	4.00	11.00	$Z = -0.51$
	IQR	5.00	13.00	$p = 0.61$
	Range	0-17	0-18	

¹HADS scores: 0-7 within normal range, 8-10 =borderline, 11-21 = abnormal (Bowling 2002)

²red text = statistically significant

People in work scored significantly higher scores on the EQ5D visual analogue scale compared to those not working at baseline, three, six and twelve months – see Table 35.

Table 35: Mean EQ5D scores for participants in and out of work:

EQ5D VAS scores		Working	Not working	Mann Whitney U
Baseline	Numbers working	11	82	U =279.00* Z = -2.10 p = 0.04
	Median	7.00	5.00	
	IQR	2.00	2.62	
	Range	3.00-10.00	1.00-9.00	
3 months	Numbers working	39	35	U =327.00 Z = -3.88 p = 0.001
	Median	8.00	6.25	
	IQR	1.92	3.00	
	Range	5.00-10.00	3.00-9.70	
6 months	Numbers working	41	26	U =287.00 Z = -3.17 p = 0.002
	Median	8.00	6.00	
	IQR	2.60	3.00	
	Range	3.00-10.00	2.80-10.00	
12 months	Numbers working	38	22	U =228.00 Z = -2.93 p = 0.003
	Median	8.25	7.00	
	IQR	1.50	3.85	
	Range	2.00-10.00	2.50-10.00	
18 months	Numbers working	28	12	U =96.00 Z = -1.47 p = 0.143
	Median	8.50	7.00	
	IQR	2.50	4.00	
	Range	5.50-10.00	3.00-10.00	

*red text = statistically significant

3.3.4.5. Summary of secondary outcomes

There were no significant differences in functional ability (BICRO), mood (HADS) or reported quality of life (EQ5D) between groups at any time point post-injury. The BICRO showed significant agreement between all participant and carer scores both at baseline and at 12 months. Overall both groups showed a similar pattern of responses on the secondary outcome measures at all time points.

Significant differences found were between participants who were in work and those who were not. Those in work recorded lower levels of anxiety and depression and a higher quality of life over 13 months since hospital discharge.

3.3.5. Factors which may affect work

Factors examined were job category, returning to the same job or employer, activity other than work, services received, length of time taken to return to work, graded return to work and work place adjustments.

3.3.5.1. Work status at 12 months

Effect of job category

Participants in the lowest skilled jobs (SOC level 1) experienced the greatest amount of job loss. Participants in the highest skilled job (SOC level 4) experienced the least job loss – see Table 36. Specialist group participants achieved less job loss in all job categories.

Table 36: Participants in work according to job code at 12 months

Job code ¹		Specialist group			Usual care group		
		Pre-injury	One year	Difference	Pre-injury	One year	Difference
1 (Lowest skill level)	no's	11/12 ²	8/12	25%	10/10	5/9 ³	44.1%
	%	91.7	66.7		100	55.6	
2	no's	12/12	8/10	20%	18/20	9/17	37.1%
	%	100	80		90	52.9	
3	no's	10/11	7/10	20.9%	19/19	10/14	28.6%
	%	90.9	70		100	71.4	
4 (High skill level)	no's	5/5	4/4	0.0%	5/5	3/5	40%
	%	100	100		100	60	

¹ Based on pre-injury SOCv2000 codes. See 3.2.4.2. for details of SOC levels. ²

² Participants not working pre-injury were coded to their reported job level.

³ The numbers of responses vary between pre-injury and 12 months due to loss to follow up.

Participant's employer and job status

There were no statistically significant differences between the group on employment status. Participants in both groups were more likely to remain with their pre-injury employer than to change employer although this trend decreased over time. At 3 months 83.30% of the specialist group (15/18) and 88.0% (22/25) of the usual care group participants remained with their pre-injury employer. At 12 months 57.89% of the specialist group respondents (11/19) and 76.9% of the usual care group respondents (20/26) reported being with the same employer –see Table 37. At 18 months post-injury this changed. Proportionately more people in the specialist group, 10/14 (71.4%) reported working for the same employer than in the usual care group, 10/18 (55.6%).

The numbers of specialist group participants who reported they were doing the same job reduced from 15/19 (79%) at three months to 13/20 (65.0%) at 12 months. However, in the usual care group, the numbers remained similar: 17/25 (68%) at three months v 17/26 (65.38%) at 12 months – see Table 37.

Table 37: Participants work status at 12 months

12 month work status		Specialist group	Usual care group	Percentage difference	Odds (95% CI)
On a scheme to help stay in work	no's	1/6	0/8	16.7%	Cell frequency too low
	%	16.7	0.0		
With same employer	no's	11/19	20/26	19.0%	0.41 (0.11, 1.50)
	%	57.9	76.9		
With a new employer	no's	8/16	5/17	27.3%	3.4 (0.84, 13.76)
	%	50.0	22.7		
Doing the same job	no's	13/20	17/26	0.4%	0.98 (0.29, 3.34)
	%	65.0	65.4		
Doing a different job	no's	9/18	7/22	18.2%	2.14 (0.59, 7.77)
	%	50.0	31.8		

Activity other than paid work or education

There were no statistically significant differences between the groups .

However, response to this questions was poor—see Table 38. More people in the specialist group reported being active outside the home i.e. undertaking voluntary work, being unemployed but seeking work, and on a programme to help find work compared to participants in the usual care group –see Table 38. Proportionately more people in the usual care group reported being active in the home, such as looking after children or being a housewife, compared to those in the specialist group.

Table 38: Status of participants other than paid work or education

12 months status		Specialist group	Usual care group	OR (95% CI)
In voluntary work	no's	4/12	2/13	3.25 (0.48, 22.00)
	%	33.3	15.4	
Unemployed but seeking work	no's	4/23	2/24	2.32 (0.38, 14.80)
	%	17.4	8.3	
On a scheme to stay in work	no's	1/6	0/8	Cell frequency too low
	%	16.7	0.0	
On a programme to help find work	no's	5/22	1/22	6.18 (0.66, 58.03)
	%	22.7	4.5	
Total: Outside home activities*	no's	14/63	4/67	
	%	22.2	6.0	
Looking after children	no's	2/12	7/10	0.29 (0.05, 1.73)
	%	16.7	70.0	
Housewife	no's	2/12	4/16	0.60 (0.9. 3.99)
	%	16.7	25.0	
Total: Inside home activities*	no's	4/22	11/36	
	%	18.2	30.6	

* Bold indicates total numbers for each section

3.3.5.2. Services received

Both groups reported receiving health and social care services– see Table 39. Both groups made a similar number of visits to GPs throughout the study. A similar number of participants saw a consultant up to six months post-baseline, but after six months proportionally more usual care group participants saw consultants compared to specialist group participants at 12 and 18 months.

More people in the specialist group reported seeing case managers, a cognitive behavioural therapist and an OT at all-time points. Similar proportions in each group saw a physiotherapist at baseline, three, six and eighteen months but approximately 10% more usual care participants saw a physiotherapist at 12 months.

Proportionately more people in the usual care group saw a benefits advisor, especially at 6 and 12 months. More people in the usual care group reported having informal support, from family, friends and even the local vicar. Headway was the most commonly cited form of third sector support. After consultants and GPs, solicitors were the profession most frequently seen- see Table 39.

Table 39: Services received by participants

Services	n=number of visits % of group x=range of appointments	Specialist group					Usual care group				
		Baseline (n=40)	3 months (n=27)	6 months (n=28)	12 months (n=24)	18 months (n=14)	Baseline (n=54)	3 months (n=46)	6 months (n=38)	12 months (n=38)	18 months (n=22)
Consultant	n	5	16	14	9	3	11	32	21	19	12
	%	12.5	61.5	56.0	37.5	25	20.4	68.1	52.5	48.7	44.4
	Range	1-2	1-7	1-11	1-5	1-6	1-3	1-5	1-8	1-6	1-10
GP	n	26	20	21	14	8	37	33	30	22	13
	%	65	74.1	77.8	51.9	53.3	68.5	70.2	76.9	57.9	50.0
	Range	1-5	1-10	1-12	1-6	1-10	1-4	1-20	1-26	1-13	1-10
Case manager	n	20	8	10	10	5	0	1	6	3	0
	%	50.0	32.0	37.0	37.0	31.2	0.0	2.2	16.2	7.9	0.0
	Range	0-4	1-8	1-12	1-18	1-11	0	1-2	20	1-8	0
Neuro psychologist	n	3	5	5	10	2	2	13	12	9	4
	%	7.5	19.2	17.9	37.0	14.3	3.7	28.3	30.8	23.1	15.4
	Range	0-1	1-10	1-5	1-8	2-6	1	2-3	1-7	1-10	1-2
Cognitive behavioural therapist	n	4	3	4	5	3	0	0	3	1	0
	%	10.0	11.1	14.3	18.5	21.4	0.0	0.0	7.7	2.6	0.0
	Range	1-4	1-11	1-6	1-12	3-12	0	0-1	0-1	0-6	0-1
Occupational therapist	n	28	13	19	10	6	2	11	10	8	2
	%	70.0	48.1	70.4	35.7	37.5	3.7	23.9	26.3	21.1	7.7
	Range	1-5	1-10	1-16	1-20	1-10	0-3	1-12	1-12	1-10	1-2

Table 39: Services received by participants (continued)

Services	n=number of visits % of group x=range of appointments	Specialist group					Usual care group				
		Baseline (n=40)	3 months (n=27)	6 months (n=28)	12 months (n=24)	18 months (n=14)	Baseline (n=54)	3 months (n=46)	6 months (n=38)	12 months (n=38)	18 months (n=22)
Physiotherapist	n	6	9	11	4	3	9	19	16	10	5
	%	15.0	33.3	39.3	15.4	20.0	16.7	40.4	40.0	26.3	18.5
	Range	1-2	1-15	1-50	1-12	1-24	1-6	1-32	1-48	1-52	1-52
Speech and language therapist	n	0	3	3	0	1	1	8	4	3	1
	%	0	11.1	10.7	0.0	6.7	1.9	17.8	10.5	7.9	3.8
	Range	0	1-3	1-2	0	0-1	0-1	1-20	2-24	1-13	0-24
Social Worker	n	1	0	0	0	0	5	2	1	3	1
	%	2.5	0.0	0.0	0.0	0.0	9.3	4.4	2.6	5.3	3.8
	Range	0-1	0	0	0	0	1-2	1-3	1-2	1-2	0-4
Other health related services ¹	n	2	2	3	0	2	7	8	6	6	1
	%	5.0	7.4	10.7	0.0	14.3	13.0	17.4	15.4	15.8	3.8
Benefits advisor	n	4	1	4	3	2	3	11	8	7	3
	%	10.0	3.7	14.8	11.5	14.3	5.6	23.9	20.0	19.4	13.6
	Range	1-3	0-1	1-5	1-5	1-2	1-2	1-3	1-2	1-2	1-10
Disability Employment Advisor	n	0	2	4	1	3	0	3	5	4	3
	%	0.0	7.4	14.8	3.8	23.1	0.0	6.5	12.8	11.1	13.6
	Range	0	1-2	1-2	0-2	2-3	0	1-3	1-2	1-2	1-2

Table 39: Services received by participants (continued)

Services	n= number of visits % of group x=range of appointments	Specialist group					Usual care group				
		Baseline (n=40)	3 months (n=27)	6 months (n=28)	12 months (n=24)	18 months (n=14)	Baseline (n=54)	3 months (n=46)	6 months (n=38)	12 months (n=38)	18 months (n=22)
Other DWP services	n	0	4	5	4	2	0	6	2	2	3
	%	0.0	14.8	18.5%	15.4	14.3	0.0	12.8	5.1	5.6	13.6
	Range	0	1-5	1-4	1-2	1-6	0	1-4	0-1	0-1	1-2
Solicitor	n	7	7	11	6	6	6	12	9	11	3
	%	17.5	25.9	40.7	23.1	42.9	16.7	25.5	23.1	30.6	13.6
	Range	1-2	1-5	1-7	1-6	1-4	1-5	1-5	1-7	2-9	2-6
Work related services e.g. OH	n	1	4	2	1	0	3	2	4	5	2
	%	2.5	14.8	7.4	3.6	0	5.6	4.3	10.3	13.9	9.1
	Range	0-2	1-7	1-6	0-2	0	1-2	1-2	1-3	1-18	1-2
Self-help group ²	n	1	1	3	0	0	5	1	3	1	1
	%	2.5	3.7	11.1	0	0.0	9.3	2.2	7.7	2.9	4.5
	Range	0-2	0-2	1-4	0	0	1-10	0-1	1-3	0-4	0-1
Other ³	n	9	4	5	2	4	11	7	7	7	2
	%	22.5	14.8	18.5	7.7	28.6	20.4	14.6	17.9	19.4	9.1

¹ E.g. Outpatient OT, ophthalmic department, ENT dept., hospital for total hip replacement, district nurse, social services for rails, counsellor from GP surgery, hydrotherapy, community psychiatric nurse, 'student SW but no-one else since'

² E.g. Headway, Victim Support, local women's group, Red Cross for wheelchair, website for RTA victims

³ E.g. Welfare rights, local vicar, personal tutor at university course leader at university, family, friends

3.3.5.3. Time taken to return to work

There was no statistically significant difference between the groups in the time taken to return to part time or full time work. However, the specialist group took five and a half weeks longer to return to part time work than the usual care group (25.5. weeks v 7.00 weeks [median figures]) – see Table 40.

As not all participants initially worked part time, the time taken to return to full time work appears less than that for participants who returned to work on a part time basis– see Table 40.

Of participants who initially returned to work on a part time basis, specialist group participants worked a median of four weeks longer part time compared to usual care participants before returning to full time hours. This differed according to injury severity. People with minor TBI took six week longer while those with moderate/severe TBI took two weeks longer compared to usual care participants – see Table 40.

Table 40: Number of weeks to return to work (All injury severity).

Number of weeks to return to:-	Injury severity	Number of weeks	Specialist group (n=28)	Usual care group (n=23)	Mann Whitney U
Part time work	All	Median	12.5	7.0	U=257.00
		IQR	13.5	15.0	Z=-0.83
		Range	2-48	1-52	p=0.40
	Moderate & severe	Median	14.0	14.0	U=76.00
		IQR	25	25.5	Z=-0.21
		Range	0-48	0-52	p=0.83
	Minor	Median	10.0	6.0	U=56.00
		IQR	11.75	6.5	Z=-0.56
		Range	0 -18	0-26	p=0.58
Full time work	All	Median	10.0	10.0	U=307.50
		IQR	12.0	14.5	Z=-0.28
		Range	1-64	1-78	p=0.78
	Moderate & severe	Median	12.0	12.5	U=49.00
		IQR	22.75	24.0	Z=-0.08
		Range	2-64	1-78	p= 0.94
	Minor	Median	9.0	10.0	U=102.00
		IQR	10.0	12.5	Z=-0.60
		Range	1-23	1-57	p= 0.55
Length of time working part time before resuming full hours (weeks)	All	Median	6.0	2.0	U=309.00
		IQR	15.3	9.0	Z= -0.31
		Range	0-33	0-50	p=0.69
	Moderate & severe	Median	3.0	1.0	U=40.0
		IQR	13.0	15.5	Z=-0.42
		Range	0-17	0-50	p=0.68
	Minor	Median	9.0	3.0	U=35.0
		IQR	20.0	9.5	Z=-1.58
		Range	0-33	0-28	p=0.11

3.3.5.4. Graded Return to work

More people in the specialist group reported having undergone a graded return to work at all time points –see Table 41. Statistically significant differences were found at three months and at 18 months– see Table 41. At three months, 50% of minor TBI’s in the specialist group underwent a graded return to work compared to none in the usual care group.

Table 41: Participants who undertook a graded return to work

		Specialist group		Usual care group	OR (95%CI)
3 months					
All participants	no’s	9/23		4/30	4.2* (1.1,16.0)
	%	39.1		13.3	
Moderate/severe	no’s	5/33		4/17	1.6 (0.3, 7.7)
	%	33.3		23.5	
Minor	no’s	4/8		0/13	Cell frequency too low
	%	50.0		0.0	
6 months					
All participants	no’s	5/23		2/28	3.6 (0.6, 20.7)
	%	21.7		7.1	
Moderate/severe	no’s	5/11		1/12	5.0 (0.5, 50.1)
	%	31.2		8.3	
Minor	no’s	0/7		1/15	Cell frequency too low
	%	0.0		6.2	
12 months					
All participants	no’s	5/22		2/24	3.2 (0.6, 18.8)
	%	22.7		8.3	
Moderate/severe	no’s	4/13		2/12	2.00 (0.3, 13.5)
	%	28.6		16.7	
Minor	no’s	1/8		0/1	Cell frequency too low
	%	12.5		0.0	
18 months					
All participants	no’s	5/11		1/17	13.3 (1.28, 138.9)
	%	45.5		5.9	
Moderate/severe	no’s	5/8		0/8	Cell frequency too low
	%	62.5		0.0	
Minor	no’s	0/3		1/9	Cell frequency too low
	%	0.0		11.1	

*Red text = statistically significant

3.3.5.5. Work place adjustments

More people in the specialist group reported having work place adjustments at 3, 6 and 12 months compared to the usual care group– see Table 42. At 12 months, 41% of the specialist group participants reported that adjustments were still in place compared with 24% of usual care participants. However, at 18 months post- baseline, this trend was reversed; more usual care group participants reported work place adjustments. The differences were not statistically significant

Table 42: Participants reporting work place adjustments

		Specialist group	Usual care group	% difference	OR (95% CI)
Baseline	No's	3/7	2/3	-23.8% ¹	0.38 (0.02, 6.35)
	%	42.9	66.7		
3 months	No's	9/17	6/23	26.8%	3.19 (0.84, 12.07)
	%	52.9	26.1		
6 months	No's	8/21	8/22	1.7%	1.08 (0.31, 3.71)
	%	38.1	36.4		
12 months	No's	9/22	7/29	16.8%	2.18 (0.65, 7.24)
	%	40.9	24.1		
18 months	No's	1/12	7/17	-32.9%	0.13 (0.01, 1.25)
	%	8.3	41.2		

¹Negative differences reflect greater work place adjustments in the usual care group

Type of work place adjustments

Being allowed more breaks and having a reduced work load were the most frequently cited adjustments within the first six months back at work in both groups – see Table 43.

At 12 and 18 months participants in both groups reported having reduced work load, reduced responsibilities, receiving increased supervision and having flexibility around taking breaks, to varying degrees (between 17%-50%). Many participants reported they could take breaks whenever they wanted.

Table 43: Work place modifications

	Specialist group		Usual care group		% Difference ¹	OR (95% CI)
More breaks						
	No's	%	No's	%		
baseline	2/3	66.6	1/2	50.0	16.6%	2.00 (0.5, 78.25)
3 months	6/12	50.0	3/18	16.7	33.3%	5.00 (0.93, 26.79)
6 months	4/14	28.6	4/9	44.4	-15.8%	0.50 (0.09, 2.89)
12 months	4/12	33.3	4/11	36.4	-3.1%	0.88 (0.16, 4.87)
18 months	0/10	0.0	3/13	23.1	-23.1%	Cell frequency too low
Reduced amount of work						
baseline	3/3	100.0	0	0.0	100.0%	Cell frequency too low
3 months	6/13	46.2	5/17	29.4	16.8%	2.06 (0.46, 9.30)
6 months	7/17	41.2	6/12	50.0	-8.8%	0.70 (0.16, 3.10)
12 months	5/11	45.5	2/9	22.2	23.3%	2.92 (0.41, 20.90)
18 months	2/4	50.0	1/6	16.7	33.3%	5.0 (0.27, 91.52)
Reduced responsibilities						
baseline	2/3	66.6	0	0.0	66.6%	Cell frequency too low
3 months	5/14	35.7	5/16	31.2	4.5%	1.22 (0.27, 5.59)
6 months	4/15	26.7	6/11	54.5	27.8%	0.30 (0.06, 1.58)
12 months	3/11	27.3	3/9	33.3	6.0%	0.75 (0.11, 5.11)
18 months	2/4	50.0	2/4	50.0	0.0%	1.00 (0.8, 12.56)
Provided more supervision						
baseline	1/3	33.3	0	0.0	33.3%	Cell frequency too low
3 months	9/14	64.3	5/17	29.4	34.9%	4.32 (0.95, 19.58)
6 months	5/15	33.3	6/12	50.0	-16.7%	0.50 (0.11, 2.38)
12 months	2/11	18.2	2/9	22.2	-4.0%	0.78 (0.09, 6.98)
18 months	1/4	25.0	1/6	16.7	18.3%	1.67 (0.07, 37.73)
Allowed to work at home						
baseline	1/2	50.0	1/2	50.0	0.0%	1.00 (0.02, 50.40)
3 months	2/13	15.4	1/17	5.9	9.5%	2.91 (0.23, 36.16)
6 months	2/15	13.3	0	0.0	13.3%	Cell frequency too low
12 months	0/11	0.0	0/11	0.0	0.0%	n/a
18 months	0/3	0.0	0/6	0.0	0.0%	n/a
Other agencies (Including: NTBIS, OH, DEA, physiotherapist)						
baseline	0	0.0	0	0.0	0.0%	n/a
3 months	4/14	28.6	2/16	12.5	16.1%	2.80 (0.43, 18.38)
6 months	3/15	20.0	2/11	18.2	1.8%	1.13 (0.16, 8.2)
12 months	1/11	9.1	1/8	11.1	-2.0%	0.80 (0.04, 14.89)
18 months	0/4	0.0	2/6	33.3	-33.3%	Cell frequency too low

¹ A negative difference reflects greater work place adjustment in the usual care group

Few people reported receiving help from other agencies with regard to work. Apart from the NTBIS or OT, none were involved at four weeks post-discharge. The NTBIS team was the most frequently cited help with return to work followed by Occupational Health. One person in the usual care group cited help from a physiotherapist. Usual care group participants had fewer agencies involved before six months.

3.3.5.6. Summary of factors which may affect work

The majority of participants returned to their pre-injury employers, with specialist group participants experiencing fewer job losses across all job categories. Proportionately, more specialist group participants reported activity outside the home compared to the usual care group, who reported more home based activity.

The specialist group reported receiving more case management and OT appointments overall. Both groups reported receiving similar numbers of appointments with consultants and GPs, up to six months post-TBI. Solicitors were the profession most frequently seen after consultants and GPs in both groups.

The specialist group were more likely to undertake a graded return to work at all time points. This difference was statistically significant at three months. Specialist group participants took approximately five weeks longer (median) to return to part-time work compared to the usual care group. This was statistically significant. They also worked longer on a part time basis before returning to full time work compared to usual care participants, but this was not statistically significant.

There was no statistically significant differences in work adjustments between groups. More breaks and reduced workload were the most frequently reported work adjustments in both groups with many adjustments still in place at 12 and 18 months post injury.

3.3.6. Environmental and personal factors related to returning to work

Personal factors related to return to work rates measured included: reasons for returning to work, perception of recovery, receiving adequate care, employer support, coping at work and enjoying work. Environmental factors included cause of injury, driving ability and claiming compensation.

3.3.6.1. Personal factors

Personal reasons for returning to work

Participants were asked why they returned to work. Wanting to return and feeling able to cope were the most commonly cited reasons for returning to work at all time points – see Table 44. Needing the money and feeling work needed them were the least popular reasons cited at all time points. Both groups showed a similar pattern but more people in the usual care group felt that returning to work would help them recover at all time points.

Table 44: Personal reasons for return to work

Personal reasons for returning to work			Specialist group	Usual care group	OR (95%CI)
Wanting to return	3 months	no's	13/17	19/24	0.86
		%	76.5	79.2	(0.19, 3.80)
	6 months	no's	17/21	17/23	1.50
		%	81.0	73.9	(0.36, 6.29)
	12 months	no's	12/17	16/22	0.90
		%	70.6	72.7	(0.22, 3.66)
Felt able to cope	3 months	no's	12/16	15/23	1.60
		%	75.0	65.2	(0.39, 6.62)
	6 months	no's	16/20	18/23	1.11
		%	80.0	78.7	(0.25, 4.87)
	12 months	no's	12/17	16/22	0.90
		%	70.6	72.7	(0.22, 3.66)
Felt it would help their recovery	3 months	no's	6/17	11/24	0.65
		%	35.3	45.8	(0.18, 2.32)
	6 months	no's	7/21	12/23	0.46
		%	33.3	52.2	(0.14, 1.56)
	12 months	%	6/17	9/22	0.79
		%	35.3	40.9	(0.21, 2.92)
Needed the money	3 months	no's	9/17	14/23	0.72
		%	52.9	60.9	(0.20, 2.57)
	6 months	no's	17/21	17/23	1.5
		%	81.0	73.9	(0.36, 6.29)
	12 months	no's	10/18	14/22	0.71
		%	55.6	63.6	(0.20, 2.55)
Work needed them	3 months	no's	4/16	5/23	1.20
		%	25.0	21.7	(0.27, 5.40)
	6 months	no's	3/21	6/23	0.47
		%	14.3	26.1	(0.10, 2.20)
	12 months	no's	5/17	6/22	1.11
		%	29.4	27.3	(0.27, 4.52)

Participant's perception of their recovery

There were no statistically significant differences between the groups regarding self-perception of recovery –see Table 45. More people in the usual care group reported feeling fully recovered at baseline, three months and six months, compared to the specialist group. This pattern was reversed at 12 months. More people in the specialist group felt fully recovered, especially those with moderate or severe TBI, but approximately half of all participants did not feel fully recovered at 12 months.

Table 45: Participants reporting feeling fully recovered

Participants feeling fully recovered		Specialist group	Usual care group	Difference (%)	OR (95% CI)
Baseline					
All participants	no's	2/35	8/54	-9.10 ¹	0.35 (0.07, 1.75)
	%	5.7	14.8		
Moderate/severe	no's	1/22	1/28	0.90	1.29 (0.08, 21.78)
	%	4.5	3.6		
Minor	no's	1/13	7/26	-19.20	0.23 (0.03, 2.08)
	%	7.7	26.9		
3 months					
All participants	no's	9/26	18/46	-4.20	0.82 (0.30, 2.24)
	%	34.9	39.1		
Moderate/severe	no's	4/15	7/22	-5.10	0.78 (0.18, 3.34)
	%	26.7	31.8		
Minor	no's	5/11	11/24	-0.30	0.96 (0.26, 4.13)
	%	45.5	45.8		
6 months					
All participants	no's	12/29	19/38	-8.60	0.71 (0.27, 1.87)
	%	41.4	50.0		
Moderate/severe	no's	7/18	4/17	15.40	2.07 (0.48, 8.97)
	%	38.9	23.5		
Minor	no's	5/11	15/21	-16.90	0.33 (0.7, 1.52)
	%	54.5	71.4		
12 months					
All participants	no's	15/26	17/38	13.00	1.68 (0.62, 4.61)
	%	57.7	44.70		
Moderate/severe	no's	6/14	4/16	17.90	2.25 (0.48, 10.60)
	%	42.9	25.0		
Minor	no's	9/12	13/22	15.90	2.08 (0.44, 9.87)
	%	75.0	59.1		

¹ Minus = more participants in usual care group reporting fully recovered compared to specialist group

Participant's perception of adequate care

The specialist group reported higher levels of satisfaction with care received at all time points compared to the usual care group – see Table 46. The difference was statistically significant at three months. Satisfaction with care received was consistently above 80% for the specialist group and consistently above 70% for the usual care group.

Table 46: Participants reporting receiving adequate care

		Specialist group	Usual care group	Difference (%)	OR (95% CI)
Baseline	no's	25/34	25/52	21.6	3.00* (1.18, 7.65)
	%	73.5	51.9		
3 months	no's	24/27	35/45	11.1%	2.29 (0.57, 9.19)
	%	88.9	77.8		
6 months	no's	22/24	27/37	18.7%	4.07 (0.81, 20.57)
	%	91.7	73.0		
12 months	no's	19/21	25/34	17.0%	3.42 (0.66, 17.71)
	%	90.7	73.5		
	%	80.0	73.7		

*Red text = statistically significant

Informing employers of the TBI

There was no statistically significant difference between the groups regarding informing employers about their TBI. However, more specialist group participants had informed their employers of their injury at all-time points. At three months 19/20 (95%) of the specialist group had informed their employer about their TBI compared to 22/25 (88%) of the usual care group (OR 2.59, [0.29, 27.03]). At six months, those informing their employers had increased (specialist group 21/21 (100.0%) v usual care group 22/23 (95.7%) (cell frequency too low for OR) but then decreased slightly at 12 months, (specialist group 17/18 (94.4%) v usual care group 20/24 (83.3%) (OR 3.4, [0.36, 33.40]).

Employer Support

Respondents felt employers were supportive at three months (specialist group 16/17 [94.1%] v usual care group 25/27 [92.2%], OR 1.28 [0.11, 15.30]). At six months, employer support reduced (specialist group 16/21 [76.2%] v usual care group 20/23 [87.0%], OR 0.48 [0.01, 2.32]) but increased at one year (specialist group 17/17 [100%] v usual care group 19/23 [82.6]).

Coping at work

Usual care group participants reported more difficulty coping at work than specialist group participants at all time points. At three months, more specialist group participants reported coping the same or better at work compared to before their injury (Specialist group 13/18 [72.2%] v usual care group 16/28 [57, 1%]). A similar pattern was found at six months (specialist group participants reporting coping the same or better at work 15/21 [71.4] v 16/25 [64.0%]) and at 12 months (specialist group 17/21 [80.95%] v usual care group 18/26 [69.23%]).

Enjoying work

When enjoying work was measured as 'the same or better than before', both groups reported similar levels of enjoyment. The main difference was that 15% fewer usual care group participants reported enjoying their job at six months (Enjoying the job: specialist group 13/16 [81.2%] v usual care group 15/23 [65.20%]). At 12 months both groups reported the same level of enjoyment as prior to the injury 14/17 (82%) in the specialist group v 18/22 (82%) in the usual care group. These are similar to reported pre-injury levels of enjoyment which were: specialist group 92.5% (37/40), usual care group 46/54 (85.2%).

3.3.6.2. Environmental factors

Driving

There was no statistically significant difference in the number of participants who ticked whether or not they had resumed driving at 12 months (Resumed driving: specialist group 12/23 (52.25) v usual care group 22/37 (59.5%) OR 0.74, [0.26, 2.12]).

At 12 months, three specialist group participants 3/29 (10.3%) reported that not driving was affecting their ability to work. Of these, one did not own a car and although intending to work pre-injury was not working post-injury, the second person did not want to resume driving and was not working post-injury and the third person had disengaged from treatment without resuming work. In the usual care group 3/39 (7.7%) people reported that not driving was affecting their ability to work, one of whom had additional disabilities which made using public transport difficult. The usual care participants who drove HGVs prior to their injury (n=2) did not indicate that not driving affected their ability to work.

Compensation

At one year, slightly more specialist group participants who did not return to work were claiming compensation (10.7% more) –see Table 47.

Table 47: Claiming compensation and working at 12 months

Working at 12 months	Pursuing a compensation claim at 12 months	Specialist group		Usual care group		Statistic
		No's	%	No's	%	
Yes	Yes	5/18	27.8	10/22	45.5	Cell frequency too low
	No	11/18	61.1	12/22	54.5	
	Looking into it	2/18	11.1	0/22	0.0	
No	Yes	2/8	25.0	4/14	28.6	Cell frequency too low
	No	6/8	75.0	9/14	64.3	
	Looking into it	0/8	0.0	1/14	7.1	

3.3.6.3. Summary of personal and environmental factors

There were no statistically significant differences regarding environmental or personal factors between the groups. People in both groups went back to work because they wanted to and felt it would help them recover. Most people informed their employers of their injury and reported employers were supportive. Over 80% of all participants in both groups reported enjoying work at 12 months. More usual care group participants reported difficulty in coping at work compared to specialist group participants.

3.4. Discussion

The practical aspects of conducting the cohort comparison study and the findings will be discussed separately.

3.4.1. Practical considerations

The main practical considerations were: recruitment, data collection, the use of 'work' as an outcome measure and the secondary outcome measures used.

3.4.1.1. Recruitment of participants

The recruitment difficulties were: identifying potential participants, contacting participants after hospital discharge and obtaining consent.

The lack of any central registers of people admitted with TBI meant each ward had to be contacted individually. Furthermore the fast turnover of patients found in a regional neurosurgical unit required almost daily contact with the wards. Therefore, identification of potential participants relied heavily on personal contact by the OT researcher. Additionally, ascertaining eligibility of the large number of potential TBI participants, many of whom stayed in hospital less than 48 hours, was time consuming. Wade et al (1998) also commented on the difficulty of tracking the large number of minor TBI patients admitted to hospital and how staff intensive this was.

Approximately 8% of those eligible to participate did not reply to letters, answer phone calls or did not have a valid telephone number for contact after hospital discharge. Other TBI studies have reported similar problems when recruiting potential participants whilst in hospital. For example Langley et al (2010) were unable to contact 15% of the 1790 people with TBI following initial medical treatment, Wade et al (1998) could not contact 24% (44/181) of TBI patients when offering follow up treatment after hospital admission despite attempting to contact them both by telephone and letter.

One reason for this difficulty could be that many people only provided a mobile phone number as a contact number. Mobile phones are lost, damaged

and/or are kept by police for evidence after some accidents or assaults. Langley et al (2010) has also noted the problem of disconnected mobile phones in a study with a TBI population. As more people rely solely on mobile phones, the problem of contacting potential TBI participants in this way become increasingly problematic in the future.

Approximately a quarter of eligible patients declined to participate. In a RCT of USA military personnel with TBI, 60% (537/897) of eligible participants also declined to participate when offered two different types of in-patient treatment (Vanderploeg et al. 2008). This reflects the general problem of recruiting participants into research studies. For example; Ahlstrom et al (2010) invited a cohort of female Swedish workers who were on long-term sick leave to complete a questionnaire related to work. Of the 633 people sent information about the study, only 324 (51%) replied.

Recruiting TBI patients whilst in hospital is problematic. Some people declined to participate because they felt unwell, some because they had already returned to work and felt a study entitled 'return to work after TBI' did not apply to them, and others with obvious physical injuries did not feel they had a TBI, despite documentation in the medical records. Difference in recovery rates, combined with the hidden problems of TBI make it difficult to judge when to approach people to take part in a study. Interestingly, of the eleven participants not seen by the OT on the ward, nine declined to participate, suggesting face-to-face invitation may be more effective than a written one.

Potential participants were visited at home four weeks after hospital discharge to obtain consent. However, a few people could not remember why they were being visited or thought the visit was part of the hospital routine discharge process even though they had been sent written information about the study. The same problem was also reported by Langley et al (2010) who also followed up TBI patients four weeks post-hospital discharge. This suggests that some people with TBI may not fully understand what they are consenting to, particularly if consent is obtained whilst an in-patient. As everyone in this current study consented when visited at home, obtaining consent at four weeks

post-hospital discharge appeared to ensure participants fully understood what they were consenting to.

Finally, five people with minor TBI agreed to take part in the study but did not want or feel they required any intervention. This may be because at four weeks post-hospital discharge, 10/89 (11%) of all participants TBI reported feeling fully recovered. This may suggest that not all people with TBI require intervention. However Wade et al (1998) reported a similar finding when they contacted 181 TBI patients admitted to hospital seven to ten days post-TBI and offered specialist TBI intervention as part of a RCT. They found 35% (63/181) of those offered intervention did not take up the offer to be seen. At six months Wade et al found significantly fewer post-concussion symptoms and less social morbidity in patients who had received early intervention compared to those who had not been offered the early intervention. This suggests that early post-injury, patients may not have been fully aware of problems arising from their TBI or that their needs and abilities change over time. This lack of awareness of possible TBI sequelae may affect recruitment into TBI studies, which approach patients early post-injury.

3.4.1.2. Data

There were issues with the timing of data collection, the participant questionnaire, loss to follow up, the accuracy of data collected, the wording of questions and the 18 months data.

Timing of data collection

Baseline data was collected at four weeks post- hospital discharge. When this was combined with the median time spent in hospital (specialist group: 6 days, usual care group;17 days), this meant the 12 month data for the majority of participants was approximately 13 to 14 months post-injury. This is comparable with other studies. For example one year post-TBI data has been reported as being collected between 10 and 14 months post-injury (Walker et al. 2006), between 12-15 months post-injury (Wagner et al. 2002), and within a six month window of the initial injury (Corrigan et al. 2003). However, a wide variation in length of hospital stay meant people were providing baseline

data between 2 and 104 days post-injury. Collecting data at a set point from injury would avoid this wide variation. Other studies appear to collect baseline data retrospectively from case records or do not report when baseline data is collected (Leung et al. 2005; Sorbo et al. 2005).

Participant questionnaire

Even though the questionnaire was piloted on TBI clients and every effort was made to keep it as brief as possible, some participants did not fully complete or return the questionnaire. Willer et al (1994) reported 31/310 (10%) of the TBI sample used to develop the Community Integration Index did not fully complete it. Many participants were willing to answer questions when telephoned. However, as it was anticipated participants were likely to have cognitive problems, the call needed to be brief. These factors suggest the questionnaire may have been too long at 19 pages or presented difficulties for some participants. An alternative or additional explanation is that the TBI population is generally young, has low academic abilities, frequently changes addresses and has a low tolerance level for completing and returning postal questionnaires (Johnstone et al. 2006). Interestingly, there is very little discussion in the literature about the best way to obtain information from a TBI sample in which there is the added complication of cognitive problems. It is not known if a TBI sample differs from a mixed aetiology sample regarding returning and completing questionnaires. As three people requested the questionnaire by email this suggests that future studies should consider offering a variety of ways to collect data. Text messaging to remind people to return postal questionnaires or arrange phone interviews may be useful in this younger population.

Loss to follow up

The loss to follow up for the total cohort was 16% at 12 months but, when combined with participants who only returned partial information and had to be telephoned, the loss to follow up was higher at approximately 34%. Although the loss to follow up varies widely in TBI studies this level of loss to follow up is comparable to other TBI studies (Corrigan et al. 2003; Burrus et al. 2009; Langley et al. 2010). For example a systematic review of 14 prospective

cohort studies found loss to follow up rates varied between 5% and 58% at one year (Willemse-van Son et al. 2007). Unsurprisingly, the loss to follow up rate varies depending on the type of TBI samples studied with those in work prior to injury less likely to drop out (Corrigan et al. 2003). For example Corrigan et al (2003) reported a dropout rate of 34% at one year post-TBI in participants who were working pre-injury, predominately white and had a high school or better education (n =260). This is a similar level to that found in this cohort comparison study. Although this level of loss is not ideal, no convincing solutions have yet been found to address this in the TBI population (Wilde et al. 2010).

Collecting data at three and six months enabled people to inform us of changes of address as many as 17% of participants reported changing address in the year post-TBI. This may have reduced some loss to follow up.

Wording questions

For both groups, some questions proved problematic. From the responses to the question about whether participants undertook a graded return to work, it was not possible to ascertain whether those who answered '*no, they were not undertaking a graded return to work*' was because they had not returned to work or because they were working their usual hours. No definition of what constituted a 'graded return' was provided so the answers relied on participant's interpretation. This raised the question: 'at what stage does someone classify themselves as back at work': is it at the start of a graded return, or when they reach their maximum hours? Non-TBI VR studies have suggested this is an issue for all return to work studies and highlights the need for a core set of standard 'work' questions for use in VR studies. (Holtslag et al. 2007; Wasiak et al. 2007).

The question asking whether participants had changed their job or educational status did not reveal whether the change was due to the TBI or would have occurred anyway. For example some participants completed educational courses or were self-employed contractors. A more pertinent question would

have been ‘did you change your job or future plans as a direct result of your TBI. If so, why?’

18 month data

Some trends observed in the 12 month data were noted to be reversed in the 18 month data. For example more people in the usual care group reported having work adjustments compared to the specialist group at 18 months. As only half of the potential 70 participants returned questionnaires at 18 months, caution must be applied to the 18 months figures due to the lower number of participants responding at this time point. The data was examined to see if there were any reasons for these anomalies. There appeared to be some bias in those who responded at 18 months. Compared to their last known work status, fewer specialist group participants who were working replied and more usual care group participants who were working returned questionnaires at 18 months. Although it is unknown why this anomaly occurred, it may suggest bias due to the differential follow-up rates. It may also suggest that those that respond to questionnaires after 12 months may be a slightly different cohort.

3.4.1.3. Use of ‘Return to Work’ as the primary outcome

For the sake of brevity and because it had been used as a dichotomous outcome in other studies, the operational definition for the question ‘are you now working or in education’, was not included in the study questionnaire (Johnson 1998; Sorbo et al. 2005). This meant that participants defined whether they were working or in education themselves. As found in the literature review, participants had different definitions of what constituted being at work. For example a person worked the day they completed the questionnaire ticked they were at work and then took sick leave for the next few months. Whilst participants’ own definition of being in work can be regarded as the ultimate measure, the lack of a clear definition of work will limit comparison of future TBI VR studies.

The difficulties in achieving a consensus in TBI VR are illustrated by the fact that a group of 16 USA TBI research experts were able to agree a set of non-work TBI outcome measures for use in future TBI studies but could not reach a

consensus regarding TBI VR measurement (Wilde et al. 2010). They acknowledged that this was due to the complexity of possible VR outcomes.

After this study commenced, the ICF generated definitions of vocational states (World Health Organisation 2011). Unfortunately, the ICF VR definitions only capture broad outcomes as they do not measure factors such as the number of hours worked or work modifications used. Adoption of these definitions, and the expert TBI core set, may encourage greater uniformity of terminology in future TBI VR studies.

Additionally, knowing if someone's job or employer changes does not tell us if the change occurred as a result of the injury or for other reasons. In this study, job changes occurred for a variety of reasons. For example, students completed their course and started work or progressed on to the next course as planned, one participant was in the process of changing jobs at the time of the injury, one person's job was internally re-organised and one person changed from agency work to permanent work. Therefore, determining if the TBI was the reason for the change of job or employer may be more pertinent than just asking if a person has changed job or employer.

After this study started, the UK underwent an economic recession. This caused unemployment levels to rise (Office for National Statistics 2010). This highlighted the problem of using paid employment as an outcome measure. Paid work is outside a clinician's control so there is a need for outcome measures that are within the clinician's control. Measures such as perceived work ability, readiness to work scales or self-efficacy scales are widely used with other populations in VR studies but not TBI studies (Franche et al. 2007; Taskila et al. 2007; Brouwer et al. 2010). This is surprising given that motivation, self-efficacy and self-awareness have been found to be important in TBI work rehabilitation (Shames et al. 2007; Tsaousides et al. 2009). These types of measures may better reflect the effect of the intervention and are less susceptible to environmental factors such as the economic recession that occurred during this study.

3.4.1.4. Secondary outcome measures used

The secondary measures of function, mood and quality of life all showed similar scores between both groups and a similar pattern of change over time. This could be the natural recovery process and/or the effect of intervention.

Similar to findings by Powell et al (1998; 2002), participants and carers in both groups showed a high degree of agreement on the BICRO throughout the study. However the BICRO proved to be an insensitive measure for work outcomes. In the BICRO productivity scale looking after children carried equal scoring with paid employment. Thus this section measured participation not just employment. As more specialist group participants returned to work and more people in the usual care group reported undertaking childcare these cancelled out any potential for differences regarding employment to be detected by the BICRO. Additionally the BICRO also proved too long to be completed over the phone and some participants found questions such as ‘how much help do you need writing private letters’ not relevant to their lives. Finally the BICRO has been used in very few published studies since its development (Powell et al. 1998). For these reasons an alternative measure of social participation and work would be required in future studies.

Both the HADS and the EQ5D proved useful measures. They were simple to use, could be administered by phone and both showed a difference between those in and not in work. Additionally the EQ5D enabled quality adjusted life years (QALYs) to be calculated in order to evaluate cost-effectiveness.

3.4.1.5. Absence of cognitive measures

One criticism of this study could be the lack of any cognitive measures to ascertain how cognitive problems related to the ability to return to work. Cognitive tests, which measure actual ability as opposed to reported ability, were not included for pragmatic reasons. Administering neuropsychology tests in person are costly and time consuming. However, having a baseline cognitive measure would have facilitated a more detailed comparison of both groups. There is little consensus about what cognitive measures to use with regard to

return to work and the optimal time to administer them (Wade et al. 1998; Stergiou-Kita et al. 2011).

Although cognitive impairment and perception of cognitive impairment are different factors, surprisingly, few studies on return to work after TBI have specifically reported participants' perceptions of which cognitive problems have affected their ability to work. As patients perceived symptoms are the ones most important to them, inclusion of self-report cognitive questionnaires may increase our understanding of the many factors that affect a person's ability to work after TBI.

3.4.1.6. Summary of methodological findings: Cohort comparison

This cohort comparison study demonstrated that the vocational outcomes of a cohort of participants receiving specialist intervention and those receiving usual care could be collected and compared. The two main practical considerations were the time consuming nature of patient recruitment and the need to collect a short and complete data set. This study found that participants had different definitions of what constituted a 'return to work' thus a clear definition is required in future studies.

3.5. Findings from the Cohort Comparison study

Differences between the groups in return to work rates, secondary outcome measures, factors impacting on post-TBI employment and participation factors will now be discussed.

3.5.1. Primary outcome measure: Return to work

Proportionately, more people in the specialist care group returned to work compared to participants in the usual care group at all time points: 17% more at three months, 18% more at six months and 15% more at 12 and 18 months respectively. No-one who ticked that they were at work post baseline was working solely as a volunteer. As participants were not randomised all factors that may explain why the specialist group had a higher rate of return to work need to be explored, namely any group differences, the impact of those differences and potential problems with the study design.

3.5.1.1. Comparison of both groups

Demographically both groups were similar in gender, age, ethnicity, educational level, job level and past medical history. This study cohort was also similar in gender distribution, age and severity of injury to other TBI study populations (Salazar et al. 2000; Avesani et al. 2005; Johnston et al. 2006; Klonoff et al. 2006; Novack 2006; Walker et al. 2006). There were no significant differences between the groups on any of the secondary measures of participation, mood or quality of life at baseline. None of these factors offer an explanation that accounts for the higher rate of return to work in the specialist group.

However, there were differences between the groups in terms of: injury severity, length of hospital stay, numbers in work at baseline and availability of jobs. The possible implications of these factors will now be explored.

3.5.1.2. Differences between the groups

Although the evidence for a direct correlation between return to work and injury severity remains inconclusive, there is general agreement that people

with minor TBI are more likely to return to work than people with moderate and/or severe TBI (Wagner et al. 2002; Turner-Stokes et al. 2005; Shames et al. 2007; van Velzen et al. 2009a). This is supported by the results of the logistic regression, which showed that those with minor TBI were more likely to return to work compared to those with moderate or severe TBI.

Even though the usual care group stayed in hospital a median of 10.5 days longer, which was statistically significant, logistic regression suggested that this did not predict work rates at 12 months. As length of hospital stay has been associated with more severe primary or secondary injuries following TBI, this difference in length of hospital stay could suggest that participants in usual care group were more severely injured (Arango-Lasprilla et al. 2010). However, the usual care group contained proportionally more participants with minor TBI. Also more usual care group participants reported feeling fully recovered at baseline, compared to the specialist group and no differences were found in the BICRO scores. These facts suggest the usual care group were not more severely injured.

In addition to severity of injury, length of hospital stay for people with TBI has been found to result from many other variables. For example, delays in hospital transfers, poor communication between services and even patients' own education levels have all been found to affect length of hospital stay (Cifu et al. 1997; Ownsworth et al. 2004; Mammi et al. 2006; Hammond et al. 2009; Arango-Lasprilla et al. 2010). As the majority of study participants were treated at a regional neurosurgical centre, transfers between the neurosurgical centre and local hospitals may have caused extra delay (Fuller et al. 2011). Additionally participants in the specialist group received input from a case manager whose role was to ensure an integrated treatment pathway. Previous research has shown having an integrated treatment pathway can reduce the average length of hospital stay for people with TBI from 30.5 days to 11.4 days (Khan et al. 2002). Similarly, findings from stroke research, indicate that organised care can make a difference in length of hospital stay (Langhorne et al. 2002). Therefore it seems that the difference in length of hospital stay between groups could be due to being transferred to/from a regional

neurosurgical centre and the receipt of specialist TBI case management rather than severity of TBI. The difference in length of hospital stay does not offer an explanation into the differences in return to work rates between the groups.

Baseline difference in return to work rates

It is not known why more specialist group participants reported working at baseline compared to participants in the usual care group, but it could suggest that people in the specialist group were less affected by their TBI than those in the usual care group. However, logistic regression showed that working at baseline did not predict work status at 12 months. Post-hoc analysis suggested the difference may have been due to how participants defined being at work. Therefore the higher numbers of specialist group participants reporting working at baseline does not appear to offer an explanation of why more specialist group participants were working at 12 months.

The availability of jobs

The availability of jobs locally between the groups differed –see Appendix 6 Unemployment rates. At both the start and end of the study, the area the specialist group were recruited from, had higher local unemployment rates compared to the usual care group (Office for National Statistics 2010). As this could have had the effect of lowering the return to work rates in the specialist group this does not explain the difference in return to work rates at 12 months.

Influence of study design

Study design factors such as bias, confounders and chance also need to be considered as they can influence study results.

Every effort was made to minimise any potential source of bias. Having an independent person collect baseline data, as opposed to the research OT, would reduce any potential risk of recruitment bias in future studies. Participants in both groups received their usual treatment which reduced the risk of recall bias. The use of postal questionnaire, sent in the name of the principal investigator who was not known to the participants, and the use of identification numbers

when inputting and analysing the data, will have reduced any bias which may have arose from the OT treating participants and collating the data.

For TBI patients not being treated at a neurosurgical unit is associated with a 2.15-fold increase in the odds of death (Morris et al. 2008; Lyman 2010). However it is not known if there is also an effect on vocational outcome if patients are treated in a neurosurgical centre. As the majority of the cohort were treated at the regional neurosurgical centre it is unlikely that this represented a possible source of bias.

Confounders can affect study results. Confounders are factors which interact with both the dependent and independent variables being studied making it difficult to disentangle the individual contribution of each factor (Bowling 2002). The influence of confounders can be reduced by the use of logistic regression analysis which controls for the effect of several independent variables. In this study logistic regression analysis showed a participant, who was less than 40 years old, who had a mild TBI and who received specialist intervention, was significantly more likely to return to work than someone who was over 40 years old, who had moderate or severe TBI and who received usual care. This finding is consistent with findings from systematic reviews of predictors of post-TBI employment (Ownsworth et al. 2004; Willemse-van Son et al. 2007; van Velzen et al. 2009a). These have also found people who were of a younger age, who had a mild TBI and who received VR were predictive of return to work in some but not all TBI studies.

Finally, there is a possibility the findings could have happened by chance. The study was not randomized or sufficiently powered to detect with certainty that the increased return to work rates of the specialist group were the result of the specialist intervention. Indeed, multiple analyses can lead to some results being significant as a result of chance (Bowling 2002).

3.5.1.3. Intervention received

It was anticipated that the usual care group would be offered fewer services compared to the specialist group. Surprisingly, analysis of services received showed both groups reported approximately the same amount of GP, consultant and physiotherapy input up to six months. The usual care group received more GP, consultant, and physiotherapy input compared to the specialist group after six months. Unsurprisingly, the specialist group received more OT, case management and cognitive behavioural therapy at all-time points. This suggests people with brain injury access medical and physiotherapy services within the first six months post injury irrespective of what other services they receive.

From participants' responses, it was not possible to determine whether participants from Derby and Leicester had been seen by TBI specialists in those areas and conversely if Nottingham treated any participants who would have return to work successfully without any intervention. Also, whilst participants recorded how much input they received and from which type of service provider, what remains unclear is whether any of these services provided vocational rehabilitation interventions, were co-ordinated, or were perceived to be helpful in returning to work. Future studies should attempt to validate self-reported service use with the services. They also need to identify and describe the all components of any usual care services, including VR components so that any differences in outcome between the specialist and usual care group could be interpreted in light of services received. Therefore in order to increase our understanding of what helps a person return to work, we need to know more than just how many times a person was seen by any individual profession. This variation in service provision reported by participants is consistent with findings from the UK VR mapping study for people with neurological conditions, which also found a wide variation and limited VR provision (Playford et al., 2011).

A systematic review of 50 studies on predictors of return to work after TBI and the logistic regression conducted in the study, both suggest it is feasible that the specialist VR received by participants in this study contributed towards

increased post-TBI employment rates especially as this appears to be one of the main difference between the groups (Ownsworth et al. 2004). Other factors do not offer a full explanation. As smaller reviews have been equivocal as to whether VR increases post-TBI employment, caution needs to be applied (Willemse-van Son et al. 2007; van Velzen et al. 2009a).

This study does not tell us which aspect of the specialist intervention, if any, may have caused the difference in return to work rates between the groups. It could be the combined effect of the whole team which provided timely, coordinated specialist TBI care, the case management model, or the clinical expertise of the team which was experienced in delivering specialist TBI treatment. It could also be the effect of targeted VR by an OT who had been working specifically in this area for over twelve years, or a combination of all these factors. Others have concluded that specialist TBI community teams achieve higher levels of community integration due to the input of the team as a whole (Semlyen et al. 1998; Turner-Stokes et al. 2005; Wade 2005a; Wehman et al. 2009; Boschen et al. 2010). For example a systematic review of ten studies of TBI community integration, (which included employment within the definition of community integration), concluded that the provision of coordinated multidisciplinary rehabilitation, including OT, significantly increased community integration (Kim et al. 2010). Therefore which aspects of the intervention were effective remain unknown.

3.5.1.4. Summary of primary outcome: Return to work

In summary, 15% more people in the specialist group returned to work than the usual care group at one year despite having fewer people with minor TBI and higher local unemployment rates than the usual care group. The increase in the numbers employed following specialist TBI VR is consistent with findings from other studies of TBI VR which suggests that the provision of specialist TBI VR does increase post-TBI employment rates (Ownsworth et al. 2004). However as the groups were not randomised we cannot say with certainty that it was the effect of the specialist intervention or what aspect of the intervention may have made a difference.

3.5.2. Findings specific to the secondary measures

Incidental observations resulting from the secondary measures showed there were differences in mood between those in work and those not in work, and high rates of depression and anxiety at one year post hospital discharge.

3.5.2.1. Mood, quality of life and work

Participants in work reported significantly less depression, less anxiety and a higher quality of life compared to those not in work, irrespective of which group they were in. This is consistent with other TBI studies and other conditions which have all concluded that work is one of the most consistent predictors of improved quality of life after TBI (Pierce et al. 2006; Waddell et al. 2006; Tsaosides et al. 2008; Truelle et al. 2010). For example, in a sample of 218 TBI patients, life satisfaction (as measured by the Satisfaction with Life Scale) was positively related to employment at both one and two year post-TBI but not to age, marital status, social integration or being depressed (Corrigan et al. 2001). However, in this current cohort comparison study, as in other studies, it cannot be determined if depression or anxiety was the cause or consequence of not working (Eriksson et al. 2006). Thus, as with many other conditions, mood does appear to have an important relationship to work for people with TBI (Glozier et al. 2008; Richmond et al. 2009).

As found in other studies approximately a third of all participants in this study reported borderline or abnormal levels of depression and anxiety at one year post-TBI (using cut off rate of ≥ 8 for HADS) (Kersel et al. 2001; Simpson et al. 2007; Andelic et al. 2009). As depression and anxiety have been found to impact on work ability, these findings suggest that mood should be addressed as part of a rehabilitation programme for people with TBI who wish to return to work (Rusconi et al. 2003; Dikmen et al. 2004; Catalano et al. 2006; Knottnerus et al. 2007; Fann et al. 2009; Ouellet et al. 2009).

3.5.2.2. Summary: Findings from secondary measures

Similar to other diagnoses people with TBI in work reported less depression, less anxiety and a higher quality of life compared to people not in work

(Corrigan et al. 2001; Franulic et al. 2004; Waddell et al. 2006). However, it is not clear whether there is a causal relationship. As in other TBI studies, high levels of reported depression and anxiety were found at one year after injury, suggesting these are important factors that need to be addressed during TBI VR.

3.5.3. Factors impacting on post-TBI employment

The following factors affected post-TBI employment between the groups and will now be discussed: the severity of injury, the impact of VR, how long it took participants to return to work and the participants' pre-injury employment.

3.5.3.1. The impact of injury severity

Return to work after moderate and/or severe TBI

For those with moderate or severe TBI, there was an 8% difference between groups of participants in work at three months. However at six months 27% more specialist group participants were in work. This approximate difference was maintained at one year and at eighteen months. Therefore, the specialist intervention appeared to have a greater effect on those with moderate and severe TBI compared to those with minor TBI. This finding supports other TBI studies and guidelines which suggest that people with moderate or severe TBI benefit most from intervention (Johnson 1989; Salazar et al. 2000; Gamble et al. 2003; Sorbo et al. 2005; Turner-Stokes et al. 2005; McCrimmon et al. 2006).

Return to work with minor TBI

There was a different pattern of return to work for people with mild TBI compared to those with moderate or severe TBI. Even though the specialist and usual care groups both reported similar levels of feeling recovered at three months, 37% more specialist group participants with minor TBI had started working at three months. As more specialist group participants undertook a graded return to work this may have enabled them to return earlier than the usual care group. This rate of return to work is slower than reported in a six year audit of a minor TBI clinic run on the UK by a specialist brain injury

nurse and assistant psychologist which found only 49/391 (13%) people were not back at work at six weeks after minor TBI (Haboubi et al. 2001). However, the participants in that audit included people who stayed in hospital less than 48 hours and it did not report how many people maintained employment over a longer period. In the cohort comparison study, all specialist group participants who received intervention and returned to work, remained in work throughout the period of data collection.

Proportionately at 12 months, ten percent more specialist participants were in work than those in the usual care group and 16% more specialist group participants with minor TBI reported feeling fully recovered. This could indicate that this group was less affected by their TBI than the usual care participants. Alternatively, the early specialist intervention, which included education about TBI, could account for this. A systematic review of the effectiveness of interventions for mild TBI found patient education was an effective treatment for people with minor TBI (Comper et al. 2005).

Additionally, a RCT of 105 people with mild TBI who were offered treatment immediately following injury found improvements typically occurred within three months and were maintained at one year (Paniak et al. 2000). Therefore, it is plausible that education, combined with a graded return to work, delivered very soon after hospital discharge, may have assisted specialist group participants to return to work earlier and feel better than they would have done without the specialist intervention.

3.5.3.2. Graded return to work and work modifications

The specialist group were more likely to undertake a graded return to work at three months than the usual care group. This was statistically significant.

Although not statistically significant, the specialist group took a median of five and a half weeks longer to begin to return to part time work. For those who commenced on a part time basis, they worked a median of four weeks longer. These differences may be a result of the specialist intervention, which was aimed at encouraging participants not to return to work too soon and to return on a part time basis. The literature review did not identify any other studies

with this level of detail in for comparison. As there was no difference between both groups in median time to return to full time work, it remains unknown if returning on a graded return is beneficial.

Specialist group participants had more work place modifications in place earlier, compared to the usual care group. The four most common work modifications were: flexibility of extra breaks, decreased hours, reduced duties and reduced days. The higher employment levels in the specialist group, support others who suggest factors such as undertaking a graded return and having work modifications positively aid return to work post-TBI (Johnson 1998; British Society of Rehabilitation Medicine et al. 2004; Sorbo et al. 2005; Catalano et al. 2006; Kendall et al. 2006; British Society of Rehabilitation Medicine 2010; Trexler et al. 2010).

Similar to findings by Johnson et al (1987), work adjustments were in place at 12 and 18 months for participants in both groups. This suggests that people with TBI require work place adjustments for a long period or alternatively, once adjustments are made they are not reviewed or changed. It is unknown how acceptable this need for long term adjustments is for employers and whether this is a contributory factor to the known difficulty people have sustaining post-TBI employment (Johnson 1998; Possl et al. 2001). Conversely, it is also not known if the lack of work modifications is a factor in maintaining employment post-TBI.

3.5.3.3. Timing of the return to work

Approximately 12% of the whole cohort said they had returned to work one month after hospital discharge. Two thirds of people had started to return to work by seven months after hospital discharge. This suggests people with TBI are keen to return to work. Interestingly a retrospective UK study (n=20), found people with TBI had returned to work at seven months (between 3 and 63 weeks post-TBI), which was identical to this study (McCrimmon et al. 2006).

Only a few TBI studies, that included people with moderate and severe TBI, have reported people returning to work within four weeks of hospital discharge (McCrimmon et al. 2006). This may be because very few studies on VR after TBI see TBI patients so soon after discharge from hospital.

Additionally, as found by Wade et al (1998), people may have returned to work so soon because they did not expect any problems, especially if they did not sustain any physical injuries. Not receiving specific vocational advice may have supported this assumption. For example two specialist group participants, neither of whom had any obvious physical problems, returned to work full time with no work adjustments in place, before being seen by the OT or specialist team at four weeks after hospital discharge. Both reported problems with fatigue, headaches and cognition, when seen by the OT. They immediately accepted VR (one person stopped work temporarily after just one day at work and the other greatly modified their workload). Both successfully returned to and maintained employment during the study.

TBI participants in retrospective qualitative studies have frequently reported returning to work too soon after TBI and that work became a negative experience or unsustainable (Johansson et al. 2006; Rubenson et al. 2007; Gilworth et al. 2008). These findings suggest that a patient's impetus to return to work early requires careful management so that a successful return can be achieved. The implication is that vocational advice is required for people with TBI at hospital discharge or immediately a person considers returning to work even if the person does not initially feel they have any problems.

How long after injury did people return to work?

Of the entire cohort, approximately half reported being in work at three months and two thirds by six months. It appears Johnson's (1998) advice that people with severe TBI should not return to work sooner than six months was not generally followed. The numbers in work only rose by 2% at one year and by 1% at 18 months post-baseline. This supports findings from TBI systematic reviews which suggest that, of those who return to work following TBI, most do so within one year of their injury (Kendall et al. 2006; McColl 2007;

Wehman et al. 2009; van Velzen et al. 2009b). As the DWP schemes to help people claiming sickness benefits back to work do not commence until approximately six months after stopping work, this is too late to help people with TBI.

Other TBI and stroke studies have also found an association between benefits and work (Catalano et al. 2006; Saeki et al. 2010). In this study the fact that statutory sick pay (SSP) ceased at six months appeared to influence when people aimed to return to work. Anecdotally participants appeared to use this as a target date for return to work even though they were entitled to apply for other sickness benefits when SSP ceased.

Possible reasons why early intervention may have been effective in this study

As more people in the specialist group returned to work this supports other studies which have concluded that **early** specialist intervention, that is within the first year after injury, increases the likelihood of post-TBI employment (Johnson 1998; Chesnut et al. 1999; Kendall et al. 2006; Malec et al. 2006; Mammi et al. 2006; Wehman et al. 2009). The transition from hospital to home, that is the first three months, is known to be a difficult time for people with TBI (Turner et al. 2009). Early specialist intervention may have helped both patients and families acquire positive coping strategies (Wade et al. 1998; Bay et al. 2008; Berendsen et al. 2009).

Furthermore, the specialist group reported statistically significant higher levels of adequate care four weeks after hospital discharge compared to the usual care group. Therefore, the fact that specialist group participants may have been seen by someone with specialist knowledge of TBI, whilst an inpatient and/or post-hospital discharge, may have contributed to this. Other studies have suggested that satisfaction with care improves therapeutic alliance which in turn has been shown to positively affect outcomes (Rasmussen et al. 2005; Schonberger et al. 2006; Klonoff et al. 2007; Sherer et al. 2007; Kissinger 2008).

In summary, this study found that specialist intervention in the first year after TBI may have improved post-TBI employment rates. However, it is not possible to conclude that early specialist intervention alone was a causal factor, as maintaining jobs after TBI is known to be multifactorial (Possl et al. 2001; Franulic et al. 2004).

3.5.3.4. Returning to previous employment

As found in other TBI studies, this study found returning to a pre-injury employer was the preferred option, that some pre-injury employers altered the job for their employees and that job changes were common after TBI (Johnson 1987; Cifu et al. 1997; Malec et al. 2000; Johansson et al. 2006; McCrimmon et al. 2006; Walker et al. 2006; Wehman et al. 2009). At 12 months post-TBI, two thirds of participants in the overall cohort remained with their pre-injury employer, with approximately half reporting they were working in their pre-injury role. Interestingly, of those treated by the OT, only one job change was identified as being a direct result of the TBI. Other changes occurred irrespective of sustaining a TBI.

The majority of pre-injury employers were reported to be initially supportive. For example, specialist group participants reported being able to take breaks whenever they wanted. Qualitative TBI studies have commented that supportive employers and work colleagues have been instrumental in facilitating a successful return to work (Johansson et al. 2006; Rubenson et al. 2007; Gilworth et al. 2008). More specialist group participants reported that their employers were supportive at one year compared to those in the usual care group. It is not known if this difference resulted from OT contact with the employer, increased understanding of the person with TBI of the impact of their injury on their ability to work or for any other reasons. Conversely, reasons for the reduced level of employer support found in the usual care group are not known. Possible reasons could be: a lack of information, mistaken beliefs about TBI, limited understanding of the implications of TBI or the dissipation of the initial goodwill which can be engendered by a potentially life threatening accident (Chapman et al. 2010). Employers' concerns about re-employing people with TBI require more understanding.

The impact of occupation on return to work

As in other studies, this study found that people in the highest skilled job category were more likely to return to work and those in lower skilled jobs were less likely to do so (Ownsworth et al. 2004; Walker et al. 2006).

Additionally participants in higher skilled jobs were more likely to participate in the VR process. In addition, the presence of sick pay schemes alleviated the need for a graded return to work to be governed by the constraints of the welfare benefit system. In this study, those in lower skilled jobs appeared to have less job security or flexibility. Agency workers, for example, did not return to agency work due to the agency's inability to offer planned or flexible work (people would only find out what work they were doing on the day they turned up). This may become a more prominent problem in the future if more companies outsource lower skilled jobs to agency work.

Finally, environmental factors influenced which occupations returned to work. The building trade was particularly affected by the economic recession, which occurred during the timeframe of this study. Consequently, self-employed tradesmen, for example, bricklayers, reported little flexibility regarding their return to work.

3.5.3.5. Summary of factors related to TBI return to work

As some participants had returned to work at four weeks after hospital discharge, these findings suggest that for some patients specialist TBI VR appears to be required within four weeks of leaving hospital and may be needed for over 12 months post-TBI (Ownsworth et al. 2004; Catalano et al. 2006). Compared to usual care participants, specialist participants with moderate and severe TBI continued to return to work after three months post-hospital discharge, specialist participants with minor TBI returned to work earlier and specialist group participants were more likely to undertake a longer graded return work and have more work adjustments in place. It is plausible that the early specialist intervention may have positively influenced the employment outcome by helping participants and families understand and cope with the consequences of TBI. As this level of detail is not usually reported in

TBI VR studies, it is not known if these findings are typical of this type of intervention.

3.5.4. Participation factors related to TBI return to work

It proved difficult to disentangle the impact of environmental and personal factors. For example, one self-employed tradesman who declined specialist intervention cited the economic recession as the cause of his unemployment at 12 months post-TBI, but there is also the possibility that problems resulting from his TBI may have also contributed towards his unemployed status.

3.5.4.1. Environmental factors

Statutory help

Very few people in both groups received help from the DWP, disability employment advisors (DEAs) or Occupational Health services. Although Trexler et al (2010) found access to other services was facilitated by the specialist intervention, due to the small numbers that accessed other services, it cannot be ascertained if the specialist intervention did increase access or whether proactively accessing other appropriate services increased people's chances of a successful return to work.

Driving

This study found that less than 11% of people in both groups reported not being able to drive was affecting their ability to work at one year after hospital discharge (Catalano et al. 2006; Klonoff et al. 2006). This may be because in the UK, many people with TBI can resume driving after six months or one year after TBI. Therefore, some participants may have resumed driving at the point of the final questionnaire (13 months post-hospital discharge). Part of the specialist intervention involved looking at alternative means of transport and prompting people to re-apply for their driving licence when appropriate. However, there was very little difference between the groups regarding the effect of not driving on work. This may mean that the specialist intervention had little effect. Alternatively, it has been documented that many people with TBI resume driving without informing the licencing authorities. Therefore

some participants could have been driving when they should not have been (Rapport et al. 2008).

Effect of claiming compensation

In line with other studies, this study found no difference in return to work rates between the groups and those who were claiming compensation and not returning to work (Deutsch et al. 2006; Klonoff et al. 2006).

This study found that solicitors were the most frequently seen profession after GPs and consultants in both groups. This frequency of contact suggests solicitors may play an important role as providers of information about TBI. However it was not known what advice was given, or whether it was in accordance with the best practice guidelines on rehabilitation produced by the Association of Personal Injury Lawyers (Association of Personal Injury Lawyers 2004).

3.5.4.2. Personal factors

Feeling recovered

This study found that feeling fully recovered did not automatically equate to a return to work. More usual care group participants reported feeling fully recovered at three and six months even though fewer reported being back at work in comparison to specialist group participants. This is consistent with other studies which have found that returning to work requires targeted intervention and does not appear to occur as a by-product of general TBI rehabilitation (Powell et al. 2002; Ponsford et al. 2006).

More people in the specialist group reported feeling fully recovered at 12 months than those in the usual care group. This may be due to the early intervention as this appears to reduce post-TBI problems (Wade et al. 1998). Additionally, successfully returning to work can contribute to participant's sense of recovery so it is feasible the specialist intervention may have had a positive impact (Corrigan et al. 2001; Franulic et al. 2004). However only half of the whole cohort reported feeling fully recovered at one year. This suggests there is a need for long term support after TBI.

Why return to work?

Surprisingly, people reported that aiding their recovery and restoring normality were more important reasons for returning to work. The concept of work helping to give meaning to life again is consistent with findings from qualitative studies of people who had returned to work following ABI (Johansson et al. 2006; Rubenson et al. 2007; Gilworth et al. 2008). The notion that returning to work is beneficial differentiates people with TBI from other populations on long term sickness benefits, such as those with back pain, mild mental health problems or even stroke, who often believe work caused their health problems or fear that it will increase them (Johansson et al. 2006; Waddell et al. 2008).

Coping at work

Being unable to cope at work has been highlighted as a problem after TBI (Gilworth et al. 2008). However, more specialist group participants reported coping well at work at all time points, compared to usual care group participants. This was surprising given that the usual care group contained proportionally more people with minor TBI who, theoretically, may have been expected to experience fewer problems. However the education and targeted VR received by the specialist group participants supports findings from other studies that show that these factors increase self-confidence and self-efficacy in the ability to work after TBI (Paniak et al. 2000; Comper et al. 2005; Tsaosides et al. 2008; Tsaousides et al. 2009).

Enjoying work

At 12 months, approximately 80% of participants in both groups reported enjoying their jobs the same or better than before their injury. This high level of enjoying work may reflect a restored sense of normality. In addition, participants had the intention to return to work when they consented to take part in this study and many achieved their goal. Congruence between a person's goal and outcome with regard to employment has been shown to be related to an increased quality of life and reduced depression when achieved (Tsaosides et al. 2008).

Informing employers

Nearly everyone told their employers of their initial injury. Due to the often dramatic nature of the injury some participants reported it was difficult not to tell them. Some participants said employers knew about their injury as it had been reported in the local newspaper. A few people reported that they would be less likely to inform future employers. This reticence to inform new employers was also mentioned in a quantitative study of working with a TBI (Rubenson et al. 2007). As the average age of participants in this study was 35 years old, with potentially 30 years of working life ahead of them, possibly with many different employers, this may be an important finding. Reasons for this non-disclosure were not volunteered in this study. Possible reasons could be because the patient perceived themselves as recovered, were not fully aware of their problems, did not class themselves as disabled or feared discrimination (Chapman et al. 2010). To publicly acknowledge problems can be part of the acceptance process and has been found to be positively associated with TBI return to work (Holzberg 2001; Gracey et al. 2009). Not realising that a new job may cause problems and not disclosing potential problems may be a contributory factor to the poor post-TBI employment rates.

3.5.4.3. Summary of environmental and personal factors

Environmental factors such as accessing statutory help, claiming compensation and resuming driving appeared not to greatly affect returning to work for study participants. However, an interesting finding was that solicitors were the most frequently seen professionals after GPs and consultants.

Interestingly, there was a difference between the groups regarding personal factors and returning to work. More participants in the specialist group felt recovered and able to cope at work at one year post-TBI although whether that finding is a direct result of the intervention received is not known.

Possibly, in contrast with other populations on long term sickness benefits, the majority of participants in both groups felt that working would help them recover. Participants did report being less likely to inform subsequent employers about their TBI. It is unknown what impact this may have on future employment success.

3.5.5. Limitations and strengths

Limitations

As the research post was only part time, the research OT was only able to visit the wards on three days. As eligibility criteria included an inpatient stay of ≥ 48 hours, potential patients admitted for only 48 hours may have been missed. It was not known how many patients fell into this category. However, the NTBIS did not identify any additional patients to those identified by the research OT which suggests the number of possible patients missed was small.

While the amount of missing data was comparable to other TBI studies, this still meant that complete data was only obtained from approximately three quarters of the entire cohort.

One-year outcomes, were collected 12 months from baseline, which was four weeks post hospital discharge. Although the median length of hospital stay was no longer than 17 days, the longest length of stay due to TBI was 104 days. This meant the one-year outcomes in this study varied from point of injury.

Strengths

The significant strength of this study was the fact it had a comparison group, collected data prospectively from the participants' perspectives and examined the differences in current NHS provision for people with TBI.

Another key strength was the level of detail collected. The following important factors were rarely reported in the TBI VR studies identified in the literature review; whether participants undertook a graded return to work, had work modifications, and returned to the same job or employer. It is important to know if specialist intervention can affect these factors.

3.5.6. Summary of the Cohort Comparison study

The cohort comparison study compared the return to work rates of participants who received specialist VR from an OT working independently or as part of a specialist TBI community team with participants who received usual care.

Demographically, both groups were very similar. The two main differences between the groups were that the usual care group stayed in hospital longer and more specialist group participants reported being at work four weeks post-hospital discharge. Logistic regression found neither of these factors were associated with work rates at one year.

Two thirds of the entire cohort returned to work by seven months post-hospital discharge. However, more specialist group participants returned to work post-TBI at all time points. Consistent with a systematic review of TBI VR, this study found that younger participants, those with a minor TBI and those who received specialist intervention, were more likely to return to work at 12 months (Ownsworth et al. 2004). Differences in return to work rates were found according to injury severity. At six and 12 months, 27% more specialist group participants with moderate or severe TBI were in work. Specialist group participants with a minor TBI returned to work earlier compared to usual group participants. Factors such as local unemployment levels did not account for these differences. However, as this study was not randomised, it is not known if the increased return to work rates were due to the specialist intervention.

Unlike many other TBI VR studies, this study was able to report what services and VR components both groups received. Specialist group participants received more OT, case management, started returning to work later, were more likely to undertake a graded return to work (and for longer), had more work adjustments put in place and reported higher levels of socialisation at one year compared to the usual care group. When asked if they were coping better, the same or worse at work, specialist group participants reported higher levels of coping at work at all time points compared to usual care participants.

This study suggests VR needs to start early as some participants returned to work just four weeks post-hospital discharge. Finally, in line with other studies, we found those in work reported less anxiety, less depression and a higher quality of life regardless of what group they were in (Corrigan et al. 2001). These findings suggest that returning to work post-TBI is a positive outcome.

Chapter 4: Content Analysis

4.1 Introduction

The details of the content of the intervention delivered in traumatic brain injury vocational rehabilitation (TBI VR) studies are seldom described. Thus, the aim of the content analysis was to develop a method of recording the content of the occupational therapy (OT) delivered to specialist group participants in this study that could enable the VR intervention to be described and quantified. This chapter describes the development, use and outcomes from the recording method (a proforma) developed specifically for this study.

4.1.1. The importance of a recording method

Only rarely do studies record specific details of the content of the OT provided in trials (Chappell et al. 2003; Brewin et al. 2004; Jackson et al. 2004). Due to the scarcity of OT studies specifically related to TBI and VR, there is even less documented intervention (Bootes et al. 2002). A constant theme found during the literature review was the lack of detailed description of the TBI VR delivered (Whyte et al. 2003; Ownsworth et al. 2004; Hart et al. 2006; Hart et al. 2006a). No methods of recording the VR delivered in intervention studies were identified during the literature review regardless of whether this was OT specific or not. This may be because both OT and VR are complex interventions, which are difficult to describe (Creek et al. 2005). On the rare occasions where descriptions were given, different aspects were reported (Murphy et al. 2006; O'Brien 2007).

Defining and specifying rehabilitation interventions is one of the most neglected areas in rehabilitation research (Whyte et al. 2003). It is important to be able to describe and measure any intervention provided. Researchers need to be able to replicate interventions accurately to ensure consistency (Wade 2005a; Hart 2009). Comparisons with other services may allow both effective and ineffective interventions to be identified. Clinically, professionals need to know which interventions are effective. Purchasers and policy makers need to know what they are buying. Therefore, there is a need for a simple method of recording an intervention, which allows the intervention to be described.

4.2. Method

The development of the recording method (a content of OT VR intervention proforma), its use and the information it provided will now be described.

4.2.1. Development of the proforma

The literature review identified a recording method used in a stroke rehabilitation study to compare OT and physiotherapy (Ballinger et al. 1999). The method developed by Ballinger et al (1999) discriminated between therapists' practices and the amount of intervention delivered when treating stroke patients in community and hospital settings. This method was modified for use with TBI participants and adapted to describe the intervention delivered by the OT in this study. The proforma developed for this study was based on best practice guidelines for VR and TBI (British Society of Rehabilitation Medicine et al. 2004). Other guidelines were also taken into consideration (British Society of Rehabilitation Medicine 2000; British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine 2003a; Department of Health 2005; Vocational Rehabilitation Society 2007; Department for Work and Pensions and Department for Health 2008c).

An iterative approach was used to develop the proforma. The adapted proforma was sent to an expert group for comments on its content, potential ease of use and suitability for research. This group comprised: three experienced rehabilitation researchers, an author of VR guidelines for TBI, a health economist, an ex-TBI patient and a community TBI case manager. Ballinger et al (1999) reported that classifying interventions was difficult for therapists in her study as therapists worked on multiple interventions at the same time. Due to this anticipated problem and in order to reduce ambiguity, explanatory notes specific to items in each category were produced -see Appendix 7: OT proforma – Explanatory notes. The expert group agreed that if there was ambiguity regarding categorising an intervention, the main aim of the intervention would be recorded. For example, if a participant was asked to take their dog for a daily walk to increase their stamina in preparation for a job that involved standing all day, this would be classified under 'work

preparation' not 'mobility'. Minor alterations, such as more detail of the intervention carried out with employers, were suggested by the expert group and included. The revised version was re-distributed to the expert group and used. Fifteen categories were included on the proforma - see Appendix 8. These were: assessment, current issues of concern, goals, personal activities of daily living (PADL), general education about TBI and/or return to work, instrumental ADL, mobility, physical, psychological issues, cognitive/executive skills, work preparation, miscellaneous, the return to work process, liaison, and general issues.

The research OT also recorded a subjective opinion of the attitude of the employer based on the participant's and OT's opinion. The terms used were 'very helpful', 'OK', 'cautious'. The expert group agreed that these terms would be easily understood by participants.

4.2.2. Use of the proforma

The number of units were recorded beside the relevant component on the proforma by the OT (JP) immediately following each OT session. Although Ballinger et al (1999) used 15 minute units, the consensus of the expert group was that ten minute units would provide a more detailed picture of the intervention delivered.

4.2.3. Participants

The proforma was completed on all participants in the specialist group who, in addition to the eligibility criteria described in 3.2.2.2., had to have been treated by the OT for two or more OT sessions. Two or more sessions of OT were chosen because part of the first OT session involved a discussion about the study which was not felt to be representative of OT clinical intervention. Participants also had to have commenced and finished intervention with the OT and the Nottingham TBI service (NTBIS) between January 2007 and July 2009 (31 months)

The proforma was not used with usual care participants. It was only completed on patients treated by the research OT in this study. It was beyond the scope of this study to include other therapists in the development and use of the proforma.

4.2.4. Analysis

The data was collated and analysed by the researcher (JP) and the principal investigator of the study (KR). Anonymised client case notes and records of time spent by the other members of the NTBIS were scrutinised by the principal investigator (KR). This confirmed the accuracy of recording by checking that every recorded intervention in the patient's notes had a completed proforma. Additionally, this enabled additional information such as whether a person had returned to work on a graded program and return to work outcomes to be obtained as this information was not recorded on the proforma.

This was an exploratory study to determine whether the content of the OT intervention could be captured. Participants were analysed as an entire group and by injury severity (severe, moderate or minor TBI) to ascertain if intervention differed according to injury severity.

Time taken to return to work was taken from the date of injury to the date participants started any form of work. For example, if a person started a graded return to work on 1.1.2008 consisting of two mornings a week but did not reach their final working status of five days a week until 1.6.08, the date of their return to work was recorded as 1.1.2008. Descriptive statistics such as frequencies (percentages) were used unless stated otherwise.

4.3. Results

The results are presented using Wade's (2005a) suggested method for describing rehabilitation. These are: **process**: what actually took place, **structure**: what was needed for the intervention to take place and **outcome**: what happened because of the intervention. Vocational outcomes were originally omitted from the proforma, but are reported in this section for two reasons. Firstly, inclusion of vocational outcomes was felt to be important as one reason for recording the intervention is to determine whether the intervention or any specific component influenced the outcome. Secondly, the outcomes reported in this section reflect only participants who received two or more sessions of OT and therefore potentially differed from the results of the specialist group in the cohort comparison study, which used an intention to treat analysis.

4.3.1. Participants

Of the 40 specialist group participants in the cohort comparison study eleven were not included in the content analysis. This was because: five were undergoing intervention when the study ended, one did not receive OT whilst being treated by the specialist team and five minor TBI participants felt that no further intervention was required after the initial recruitment meeting. Therefore, the proforma was trialled on 29 participants, all of whom received two or more OT sessions targeted at VR, all of whom were working prior to injury and all of whom had completed their intervention within the study period.

The mean age of the 29 participants was 36 years (SD 13 years), 14 (83%) were male, 21 (72%) had moderate or severe TBI and two thirds of all participants (n=19, 65.5%) had lower skilled occupations (SOC levels 3 and 4) – see Table 48. This was similar to participants in the cohort comparison study. Three quarters of these participants (21/29 [72%]) were working full time prior to injury.

Table 48: Pre-Injury demographics of participants

		Severe TBI	Moderate TBI	Minor TBI	Total numbers
	GCS	3- 8	9- 12	13- 15	
Numbers	no's	14	7	8	29
	%	48.3	24.1	27.6	
Male	no's	14	5	5	24 (82.8%)
	%	58.4	20.8	20.8	
Female	no's	0	2	3	5 (17.2%)
	%	0	40.0	60.0	
Age	Mean	35	32	42	36
	SD	16	11	9	13
	Range	19-66	19-46	34-62	19-66
Cause of injury	RTA	5	1	1	7
	Assault	5	3	1	9
	Fall	3	3	5	11
	Other ¹	1	0	1	2
Work status	Full time	10	7	4	21 (72.4%)
	Part time ²	4	0	4	8 (27.6%)
Job category ³	1. Professional	2	1	1	4 (13.8%)
	2. Skilled	4	1	1	6 (20.7%)
	3. Semi-skilled	2	4	4	10 (34.5%)
	4. Non-skilled	6	1	2	9 (31.0%)

¹Other = hit by falling object, participant unsure if fell or assaulted

²Part time was defined as less than 29 hours a week (Malec et al. 2000)

³Classed using the Standard Occupational Codes 2000 (Office for National Statistics 2008). Students classified according to their course if it was vocational or level three when course was not directly vocational.

4.3.2. Use of the proforma

The OT recorded every OT session given by the research OT over the entire intervention period thus giving a complete picture of the OT received by these participants. The proforma took less than five minutes to complete after each session.

Of the fifteen categories included on the proforma, ‘liaison’ was analysed separately as this was not part of the intervention conducted face-to-face with a participant.

When using the proforma, some categories on the proforma proved problematic. For example, issues regarding sleep were addressed when looking at fatigue management so coded under ‘fatigue management’ and/or the ‘use of routines’. Components in the category ‘general issues’ were also found to duplicate other categories. There were:

- ‘Identifying problems’. This duplicated ‘assessing difficulties/problems’ in the assessment category. Therefore, any problems identified were coded under ‘assessment’.
- ‘Written information given’. This duplicated ‘liaising with patient’ by letter in the Liaison category. Therefore, all written information was coded under ‘liaison’.
- ‘Homework tasks set’, ‘external feedback systems in place’ and ‘use of in/external strategies’ were found to be part of other interventions and not interventions in their own right. For example teaching a person to use a diary was part of developing memory strategies and thus coded under ‘cognitive /executive skills’.

Therefore, the categories used for the proforma required further refinement.

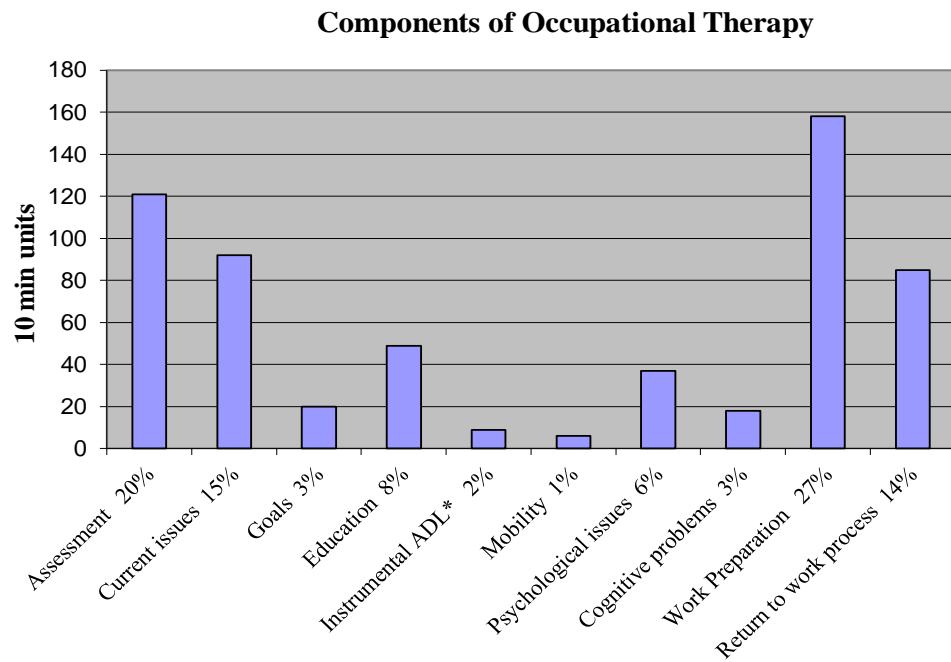
4.3.3. Process: Components of OT delivered

The four most frequently used categories accounted for 63% of the OT face-to-face intervention with participants –see Figure 8. They were:

1. ‘Work preparation’ (23%) such as discussing work options, pacing/fatigue management, job analysis.

2. 'Assessment' (15%) of current difficulties/abilities resulting from the TBI, pre-morbid lifestyle, roles and family's views.
3. 'The return to work process' (13%) including meetings with employers and participants to plan the return to work, assess and review performance.
4. 'Current issues' (12%). This comprised non-work related matters raised by participants such as queries about benefits and medical conditions. Although the case managers also dealt with these issues, participants also raised them with the OT.

The categories: - 'personal and instrumental activities of daily living (PADL)', 'physical', 'miscellaneous' and 'general issues' were rarely used.



*Personal ADL= personal activities of daily living e.g. dressing, bathing
 **Instrumental ADL = domestic activities of daily living e.g. cooking, shopping, budgeting, leisure activities etc.

Figure 8: Components of OT face-to-face sessions

With the exception of the return to work process and assessment, the components of face-to-face OT sessions showed the percentage of OT for each component was broadly similar for all TBI categories –see Table 49.

Participants with severe TBI had more time spent on the return to work process (21%), such as meeting with employers, than the moderate (7%) or minor TBI participants (0%). As participants with minor TBI had fewer OT sessions than participants with moderate or severe TBI; proportionately more time was spent on assessment.

Table 49: Components of OT according to TBI severity (in 10 mins units)

Components of OT intervention		Severe TBI (n=14)	Moderate TBI (n=7)	Minor TBI (n=8)	Overall total
Assessment	no's	89	42	40	171
	%	14.7	10.7%	25.0	14.8
Current Issues	no's	77	45	22	144
	%	12.7	11.5	13.8	12.5
Goals	no's	20	14	9	43
	%	3.3	3.6	5.6	3.7
Personal Activities of Daily Living	no's	2	0	0	2
	%	0.3	0.0	0.0	0.2
Education	no's	38	29	17	84
	%	6.3	7.4	10.6	7.3
Instrumental ADL	no's	15	7	1	23
	%	2.5	1.8	0.6	2.0
Mobility	no's	11	39	4	54
	%	1.8	10.0	2.5	4.7
Physical	no's	0	0	0	0 (%)
	%	0.0	0.0	0.0	0.0
Psychological Issues	no's	42	40	4	87
	%	6.9	10.2	3.1	7.5
Cognitive Problems	no's	21	37	10	68
	%	3.5	9.5	6.3	5.9
Work Preparation	no's	144	81	44	269
	%	23.8	20.7	27.5	23.3
Return to work process	no's	130	26	0	156
	%	21.5	6.6	0.0	13.5
General Issues	no's	3	20	3	26
	%	0.5	5.1	1.9	2.5
Miscellaneous	no's	13	11	5	29
	%	2.1	2.8	3.1	2.5
Total number of 10 minute units	no's	605	391	160	1156
	%	100.0	100.0	100.0	100.0

4.3.2.1. Intervention approach

Information obtained from both the proforma and case notes showed participants received four different styles of OT intervention. These were:

- Advice only. This comprised giving advice to the participant. Both the participant and OT agreed no further action was required (2/29 participants, 7%),
- OT without direct contact with the employers (14/29 participants, 48%),
- OT with direct employer contact (8/29 participants, 28.5%),
- Support to access other services (5/29 participants, 17%), such as Occupational Health (OH), a private insurance VR service, Disability employment advisor (DEA), Remploy, Department of Work and Pensions (DWP) work provider.

The OT did not have direct contact with employers for a variety of reasons. For example, when the person was self-employed or did not have a job to return to, there was no employer to visit. Often some participants were able to negotiate the return to work process with their employers themselves. This tended to occur when participants reported having a good relationship with their employer, felt their employer would be accommodating, generally had mild problems and the OT perceived the participant to have a good insight into their own needs and abilities. These participants had usually maintained frequent contact with their work place during their time off work. Additionally some participants had relatives who were closely involved in their rehabilitation and/or worked in the same place. With these participants, the OT was able to obtain feedback from the relatives about how the person was coping at home and work. Therefore, clinically, there was no reason to see the employer. The OT treated these participants with the relative present when possible and together would review the work situation. The participant would negotiate any work modifications required with their work place. This tended to occur in small and medium size businesses where the employer had flexibility. Two participants did not want the OT to visit the work place. One had problems pre-injury at work, felt contact would exacerbate these, disengaged almost immediately from intervention with the team and study before a worksite visit

was required. The other person, who had no obvious TBI problems, had just started a new temporary part time job after finishing university and felt contact with the work place would cause ‘unnecessary fuss’. All participants who completed intervention and did not have direct OT employer involvement successfully returned to work

The OT initiated contact with employers with participants’ consent. Although no one refused contact with the employer when the OT felt contact was required, one person requested no further intervention from the specialist service after initial contact with the employer had been made. This person then immediately disengaged from the service. One small employer, who was the owner of the business, felt an OT visit was not necessary. The employer said the participant had problems before this TBI; they knew him well and felt able to handle any potential future problems.

Reasons for employer involvement included: both the OT and participant anticipated problems that may have interfered with a straightforward return to work, participants felt the OT would help employers gain a better understanding of their problems and participants wanted the professional support when people were involved in the return to work process that they did not know such as human resources personnel. Additionally, participants who had a good relationship with their employer perceived visiting work to be part of the intervention process and finally some participants thought it may speed up their return. Employer involvement tended to occur more frequently in larger businesses where there was a formal procedure for when employees were off sick.

4.3.2.2. Graded return to work

Although 25 participants returned to work, one participant disengaged from intervention before returning to work, so it was unknown whether they undertook a graded return to work. Of the 24 participants whose return to work history was known, the numbers who undertook a graded return to work:-

- Severe TBI 11/12 (92%)
- Moderate TBI 3/5 (60%)

- Minor 7/7 TBI (100%)
- Total 21/24 (88%)

4.3.2.3. Specific intervention with employers

Information collected from the proforma showed that the same amount of time (17%) was spent providing: general information about TBI, specific advice about how the TBI had affected the individual, information about the rehabilitation process, advice about work place assessment and advice and support about a graded return to work. Less time was spent dealing with specific problems which arose regarding issues (10%) or liaising with statutory services directly related to the work place (7%).

4.3.2.4. Work modifications

The most frequently used work modifications were: reduced hours (18%), flexibility of extra breaks (18%), reduced responsibilities (15%) and reduced days (15%). Some employers provided special measures such as access to the work intranet at home and allowing another staff member time to give a participant lifts to and from work – see Figure 9. More participants with a severe TBI resumed working with adjustments than those with moderate or minor TBI.

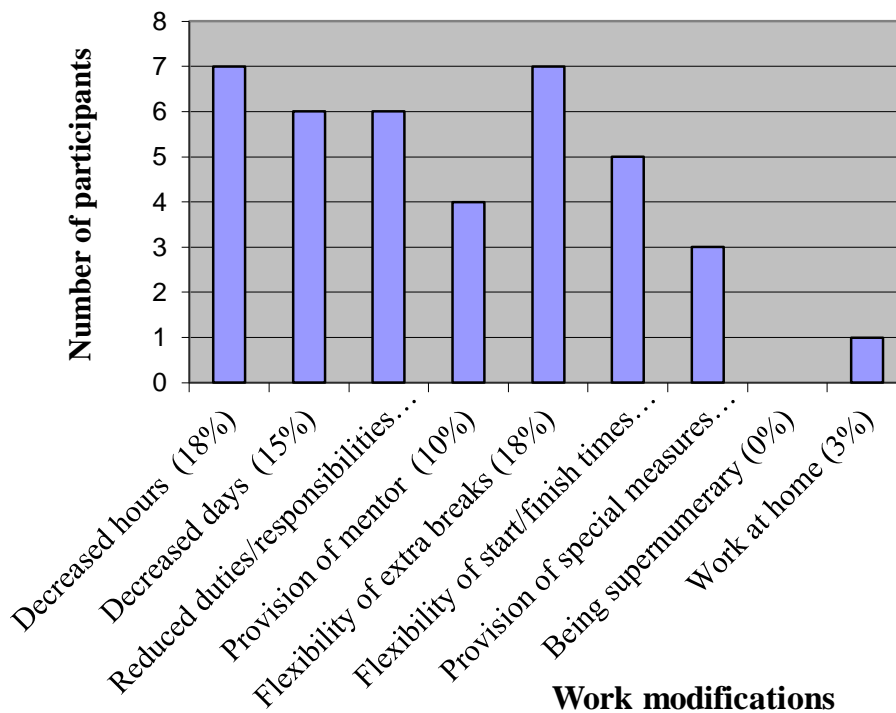


Figure 9: Work Modifications

4.3.2.5. Attitude of employers

It was not possible to record an opinion regarding the attitude of their employer for participants who were self-employed, not working, disengaged, students, agency workers or those who did not express an opinion. Of the participants who had an employer and responded; four felt their employer was cautious and nine rated their employer as OK or helpful. Of those who rated the employer as cautious, two disengaged (stopped attending all rehabilitation appointments) and two were agency workers: of these, one did not return to work and the other found new work. Of those who perceived their employer as OK or helpful all returned to work. The participants and OT agreed over subjective ratings regarding employer's attitudes.

4.3.3. Structure: Number and length of OT

The number of OT sessions, amount of OT face-to-face contact time (in hours) and length of OT intervention (days from hospital discharge) were recorded on the proforma. The results are shown in Table 50. Participants with minor TBI received fewer OT sessions, contact time and length of involvement compared to participants with moderate or severe TBI.

The number of ‘did not attends’ (DNAs) was 6% for participants with severe TBI (6 DNAs out of 91 appointments) and 15% among participants with moderate TBIs (8 DNAs out of 51 appointments. This included five DNAs from one participant). Nobody with minor TBI failed to attend an appointment.

Table 50: Quantity of OT received

Quantity of OT received		Severe TBI (n=14)	Moderate TBI (n=7)	Minor TBI (n=8)	Overall total
Number of OT sessions per participant	Mean	6.5	7.3	3.6	5.9
	SD	6.1	7.5	1.7	5.7
	Range	1 – 20	2 – 23	2 – 7	1-23
OT face-to-face contact time per participant (hours)	Mean	7.1	8.6	3.5	6.5
	SD	7.9	9.6	1.6	7.3
	Range	1.0- 24.7	2.1 – 29.1	2.3-7.0	1.0 - 29.2
Length of OT intervention (days)	Mean	268.6	250.7	144.6	230.1
	SD	239.4	262.3	100.5	216.3
	Range	21-838	79-770	23-345	21-838

4.3.3.1. Location of OT sessions

OT sessions took place mainly in the client’s home (65.5%), with the remainder taking place in the client’s workplace (17.0%) and other locations (14.0%). These included family members’ home, hospital clinic and the job centre– see Table 51. One participant had three meetings with his employer at the hospital as the employer did not have anywhere suitable to hold the meetings at work.

Table 51: Location and number of OT sessions

		Home	Work	Job Centre	Other
Severe TBI (n=14)		57	23	2	9
Moderate TBI (n=7)		30	5	4	12
Minor TBI (n=8)		25	1	0	3
Total number of visits	No.	112	29	6	24
	%	65.5%	17.0%	3.5%	14.0%
	SD	31.1	10.6	2	6.9
	Range	1- 11	0-12	0-3	0-9

4.3.3.2. Distribution of OT time

Approximately one third of the total OT time was spent in face-to-face contact with participants (188 hours, 32.1%), 30.0% on administration (53.8 hours) and travel (121.8 hours 20.8%) and the remaining 37.9% of OT time was spent in non-face-to-face liaison about participants (221.8 hours) – see Figure 10. Telephone calls, emails and letters were classed as non-face-to-face liaison. A third of all non-face-to-face liaisons concerned the participant consisting of telephone calls, emails and provision of written information. The remaining non face-to-face liaison was with specialist team members, family/carers, employers, human resources, OH, DEA, the DWP work provider, GPs, consultants, physiotherapists, outpatient OT, speech and language therapists and solicitors.

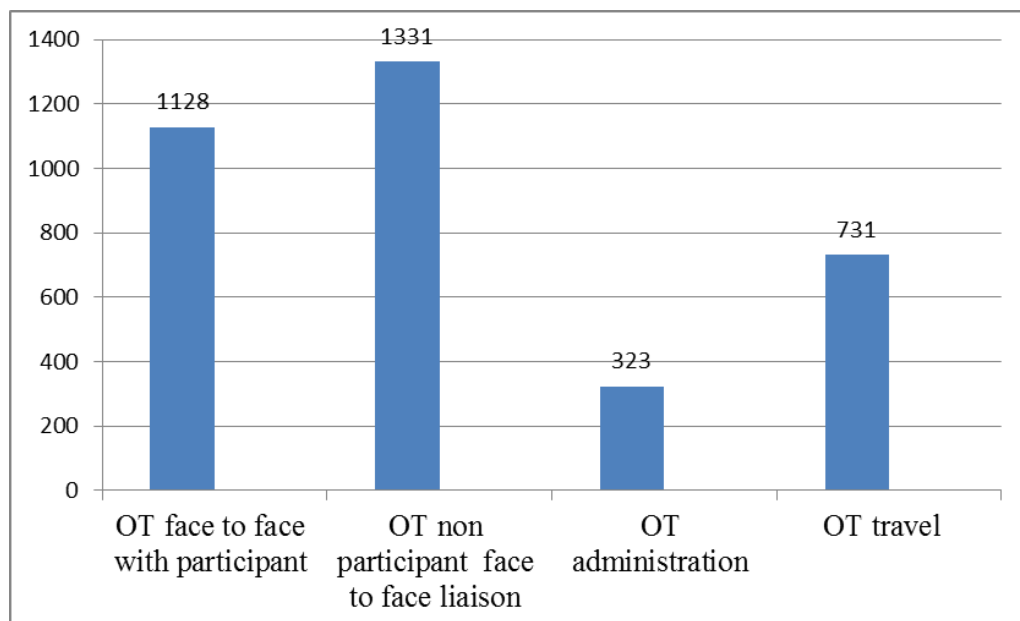


Figure 10: Breakdown of time spent by OT
(in 10-minute units)

Of the OT face-to-face contact time with participants, other people were present for 77% of the time. These included other specialist team members (mainly the case manager), family members and the employer.

4.3.4. Outcome: Vocational outcomes

Vocational outcomes were obtained from case notes in addition to the participant questionnaire used in the cohort study.

4.3.4.1. Time taken to return to work

The mean time taken from the date of the TBI to starting back at work was 181 days, for people with severe TBI compared with 66 days for people with moderate TBI and 73 days for those with mild TBI –see Table 52. There was a large range within each category.

Table 52: Length of time taken to return to work

Participants in work*	Days	Severe TBI (n=13)	Moderate TBI (n=5)	Minor TBI (n=7)	Overall total
Number of days to return to work from injury*	Mean	188.8	66	73	132
	SD	151.9	50.4	35.8	126.8
	Range	32 - 528	28- 140	33 -127	28-528

* Participants who did not return to work are not included in these figures

4.3.4.2. Return to work rates

At discharge from the specialist intervention 25/29 participants (86%) had returned to some form of paid work (one started back at work more than 12 months post-hospital discharge) with 76% (22/29) returning to their pre-injury employment in some capacity when discharged from the specialist intervention– see Table 53. Three participants with severe TBI reported having a new job.

Of the 4/29 participants not working, two participants had been treated by the OT and two had disengaged from the specialist service. The last known work status of the two participants who had disengaged was ‘not working’.

In total, three participants disengaged from the specialist service (two severe and one moderate TBI): two were not working and one disengaged during the rehabilitation process whilst returning to work. No one with a minor TBI disengaged.

Table 53: Vocational status on discharge from intervention

Participant discharge status¹		Severe TBI (n=14)	Moderate TBI (n=7)	Minor TBI (n=8)	Overall Total (n=29)
Resumed pre-injury status i.e. same job, hours, roles	no's	4	5	5	14
	%	28.6	71.4	62.5	48.3
Resumed pre-injury work status with adjustments ²	no's	6	0	2	8
	%	42.9	0.0	25.0	27.6
Started a new job	no's	3	0	0	3
	%	21.4	0.0	0.0	10.3
Total numbers in paid employment at discharge	no's	13	5	7	25
	%	92.9	71.4	87.5	86.2
Not working	no's	1	2	1	4
	%	7.1	28.6	12.5	13.8

¹Last known work status was recorded for participants who disengaged from intervention:

² E.g. Fewer hours, days, responsibilities

4.3.5. Results: Summary

A proforma was designed that was used to record the OT delivered. It was used with 29 participants. Use of the proforma highlighted difficulties categorising this complex intervention.

The analysis showed that the majority of OT was directly targeted at preparing participants to return to work and that for every hour of face-to-face contact with a participant an additional two hours was spent by the OT liaising or travelling. The majority of intervention took place in the participant's home (65%). The OT had direct employer involvement with 48% of participants. Eighty eight percent of participants undertook a graded return to work. Those with minor TBI required less intervention and returned to work more quickly than those with severe TBI. At discharge from intervention, 86% (25/29) of participants had returned to some form of work with 76% returning to their previous employer in some capacity.

4.4. Discussion: Content analysis

The discussion is in two parts; the practical considerations and findings from using the proforma.

4.4.1. Practical considerations

4.4.1.1. Utility of the proforma

Further refinement of the categories on the proforma is required as some categories including 'personal and instrumental activities of daily living (PADL)', 'physical', 'miscellaneous' and 'general issues' were rarely used or were duplicated in other categories. 'Personal and instrumental ADL' and 'physical activities' were not used because participants in this study were living independently in the community. Additionally, participants in this study did not present with physical problems requiring intervention for, example splints. The category 'miscellaneous' was also not used. The items in this category were: 'sleep' and 'carer support'. Carer support was provided by the specialist TBI case managers as it was one of their main roles so it is unsurprising that 'carer support' was not directly provided by the OT. The proforma showed OT involvement with carers consisted of educating the carer about the effects of TBI especially in relation to factors affecting return to work.

Additionally, categorising interventions proved problematic. This was because the OT found that some interventions were covered by two categories. For example discussing the effects of memory problems and how to deal with them at work could have been classed under the category 'cognitive/executive skills' or the category 'work preparation.' Other therapists have reported similar problems when attempting to categorise intervention (Ballinger et al. 1999; De Wit et al. 2007).

Recording how pay was affected on the proforma proved difficult especially with participants with whom the OT had no direct employer involvement so was not involved with pay arrangements. A graded return meant the situation was constantly changing for some participants. For those who did discuss their

pay arrangements: one returned for one day a week whilst on sick pay, three went on to the Permitted Work scheme whilst on Incapacity Benefit, two took a pay cut whilst undergoing a graded return and two returned on full pay even though they were only working part time hours. The variation in pay arrangements reflects the complexity of this issue when returning to work after TBI. Recording pay for research purposes remains a challenge.

Clearly, the problem of coding and categorising OT aimed at VR is likely to remain due to the fact OT is a complex intervention (Creek et al. 2005). As the multifaceted nature of OT is its strength, further discussion among others delivering VR for people with TBI on what to record is required. Removing the categories found to be redundant and having more clearly defined categories may reduce ambiguity. However, the proforma was quick to use and the information gathered was easily collated using a spreadsheet. The resulting analysis did enable the OT delivered to be quantified and described. Therefore, the proforma was felt to have potential for future clinical and research use.

4.4.1.2. Did the proforma capture the content of the OT intervention?

The proforma appeared to capture the OT intervention. It showed two thirds (63%) of the OT face-to-face intervention was focused directly on the return to work process. The most frequently recorded interventions were: assessment, work preparation, education and involvement with employers. However, until comparisons are made, it is not known whether this is typical of OTVR carried out in similar services elsewhere, whether too little or too much intervention was provided, or whether the intervention affected post-TBI employment outcomes.

4.4.1.3. What to record?

There is a consensus about the need to describe any intervention given as part of a research study or in clinical practice. This will enable studies to be replicated and comparison to be drawn with other services (Wade 2005a; Hart 2009; Whyte 2009). However, as very few studies report information on TBI VR interventions, the issue of which components to record is important. For example, O'Brien (2007) conducted a retrospective descriptive study of a

vocational neuro-rehabilitation programme in Australia for people who had successfully achieved employment (n=27, with 13 (48%) having a TBI). She reported on different aspects of the service to those recorded in this study. For example, she reported which standardised assessments were used whereas these were not recorded in this study. The only item that could be compared between that study and this one was the number of work site visits undertaken. Both studies found that not all clients had a worksite visit. O'Brien found that only 9/27 (29%) clients who returned to work received a work site visit. However, of those who had a job to return to, O'Brien reported that 8/10 (80%) people received a worksite visit, which is a greater percentage than in this study. As work site visits are one of the core interventions of VR, being able to pool this data (by collecting it on a proforma) from different services may assist in determining whether there is a link between having a work site visit and being employed. This demonstrates the need for a consensus of what to record, the benefit of being able to pool data and the potential use of the data to identify effective (or ineffective) components of interventions.

4.4.1.4. Did the proforma show how the intervention was delivered?

Data from the proforma enabled the following information to be quantified:- number of sessions delivered, length of contact time, how the OT's contact time was spent and how this varied according to injury severity. Although this information was recorded accurately in this study, it is not known how well it would be recorded in routine clinical work. This type of information is important for replication in future research, costing or commissioning services.

4.4.2. Summary of the practical consideration found when using the proforma

This study developed a recording method (a proforma) through expert consensus. The proforma enabled the intervention provided by the OT, (for people with TBI aiming to return to work), to be recorded, quantified and described. Using it highlighted the difficulties of categorising this complex intervention and the need for further work to obtain a consensus as to what information to record and for what purpose.

4.4.2.1. Findings from the content analysis

Findings from the content analysis will be also discussed using Wade's (2005a) format of process, structure and outcome.

Process: Content of OT intervention

The intervention provided was in line with both general and TBI specific VR guidelines (British Society of Rehabilitation Medicine 2003a; British Society of Rehabilitation Medicine et al. 2004; Holmes 2007; British Society of Rehabilitation Medicine 2010; Wilson 2010). The majority of OT was aimed at assessment and work preparation. Work preparation consisted of job analysis, discussing work options, with intervention planned around graded activities directly relevant to their work where practical. As discussed previously, this may have facilitated errorless learning and increased participants' motivation. These have been identified as important factors in returning to work after TBI (Gilworth et al. 2008; Stergiou-Kita et al. 2010). Directing activities explicitly relevant to work almost immediately after hospital discharge may also have helped maintain participants' self-concept as a worker which has been found to be important (Power et al. 2003). For example, a computer programmer used tasks on his home computer to assess how long he could concentrate for and what breaks he required. Participants were willing to practice tasks when these had direct relevance to their employment. This functional approach had been found to be useful in aiding employability in other studies (Klonoff et al. 2007; Wehman et al. 2009; Stergiou-Kita et al. 2010).

Goal setting

Surprisingly, very little intervention was recorded as goal setting despite its value in TBI and VR being well recognised (Kuipers et al. 2003; Power et al. 2003; Cullen et al. 2007; Turner et al. 2008; McPherson et al. 2009; Playford et al. 2009). The lack of recorded time spent goal setting could be due to the way the intervention was recorded and indicates the need for more explicit work on goal setting or a reflection of how goal setting was used in this study. All participants had stated they had a goal to return to work and the intervention

was targeted explicitly at activities aimed at return to work. As a result very few OT sessions were spent on explicit goal setting.

In this study, explicit goal setting was used mainly when the person was not fully engaging with rehabilitation, not making progress or appeared unrealistic in their assessment of their situation or their abilities. This supports findings from a consensus agreement suggesting that the actual clinical practice of goal setting is varied (Playford et al. 2009). It may also indicate that people with TBI may need different approaches to goal setting depending on their individual needs. McPherson et al (2009) explored two different methods of goal setting with people with TBI which appear to fit with the type of goal setting used in this study. These were Identity Orientated Goal Training and Goal Management Training. They found Identity Orientated Goal Training was helpful in engaging people in the goal setting process as it was a top down approach that addressed the person's motivation. This was the approach used for participants who were not making progress as it explored participants' reasons for continuing rehabilitation. McPherson et al found Goal Management Training was useful in providing a structured framework for error prevention in functional performance using a bottom-up approach. This approach was used when grading activities or presenting new tasks with participants in this study. As these activities were mainly targeted at work tasks, they were classed as work preparation and not goal setting in this study.

Education

Another surprising finding was that education was infrequently recorded as the main component of the intervention. This is despite its recognition as an effective intervention for people with TBI (Paniak et al. 2000; British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine et al. 2004; Comper et al. 2005; British Society of Rehabilitation Medicine 2010). Again, this could be a consequence of the way the intervention was documented. The proforma only captured information provided by the OT. It did not capture information provided by others such as the case managers and highlights the fact that rehabilitation is a team effort. Alternatively, not as much education was delivered as the OT perceived.

Despite the lack of recorded education, a key component of the VR process was to enable the participant, their family and their employer, to become fully aware of problems arising from the TBI and the appropriate strategies to use. This is important given the long-term nature of the sequelae of TBI. This process could be termed education but has also been referred to by different authors as self-management, enablement or empowerment (Kowalske et al. 2000; Varekamp et al. 2009; Ellis et al. 2010). All have found it to be important in successfully returning to work. Whether participants, family and employers felt the intervention helped them manage the sequelae of their TBI may be the key factor rather than the amount of education received. The concept of self-management would not be easy to record on a proforma.

Dealing with issues unrelated to work

The content analysis revealed approximately a fifth of OT face-to-face time with participants was spent on issues not directly related to work. These included queries around benefit claims, other intervention received, compensation, transport and problems such as use of alcohol. The amount of time spent was unexpected because the majority of participants had case managers whose role was to deal with these issues. This may reflect the fact that participants and carers were not particularly concerned about the professional roles of the people and voiced their concerns to the first professional person they saw. It may also be an indication of the complexity of factors that a person and their family have to deal with after a TBI and how important these personal and environmental issues are to them. Returning to work appears just one factor amongst many. As people who have problems regarding welfare benefits and transport issues have been found to have lower post-TBI employment levels, it appears people with TBI require help with these aspects (Catalano et al. 2006).

Participants who disengaged from rehabilitation

Three participants who initially consented to OT disengaged from intervention (10%) (stopped attending intervention sessions). All had pre-injury personal and social problems and levels of pre-injury education. One returned to work and two did not return to work. None gave a reason why they disengaged. This

may be typical of the TBI population. For example, in a study of military personnel the rate of disengagement was 7% (5/67) from the inpatient cognitive rehabilitation group and 11% (6/53) from the telephone support at home group (Salazar et al. 2000). A vocational case-co-ordinator service reported a dropout rate of 10% (12/ 114) (Malec et al. 2006). Unfortunately, reasons why TBI participants disengage from intervention programmes are inherently difficult to explore. One suggestion is that there is reduced therapeutic alliance which has been found to be associated with fewer years of pre-injury education (Sherer et al. 2007; Evans et al. 2008). However, as the people in this study who disengaged had pre-injury and post-injury social and personal problems unrelated to the TBI, this suggests the reasons for disengagement may be more complex than poor therapeutic alliance.

4.4.2.2. Process: Style of OT intervention

This study identified four types of OT intervention: advice only, no direct employer intervention, direct employer intervention and lastly assistance when accessing other services such as a DEA or OH. The OT saw a lower number of employers than was initially anticipated. As this level of detail of OT intervention appears not to have been described in relation to TBI VR studies before, the author has discussed these findings with local clinical colleagues. Anecdotally, this appears typical of OT VR in a TBI community team. It is not known if this is typical practice elsewhere. Reasons for the different types of intervention will now be discussed.

Advice only

This study showed that not all people with TBI need, want, or are receptive to VR after their TBI, as some who only had advice did return to work. No participants who initially felt intervention was not required took up the offer of re-accessing OT. This is in line with other studies which show some people with TBI do manage a successful return to work with minimal or no intervention (Wade et al. 1998; Catalano et al. 2006; van Velzen et al. 2009a). However, whether these patients can initially be identified or have problems later on is not known.

No employer involvement

Although it is suggested that contact with employers is good practice, the OT did not have direct employer involvement for nearly half of the participants (British Society of Rehabilitation Medicine et al. 2004). Reasons for employer involvement are detailed in 4.3.2.1. For participants who had an employer, but not direct OT involvement, this was a mutual decision by the OT and participant. It meant that the participant arranged a graded return to work and work modifications themselves directly with their employer whilst receiving on-going support from the OT. This had the added bonus that it helped the person regain control in their life and a sense of empowerment which has been identified as important in returning to work (Gilworth et al. 2008; Varekamp et al. 2009).

From a clinical perspective, participants or employers not wanting OT involvement raises potentially difficult issues. No health professional can insist on seeing a person's employer if either the person or employer does not want this to happen. Obviously, respecting a patient's rights and preferences is good practice (Borg et al. 2008). In this study, the OT continued to treat these participants outside of the work situation and no problems occurred. However, these situations raise issues which are rarely, if at all, discussed in the literature. For example, where does the duty of care lie in a situation where a patient chooses not to disclose information about their injury, particularly if they are in a job such as scaffolding where there may be serious consequences due to the risk of epilepsy?

Finally, due to organisational difficulties, one employer and the OT were unable to meet. This illustrates the practical difficulties involved and the need for flexibility on the part of the OT and service in accommodating employers' needs. Others have reported that funding mechanisms may also prevent worksite visits and that employers may not be willing to assess a person's work readiness (Chappell et al. 2003).

In summary, participants who had intervention from the OT but no direct contact between their employer and the OT, all maintained work throughout

the study period. This suggests this style of intervention may be as effective as having direct employer intervention for people with insight into their abilities and understanding employers. However, it does raise ethical issues if a person with TBI refuses contact or to tell their employer about their TBI.

Employer involvement

The OT only saw approximately a quarter of employers. Interestingly, Stergiou-Kita (2010) suggested that part of helping a client become ready for work was also helping the employer become ready to accommodate the person with TBI back to work. Of the employers seen by the OT all were receptive to suggestions and appeared keen to increase their understanding of the situation. The willingness of employers to implement work modifications has been suggested as an area that warrants investigation (van Velzen et al. 2009a). In this study, both employers who the OT saw in person and employers who had no direct contact with the OT, were willing to implement a graded return to work and work modifications for their employees. This suggests that in some cases, direct employer involvement is not necessary if the participant has a good understanding of their own needs and is able to negotiate work modifications themselves. Therefore, a flexible approach is required.

Accompanying the person to see others involved in return to work process

There were a number of situations where the OT accompanied participants to other appointments. For example, some participants felt the person they were seeing may not have had a full appreciation of the hidden aspects of their TBI. Others saw someone they did not know in relation to their workplace, such as Occupational Health, and some did not have a job to return to and saw a DEA. Although anecdotally both parties stated they found it useful, it is not known whether the presence of the OT affected whether or not a person returned to work.

4.4.3. Structure: Where the intervention took place

The majority of sessions took place in the person's home. Other sessions took place in the person's work place or other places such as job centres. Delivering intervention in these locations meant family members, employers and others were also present. As found by Bootes et al (2002), this enabled the OT to triangulate information from a variety of sources. For example visiting a person at home with a family member present revealed whether the participant was expecting the OT's visit. Seeing a participant at work increased the OT's understanding of the workplace including relationships at work. This also enabled the OT to educate and address concerns from participants and family/employer/others about TBI and intervention to be planned and adjusted collaboratively. This partnership may have facilitated both returning to and maintaining work as good therapeutic alliance has been found to improve work outcomes (Sherer et al. 2007; Evans et al. 2008; Gordon et al. 2008; Kissinger 2008; Wilson 2010). For example, one participant and employer said the person was coping well during his graded return at work and was ready to increase hours, however the family said the participant was so tired at home it was a struggle to get them out of bed in the morning to go to work. A compromise had to be agreed.

Coetzer et al (2008) also suggested that TBI community intervention may facilitate greater therapeutic gains. However, a systematic review found no studies comparing the relative effectiveness of TBI rehabilitation in the community with a clinical setting (Doig et al. 2010). The authors of that systematic review conducted a small cross-over design trial with severe TBI patients (n=14) (Doig et al. 2011). They compared six weeks of intervention in a day hospital followed by six weeks of intervention at home and vice versa. They found that patient's preferred home intervention over intervention in clinic but found no other differences between the groups. This, however, was a very small study over a short time frame.

The disadvantage of community intervention in this present study was that no formal group work took place during the study period. This meant that

participants did not meet another person with TBI as a result of the specialist intervention, which may not necessarily have been a problem. Findings from a qualitative study which asked 24 patients with multiple sclerosis what they would want from a vocational rehabilitation service, found that they wanted a 1:1 relationship with someone who was knowledgeable about their condition and would act as an advocate for them in the work situation (Sweetland et al. 2007). This is what participants received in the current study.

Two studies examined employment outcome relative to location of intervention. Salazar et al(2000) compared an 8 week intensive in-patient cognitive rehabilitation programme (n=67) inpatient to a limited home rehabilitation programme with weekly telephone support from a psychiatric nurse (n= 53). At one year there was no significant difference between the groups in employment rates or in scores on cognitive, behavioural or quality of life measures. Ponsford et al (2006) also retrospectively compared intervention given in a rehabilitation unit to intervention received in the community. They also found no difference in employment outcomes. It appears inconclusive how and where VR is delivered influences employment outcomes.

4.4.3.1 Structure: Dosage

There was a large variation in the amount of intervention provided but generally participants with a severe or moderate TBI received more intervention sessions and were treated for longer than those with a minor TBI. No studies were found in the literature that reported a relationship between severity of TBI and amount of intervention required. Although the effect of increasing the dosage of rehabilitation has been shown to have a positive effect on outcome in stroke, it is not known if the same holds true for people with TBI (Huang et al. 2009).

Interestingly, in this study the two participants who did not return to work received the most intervention, possibly because more liaison with external agencies was required and the end point was uncertain. Similar findings were reported in two USA studies (Gamble et al. 2003; Catalano et al. 2006). One was a study of 7,366 people with TBI whose cases were closed by vocational

services and the other was a study of 1073 people all of whom received VR. Both studies found those who did not return to work and/or had cases closed as unsuccessful, received rehabilitation for longer compared to those who were employed. This may have implications for service planning. It suggests that people who do not return to work require more intervention over a longer period compared to those who do return to work or that they may need a longer period to help them return to work.

4.4.3.2. Structure: How the OT time was spent

This study showed that for every hour the OT spent in face-to-face contact with a participant two hours were spent in activities related to the participant where they were not present. These figures demonstrate the considerable amount of liaison that is involved in facilitating a return to work. However, it is not known whether good liaison with family and employers increases the chance of a successful return to work.

4.4.4. Outcomes of the intervention

Analysis of the outcomes showed that most participants did return to their pre-injury employer, albeit with some modifications, therefore supporting the view that this is the preferred and may be the easiest option (Walker et al. 2006). If all TBI services systematically recorded the same broad categories of work outcomes this may help identify the effectiveness, or ineffectiveness, of different service provision.

4.4.5. Limitations

This study only collated information from one OT within one NHS service using data from 29 participants. It did not record other interventions participants received, such as medical or psychology input. This may be an limitation as rehabilitation success is often due to the multi-disciplinary team's input and not just one specific component (Wade 2001).

Some categories on the proforma were ambiguous or redundant. Others such as vocational outcomes were added. Vocational outcomes were not recorded on

the proforma as they were recorded on the participant questionnaire for the Cohort study– see Appendix 4: Participant questionnaire.

It is not known if this method of recording and the content of the proforma, which was developed by an expert group, has generalizability. For example, whether it would be a suitable method for capturing ‘usual care’, non-specialist intervention or for use by non-specialist staff.

Lastly, the data was collected in 10-minute units by the OT and presented in set categories. This only gives a broad picture and does not reflect the nuances of the intervention or how useful or not the participants perceived it to be.

4.4.6. Strengths

The proforma was developed through expert consensus and reflected best practice. To the author’s knowledge, no other method for recording TBI VR OT intervention has been developed.

The proforma enabled the VR undertaken by the OT to be recorded, quantified and described. The literature search and clinical experience suggests that this level of detail has not been previously reported in OT or VR studies and is not routinely collected by TBI or VR services. This study provides new descriptive detail about the content of TBI OT VR delivered in the UK (Phillips et al. 2010).

The detail provided enabled some interesting reflections about the OT intervention. For example, variation in contact with employers, and the fact participants who did not return to work received more OT sessions over a longer period.

4.4.7. Summary of findings from the content analysis

Using the proforma developed specifically for this study enabled the intervention provided to be recorded, quantified and described. Analysis showed that the majority of the intervention was directly targeted at preparing

participants to return to work and revealed the time required by the OT to implement individually tailored VR. It also showed that for approximately half of all participants there was either no employer to contact or the OT and participant felt there was no reason for the OT to directly meet the employer. Whether or not the OT met the employer did not appear to influence the outcome. As this level of detail has been rarely documented in OT VR TBI studies, it is not known whether this is typical of intervention provided elsewhere.

Use of the proforma highlighted the fact that its content may require adaptation for future use. The inclusion of vocational outcomes would enable both the content and outcomes of the intervention to be recorded using the same measure and would facilitate the comparison of outcomes from different types of clinical service or service provider (such as the NHS, private or third sector) and between different models of VR intervention. However, refining the content, that is the headings and subheadings which relate to the components of the VR intervention, requires further research to decide which are the most important components to record and how best to describe them and indeed which are the most important 'work' outcomes to record. This would best be decided by consensus from experts in the field so that the tool can be universally understood and widely adopted in research and clinical practice.

Our current lack of ability to describe the 'black box' labelled 'intervention' limits the ability to accurately describe, replicate or monitor the uniformity of interventions used in research or clinical practice (Ballinger et al. 1999; Wade 2001; Whyte et al. 2003; Dejong et al. 2004; Hart et al. 2006a; Whyte 2009). Failure to describe rehabilitation interventions can reduce the credibility of rehabilitation in a competitive health market (Wade 2005a). Therefore, finding ways of describing the complex intervention that is OT VR is important. The development of the proforma used in this study is an important first step. It has the potential to enable detailed comparisons of VR interventions and the potential impact these have on vocational outcomes to be explored. It also offers potential to monitor fidelity of intervention in future research studies and facilitate costing the intervention when commissioning services.

Chapter 5: Feasibility economic analysis

5.1. Introduction

This chapter will discuss the findings from the literature review regarding the economic impact of traumatic brain injury (TBI), cost effectiveness of TBI vocational rehabilitation (VR) and types of economic analyses –see 2.2.

Literature review. The method, results and the discussion of the economic analysis will then be reported.

5.1.1. Economic Impact of TBI

The aim of VR is to return an individual to work so they can pay taxes and do not require state benefits. It has, therefore, been assumed that investment in VR is sensible and may be cost effective in the longer term (Abrams et al. 1993; Turner-Stokes 2004; Beecham et al. 2009; Rickels et al. 2010). An intervention can be said to be cost effective if it results in greater gain than would be achieved by using the resources in an alternative way (Harwood 2008). Despite the fact the National Service Framework (NSF) for people with Long Term Neurological Conditions states that VR should be provided and given that returning people with disabilities to work is high on the government agenda, systematic reviews and robust studies examining if TBI VR is cost-effective are scarce (Turner-Stokes 2004; Department of Health 2005; Turner-Stokes et al. 2005; Department for Work and Pensions and Department for Health 2008c). As TBI predominately affects people of working age, it has a major economic impact on the individual and society when these people do not return to work (Tennant 2005). However, not everything gained from TBI VR can be measured or costed in purely financial terms therefore cost effectiveness must be considered as part of a broader evaluation (Coast 2004). Provision of information, support and increased confidence are all important components of VR. The financial impact of TBI for society, the individual and the cost of VR will now be examined.

5.1.2. Financial Impact of TBI to Society

It is recognised that the TBI has a huge cost to society. For example; Brown et al (2008) estimated that the total economic impact of TBI in the USA in 2000 was \$60.434 billion, which included \$51.212 billion in lost productivity.

Whilst the precise cost to the UK economy is unknown, it has been estimated that £47.2 million per year is spent on health and social care costs for young adults (18-25 years old) who need care as a result of an ABI (Beecham et al. 2009). In 2004, the average cost to the NHS of treating a person with TBI whilst in hospital was £15,462 (SD £16,844) per patient, based on a UK study of 6,484 patients hospitalized due to TBI (Morris et al. 2008). Other studies have extrapolated costs found in their study populations to the whole population (Johnstone et al. 2003). A European study used the same principle (Rickels et al. 2010). Health costs and productivity losses incurred by a cohort of 6,738 TBI patients who presented at a German hospital emergency department between 2000- 2001 were extrapolated from the study population to include the whole of the German TBI population using a human resource approach (Rickels et al. 2010). Again, the lost time at work and dependency on state benefits were the main cost factors, estimated at 2.8 billion Euros p.a. (exact year of costs was not specified).

Despite this huge cost, the literature on the costs associated with TBI is limited. For example, a systematic review of mild TBI 1982 – 2000 screened 38,806 abstracts which only resulted in 16 articles specifically related to the economic costs of mild TBI (Borg et al. 2004). Of these 16 articles, only seven articles were RCTs or large cohort studies and five had data that was 15 years old. The authors concluded that the direct costs such as health costs for mild TBI were high but the main costs were indirect costs such as loss of productivity. No costs relating to providing rehabilitation were reported. Given that the majority of people have a mild TBI (approx. 85-90%); this illustrates the limited knowledge of the costs of TBI.

Although figures vary, there is a consensus that TBI causes high initial medical costs. The main costs to society, however, come from the long term

dependency on welfare benefits, from loss of taxes and from dependency on social care.

5.1.3. Financial Impact of TBI to the individual

As only 41 % of people were found to return to work two years after TBI, the loss of wages can be a major financial factor for an individual and their family (van Velzen et al. 2009b). Of those who do return to work, many experience reduced income due to working fewer hours, or undertaking a less demanding job (Shigaki et al. 2009). This can result in decreased wages and an increased reliance on state benefits compared to their pre-injury status. For example, Klonoff et al (2006) studied 93 TBI patients discharged 1- 7 years previously from a USA holistic milieu-orientated neuro-rehabilitation program. Although 74% of participants were in paid work or education on discharge, of those working at follow up 37% reported a decrease in their post-TBI annual income and a further 38% were receiving government financial support compared to pre-injury. The authors also reported that financial hardship was a major source of depression. Johnstone et al (2003) also found reduced income post- TBI when they followed up 35 TBI patients (who had a 69% pre-injury employment rate) recruited from an inpatient unit for a year (31% post-TBI employment rate). Compared to pre-injury patients' average earned monthly income in 2002 declined by 51% per month (from \$1491 to \$726 per person) and at one year post-TBI the mean total state benefits received per month increased by 275% (from \$153 to \$421 per person). They also concluded that even on reduced incomes and state benefits people with TBI lived on or near the poverty line. Additionally, in the USA, the costs related to TBI have also been shown to be a cause of personal bankruptcy (Relyea-Chew et al. 2009). The aforementioned studies only covered one year after TBI. A study of 49 employed people pre-TBI showed the employment rate increased slightly from 35.5% employed at one year, to 38% employed at two years (n=32) (Shigaki et al. 2009). However, participants' median earnings had decreased 50% from \$2000 per person per month pre-injury to \$1000 per person per month two years post- injury. Additionally, the numbers receiving some form of welfare payment had increased from 9/49 (18%) pre-injury to 11/29 (38%) two years

post-injury. The authors concluded the longer-term financial picture for people with TBI appeared stable and not likely to change.

However due to the heterogeneity of TBI, there will be exceptions. A retrospective UK study investigated the characteristics of people with TBI who had, or had not, returned to work six months to four years post-TBI (McCrimmon et al. 2006). Potential participants who fulfilled the inclusion criteria of working at the time of injury, moderate to severe TBI, and aged 18 - 55 years old, were contacted in writing to take part (n=166). Only 20 people with TBI replied who were employed post-TBI. Of these, three reported an increase in their salary, six reported a decrease in salary and 11 reported their salary remained the same. It is unknown how representative these 20 participants were of the total sample. Although TBI studies often only have a small number of participants, the findings consistently show that many people earn less in post-TBI employment. Very few studies have examined the financial impact on the individual and the state over a period greater than two years.

Even though dependency on welfare benefits results in a low standard of living, a retrospective study of the vocational outcomes of 7,366 people whose cases were closed by US state vocational agencies found that the fear of losing benefits acted as a disincentive to return to work (Catalano et al. 2006). As survivors of TBI do not generally have a reduced life expectancy and are unlikely to return to work if they have not done so by two years, the personal financial impact of TBI can be lifelong.

Families also feel the financial impact. One of the very few studies to examine the costs for carers is a retrospective Vietnamese study (Hoang et al. 2008). This study examined the costs for 35 TBI patients who had motorcycle accidents. They found the mean time off work for carers varied from 5.5 – 15.5 weeks according to injury severity. The study found many households tried to minimise the cost of providing care by using non-working family members, the elderly and even taking children out of school. Although the study did not

describe what rehabilitation or welfare benefits were provided, the study does illustrate that TBI impacts on the family and the impact of contextual factors.

In summary, following TBI, there is a high probability of either not working, working for reduced wages or being dependent on state benefits over a life time (Gamboa et al. 2006). These factors impact financially on both the person with TBI and their families.

5.1.4. Cost of provision of TBI rehabilitation

Surprisingly, only a few studies have examined the cost-effectiveness of providing TBI VR. Abrams et al (1993) undertook what they termed a 'cost benefit analysis' of 142 people with TBI who received individualised return to work services between 1988-1992 in the USA, of whom 75% returned to work. The average cost per client of the programme in 1992 was \$4,377. They concluded that when all monies to run the service were included, along with taxes paid by clients returning to work, taxpayers received a twofold return on their investment and the ratio of taxpayer benefit to state cost was fourfold. Although they concluded the service was cost-effective they did not make any comparisons to alternative provision. Although costs of services will have changed since the study was conducted 19 years ago and the funding system is different to the UK, it does give an indication that VR for people with TBI could be financially cost effective.

Other studies have also concluded the VR service they provided was cost effective simply on the number of people who returned to work from their service. For example, in a USA retrospective study, Wehman et al (2003) described the follow up costs of a supported employment programme for 59 people with TBI over a 14 year period. They found that the average cost of supplying the programme based on costs for 1998 was \$8614 per person, which decreased over time (mean monthly programme cost of \$202 per person). Even though they did not include the costs of other rehabilitation professions such as speech therapists or compare this service to alternate or no provision, they concluded that the service was cost effective. In another

retrospective study in the USA, Gamble et al (2003) compared TBI patients who received VR services (n=78) to TBI patients who did not receive similar services (n=995). They surmised that the increased number of people in paid work justified the increased costs. However, they did not explain why some people received supported employment, what it consisted of, or how much it cost. Another retrospective study in the USA, reviewed 7,366 TBI closed cases, with 50% returning to competitive employment (Catalano et al. 2006). The average case expenditure based on costs for 2004 was \$4,237.36 (SD \$7,837.65). They found a difference in costs depending on whether a client did or did not return to work. Clients who returned to work required less rehabilitation and cost more (mean time in rehabilitation 28 months, SD 23 months, cost \$4,809 per client in 2004) than those who did not return to work (mean time in rehabilitation 33 months, SD 24 months, cost \$3,656 per person in 2004). They did not state what these costs were. All of these studies suggest that the cost of VR varies with figures dependent on what was costed, over what period of time and when the study was conducted. None of the aforementioned studies made comparisons to alternative or no provision; therefore none were formal economic analyses. Consequently, it is difficult to say whether VR is cost-effective in supporting people with TBI to return to work.

No cost-effectiveness studies specifically for OT, TBI and VR were found in the literature search. However, a formal cost effectiveness study of VR including OT was conducted alongside a Dutch randomised control trial (RCT) of 62 adults with clinical depression. The authors concluded the addition of OT alongside usual care did not improve the depression, but did reduce the amount of work loss days without increasing work stress. The authors suggested there was a 75% probability that the OT intervention alongside usual care was more cost effective than usual care alone (Schene et al. 2007). Therefore there is some evidence for the cost effectiveness of OT VR for depression but more evidence is required to ascertain whether it is true in other clinical contexts.

In summary, only a few studies have examined the cost effectiveness of TBI VR with people with TBI. Although all have concluded that their services

were cost effective, very few made comparisons to an alternative service so their conclusions may not be justified.

5.1.5. UK perspective of the financial impact of TBI

None of the aforementioned studies have been conducted in the UK despite the fact that there is an increasing consensus that all interventions provided by the NHS should be evaluated to ascertain their cost effectiveness (National Institute for Health and Clinical Excellence 2009). The literature review only identified a few UK studies relating to costs and TBI (McGregor et al. 1997; Powell et al. 2002; Turner-Stokes 2004; Murphy et al. 2006; Turner-Stokes 2007; Morris et al. 2008; Beecham et al. 2009).

Since 1997, a few UK economic studies have been published. For example, the costs of 6,484 patients who were admitted to UK hospitals with a TBI concluded that the average hospitalisation cost of treating a person with TBI was £15,462 (SD 16 844) per patient (Morris et al. 2008). Although this included the costs of the ambulance, critical care, regular ward costs and the costs of any procedures required, it did not include any post-hospital treatment costs. Beecham et al (2009) examined the health and social care services costs for people with ABI after presentation at A&E but only for people aged between 18-25 years and only for a notional first year post-TBI. They acknowledged that costs would extend beyond one year. They divided people into four user groups – see Table 54. They also concluded that although most young adults use minimal health and social care for those with subsequent disabilities the cost to the health and social care budget may be in excess of £47.2 million per year using costs for 2006.

Table 54: UK Health and social care costs of people with ABI
(18-25 years old)

Group	Characteristics of group	Total costs per year (UK£2006)	Average costs per person p.a.
1	Largest group. Attend A&E or short in-patient stay. Only 1 in 5 will have follow up GP appointment. Mainly mild TBI but 20% will have residual symptoms at 6 months	£23.8 million p.a.	£240 p.a.
2	Likely to return home but are more disabled. Rely on personal care support from informal carers. 47% will have outpatient appointments, 28% will receive physiotherapy, 15% will see a Social Worker, 91% will see a GP with 54% of appointments TBI related	£6.0 million p.a.	£17,160 p.a.
3	People in supported accommodation with paid carers, some will require overnight supervision and part time supervision during the day	£30.9 million p.a.	£32,900 p.a.
4	The most severely disabled group and need mainly residential care	£10.4 million p.a.	£33,900 p.a.

Two studies examined the cost of providing general TBI rehabilitation (Worthington et al. 2006; Turner-Stokes 2007). Both concluded that the extra costs of providing longer and/or specialist inpatient rehabilitation would be offset by the savings in long-term care. For example, Turner-Stokes (2007) suggested that the mean additional cost of a stay in a NHS rehabilitation unit would be offset by the mean weekly savings in cost of care within 36 months. Worthington et al (2006) suggested that treatment at a private residential neurobehavioral service saved an estimated life-time care cost of approximately £1.1 million per person if admitted to the service within 12 months of injury. These studies support findings from other countries that the medical and social care costs following TBI are high. No UK studies were found that included costs from a TBI carers perspective.

One UK study examined the cost of providing specialist TBI community rehabilitation (Powell et al. 2002). This study costed the provision of a

community TBI team at £6000 per person; it is assumed the cost year was 1992 as this is when the study started although this is not stated in the paper. Costs were based on the provision of two community therapy sessions a week for six months, including costs for administration and liaison. The paper did not specify whether the costs of GP's and consultants appointments were also included. Even though this was reported as part of a RCT, the costs of providing written information to the comparator group were not included, nor were the costs combined with outcome to assess cost effectiveness.

In this literature review only one UK study was identified that specifically focused on TBI VR and costs (Murphy et al. 2006). The authors acknowledged that they did not undertake a complete cost effectiveness analysis but rather attempted to cost the service in relation to return to work. They concluded that the average cost of the VR programme was £8,363 per client which they argued was recouped in savings from payment of incapacity benefit alone (£76.45 per week) in 26 months if a person returned to work (as they did not state the year the costs were based on it is assumed they are based on 2000 which is when the study began). However, they omitted to include the cost of providing a service to those who did not return to work. As only 41% of the sample returned to paid competitive employment it would take longer than 26 months to recoup the cost of paying benefits if the cost of those not returning to work and receiving the service was included. Moreover state benefits are considered a transfer payment, that is a payment from one Government service to another and are not usually considered as an outcome in health economic analysis nor set against service costs (Richardson et al. 2007). However, these caveats aside, this study suggests that providing VR may save costs in the longer term especially given the younger age of many people with TBI. The lack of studies on the costs of TBI suggests this is a much needed area of research in the UK.

5.1.6. Summary: Economic aspect of TBI

In summary, TBI is very costly to the person with the injury, their families and the state. Due to the dearth of studies, there is a consensus that further research into the cost-effectiveness and financial impact of TBI is required, especially in the UK (Gamble et al. 2003; Johnstone et al. 2003; Turner-Stokes 2004; Murphy et al. 2006). Within the few specialist community TBI teams that exist in the UK current NHS practice is for VR to be provided by an OT. No studies were found which examined whether this intervention was cost effective. Therefore, there appears to be a need to examine the cost-effectiveness of this type of intervention.

5.1.7. Types of economic evaluations

Economic evaluations compare the costs and consequences of two or more courses of action. As health resources are scarce, the aim is usually to determine the maximum benefit at the least cost, or to be aware of the cost to allow informed decisions to be made (National Institute for Health and Clinical Excellence 2009). There are four main approaches:-

- **Cost-effectiveness analysis (CEA)** – This measures outcomes in natural units, such as rates of return to work, which are then compared to the cost of obtaining that outcome. The ratio of the mean change in costs compared to the mean change in health outcomes is an incremental cost effectiveness ratio (ICER). ICERs allow the cost per change in health status, such as return to work, to be calculated thus enabling the cost of returning to work with and without the specialist intervention to be compared. However this method does not allow direct comparisons between different outcomes. For example it would not be meaningful to compare the cost of return to work against the cost of a hip fracture (Palmer et al. 1999).
- **Cost-utility analysis (CUA)** – This allows comparisons between different interventions as it converts outcomes to a utility based measure such as quality adjusted life years (QALYs). QALYs combine a change in survival with a weighting factor for health related quality of life to give an overall measurement (Bowling 2002). The CUA calculation is performed

in the same way as a CEA. An outcome, for example, 'return to work', is deemed more cost efficient if it results in higher or equal benefits at a lower cost compared to other interventions using the same utility measure. Therefore, CUAs allow the cost utility of a total hip replacement to be compared to the cost of returning someone to work following TBI.

- **Cost-benefit analysis (CBA)** - This values all costs and benefits in monetary terms to compare services. It is not widely used in health care in the UK as outcomes tend not to be measured in monetary units (Palmer et al. 1999).
- **Cost-minimisation** – Costs are compared in two different groups that have the same outcome, the cheaper option is chosen. This is an unsuitable method for a study where it is not known whether the outcomes of the usual care group will be the same for the specialist group.

Willingness to pay (WTP) is another method of economic evaluation but there is still much debate about how to use it (Cookson 2003). It assigns a value to a health benefit by asking a person how much they would be prepared to pay to gain a benefit or to avoid certain events, but does not expect them to actually pay (National Information Center on Health Services Research and Health Care Technology 2010). A study on WTP after TBI was conducted on members of the Japanese Brain Injury Association with people who had some knowledge or experience of TBI. It showed the level of WTP for the recovery of a family member from the sequelae of TBI was the equivalent to the willingness to pay for the recovery of a family member from an incurable terminal illness. This suggests that families perceived the burden of TBI as being as great as that of a terminal illness and people would be willing to pay for treatment (Hashimoto et al. 2006). However the study did not state how rehabilitation was usually paid for in Japan. If families expected to self-fund rehabilitation this may mean the results may not be transferable to a country where governments or insurers are normally expected to pay. As some people find the concept of WTP difficult, it has been suggested that WTP as an economic outcome is likely to remain hypothetical in UK (Bloor et al. 2006).

In summary, a cost effectiveness analysis (CEA) appears the most suitable approach to inform whether the provision of specialist TBI VR is efficient at helping people with TBI return to work compared to the provision of usual care (technical efficiency). Whereas a cost-utility analysis (CUA) using health related QALYs is required to enable comparisons with competing alternatives from across the health service (allocation efficiency).

5.1.8. Economic research question

The aim of the economic analysis was to ascertain the feasibility of conducting a prospective cost effectiveness analysis alongside the cohort comparison study to determine whether the provision of specialist intervention was more likely to be cost effective when compared to usual care, from both a health and social care perspective and a societal perspective, over a 12 month period.

5.2. Method

Perspectives to consider in health economic analyses will now be discussed, followed by the methodology used.

5.2.1. Perspective, costs and outcomes in health economics

All economic evaluations must clearly define the **perspective taken**, the **costs**, the **outcomes** and the length of time over which they are evaluated (Drummond et al. 2005; Mogyorosy et al. 2005).

5.2.1.1. Perspectives

All health economic studies should state the perspective used. For this study two perspectives were taken. Firstly, a health and social care perspective was adopted as the intervention was provided by the NHS and possibly social services. Secondly, a societal perspective was undertaken to reflect that helping a person work again has implications for the wider society. These perspectives are recommended by National Institute for Health and Clinical Excellence (N.I.C.E) (National Institute for Health and Clinical Excellence 2009). The societal view included patient, carer, Department of Work and Pensions (DWP) and employer's costs. An alternative perspective would be that of the patient.

5.2.1.2. Costs

Costs can be participant-specific or gross costs. Participant-specific costs are specific to the study context and can reflect the inequalities of society, such as men as higher wage earners. Gross costs are more generalised, less accurate but easier to collect. What is collected will depend on what the people providing the data will tolerate in terms of length of questionnaire and details required. Malec et al (2006) found that 31% of TBI participants declined to provide information about salary at follow up which makes comparisons between pre and post-injury earnings difficult. They did not offer an explanation as to why patients may not have disclosed this information. Therefore, in this study participants were asked for their household income in bands of £10,000 to reduce sensitivity of disclosing personal economic data.

Not all cost factors can be measured easily. A systematic review of nine trials focusing on workplace interventions, mainly for people with musculoskeletal problems, showed that interventions that included a workplace component were likely to be more cost effective (Carroll et al. 2010). Unfortunately the review did not include details of how the workplace interventions were costed. No studies in the literature review were found that costed work modifications from an employer's perspective for people with TBI. Obtaining costs directly from employers were not included in this study as that would have meant obtaining participants' permission to contact employers which may not have been forthcoming.

Additionally, presenteeism, which is reduced productivity whilst at work, can occur after TBI. Pauly et al (2008) tried to measure the effect of presenteeism in a variety of workers in the USA. They concluded that in many professions it was more costly than absence. Pauly et al (2008) also found that the concept of presenteeism was confusing to managers and was not easily costed. Although the cost of employing someone with a TBI may be substantial to the employer due to the need for work modifications, these are difficult to quantify and cost. Therefore these were not costed in this study. They are reported descriptively – see 3.3.5.5. Work place adjustments.

5.2.1.3. Outcomes

Outcomes in health economic evaluations can be clinical end points, a quality of life measure such as a Quality adjusted life year (QALY) and/or willingness to pay (Torgerson et al. 1999). The primary outcome for the economic analysis in this study was the number of people at work - see 3.2.4.1. Primary outcome: Return to work. QALYs as measured by the EQ5D were used to generate an incremental cost utility ratio—see 3.2.4.2.Secondary measures.

5.2.1.4. Welfare benefits

Dependency on state benefits is a costly long term consequence of TBI and fear of losing benefits has been cited as a disincentive to return to work (Catalano et al. 2006). Therefore some studies have reported the costs of providing state benefits when examining the costs and benefits of rehabilitation

(Johnstone et al. 2003; Murphy et al. 2006). Grahame (2002), an ex NHS rheumatology consultant and chair of the Disability Living Allowance board (a UK welfare benefit) commented on the possible relationship between VR and provision of welfare benefits. He stated that he had witnessed a decline in British rehabilitation and seen an increase in the provision of disability benefits and wondered if these two facts were related. However, welfare payments are not usually included in health economic analysis, as they are regarded as a transfer payment (Richardson et al. 2007). For example, where there is high unemployment in the labour market, a person with TBI may arguably be replaced by an unemployed person resulting in no change in benefits paid out or tax received.

Additionally guidelines from the National Institute for Health and Clinical Excellence (NICE) state that outcomes should be direct health benefits and costs should be from the NHS or social care perspective, that is, not State benefits (National Institute for Health and Clinical Excellence 2009). However as the fear of losing benefits may be a disincentive to return to work and there is an increased reliance on benefits after TBI, the issue of welfare benefits seems highly pertinent for this population so will be considered in a secondary analysis.

5.2.2. Feasibility Economic analysis study design

This economic analysis compared the specialist group and the usual care group at 12 months post-baseline in two stages, each using accepted methodology: an incremental cost analysis and a cost effectiveness and cost utility ratio from a health and social care perspective and societal perspective (Drummond et al. 1997; National Institute for Health and Clinical Excellence 2009). Finally, patient and carer costs were examined by comparing annual household income and benefit status at 12 months to pre-injury status. Employer's perspectives were considered by examining extra costs incurred at work as reported by participants.

5.2.3. Participants

The participants used for the economic analysis were the same participants used for the cohort comparison – see 3.2.2. Baseline demographic information.

5.2.4. Obtaining economic data

Data for the economic analysis was obtained via participants' responses in the participant questionnaire at three, six and 12 months after baseline along with the primary and secondary outcomes—see 3.2.3.2. and Appendix 4: Participant Questionnaire.

The questions in the participant questionnaire drew upon the Annotated Cost Questionnaire for Patients (Thompson et al. 2001). This is a research resource developed by the UK Working Party on patient costs that gives examples of questions for use in prospective health economic studies to collect information from patients about costs, such as productivity loss due to illness and use of prescribed medication. It is not meant for use in its entirety and questions sometimes need reformatting. Advice from a Health Economist (TS) was also used.

5.2.5. Resource use and costs

Resource use and costs were analysed from a health and social care perspective and from a wider societal perspective separately. In the health and social care perspective, participants were asked how many appointments they had received from the professions listed on the questionnaire. They were also asked whether they were on any medication and if so, what it was. Where possible, these services were costed using published sources as detailed in Table 55. The cost of professionals or services recorded under 'other' such as visits from a district nurse were costed individually from published sources. The frequency and costs of all NHS, social services and medication were calculated for each group.

Table 55: Health and Social Care: Unit costs and resources

Health and social care perspective: (UK£2007)		
Cost Item	Unit cost	Source
NTBIS ¹ Case manager	£83	Community Rehabilitation teams DH Reference costs 2007-8 ²
NTBIS CBT (per hour of face-to-face contact)	£67	PSSRU unit cost 2007 ³
OT (JP) (Adult one to one services)	£69	Community Therapy Services DH Reference costs 2007-8
NTBIS Neuro-psychology (per hour of face-to-face contact)	£67	PSSRU unit cost 2007
Health and social care costs incurred by both groups		
Rehabilitation Consultant (Follow up attendance, non-admitted face-to-face appointment)	£196	DH Reference costs 2007
GP (per surgery consultation lasting 11.7 min)	£34	PSSRU unit cost book 2007
Medication Cost per prescription as prescribed by GP, PSSRU or cost of prescribed drugs if known [BNF])	£10.78 or individual costs	BNF 2007 ⁴ PSSRU 2007
Physiotherapy (Adult one to one services)	£40	Community Therapy Services DH Reference costs 2007-8
Speech therapy (Adult one to one services)	£69	Community Therapy Services DH Reference costs 2007-8
Adult Social worker (per hour of face-to-face contact)	£126	PSSRU unit cost 2007
Case manager	£83	DH Reference costs 2007-8
Neuro-psychology (per hour of face-to-face contact)	£67	PSSRU unit cost 2007
CBT (per hour of face-to-face contact)	£67	PSSRU unit cost 2007
OT (Adult one to one services)	£69	Community Therapy Services DH Reference costs 2007-8
Other individual services received	As required	DH Reference costs 2007-8 PSSRU unit cost 2007

¹ Nottingham Traumatic Brain Injury Service (NTBIS)² 2007 data from Department of Health in 2009 (Department of Health 2009)³ Unit Health and Social Services costs (Personal Social Services Research Unit 2007)⁴ British National Formulary 2007 (Joint Formulary Committee 2007)

Secondly, the components of the societal related unit costs and sources from which they were derived are given in Table 56. Information from participants allowed the comparison of the specialist and usual care groups in terms of monetary value.

In the societal perspective, the number of weeks participants and carers had taken off work was recorded by participants in the questionnaire, supplied as additional information or in a telephone call. If this information was not available, it was calculated by how many weeks participants reported claiming benefits, such as statutory sick pay or incapacity benefit. For example, if a participant reported claiming benefits on the three month questionnaire but not on the six month questionnaire, it was assumed that they had lost wages up to three months as they were able to claim benefits. Therefore 13 weeks' loss of wages was recorded. All time off work was classed as loss of productive work.

Wage losses were calculated individually if the gross annual or gross hourly pay and number of hours worked was available from the participant.

Alternatively loss of wages was calculated by categorising the participant's job using the Standard Occupational Classification (SOC) 2000 job codes and using the job code to ascertain the gross weekly median wage adjusted for full/part time (part time defined as less than 20 hours) and male/female wages using the Annual Survey of Household Earnings (ASHE) (Office for National Statistics 2007) . Any sick pay or benefits were disregarded as this was additional information that was not requested on the questionnaire.

Additionally any specific information supplied from the participant regarding any extra individual costs incurred as a result of the injury were included in the societal perspective; for example the cost of buying a bed to sleep downstairs.

The use of services provided by the Department of Work and Pensions (DWP) such as the use of benefits advisers and Disability Employment Advisors (DEAs) were recorded on the questionnaire. As there were no published costs for DWP appointments costs were requested by private correspondence from the Jobcentreplus (Muirhead 2008). Estimated costs were received from

Jobcentreplus in May 2008 but as the price year was not stated, for simplicity it was assumed costs were from 2007, the last complete financial year. Based on clinical experience, it was anticipated that that only a small percentage of participants would access services from the DWP. Therefore these costs would form only a small part of the overall costs.

Costs to employers were considered by including all costs reported by the participant that occurred in the workplace. It was assumed wages remained the same regardless of any adjustments provided.

Table 56: Societal perspective – Unit costs and sources

Societal perspective – Unit costs UK£2007		
Cost item	Unit cost £	Source
Participant and carer lost wages (number of weeks not working starting from date of injury)	Job category or participant information	Job category classified by Standard Occupational Classification (SOC) 2000 codes ¹ , Annual Survey of Household Income (ASHE) 2007 (gross weekly median wage adjusted for full/part time and male/ female wages) or study questionnaire if gross annual wage or gross hourly pay was provided ² .
Participant and carers additional costs		Individual extra costs as reported on study questionnaire
Disability Employment Advisor (DEA) (per visit)	£ 37	Jobcentreplus 2007 ³
New work focused claimant	£120	Jobcentreplus 2007
Work focused interviews- existing claimant	£ 25	Jobcentreplus 2007
Other services arranged by the DWP i.e. Access to work	£37	Assumed same costs as DEA as no data available.
Benefits advisor	£37	Assumed same costs as DEA as no data available
Employers costs		Individual extra costs as reported on study questionnaire e.g. provision of specialist equipment

¹ Standard Occupational Classification codes (Office for National Statistics 2008)

² Annual Survey of Household income (Office for National Statistics 2007)

³ Obtained from private correspondence (Muirhead 2008)

The use of solicitors, private health care and self-help groups were optional, that is people chose whether or not to use them subject to whether they had an ability to pay or not. Therefore, they were reported descriptively and not costed – see 3.3.5.2. Services received.

The second stage of the economic analysis was a:

- Cost-effectiveness analysis (CEA) which combined the cost per unit of outcome. This combined the cost analysis with the change in the number of people who returned to work between groups.
- Cost-utility analysis (CUA) which combined the cost analysis with the cost per Quality Adjusted Life Year (QALYs)

The EQ5D was used to estimate the health related quality of life (HRQOL) from which QALYs were estimated using linear interpolation and area under the curve analysis over 12 months. The overall difference in mean QALYs between the specialist group and the usual care group was calculated. Point estimate incremental cost effectiveness ratios (ICERs) were generated where appropriate unless a group was both less expensive and more effective or less costly and more effective. A cost utility approach allows comparisons with interventions for other health conditions.

Finally, the patients' and employers' perspectives were considered descriptively. Participants were asked about their annual household income, welfare benefit status and whether they felt they would be financially better off if they returned to work.

5.2.6. Economic statistical analysis

Costs and resource use for participants with partial or non-returned data were omitted from the complete data set. A sensitivity analysis was conducted by imputing missing data in different ways to ascertain whether these affected the results. Thus, three Excel datasets were used:

1. A complete data set which included participants who had returned completed questionnaires at baseline, 3, 6 and 12 months.
2. A data set where the last observed value was carried forward and imputed in place of missing data: – see below
3. A data set where the mean value was imputed in place of missing data:- see below.

Last observed value carried forward imputed data set

Costs and resource use for participants with partial or absent data were imputed using the last observed value carried forward (LOCF) and adjusted for the appropriate period according to the following assumptions:

- If no data was present after baseline, that participant was not used in the analysis
- Lost wages were not carried forward if a participant was known to be working at the missing time point
- Last point carried forward was multiplied by the relevant time points. For example, if the person had seen a GP twice between three and six months (a three month period), but no data was available between six and 12 months (a 6 month period), then the number of times seen by the GP would be multiplied by two and four GP appointments entered for the absent period.
- If two consecutive time points were completely missing the participant was not included.
- If two consecutive time points had only partially missing data then data was carried forward.
- If there was partial data followed by missing data followed by partial data then that participant not used at all.

As the LOCF data sets were a sensitivity analysis, these are reported in the appendices for reference.

Mean imputed data set

This was calculated by:

- Obtaining the mean value of the costs and QALYs for each group in each period that is, one to three months, three to six months, and six to twelve months.
- The mean value of the costs and QALYs for each group in each relevant period was inputted where there was missing data. For example, the mean costs for the specialist group in the nought to three month period was £720.66, this was imputed for specialist group participants who did not have data in this period.

However, as costs for all participants could be calculated using this method, this resulted in more imputed data. Therefore this data set was only used to calculate an Incremental cost effectiveness ratio (ICER) as it was less accurate.

Resource use and costs at 12 months were estimated along with the mean difference and 95% confidence intervals. Confidence intervals for the mean difference in costs were obtained using independent t tests using SPSS version 16.0 (Levene's test of equality of variances was observed- see 3.2.4.). No other tests for statistical significance were conducted as this was a feasibility study; confidence intervals were used to determine significant differences.

Therapy appointments and costs included OT, physiotherapist, speech and language therapists, social workers, and others. Health appointments and costs included GP, consultants, and cost of medication, in addition to therapy appointments.

Data used for the incremental analysis was subject to sensitivity analyses using non-parametric bootstrapping methods (Briggs et al. 1999; Drummond et al. 2005). Cost effectiveness acceptability curves (CEAC) were drawn. CEACs show the probability of an intervention being effective at different levels of willingness to pay. Although not used to ascertain the cost effectiveness of an intervention (ICERs fulfil that function), CEAC's represent the uncertainty around the decision when compared to an alternative intervention for different levels of willingness to pay (WTP) per QALY (Barton et al. 2008).

Descriptive statistics were used for reporting annual household income, number of participants on benefits, and percentage of participants who felt they would not be financially better off working. Summary of data is reported in the text, with data in appendices for reference. Extra costs at work were reported by participants, not employers. This data was from the cohort comparison data base (SPSS 16) so all available data was used and no missing data was imputed.

An index score was obtained to enable comparison of the group's annual household income. The index score is a method of comparing the overall

household incomes of both groups, the higher the score the wealthier the group. A score was allocated to each income category which, when multiplied by the number of people in that category, gave a total category score. Category scores were totalled and then divided by the number of people in each group to obtain the index score -see Appendix 10: Household income index score.

All costs presented are in 2007 pounds sterling. No discounting was undertaken as a one-year time period was used for the economic analysis.

5.3. Results

The following will be reported: the practical aspects of collecting economic data, a comparison of groups' pre-injury economic status, results of the feasibility economic analyses and lastly, results from the participants', carers' and employers' perspectives.

5.3.1. Practical consideration of collecting economic data

There was no difference in response rate to economic questions compared to other questions in the questionnaire: – see 3.2.5. Data collection.

However partially completed questionnaires and questionnaires not returned were particularly problematic for the economic analysis as the resource use and the EQ5D needed to be completed at all time points to undertake the incremental cost effectiveness analysis (ICER). This requirement meant less data was available for analysis. This resulted in three excel data sets each with different completeness of data. These were used to calculate the resource use and costs:-

- A complete data set consisting of 17 specialist group participants (17/40, 42.50%) and 32 usual care group participants (32/54, 59.26%). These participants returned fully completed questionnaires at baseline, 3,6 and 12 months.
- An imputed data set consisting of 33 specialist group participants (33/40, 82.50%) and 45 usual care group participants (45/54, 83.33%). These participants had missing questions within their questionnaires or non-returned questionnaires at one time point. The missing data was imputed using the last observed value carried forward (LOCF) –see 5.2.6. This method of imputing depended on specific data being present; therefore not all participants could be included.
- A third excel data set was produced by imputing the mean – see 5.2.6. This data set was only used to calculate an ICER. Imputing the mean did not depend on data being present so imputed data was available for all participants (40 specialist group, 54 usual care group).

The complete data set was used for all analyses unless otherwise stated.

5.3.1.1. Problems with collecting the data

There were two specific problems related to collecting the economic data: accuracy of reporting resource use and wording of specific questions.

Accuracy of reporting resource use

Both groups reported receiving services – see 3.3.5.2. Services received. However, there was doubt about the accuracy of the data received from both groups. It was clear, from the information given on questionnaires and during follow up phone calls, that occasionally participants had little idea who had delivered the intervention. Participants often referred to people by name or to what they did. For example, one usual care participant reported seeing a ‘memory lady’ but could not state which profession she belonged to; a specialist group participant reported seeing a neuro-psychologist ten times when there was not one working in the Nottingham Traumatic Brain Injury Service (NTBIS) at the time he was treated (and to the NTBIS’s knowledge he was not receiving any other services).

Confusion over question wording

The wording of the question ‘what is your best guess of your household current yearly income from jobs and benefits (before tax and national insurance is taken off)?’ appeared to be confusing for some participants. Some reported their individual earnings as they did not know the household income. Other participants reported the household income. Overall data on total annual household income was obtained from 61/94 (64.9%) participants. As 15/94 (16.0%) did not return the questionnaire or declined to participate in the study, this meant 19/94 (20.2%) did not answer the household income question. Additionally, two of the research assistants reported feeling uncomfortable asking this question over the phone.

5.3.2. Pre-injury economic status of participants

Proportionately 9.5% more participants in the usual care group reported having the lowest household income of <£10,000. However, when split into groups earning £20,000 or above, both groups were similar (specialist group 35.0% (14/40) v usual care group 37.0% (20/54) – see Appendix 9: Total annual household income.

Pre-injury incomes of the groups were also compared using an index score -see 5.2.5, Appendix 10: Household income index scores. The average index scores were: specialist group 2.50 v usual care group 2.40, thus both groups were similar.

The majority of participants were not in receipt of state benefits pre-injury (Not in receipt of state benefits: specialist group 32/40 [80.0%] v usual care group 45/54 [83.3%]). Benefits reported were those that could be claimed whilst working such as Working Tax Credits.

5.3.2.1. Baseline resource use

Resource use was the mean number of appointments per participant. From a **health and social care perspective**, the specialist group received a mean of one more OT appointment at baseline, which was statistically significant (mean difference 1.13 appointments, CI 0.12, 2.16) and half a case manager appointment more than the usual care group, which was not statistically significant-see Table 57. This higher resource use was due to the intervention from the specialist community TBI service that, for some patients, commenced whilst in hospital. It also included OT, as participants were asked to participate whilst on the ward. If they agreed to participate in the study some participants received intervention from the OT then if appropriate. However the higher number of OT and case manager visits in the specialist group did not result in any statistically significant differences between the groups in the overall total number of therapy or health appointments at baseline.

Table 57: Baseline resource use: Health and social care perspective
(Complete data set)

Health and social care appointments	Specialist group (n=17)		Usual care group (n=32)		Mean difference (95% CI)	
	Mean	Std Dev.	Mean	Std Dev.	Mean	95% CI
Specialist team only						
Case manager	0.53	-1.07	0.00	0.00	0.53	(-0.20, 1.08)
CBT	0.06	0.24	0.00	0.00	0.06	(-0.03, 0.14)
Psychologist	0.00	0.00	0.03	0.18	-0.03	(-0.12, 0.60)
OT (NTBIS)	0.94	0.90	n/a	n/a	n/a	n/a
Total NTBIS	1.53	1.84	n/a	n/a	n/a	n/a
Other health appointments						
Consultant	0.24	0.56	0.28	0.77	-0.05 ¹	(-0.47, 0.38)
GP	1.18	1.24	1.38	1.36	-0.20	(1.00, 0.60)
OT (other)	0.35	1.46	0.16	0.72	0.20	(-0.43, 0.82)
Physiotherapist	0.18	0.53	0.47	1.29	-0.29	(-0.95, 0.37)
SALT	0.00	0.00	0.00	0.00	0.00	n/a
Social worker	0.00	0.00	0.13	0.42	-0.13	(-0.28, 0.03)
Other	0.00	0.00	0.03	0.18	-0.03	(-0.28, 0.06)
Psychologist	0.00	0.00	0.03	0.18	-0.03	(-0.12, 0.60)
Total therapy appointments	2.06	3.11	0.81	1.64	1.25	(-0.11, 2.60)
Total health and social care appointments	3.47	3.45	2.47	2.16	1.00	(-0.61, 2.61)
Total OT appts ²	1.29	1.93	0.16	0.72	1.13	(0.12, 2.16)

¹ Minus mean difference score = more appointments in the usual care group

² Total OT appointments are listed separately because the specialist OT appointments are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained. Total OT appointments are listed separately for additional detail.

From a **societal perspective**, there were no statistically significant differences in resource use between the groups at baseline – see Table 58.

Table 58: Baseline resource use: Societal perspective (Complete data set)

Societal perspective units	Specialist group (n=17)		Usual care group (n=32)		Mean difference (95% confidence intervals)	
	Mean	Std dev.	Mean	Std dev.	Mean	95% CI
Health appointments	3.47	3.45	2.47	2.16	1.00	(-0.11, 2.60)
Dept. of Work and Pensions appointments	0.18	0.39	0.00	0.00	0.18	(-0.27, 0.38)
Participant weeks lost wages	5.47	3.14	7.28	8.01	-1.81*	(-5.89, 2.27)
Carers weeks lost wages	0.59	1.33	3.19	8.44	-2.60	(-6.77, 1.57)
Total health and societal appointments	3.65	3.46	2.47	2.16	1.18	(-0.44, 2.79)
Weeks lost wages	6.06	3.88	10.47	15.84	-4.41	(-12.30, 3.48)

* Minus Mean difference score = more appointments in the usual care group

The larger imputed data set revealed a similar but more exaggerated pattern of resource use at baseline- see Appendix 11: Baseline resource use: imputed data set. The specialist group received statistically significantly more visits from case managers (mean difference =0.82, CI 0.45, 1.19) and statistically significantly more OT visits (mean difference =1.07, CI 0.48 -1.67). This impacted on the total number of therapy and total number of health appointments which in turn impacted on the total number of appointments from a societal perspective at baseline. Overall, the specialist group received significantly more therapy appointments (mean difference= 1.73, CI 0.46, 2.99), significantly more health appointments (mean difference =1.35, CI 0.08, 0.62) and more societal appointments (mean difference = 1.49, CI 0.10, 2.87) at baseline.

5.3.2.2. Baseline costs

At baseline, **the overall mean health and social care costs** per participant were: specialist group £270.84, usual care group £181.88—see Table 59.

Therefore there was an additional mean health and social care cost of £88.96 (CI -£38.61, £216.53) per participant in the specialist group at baseline.

The difference in health and social care cost resulted from higher OT costs in the specialist group which were statistically significant (mean difference £78.51, CI £8.33, £148.70) and higher case manager costs in the specialist group (mean difference £43.94, CI -£1.62, £89.50) which was not statistically significant - see Table 59. This pattern was similar to that of the resource use.

Table 59: Baseline costs: Health and social care perspective
(Complete data set, mean cost (UK£2007) per participant)

Health perspective	Specialist group (n=17)		Usual care group (n=32)		Mean difference	
	Mean UK £2007	Std Dev. £	Mean £	Std Dev. £	Mean UK £2007	95% CI
Specialist team						
Case manager	43.94	88.61	0.00	0.00	43.94	(-1.62, 89.50)
CBT	3.94	16.25	0.00	0.00	3.94	(-4.41, 12.30)
Psychologist	0.00	0.00	0.00	0.00	0.00	0.00
OT (NTBIS)	64.94	62.05	n/a	n/a	n/a	n/a
Total NTBIS	112.82	139.96	n/a	n/a	n/a	n/a
Other health appointments						
Consultant	46.12	110.21	49.03	149.34	-2.91 ¹	(-85.80, 79.97)
GP	40.00	42.05	46.75	46.31	-6.75	(-33.86, 20.36)
Medication	40.49	95.91	37.57	87.24	2.92	(-51.58, 57.42)
OT (other)	24.35	100.41	10.78	49.91	13.57	(-29.44, 56.58)
Physio	7.06	21.14	18.75	51.79	-11.69	(-38.16, 14.77)
SALT	0.00	0.00	0.00	0.00	0.00	n/a
Social worker	0.00	0.00	15.75	53.07	-15.75	(-34.89, 3.39)
Psychologist	0.00	0.00	2.09	11.84	-2.09	(-7.90, 3.71)
Other	0.00	0.00	1.16	6.54	-1.16	(-4.36, 2.05)
Total therapy	144.24	214.07	48.53	97.56	95.70	(-18.56, 9.97)
Total health and social care costs	270.84	244.29	181.88	192.05	88.96	(-38.61, 16.52)
Total OT ²	89.29	133.09	10.78	49.91	78.51	(8.33, 148.7) ³

¹Minus mean difference score = greater costs in the usual care group

²Total OT appointments are listed separately because the specialist OT appointments are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained. Total OT appointments are listed separately for additional detail.

³Red text = statistically significant

The burden of costs at baseline was reversed in the **societal perspective**. Although not statistically significant, the usual care group incurred higher mean total costs per participant (Mean difference £1, 268.61, CI -£3,837.26, £1300.13)–see Table 60. Higher participant costs and higher carer costs were the cause of this difference at baseline –see Table 60.

Table 60: Baseline costs: Societal perspective
(Complete data set, mean cost (UK£2007) per participant)

Societal view	Specialist group		Usual care group		Mean difference	
	£	SD	£	SD	£	
Health costs	270.84	244.29	181.88	192.05	88.96	(-38.61, 216.52)
Participant costs	1921.32	1614.98	2648.20	3765.41	-726.88 ¹	(-2658, 1205.10)
Carers costs ²	292.87	512.09	930.09	1673.21	-637.22	(-1285.21, 10.99)
Employer costs	0.00	0.00	0.00	0.00	0.00	n/a
DWP costs	6.53	14.54	0.00	0.00	6.53	(-0.95, 14.01)
Total health + societal costs	2491.56	1990.94	3760.17	5039.38	-1268.61	(-3837.26, 1300.13)

¹Minus mean difference score = greater costs in the usual care group

²Carers cost: Independent t test: $t=-1.986$, $df=40.459$, $p=0.054$

The imputed data set showed a similar pattern to the complete data set at baseline - see Appendix 12, Baseline costs: Imputed data set. In the imputed data set there were statistically significant higher **health and social costs** in the specialist group in costs for: case managers (mean difference £67.91, CI £37.17, £98.65) and costs for total OT visits (mean difference ££74, 02, CI -£74.02, £20.36). The usual care group incurred statistically significantly higher costs in social work visits (mean difference £16.80, CI £32.11, £1.49). These differences had a statistically significant impact on the cost of total therapy, with the specialist group incurring additional mean costs of £122.94 (CI £43.62, £202.26) at baseline. However, this significant difference in therapy

costs in the imputed data set did not impact on overall health costs.

Participants in the specialist group incurred an additional mean cost of £71.87 in overall health and social care costs compared to usual care group, this was not statistically significant.

From the **societal perspective** in the imputed data set, the usual care group incurred an additional mean cost of £999.71 (CI -£3,023.51, £901.76) compared to the specialist group. This was not statistically significant.

5.3.2.3. Baseline summary: resource use and costs

At baseline, the complete data set showed the specialist group received on average one more visit from an OT, which was statistically significant. In terms of cost, a participant in the specialist group incurred £88.96 more in health costs per participant than a participant in the usual care group. However, the cost difference was reversed in the societal perspective. A participant in the usual care group incurred an additional mean cost of £1268.61. This was due to increased participant and carer costs.

The imputed data set reflected a similar but exaggerated pattern at baseline. The specialist group received statistically significantly more visits from case managers, OTs and social workers compared to the usual group. However, the small number of visits involved indicates a need for caution when interpreting the results.

5.3.3. Findings from the feasibility economic analysis

5.3.3.1. Resource use over 12 month

When all the **health and social** care appointments were totalled over the 12 month period from baseline, the specialist group received a mean of 2.1 more appointments (specialist group = 32 appointments v usual care group =29.9 appointments, CI-20.58, 24.83), this was not statistically significant – see Table 61.

However, within this total number of health and social care appointments, the specialist group received on average 4.6 more OT appointments than the usual care group. This was statistically significant (CI. 0.81, 8.42) – see Table 61.

Table 61: 12 month resource use: Health and social care perspective
(Complete data set, mean number of appointments per participant)

Health and social care perspective	Specialist group (n=17)		Usual care group (n=32)		Mean difference	
	Mean	Std dev.	Mean	Std Dev.	Mean	95% CI
Specialist team appointments						
Case manager	4.2	-7.2	1.3	4.1	2.8	(-1.12,6.78)
CBT	1.2	4.1	0.2	1.1	1.0	(-1.20, 3.11)
Psychologist	1.3	2.6	1.9	3.6	-0.6	(-2.65, 1.36)
OT (NTBIS)	5.6	6.8				
Total NTBIS	12.2	15.6				
Other health appointments						
Consultant	2.3	2.5	3.3	3.1	-1.01	(-2.72, 0.81)
GP	6.4	4.8	8.5	10.9	-2.2	(-7.80, 3.44)
OT (other)	1.6	4.0	2.6	6.0	-1.0	(-4.26, 2.31)
Physio	7.2	10.6	7.9	23.3	-0.8	(-12.79,11.27)
SALT	0.4	1.5	2.3	8.0	-1.9	(-5.86,2.07)
Social worker	0.0	0.0	0.3	0.9	-0.3	(-0.60,0.04)
Other	2.0	8.2	1.6	5.5	0.4	(-3.53,4.40)
Total therapy appointments	23.4	19.7	18.1	38.1	5.3	(-14.65,25.17)
Total health and social care appointments	32.0	23.3	29.9	43.2	2.1	(-20.58,24.83)
Total OT appointments ²	7.2	6.8	2.6	6.0	4.6	(0.81,8.42) ³

¹Minus mean difference score = greater number of appointments in the usual care group

²Total OT appointments are listed separately because the specialist OT appointments are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained. Total OT appointments are listed separately for additional detail.

³Red text = statistically significant

In the **societal perspective** at 12 months, the carers in the usual care group reported statistically significantly more weeks lost wages – see Table 62. Both groups had on average two appointments with the Department of Work and Pensions (DWP).

Table 62: 12 month resource use: Societal perspective
(Complete data set, mean number of appointments per participant)

Societal perspective 12 month resource use	Specialist group		Usual care group		Mean difference	
	Mean	St dev.	Mean	St dev.	Mean	95% CI
Health and social care appointments	32.0	23.3	29.9	43.2	2.1	(-20.58, 24.83)
Participant weeks lost wages	15.4	20.1	17.5	21.3	-2.1 ¹	(-0.93, 2.79)
Carers weeks lost wages	0.9	2.5	8.1	18.0	-7.2	(-13.81, -0.61)
DWP	2.6	4.3	1.7	2.2	0.9	(-0.93, 2.79)
Total health and societal appointments	34.6	25.5	31.5	43.4	3.1	(-20.04, 26.16)

¹Minus mean difference score = greater number of appointments in the usual care group.

From the health and social care perspective, the imputed data set showed a similar, but exaggerated, pattern to the complete data set at 12 months - see Appendix 13, 12 month resource use: Imputed data set. The specialist group received a mean of 5.2 more OT appointments. This was statistically significant (CI 2.01-8.45). Additionally there were also on average 3.8 more case manager appointments. This was also statistically significant (CI 1.05, 6.53).

In the imputed data set, there were no statistical significant differences in the overall number of health and social care appointments between the groups

(specialist group 31.2 appointments v usual care group 37.6 appointments (CI - 8.53, 21.5) at 12 months.

From a **societal perspective**, the number of DWP visits reduced slightly to 1.9 visits for the specialist group and 1.5 visits in the usual care group (mean difference: 0.4, CI -0.80, 1.66) at 12 months in the imputed data set.

5.3.3.2. Costs at 12 months

From the **health and social care perspective** over the 12 months, the overall mean difference in health and social care costs per participant was £75.23, with increased costs in the specialist group (specialist group £2106.94 v usual care group £2031.71, CI-£1,199.82, £1350.28), this was not statistically significant –see Table 63. At 12 months, only total OT costs showed a statistically significant difference, the mean difference was £318.36 (CI: £55.70, £582.08) with the higher costs being incurred by the specialist group– see Table 63.

Table 63: 12 month costs: Health and social care perspective
(Complete data set: mean cost (UK£2007) per participant)

Health perspective	Specialist group (n=17)		Non-Specialist group (n=32)		Mean difference	
	Mean £	Std Dev. £	Mean £	Std Dev. £	Mean £	95% CI £
Specialist team						
Case manager	346.65	601.56	111.53	340.99	235.12	(-92.62, 562.85)
CBT	78.82	277.50	14.66	71.67	64.17	(-80.23, 208.57)
Psychologist	86.71	176.89	129.81	242.43	-43.11	(-177.33, 91.11)
OT (NTBIS)	385.59	468.65	n/a	n/a	n/a	n/a
Total NTBIS	897.76	1171.01	n/a	n/a	n/a	n/a
Other Health costs						
Consultant	449.65	483.91	637.00	613.78	-187.35 ¹	(-533.24, 158.54)
GP	216.00	162.59	290.06	371.75	-74.06	(-265.13, 117.01)
Medication	46.53	132.00	99.18	278.67	-52.65	(-196.93, 91.68)
OT (other)	109.59	279.28	176.81	415.83	-67.22	(-293.62, 159.17)
Physio	287.06	422.43	317.50	933.34	-30.44	(-511.69, 450.80)
SALT	24.35	100.41	155.25	552.83	-130.90	(-404.2, 142.48)
Social worker	0.00	0.00	35.44	111.94	-35.44	(-75.80, 4.92)
Other appts	76.00	313.36	64.47	202.02	11.53	(-136.79, 159.85)
Total therapy	1394.76	1240.56	1005.47	1951.93	389.30	(-662.88, 1441.47)
Total health and social care costs	2106.94	1542.83	2031.71	2352.24	75.23	(-1199.82, 1350.28)
Total OT ²	495.18	470.03	176.81	415.83	318.36	(55.70, 582.08) ³

¹Minus mean difference score = greater costs in the usual care group

²Total OT appointments are listed separately because the specialist OT appointments are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained.

³Red text = statistically significant

In the **societal perspective** at 12 months, the cost burden was reversed. Higher costs incurred in the usual care group, the mean difference of £1,862.73 (CI - £9000, £5274.66) per person— see Table 64. Participant and carers lost wages accounted for much of the cost. The costs of DWP appointments were low in comparison.

Table 64: 12 month costs: Societal perspective
(Complete data set, mean cost (£) per participant)

Societal view, 12 months	Specialist group £		Usual care group £		Mean difference £	
	Mean	St dev.	Mean	St dev.	Mean	95% CI
Health costs	2106.94	1542.83	2031.71	2352.24	75.23	(-1199.82, 1350.28)
Participant costs	6205.77	8365.27	6938.81	9363.78	-733.04	(-6188.80, 4722.63)
Carers costs	228.39	651.57	1594.21	3709.83	-1365.82	(-2735.96, 4.30)
Employers costs	147.12	606.32	20.54	77.56	126.58	(-186.08, 439.24)
DWP costs	97.82	162.54	63.50	85.09	34.32	(-53.48, 122.13)
Total health and societal costs	8786.04	9535.64	10648.77	12842.97	-1862.73	(-9000.00, 5274.66)

*Minus mean difference score = greater costs in the usual care group

The **imputed data** set showed a similar pattern to the complete data set. In the **health and social care perspective**, the specialist group incurred greater costs at 12 months: mean difference £488.37 per participant (specialist group £2234.07 v usual care group £1745.70, CI -£416.35, 1393.08) –see Appendix 14, 12 month costs: Imputed data set. This was not statistically significant. However within the health and social care costs there were statistically significantly differences. The specialist group incurred greater costs with regard to case manager costs (£397.39 specialist group v £83.00 usual care group, mean difference £314.39, CI £86.86, £541.93) and overall OT costs

(£501.82 specialist group v £142.07 usual care group, mean difference £360.75, CI £138.42, £582.08).

From a **societal perspective**, in the imputed data set, the usual care group incurred greater costs at 12 months: mean cost difference £-2969.37 CI -£8,212.37, £2,273.63) per participant (specialist group £8337.70 minus usual care group £11,307.07) – see Appendix 14, 12 month costs: Imputed data. Again, this was due to participant and carer costs, not DWP appointments.

5.3.3.3. Difference between complete and imputed costs

The complete and imputed data set (LOCF) showed a small difference in the pattern of costs over 12 months between the groups - see Table 65. Compared to the complete data set, the specialist group in the imputed data set (LOCF) had increased health and social care costs and reduced societal costs; the pattern was reversed in the usual care group.

Table 65: Difference in costs between complete and imputed data sets

Specialist care group	12 month costs UK£2007		£ and Percentage difference
	Complete data (n=17)	Imputed data (LOCF) (n=33)	
Health and social care perspective	£2106.94	£2234.07	+£127.13 (6.0%) increased costs in imputed data set
Societal perspective	£8786.04	£8337.70	-£448.34 (5.1%) less costs in imputed data set
Usual care group	(n=32)	(n=45)	
Health and social care perspective	£2031.71	£1745.70	-£286.01 (14.1%) less costs in imputed data set
Societal perspective	£10648.77	£11307.07	+£658.30 (6.2%) higher costs in imputed data set

5.3.3.4. Summary: 12 month resource use and costs

Both the complete data set and the imputed data set showed the same pattern of results: slightly higher health and social care costs in the specialist group and higher societal costs in the usual care group. The increase in societal costs was mainly due to participants' and carers' loss of earnings. The large standard deviations and confidence intervals reflect wide variation in the data collected.

5.3.4. Cost effectiveness analyses

5.3.4.1. Incremental cost effectiveness ratio (ICER) using return to work rates

The cost of returning a person to work at 12 months was calculated thus:-

$$\frac{\text{Mean health and social care costs per specialist group participant} - \text{Mean health and social care costs per usual care group participants}}{\text{Percentage of specialist group participants in work} - \text{Percentage of usual care participants in work}} = \frac{£75.23}{0.15} = £501.53$$

(£2106.94 - £2031.71) / (0.75 - 0.6)

Therefore, it cost an additional £502.53 to return a person in the specialist group to work compared to a usual group person. Dividing this cost by the percentage difference of numbers in work at 12 months (£75.23/15), resulted in a cost of £5.02. This is the cost per 1% increase in the probability of a person returning to work.

To increase the sensitivity of the results the calculation was rerun using the imputed LOCF health and social care costs per person as this produced the highest costs:-

$$\frac{(\pounds2234.07 - \pounds1745.70)}{(0.75 - 0.60)} = \frac{\pounds488.37}{0.15} = \pounds3,255.80$$

Therefore, using the imputed LOCF figures, it costs an additional £3,255.80 to return a person in the specialist group to work compared to a usual group participant.

Using the same method, a sensitivity analysis was undertaken using the societal costs gathered for this study. The complete data set showed it cost £12,418.20 less (-£1862.73/0.15) to return a person in the specialist group to work at 12 months. The imputed data set costs also showed it cost substantially less - £19,795.80 (-£2969.37/0.15) to return a person in the specialist group to work at 12 months.

In summary, it cost between £501.53 and £3,255.80 more in health and social care costs to return a specialist group to work compared to a usual care participant at 12 months. When using the wider societal costs it was substantially cheaper to return a person to work in the specialist group compared to a participant in the usual care group.

5.3.4.2. Incremental cost utility ratio using QALYs (ICUR)

(Although technically an equation using QALYs is an ICUR, it is commonly referred to as an ICER. However, as both an ICER and ICUR were conducted in this study, it will called an ICUR in this study). At 12 months, the mean health costs and the mean health benefits (per quality adjusted life year [QALY]) were higher in the specialist group – see Incremental cost utility ratio (ICUR) equation below. Therefore the results fell into the north east quadrant of the cost –effectiveness plane (higher costs and higher benefits) thus indicating the need for an ICUR to determine whether the specialist group was cost effective (Drummond et al. 2005).

ICUR (complete data set)

$$\frac{\text{Mean cost of specialist group (n=17)} - \text{Mean cost of usual care group (n=32)}}{\text{Mean QALY of specialist group} - \text{Mean QALY of usual care group}} = \text{ICER}$$

$$\frac{\pounds 2106.94 - \pounds 2031.71}{0.1938 - 0.1763} = \frac{\pounds 75.23}{0.0175} = \pounds 4,298.86$$

(95% CI -\pounds 1200, \pounds 1350)

= **Indicative ICUR** **\pounds 4,298.86** (Non-bootstrapped complete data set)

Thus, the indicative ICUR was \pounds 4,298.86. The National Institute of Clinical excellence (NICE) guidelines suggest the ‘willingness to pay per QALY threshold is implicitly \pounds 20-30,000 (National Institute for Health and Clinical Excellence 2009). Using the NICE guidelines, the specialist group would be deemed to be cost effective as it was below the \pounds 20-30,000 threshold.

The indicative bootstrapped ICUR for the complete data set was \pounds 1,731.60. This was also within the implicit NICE guidelines.

A sensitivity analysis was conducted by recalculating the ICUR equation using:-

- The **imputed data set** with the last value carried forward. Two specialist group participants and one usual care participant were omitted from this analysis as they did not have valid EQ5D scores with which to obtain a QALY – see 5.2.5. Economic statistical analysis
- And the **mean data set** which replaced all missing values with the mean costs and QALY scores - see 5.2.5. Economic statistical analysis.

ICUR: using last value carried forward imputed data set

Using the last value carried forward **imputed data set**, the pattern of the results stayed the same: higher mean health costs in the specialist group and slightly

more effective scores from the QALY in the specialist group. The indicative ICUR equation was:-

$$\frac{\text{Mean cost of specialist group (n=33)} - \text{Mean cost of usual care group (n=45)}}{\text{Mean QALY: specialist group} - \text{Mean QALY: usual care group}} = \text{ICUR}$$

$$\frac{\pounds 2021.00 - \pounds 1772.92}{0.1804 - 0.1735} = \frac{\pounds 248.34}{0.0069} = \pounds 35,873.38$$

= Indicative ICUR £35,873.38

Therefore, the last value carried forward **imputed data** set resulted in an ICUR of £35,873.58 which is higher than the implicit NICE cost effectiveness threshold.

ICUR: using imputed mean data set

The indicative ICUR equation using imputed means for missing data was:-

$$\frac{\text{Mean cost of specialist group (n=40)} - \text{Mean cost of usual care group (n=54)}}{\text{Mean QALY: specialist group} - \text{Mean QALY: usual care group}} = \text{ICER}$$

$$\frac{\pounds 1878.71 - \pounds 1690.51}{0.1814 - 0.1880} = \frac{\pounds 188.20}{-0.0066} = \text{n/a}$$

Therefore using the imputed mean data set an indicative ICUR figure was not required as the specialist group was both slightly more expensive and slightly less effective.

5.3.4.3. Cost Utility Analysis for societal perspective

In the societal perspective, the mean cost per specialist group participant was £8,786.04 and the mean cost for the control group was £10,648.77 giving a

mean difference of £-1,862.73 (CI £-9000, £5274.66), which is a cost saving for the specialist group. The mean QALY for the specialist group was 0.1938 and the mean QALY for the control group was 0.1763 giving a mean difference in QALYs of 0.0175 i.e. more effective for the specialist group. This meant an ICUR was not required as this was in the south east quadrant of the cost-effectiveness plane (cheaper and more effective). The pattern was the same for the two imputed data set thus an ICUR was not necessary in the societal perspective as the specialist group intervention was always more cost-effective.

5.3.4.4. Cost Effective Acceptability Curve (CEAC)

To explore the decision uncertainty of whether the specialist group was cost effective or not, a cost effectiveness acceptability curve (CEAC) was generated based on the bootstrapped ICER complete data set—see Figure 12. The CEAC shows both the specialist group and usual care groups very close together. However the usual care group is above the specialist group for all willingness-to-pay values. The closeness of the CEACs suggest that there is uncertainty about which group is most likely to be cost effective over 12 months.

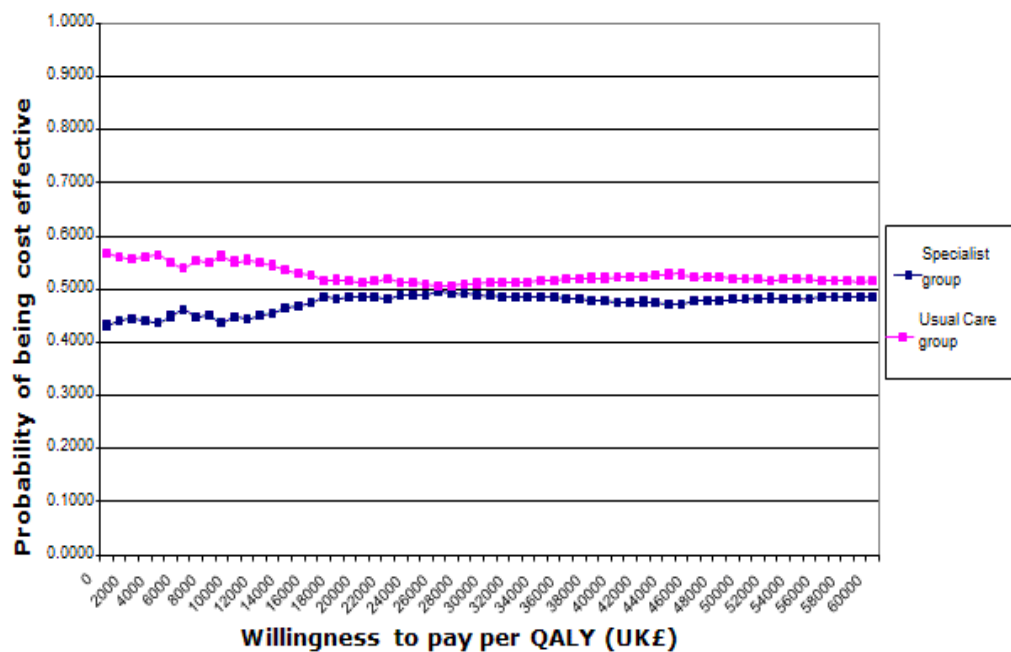


Figure 11: Cost-effectiveness Acceptability Curve
(Based on bootstrapped complete data set)

5.3.4.5. Cost effectiveness summary

The incremental cost analysis showed specialist group participants incurred a mean of £75.23 per participant more in health and social care costs over a 12 month period from baseline. The cost effectiveness analysis showed that it cost between £501.53 up to £3, 255.80 more to return a person to work in the specialist group compared to a person in the usual care group (depending on the dataset used).

The ICUR for the complete data set was £4,298.86 but the ICUR using the LVCF imputed data was £35,873.38. Therefore there is uncertainty about whether the specialist group was cost effective when calculated using health and social care costs and health benefits (QALYs) over a one year period depending on which data set was used (based on the implicit NICE cost effectiveness guidelines). However, when a societal perspective was considered, these preliminary results suggest the specialist group was cost effective if the same health benefits (QALYs) were used for the calculations.

5.3.5. Patient and carer perspective

5.3.5.1. Annual household income status: 12 months

Of the 61/94 (64.9%) replies to this question proportionately the largest change in household income occurred in the usual care group. Compared to baseline, 17.6% fewer people in the usual care group reported having a household income of under £10,000 and 18.5% more usual care participants reported having a household income between £20,000 and £39,990 – see Table 66 and Appendix 9: Annual household income.

Table 66: Annual household income: Percentage change over 12 months

	Specialist group (n=25)	Usual care group (n=36)
Less than £10,000 p.a.	+0.5% ¹	-17.6% ²
£10,000 to £19,999 p.a.	-9.5%	-3.7%
£20,000 to £29,999 p.a.	+3.5%	+18.5%
£30,000 to £39,999 p.a.	+6.0%	- 5.5%
£40,000 to £49,999 p.a.	+3.0%	+1.9%
Over £50,000 p.a.	-5.0%	+0.9%
Don't know	+4.0%	+8.3%

¹ Plus sign = more than at baseline, ² Minus sign = less than at baseline

The higher index score in the usual care group at 12 months suggest some people in the usual care group were slightly better off compared to pre-injury- see Table 67 and Appendix 10: Household Index scores.

Table 67: Comparison of group index scores

	Baseline group Index scores	12 month group Index scores	Difference ¹
Specialist group	2.45	2.40	-0.05
Usual care group	2.40	2.78	0.38

¹ Minus scores = financially worse off compared to baseline

5.3.5.2. Participant and carers costs

Over the 12 month period costs to both participants and carers consisted mainly of lost wages. At 12 months participants in the usual care group lost a mean of

2.1 weeks more wages than participants in the specialist group (number of weeks of wage lost: specialist group 15.4, usual care group 17.5, CI -0.93, 2.79) – see Table 62. The **imputed data set** showed a mean difference of 6.8 weeks lost wages between groups (specialist group 13.6 weeks, usual care group 20.5 weeks, CI -15.78, 2.12) – see Appendix 13: 12 month Resource use: Imputed data set. Neither was statistically significant.

Carers in the usual care group lost a mean of 7.2 weeks more wages than carers in the specialist group (Weeks lost wages: specialist group 0.9, usual care group 8.1, CI -13.81,-0.61) - see Table 62. This was statistically significant. This difference reduced in the **imputed data set** and was not statistically significant (specialist group carers lost 2.2 weeks, usual care group carers lost 6.9 weeks, mean difference 4.8 weeks, CI -10.3, 0.85) – see Appendix 13: 12 month resource use: Imputed data set.

Usual care participants incurred a mean difference of £733.04 in higher individual costs compared to specialist group participants (mean costs per participant: specialist group £6,205.77 v usual care group £6,938.81, CI -£6, 188,80, £4,722,63) – see Table 63. In the **imputed data set**, the mean difference increased to £2,807.18 per person with the usual care group incurring the greater loss (specialist group £5,202.80 v usual care group £8,009.98, CI -£6789.69, £1184.32) — see Appendix 14, 12 month costs: Imputed data set.

Carers in the usual care group incurred higher mean costs of £1365.82 per participant, (mean cost per carer: specialist group £228.39 v usual care group £3,709.83, CI -£2,735.96, £4.30) -see Table 63. In the **imputed data set**, the mean difference reduced to £732.09. However, carers in the usual care group still incurred the greater cost (mean cost per carer: specialist group £747.20, usual care group £1479.29, mean difference, CI -£2,341.36, £877.18) – see Appendix 14: 12 month costs: Imputed data set.

Carer and participant losses combined (lost wages and additional costs) for 12 months were: Specialist group £6,434.16 (£5950.00 in Imputed data set), Usual

care group £8533.02 (£9489.27 in Imputed data set). Additional costs reported appeared to occur during the period of hospitalisation such as cost of travel and hospital parking.

Benefit status: 12 months

At 12 months, 6/34 (18%) of the specialist group and 14/45 (31%) of the usual care group reported state benefits were their only source of income – see Appendix 15: Benefit status. The majority of participants were not on benefits prior to the injury; therefore this was an increase in dependency on state benefits for 6/34 (17.7%) of people in the specialist group and for 11/45 (25%) of people in the usual care group. Nine percent of both groups reported having no wages and no benefits at 12 months (specialist group 3/34 [8.8%]) v usual care group 4/45 [8.9%]).

Did participants feel they would be better off financially if working?

Participants were asked ‘do you think you would be better off financially if you returned to paid work’. Between 0% and 8% of people in both groups at all time points after baseline felt they would not be better off –see Table 68.

Table 68: Participants stating they would not be better off if employed

	Specialist group		Usual care group	
	No's	%	No's	%
Baseline	6/40	15.0	8/40	20.0
3 months	1/27	3.7	2/45	4.4
6 months	2/26	7.7	2/40	5.0
12 months	1/27	3.7	1/36	2.8
18 months	0/13	0.0	1/22	4.6

(Participants who said don't know or not applicable to this question were included)

5.3.6. Employers' perspective

Less than 10% of participants reported having adaptations, in the workplace or educational establishment, with a cost attached. Costs reported were:

- Specialist group: one item to negate the need to climb ladders (£2,500), the cost of enabling remote internet access at home and an extra worker to help in the participant's own business.
- Usual care group: a specialist keyboard and Dictaphone to help with college work, a safety helmet, the cost of private health care (physiotherapy) through work and a risk assessment.

No one reported adaptations that did not have a cost attached to them although work modifications such as more breaks were not costed. To the researcher's knowledge the Government's Access to Work scheme was only accessed once. This was initiated by the OT for one specialist group participant (to help with the cost of the equipment to negate the need for ladders). Other costs were met by employers or colleges.

5.3.7. Summary: Patient, carer and employer perspective

Specialist group participants and carers lost a combined total of 16.1 weeks wages (total cost £6,435.09). Usual care group participants and carers lost a combined total of 39.3 weeks wages (total cost £8,583.02).

Thirteen percent more people in the usual care group reported state benefits as their only source of income at 12 months compared to the specialist group.

Very few participants in each group felt they would not be financially better off if they returned to paid employment.

5.4. Discussion

The discussion will focus on the practical aspects of conducting the feasibility economic analysis and the findings from the analysis.

5.4.1. Economic analysis: Practical considerations

Two issues were encountered when carrying out the economic analysis: incomplete data and collecting personal economic information. Additionally, the significant differences between the groups' length of hospital stay raised the question whether including the cost of the hospital stay would have altered the cost effectiveness analysis.

5.4.1.1. Incomplete economic data

To complete the incremental cost effectiveness ratio (ICER), data regarding resource use and answers from the EQ5D at three, six and 12 months were required. Therefore, if a participant did not return a questionnaire or returned only a partially completed a questionnaire, that participant's data was excluded from the economic analysis. This resulted in three data sets: a complete data set, where participants had returned fully completed questionnaires at all time points, and two incomplete data sets, where missing data was systematically imputed. However, imputing data reduced accuracy.

The economic questions were situated in the middle of the questionnaire and the EQ5D was on the last page. This meant it was occasionally omitted if the participant did not fully complete the questionnaire. Putting economic questions at the front of the questionnaire would have reduced this problem. Additionally, information required for the economic analysis could be designed so that it could be easily captured in a brief phone call. Extra training may be required for those collecting economic data in future studies as some research assistants reported discomfort when asking for financial details over the telephone.

5.4.1.2. The implications of incomplete economic data

It is important to explore any implications arising from having both a complete and incomplete economic data sets.

In the complete data set the rates of return to work were proportionately very similar between the groups. This did not reflect the overall rates of return found in the cohort comparison study. This suggests the complete data set potentially represented a small biased sample as it consisted of participants who were able to complete and return questionnaires at all time points, which is known to be atypical of the general TBI population (Corrigan et al. 2003). However, proportionately, participants' return to work rates in the imputed data set (Last observed value carried forward -LOCF) did represent the return to work figures found in the cohort comparison study and suggests the imputed data set may more representative of the overall study cohort.

Compared to the complete data set, the specialist group in the imputed data set (LOCF) had increased health and social care costs and reduced societal costs but the reserve pattern was found in the usual care group. This may be because the last observed carry forward method of imputing data relies on the last known information being brought forward. For example, if data for 12 months was missing, the data obtained at 6 months such as two consultant appointments were inserted at the 12 month point. However, as natural recovery would be expected to occur during the first year after TBI, people are less likely to use health and social care resources over time. Therefore data obtained by this method is likely to overestimate health and social care costs in those who incur such costs as costs are brought forward. As the specialist group received input, this may be why their costs increased in the imputed data set. It will underestimate costs, in those who do not incur such costs, as there are no costs to bring forward. As the specialist group received input, this may be why their costs increased in the imputed data. The usual care group may have received less input; this may be way the usual care groups' health and social care costs decreased. The higher percentage difference between the groups in the health and social care costs could be due to over/under inflated individual participant's costs in this small sample. This suggests a different

method of imputing data may be required in future studies and suggests caution in extrapolating findings from this study.

However, from a societal perspective, carrying forward costs will have the effect of reducing overall costs if more participants return to work since the cost of lost wages will not be carried forward. This occurred in the specialist group as more people returned to work. Whereas overall costs will increase if fewer people return to work (due to lost wages being carried forward). This occurred in the usual care group as less people returned to work. Future studies need to focus on ensuring complete economic data collection from participants to ensure robustness.

This method of imputing data (LOCF method), is also likely to underestimate QALY scores as participant reported quality of life should improve over the 12 month period. Therefore the ICER based on the imputed data needs to be interpreted with caution. This is particularly relevant in this study as the ICER based on imputed data was above the implicit NICE cost effectiveness guidelines, whereas the ICER using the smaller complete data set was within the guideline threshold.

5.4.1.3. Collecting economic data

It was clear from the telephone calls that some participants found it difficult to recall how many times they had seen a service provider in a given period of time. The presence of memory problems would have exacerbated this.

Therefore, there must be some doubt over the accuracy of the information supplied. Alternative ways of collecting data or verifying its accuracy need to be considered but may be difficult, as many people do not have family or carers to assist with this. Even then, family and carers may also forget. An added complication was that participants accessed treatment from a variety of separate providers such as the NHS and primary care. Verifying accuracy against secondary sources such as GP records was beyond the scope of this study and has been shown to be problematic (Coole et al. 2010).

Other TBI VR studies which have found participants unwilling to disclose their financial situation (Shigaki et al. 2009). For example, Johnstone et al (2003) found 8/45 (18%) people declined to give financial information when entering a VR programme. Although the authors did not explore why people refused, they may have requested too much financial information as they asked about earnings, private income, welfare assistance and financial support from family. In contrast this study only asked people to disclose household income in broad income bands. This appeared to be acceptable to them.

An anomaly occurred regarding household income in the usual care group. At 12 months, there were 18% fewer people in the lowest income group (under £9,999 p.a.) and 19% more people in the next highest income bracket (£10,000 to £19,999 p.a.) compared to baseline. There was less than 10% change in all other categories between both groups. These differences were perplexing for two reasons. Firstly, fewer people in the usual care group reported being back at work at 12 months. Therefore it seemed unlikely that this group would have a higher income level at 12 months post-TBI compared to baseline or that many of their partners would have been in a more highly paid job. Secondly, the percentage differences in both categories were very similar suggesting the confusion could be connected to the wording of the question. Participants were asked for their best guess of the annual household income before tax and national insurance were taken off. Some participants said they did not know overall household income and so recorded their individual income. Given the mean age of participants was 34 years, some were young adults who were living with their parents or with friends so did not know the overall household income. Additionally, many people in this study reported moving house which may have altered the household income. For example, moving from the family home to live with friends. Therefore asking for details of **household** income in a TBI population appears problematic. Altering this to **individual** income may alleviate this problem. However, this would fail to capture changes in working behaviour by carers in response to the person having a TBI; these changes would need to be captured separately.

Despite not requesting details of lost wages a small number of participants volunteered this information. Some provided details of net income whilst others gave gross income. If wages are to be requested in future studies it needs to be clearly specified which figures are required. Unless individual gross wages were provided, data for lost wages was calculated from the Annual Survey of Hours and Earnings (ASHE) (Office for National Statistics 2007) using The Standard Occupational Classification 2000 (SOC2000) codes (Office for National Statistics 2008). This was a straightforward method and overcame the problem of asking people to disclose their earnings. It also had the advantage that it accounted for differences in male, female, part time and full time earnings.

5.4.1.4. Cost of DWP services

The costs of DWP services were obtained from private correspondence in May 2008 as they were not available from published sources. It was assumed for simplicity that the DWP costs were from 2007 as no price year was given. Had the DWP costs been assumed to be 2008 costs and discounted using the public sector inflation index, it is highly unlikely that this change would have significantly impacted on the figures and altered the conclusions reached in this study. Proportionately, the DWP costs accounted for 0.75% of the complete data set (DWP costs =£3,695, Total health and social care and societal costs = £490,123.42). In the imputed data set (LOCF), the proportion of DWP costs were even lower at 0.66% - see Appendix 14.

The low level of DWP costs show that the initial assumption that only a few people would access DWP services was correct. As government legislation changed near the end of the study, that assumption no longer held true. As the change applied to the majority of people with TBI the cost of DWP services will assume greater importance in future studies dependent on UK legislation.

5.4.1.5. Cost of hospital stay

The length of hospital stay was not costed in this study. This was because in clinical practice intervention from the NTBIS OT did not usually commence until after hospital discharge. However, an unexpected finding in this study

was that the usual care group stayed in hospital significantly longer than the specialist group. Reasons for this are discussed in 3.5.1.2. As there is a possibility that the intervention could have impacted on the length of hospital stay, the cost of this difference needs to be explored to ascertain if it would have impacted on the overall economic analysis.

‘Costs per hospital bed day’ vary according to TBI severity, so individual costs for severe, moderate and minor TBI were used (Department of Health 2009). The difference in bed days was calculated using the mean or median figures, whichever was lowest, for minor, moderate and severe TBI. Using these conservative parameters resulted in an increase in health and social costs of between £3,520 to £5,044 per usual care participant – see Appendix 16: Cost of increased length of hospital stay. This increase in costs would have impacted on the ICER undertaken in this study. The specialist group (in both the complete and imputed LOCF data sets) would become cheaper and more effective than the usual care group. In the imputed mean data set it would have changed the specialist group from being more expensive to being less expensive. Therefore, if the intervention is believed to impact on the length of stay, decisions about whether to include these costs in the analysis and the timing of baseline data collection need to be altered. In this study, the cost of the reduced length of stay did affect the ICER equations, making the specialist intervention the more cost effective option.

5.4.1.6. Summary of practical considerations

This study demonstrated it was possible to collect and compare the economic outcomes of a cohort of participants receiving specialist TBI VR to a group receiving usual care. However, incomplete data (either through non-return of questionnaires at any one time point and/or being unable to collect all the necessary information by telephone), did affect the economic analysis.

Participants were willing to disclose broad details about household income but given the demographic composition of the TBI population collecting individual income as opposed to household income would have been more pertinent.

Future studies may need to consider the length of hospital stay on costs if the intervention affects it.

5.4.2. Findings from the economic analysis

The cost of returning someone to work and the impact of societal costs to participants and carers are the two main findings that will be discussed.

5.4.2.1. Cost effectiveness of returning a person to work

A specialist group participant cost approximately £500 more per person in health and social care costs to return to work compared to a usual care participant over a one year period. Johnson (1998) showed people with TBI who successfully returned to work in a year were highly likely to remain in work for the following ten years. Therefore, the effect of the specialist intervention may last well beyond the initial intervention.

Conversely, if a person with TBI does not return to work in the first year after injury, the chances of working in the future are low (Kendall et al. 2006). This means a person with TBI who did not return to work would be dependent on welfare benefits for the rest of their life, which is a long time considering the mean age of participants in this study was 34 years old. The cost of not working and receiving welfare benefits in the first year post-TBI was approximately £4,000 per person and approximately £4,750 in subsequent years (Directgov 2010). Therefore, the additional cost required to help a person back to work are substantially less than the cost of providing benefits. For an individual, living on welfare benefits can result in financial hardship for them and their family. Financial hardship has been found to be a major source of depression and anxiety in people with TBI which may mean they then incur future health costs (Klonoff et al. 2006).

The cost of providing specialist intervention to each participant was between £75 - £488 more than usual care over the 12 month period from hospital discharge. This small cost difference suggests that a usual care participant did receive some health and social care input. However, the input received did not appear to impact on return to work rates. Specialist participants reported a higher health-related quality of life compared to usual care participants over this period. This may have resulted from the specialist intervention and thus

was achieved at a low cost. Putting this additional cost in context, the cost of visiting a consultant was £196 and that of an OT visit was £69.

Uncertainty over cost effectiveness

The incremental cost utilities ratios (ICUR) generated and the cost effectiveness acceptability curve (CEAC) showed a degree of uncertainty over the extent to which the specialist intervention was cost-effective using the implicit NICE guidelines (National Institute for Health and Clinical Excellence 2009). One possible reason for this uncertainty could be due to the fact that the ICUR was based on participants' answers from the EQ5D which was used to generate health related quality of life scores. It was not a measure of their ability to work. Although working is known to impact on quality of life, it could be argued that health-related quality of life is a broader outcome measure than return to work. Specifically, studies on cost effectiveness need to be clear about what exactly it is they are measuring. The CEAC and CUA in this study measured health-related quality of life, not return to work.

Specialist participants had slightly higher QALY scores in both the complete data set and the imputed data set (LOCF) but not the imputed data set using mean imputation. This may indicate that the specialist intervention impacted on the domains covered by the EQ5D such as usual activities, mobility, pain, self-care and mood. Specialist TBI intervention as delivered in this study may have impacted on all aspects of recovery, not just the ability to return to work.

Other reasons for the uncertainty over the cost-effectiveness of the specialist intervention could include the way missing data was imputed. Simplistic methods were used for which the underlying assumptions may not hold for this data set.

The uncertainty over the cost effectiveness of the specialist intervention in the health and social care perspective also raises the question whether this was the correct perspective in this long term condition when the outcome of the intervention affects the wider society. When the societal perspective was chosen, the specialist intervention was always cost effective.

5.4.2.2. Comparison to other studies

In relation to other UK costs studies, health and social costs in this study were lower than suggested by Beecham et al. (2009). They estimated the average cost per person per year of people who only attended A&E or had a short hospital stay was £240 per person per year (first category) and those who returned home but were more disabled cost £17,160 per person per year (second category) - see 5.1.5. In this current study, the health and social care cost per person over 12 months was £2,106 for the specialist group and £2,032 for the usual care group. As the mean length of hospital stay for participants in this study was between 12 and 23 days, the participants in this study would be classed by Beecham et al (2009) in the second category. Costs incurred in this study are substantially less than predicted by Beecham et al. This difference is unlikely to be due to variations in health and social care provision between areas as the specialist group received a higher level of provision compared to the majority of people with TBI in the UK (British Society of Rehabilitation Medicine et al. 2004; Playford et al. 2011). The difference may be because costs in this study were participant-specific and only people working pre-injury were included whereas the costs in the study by Beecham et al were general costs from a general TBI population.

The cost of providing specialist TBI community intervention in the study by Powell et al (2002) was approximately £6,000 per person. This is three times more than the costs found in this study. Additionally, more people returned to work compared to Powell's study. It is not possible to compare the costs found in this study to other TBI VR studies as none have been found that are comparable. Other studies have focused exclusively on VR, included people who were many years post-TBI and also included the costs of the whole programme, regardless of how long the intervention lasted and some studies excluded costs of other rehabilitation professionals. This study included people who had been discharged from hospital due to TBI within four weeks, costs of all rehabilitation received post-hospital discharge (as reported by participants) and only included costs one year post-TBI (Abrams et al. 1993; Wehman et al. 2003; Murphy et al. 2006).

5.4.2.3. Societal perspective: Costs to participants and carers

From a societal perspective, the specialist group was cost effective in all data sets. The main cost to participant and carers was loss of wages. This study found the combined cost to TBI participants and carers, in the year after hospital discharge, was; for the specialist group between £5,950 -£6,434, and the usual care group £9,489.27- £13,074. This was a substantial amount of money for a household to lose. The size of the loss to participants and families suggests this is an important perspective. This finding supports others who suggest that the long term socio-economic costs related to TBI need further investigation (van Baalen et al. 2003).

5.4.2.4. Costs to employers

This study found only a few people required the purchase of specialist equipment. As found in other studies, the main costs to the employer would be from the person being less productive at work, for example requiring extra breaks (Johnson 1987). Like Johnson et al. (1987), this study also found that work modifications were required for up to a year. The long-term provision of these work modifications suggests the cost to employers may be substantial. Costing these modifications from an employer's perspective may be difficult. It would require permission from patients to contact employers and assumes that they had informed their employer of the TBI. This study has shown not everyone with a TBI does inform their employer. It would also mean employers would have to cost and quantify concepts such as presenteeism which are known to be difficult (Pauly et al. 2008). Additionally, asking employers to quantify and cost work modifications such as increased supervision or more breaks may negatively highlight the costs of employing a person with TBI to the employer, which may then impact on an individual's employment.

5.4.2.5. Welfare benefits

In line with other studies, this study found a large increase in people reliant on welfare benefits post-TBI compared to pre-injury (Johnstone et al. 2003; Klonoff et al. 2006; Shigaki et al. 2009). As proportionately fewer participants in the usual care group returned to work, proportionately more of

this group were reliant on benefits. However, in contrast to other studies, this study did not find that participants would consider themselves to be better off by staying on welfare benefits (Catalano et al. 2006).

Given that approximately half of people with TBI do not return to work post-TBI and so have a corresponding dependency on welfare benefits, often for life, state benefits appear to be an important component when examining the overall cost effectiveness of VR after TBI (Kendall et al. 2006; van Velzen et al. 2009b). The cost of providing welfare benefits is even more pertinent when the UK Government's aim to reduce the numbers of people claiming sickness benefits is considered (Department for Work and Pensions and Department for Health 2008c). Some economists now suggest a broader perspective is required in NHS economic evaluations so the effects on other Government budgets are considered (Richardson et al. 2007; Drummond et al. 2009). Even NICE states interventions which have a substantial impact on costs to other government departments may need to be included in a sensitivity analysis. However it does not define what they mean by a substantial impact (National Institute for Health and Clinical Excellence 2009). Reporting the need for state benefits has the added advantage of being an easier concept for non-health economist such as commissioners to understand. Future TBI studies may wish to consider the impact of the intervention on the number of people claiming state benefits as part of a secondary analysis.

Additionally, the economic calculation conducted did not consider taxes paid to the state by a person who is earning money. Savings made by not paying welfare benefits and income from taxes may offset the extra cost to the state of providing the specialist care if funding between government departments was joined up. This illustrates the problem of considering benefits, since including taxes and benefits results in double counting, as taxes pay for benefits so it is the same money redistributed between government departments.

5.4.2.6. Participants' individual costs due to TBI

Participants were asked for any additional costs incurred. Approximately 14% of participants reported additional costs at baseline including the cost of their travel to and from hospital. As many participants were treated at a regional neurosurgical centre this involved travelling long distances every day for some people. The greatest costs occurred whilst the participant was hospitalised, especially when the injury occurred away from home. For example, one carer reported incurring costs of approximately £1500, which included the costs of overnight stays, car parking, food and drinks whilst visiting, additional childcare, travel to appointments and extra childcare when their partner came out of hospital as they could not tolerate the children's noise. The frequency and potentially high level of these initial costs may warrant further study as they appear to be of concern to patients and carers.

5.4.2.7. Is a longer term economic perspective required?

The economic analysis was conducted over a one year period. This may be a narrow viewpoint considering that TBI is a long term condition (Maas et al. 2008). At present, the relative lack of long term economic evaluations of TBI means that it is not known how costs might change at five or ten years after injury. As TBI is a relatively stable health condition, people with TBI, may use fewer health care resources in the future. Conversely, a few people may develop epilepsy or depression and incur greater costs.

Although maintaining work after TBI is known to be problematic, it is not known how many people lose jobs compared to those who obtain new jobs (Possl et al. 2001). A systematic review showed only a 0.1% increase in employment rates two years after TBI (van Velzen et al. 2009b). If it is assumed that the number of people with TBI out of work remains relatively stable, and potential future health costs decrease, these factors combined would seem to increase the cost effectiveness of the specialist group over the longer term. Yet, it has to be borne in mind that taking only a health and social care perspective over one year in a relatively young population with a long-term condition is a potentially narrow view point which may not provide the full picture of the cost-effectiveness of this intervention.

5.4.2.8. Summary of feasibility economic analysis

This was a feasibility economic analysis with a considerable amount of missing data and thus none of the results presented should be seen as definitive.

Nevertheless, this study showed that it was possible to conduct an economic evaluation alongside the cohort comparison study. It also highlighted that data relevant for an economic evaluation needed to be easily obtained and accurate.

A specialist group participant incurred a mean of £75 in extra health and social care costs per person over the one year period compared to a participant in the usual care group. However, this slightly higher cost did result in the specialist group reporting a higher health related quality of life.

Returning a specialist group participant to work cost approximately £500 more per person in health and social care costs compared to a participant in the usual care group over the first year post-TBI. Yet, from a societal perspective, the specialist group was always cost effective. Additionally, the long-term benefits to society of returning a person to work, such as reduced payment of welfare benefits, greater income from taxes and reduced rates of depression and anxiety suggest that these may outweigh any initial extra cost.

The cost utility analysis generated showed a degree of uncertainty about whether the specialist intervention was cost-effective within the NICE implicit guidelines. This was based on the participants' perception of their health related quality of life. Additionally it was only over a one-year period for a condition that is long term.

This study highlighted that although the cost of rehabilitation was borne by the NHS, the Department of Work and Pensions potentially reaped considerable economic benefits.

Chapter 6: Overall summary

Although the three parts of this study have been discussed separately, they are interlinked. This final chapter will discuss the overall key findings and the results, strengths, limitations, implications for future research, clinical practice and policy.

6.1. Conducting the study: Practical considerations

This study showed that it was possible to compare the return to work rates and costs of participants who received specialist intervention from an OT specialising in VR working either independently or as part of a specialist TBI community team to participants who received usual care.

When conducting the study, identifying people admitted to hospital with TBI for 48 hours or more was found to be time consuming due to the lack of any central registers. However, once identified, over three quarters of people consented to participate. As appears typical of the TBI population, approximately a third of participants were lost to follow up or did not return fully completed questionnaires (Corrigan et al. 2003). Additionally, as found in other TBI studies, a few people with TBI did not feel they required any rehabilitation this early after their TBI or wanted to participate in a research study (Wade et al. 1998; Salazar et al. 2000).

In this study, most participants were recruited as inpatients. Consent and baseline data were obtained a mean of four weeks after hospital discharge and all subsequent data measured from baseline. Yearly outcomes in this study varied due to the length of hospital stay, which was between 2 – 104 days (median length of stay no longer than 17 days). This variation is not ideal. It raises the question of when to obtain consent and when to collect baseline data in TBI patients, some of whom have limited cognitively ability after TBI. Even though participants were visited on the ward by the research OT and were provided with written information, followed up by a telephone call, some participants still did not appear to fully understand the reason for the initial visit, which was four weeks after hospital discharge. Some thought it was part

of standard NHS treatment. This raises concerns about consent was obtained in hospital and whether TBI participants are fully aware of what they were consenting too. Conversely, some specialist participants did not appear cognitively impaired and planned to return work within four weeks of hospital discharge.

Additionally, if length of hospital stay had been included in the economic analysis, the specialist intervention would be cost effective in all the calculations conducted for this study. Thus, the timing of consent and baseline data collection is an important consideration for future TBI studies that recruit patients soon after injury.

The majority of participants willingly engaged with the intervention. As shown by the content analysis, the intervention was in line with national guidelines, started four weeks post-hospital discharge and mainly focused on returning the person to work (British Society of Rehabilitation Medicine et al. 2003; British Society of Rehabilitation Medicine et al. 2004; Department of Health 2005). Although, the proforma developed especially for this study did enable the OT intervention to be recorded, quantified and described, categorising some aspects of this complex intervention proved problematic. Consensus of opinion with others in this field with regard to what to record could enable other services and other diagnoses, such as stroke, to describe similar VR intervention. Effectiveness (or ineffectiveness) of specific components such as work site visits could be compared. The proforma could also provide a way of monitoring fidelity of treatment in future research.

This study also showed that it was possible to undertake a feasibility economic analysis. Income was calculated using job titles based on nationally available data and most people were willing to disclose their gross household income. However, the economic analysis was sensitive to missing data.

6.2. Summary of key findings

There were no significant differences between the groups at baseline or on the secondary outcome measures at one year. However, more specialist group participants returned to work at every time point during this study. At one year post-hospital discharge 15% more specialist group participants were in work than usual care group participants. Logistic regression analysis indicated that being younger, having a minor TBI and being in the specialist intervention group increased the chances of returning to work. However, the lack of universal return to work outcomes and heterogeneity of other TBI study designs meant comparison with other TBI studies was problematic.

The specialist intervention appeared to have the greatest impact on people with moderate and severe TBI. At four months post hospital discharge, there was only a small difference in return to work rates (8%) between the groups for participants with moderate or severe TBI, but at six and 12 months, the difference was 27%, with more specialist group participants in work. This suggests that participants who could return to work without specialist support had done so by approximately four months after hospital discharge. The specialist intervention appeared to benefit those who were not able to return to work independently within four months of hospital discharge.

Specialist group participants with minor TBI returned to work significantly earlier and more were in work at one year compared to participants in the usual care group. This may be a cost effective intervention, given that the mean OT input was less than four sessions and the large numbers of people who sustain a minor TBI.

As found in other studies, participants in both groups tended to return to their previous employers and some employers changed their employee's job to accommodate them. Proportionately, more people in specialist group started to return to work later, undertook a graded return to work over a longer period, had more work adjustments and reported coping better at one year compared to the usual care group. However, as this was not a randomised trial, it cannot

be concluded whether the differences in return to work rates and differences in how people returned to work were due to the specialist OT intervention, the overall effect of the specialist community team or any other factors that influence return to work (Ownsworth et al. 2004; Willemse-van Son et al. 2007).

Detailed analysis from the proforma showed that the majority of the intervention was directly targeted at preparing participants to return to work and that for every hour of face-to-face contact with a participant, an additional two hours was spent by the OT liaising or travelling. Analysis also revealed four different styles of OT vocational intervention according to individual need: advice only, OT with no direct employment, OT and direct employer contact, and support to access other services such as job centres. As this level of detail has not been reported in other TBI studies, it is not known if this is typical of intervention provided elsewhere.

The cohort comparison study found fewer specialist group participants returned to the same employer (58%) compared to the usual care group at one year (77%) although at 18 months the situation had reversed. In contrast, the content analysis found that three quarters of the participants had returned to the same employer at discharge from the specialist service. Possible reasons for these differences could be that the cohort comparison was an intention to treat analysis measured over one year and therefore included all participants whether they had received OT intervention or not. The content analysis recorded the outcomes of participants who had received two or more sessions of OT and had been discharged from OT or the specialist TBI community team over a two-year period. This supports findings by Johnson et al (2003a) who found that engaging in VR was a strong predictor of a successful return to work. This indicates that VR may require input for longer than one year to achieve maximum outcomes. It also shows the limitations of reporting only outcomes of patients who complete a VR programme.

Furthermore, patients from both groups were keen to return to work, with some returning to work as early as four weeks after hospital discharge. This suggests

that specialist VR needs to be available on, or soon after, hospital discharge. Interestingly, money was not the main motivating factor for people to return to work. Instead, returning to work was felt to be helpful in restoring a sense of normality and beneficial to recovery. This may differentiate people with TBI from other disability populations who claim welfare benefits and sometimes have the misconception that work may be detrimental to their health (Waddell et al. 2006).

This study also found that participants in work reported significantly fewer problems with depression and anxiety and a higher quality of life regardless of which group they were in. These findings support others who suggest that being in work can be beneficial to health (Waddell et al. 2006). Specialist group participants reported slightly higher levels of health related quality of life than the usual care group one year after hospital discharge. However, only half of the entire cohort reported feeling fully recovered at one year, suggesting that there is a need for long term specialist support after TBI.

This study also showed that the usual care participants stayed in hospital longer compared to specialist participants. Although reasons for this are not known, it is surmised that the combination of time consuming transfers between local and regional units and having a specialist TBI team to follow participants up on discharge could explain the discrepancy. These factors need to be considered when examining length of hospital stay.

The cost analysis showed that the mean difference between groups in health and social care costs was only £75 (higher costs incurred per specialist group participant) over the one year period post-hospital discharge. This was approximately the cost of one therapy visit. Using the same parameters, it cost approximately £500 more to return a specialist group participant to work than it did for a usual care participant. Although the ICERs generated showed a degree of uncertainty regarding whether providing the specialist intervention was cost effective, these calculations were based only on health and social care costs over the first year post-TBI. When a societal perspective or length of

hospital stay was included in the calculation, the specialist intervention became cost- effective.

A wider societal perspective showed that TBI was costly as it resulted in loss of wages for between four and six months for most families. Carers in the specialist group took less time off work. However, as more specialist group participants and carers returned to work (and sooner) compared to those in the usual care group, they experienced a smaller loss of wages, making the specialist intervention cost effective. In addition, fewer specialist group participants reported welfare benefits as their only source of income compared to usual care participants. Given that once survived, TBI is a long-term condition which does not generally affect life expectancy, a longer term and wider cost perspective may give a more realistic view of the cost effectiveness of the intervention.

6.3. Strengths

From the patient's perspective, the outcome of returning to work is a clear strength of the study. Returning to work is frequently cited as a goal in those working prior to injury and is also a stated outcome of the NHS (National Health Service 2010). However, less than 50% of people with TBI are in work one year after their injury (van Velzen et al. 2009b).

There are only a few prospective cohort comparison study specifically focused on return to work after TBI and even less that are UK specific. In a review of 275 articles on rehabilitation of moderate to severe ABI (not UK specific), over half were single cohort interventions (Teasell et al. 2007). Maas et al (2008) suggests there is a need for more epidemiological evidence of the expected rate of recovery and outcome after TBI. Although we did use a randomised controlled trial design, the comparison group does provide some indication of the expected rate of recovery and outcome after TBI in this cohort of participants and possibly the impact of the intervention.

It is one of the larger prospective TBI intervention studies with 94 initial participants and primary outcome data on 81 participants at 12 months. In the aforementioned review, over half of the studies had sample sizes of 25 or fewer participants (Teasell et al. 2007).

This cohort comparison study used an intention to treat analysis so all participants who consented to participate were included in the analysis even though some did not receive any OT. The outcomes were reported by the participants themselves. Therefore, it is the participants' perspective of their own work situation, which has been analysed. This is in contrast to many return to work studies which are often single centred retrospective service evaluations on the researchers own patient populations (Whyte 2009) Additionally, all three parts of the study were conducted rigorously and as systematically as possible.

This study examined current NHS provision for people with TBI in the UK by comparing outcomes from existing, but different NHS provision for people with TBI. This supports the suggestion that more practice based evidence and systematic data collection of real life NHS practice is required (Dejong et al. 2004; Turner-Stokes 2008). The model of service delivery already exists and could be easily implemented if found effective.

The development of the proforma, by expert consensus, enabled the content of the OT delivered to be recorded, quantified and described. Future use of an adapted proforma has the potential to address the problem of poorly described interventions which is common in many TBI rehabilitation studies and may provide a way of measuring fidelity of intervention in future studies (Hart et al. 2006a; Turner-Stokes 2008).

Only a few TBI studies report details about how participants return to work. Information such as whether a participant undertook a graded return to work, how long this lasted, which work modifications were in place, whether or not they returned to the same employer or same job were included in this study for both groups. This level of detail is rarely reported but is important in aiding

our understanding of how people with TBI return to work and what workplace accommodations take place with and without specialist support.

Finally, but very importantly, this study is one of very few UK research studies which directly examined the cost effectiveness of TBI VR currently delivered in the NHS (Turner-Stokes 2008; Beecham et al. 2009). The costs reported are based on actual interventions delivered in the NHS and is one of very few studies to include carers costs.

6.4. Limitations

This study was an opportunistic pilot cohort comparison study. The lack of randomisation and the fact that the study was not adequately powered meant it cannot be concluded that the differences found between the groups were the result of the intervention.

This study only examined the practice of one OT within one individual UK NHS TBI specialist service. It did not explore the intervention delivered by others involved with the participant which is a limitation as rehabilitation after TBI is a multi-professional, multi-faceted intervention (Wade 2005). Nor did it explore different types of service delivery for TBI. Different OTs, the impact of others involved with the participants and different types of services for people with TBI may produce different results. The proforma was only completed by the research OT involved in its development. As some categories were found to be ambiguous, redundant or missing, further development is required if it is to be used more widely.

There were limitations regarding some of the outcomes used. The term 'return to work' was not defined on the participant questionnaire. This led to participants defining it in a variety of ways. The BICRO was used but some questions were outdated due to the increased use of mobile phones and TV remote controls. This factor combined with the fact the BICRO has not been widely reported generally limits its usefulness (Powell et al. 1998). Although

the participant questionnaire was trialled prior to use, some questions produced inconsistent responses when repeated at different time points.

This study involved only participants, who were in, or looking for paid or voluntary work or full time education at the time of injury, and intended to return to work. It was also limited by time. Different interventions may be necessary for those who require a longer period of rehabilitation, were unemployed at the time of injury or had additional problems such as alcohol misuse.

Although participant's educational levels, income and occupational levels were analysed, no further socio-economic differences were obtained. Furthermore, no cognitive measures were included. This meant any differences between the groups regarding cognitive function or socio-economic factors could not be examined nor the effect of these factors on return to work.

There was approximately a 15% loss to follow up at 12 months and a greater loss to follow up at 18 months. This combined with difficulty obtaining completed questionnaires meant data was missing in the cohort comparison analysis. Additionally, data had to be systematically imputed to complete the economic analysis. This will have decreased the precision of the analysis.

Data for lost wages was calculated from the Annual Survey of Hours and Earnings (ASHE) (Office for National Statistics 2007) using The Standard Occupational Classification 2000 (SOC2000) codes (Office for National Statistics 2008). This method assumed the ASHE figures were an accurate representation of people's current earnings and participants' jobs were coded correctly. In some SOC categories different types of similar jobs are listed. For example over 80 types of administrator are coded. Asking a participant to confirm the SOC category chosen would be useful in future studies.

Every effort was made to ensure the research assistant conducting the follow up telephone calls was blinded to group allocation; however, some participants

did name the research OT during the telephone call. Although some unbinding did occur, this was not formally examined.

This study relied on participant's self-reported use of services. The wide geographical area, combined with the lack of standard pathways for people with brain injury meant that it was not possible to independently verify the intervention received by the usual care group in this study. Thus, exactly what intervention usual care participants received during the study period remains unclear.

6.5. Possible future research

Research into TBI vocational rehabilitation is complicated by the heterogeneity of research studies. The lack of programmatic research on TBI limits identification of effective interventions with many small pilot studies rarely progressing to large RCTs (Whyte 2009). This seems particularly true for VR after TBI which is not at a stage where it is known what intervention works, what 'dosage' is required or how interventions alter their target. For example, whether interventions alter neural pathways? (Whyte et al. 2003; Lettinga et al. 2006). Therefore, it is clear further research is required. The findings from this study suggest a larger randomised controlled trial would be warranted to determine whether the increase in return to work rates in the specialist group resulted from the specialist VR intervention. Possible research questions arising from this study will now be discussed.

The aim of VR is to enable a person to return to work. However, it is not known if receiving early specialist intervention increases a person's understanding of the problems resulting from their TBI and consequently increases their ability to cope at work and sustain long-term employment compared to those who do not receive this intervention. There is some indication that early intervention may have a long-term positive effect in a TBI population. In a cohort comparison study, seventeen years after brain injury, Svendsen et al (2006) found less depression and anxiety in participants who had initially received neuropsychological intervention compared to patients

who had not. A long-term follow up study comparing people with TBI who received early specialist VR to those who received usual care is required to ascertain if this early specialist intervention has any long-term effects.

A qualitative study, triangulating employers, patients, carers' and commissioners perspectives on which aspects of the intervention helped or hindered them to return to work would have enhanced our understanding of the return to work process after TBI (Bowling 2002) Additionally, as participants reported seeing solicitors frequently, finding out what advice was given and exploring both the patient's and solicitor's perception of their role in the VR process would add depth to our understanding.

Anecdotally, some participants attributed their successful return to work to personal motivation. This supports Macaden et al (2010) who suggest motivation and coping skills were 'super factors' that helped a person successfully return to work. Although not statistically significant, this study found that specialist group participants socialised more than those in the usual care group. Whilst we do not know why this occurred, one possibility is that specialist group participants felt better able to cope with the consequences of their injury. This suggests the influence of motivation, coping skills and adjustment on return to work warrants further exploration.

In this study, specialist group participants with minor TBI required only a few OT sessions, returned to work sooner and 10% more were in work at one year compared to usual care participants. Due to the relatively large numbers of people experiencing minor TBI, even a 10% difference could potentially translate into a substantial increase in people with TBI returning to work. Examining whether the specialist VR delivered within four weeks of hospital discharge was the effective factor for this specific TBI population warrants further research including a cost effectiveness analysis.

Additionally, carers in the specialist group returned to work sooner than those in the usual care group. Few studies to date have examined the impact of TBI on the carer's employment. This appears a neglected area of research.

One problem with all return to work studies including TBI, is the lack of consensus concerning the term 'return to work' (Kendall et al. 2006; Hart et al. 2006a; McColl 2007). Obtaining consensus about the term would enable comparisons across studies. For example, should 'return to work' encompass full time education? Other questions arising from this issue is:-

- How long do people need to maintain working to be classified back at work, for example one day, a week or a month or more?
- How much time should people work in the day for example one hour or more to be classified as having returned?
- Or what proportion of their duties do people need to have resumed to be classified as returned to work, for example more than 10% of usual duties?

Additionally, there is also a need to clarify what is meant by 'a graded return to work' and when to record it. For example, should a 'graded return' be recorded from the day a person starts a graded return or when the graded return to work is completed? Standardising definitions and recording methods of work modifications would assist uniformity across VR studies.

Other research ideas include developing the proforma either for use within a research setting to monitor fidelity of intervention or to provide an in depth comparison of services and interventions would help provide fuller descriptions of the interventions delivered.

Since the inception of this study, researchers in North America have produced a consensus regarding a core set of outcome measures to use in a TBI population (Maas et al. 2010; Wilde et al. 2010). These need to be trialled in the UK to ascertain if they are acceptable to a UK population both in the clinical and research communities.

As participants in this study requested information by email, examining the best way to obtain accurate self-report data from this young, often poorly educated, mobile and potentially cognitive impaired population may help future TBI studies collect complete data.

Finally, an unexpected finding was that specialist group participants stayed in hospital approximately a week less than the usual care group. Further research is needed to establish why this occurred. If it was due to case managers making contact with patients and family whilst an inpatient and then providing follow up in the community, the small additional cost (£75 per patient per year) found in this study may mean the cost of the specialist team would be offset by the cost savings on length of hospital stay.

6.6. Clinical Implications

Findings from this study suggest that vocational rehabilitation needs to be available at the point of hospital discharge. It should commence within four weeks of hospital discharge as some participants had returned to work within that time period. To replicate this model of intervention, the vocational rehabilitation needs to be community based, delivered as part of a multi-disciplinary team, flexible, individually tailored and not limited to a set number of sessions or time frame. Additionally, as carers in the specialist group appeared to return to work sooner than those in the usual care group, there is a suggestion that carers benefited from being involved in the rehabilitation.

As more specialist group participants underwent a graded return to work, had more work modifications and more were working at one year, this suggests that employers heeded advice either directly from the OT or indirectly via the participant. This supports the need for liaison with employers and flexibility as to how, where and when the liaison takes place. Extra training for the OT and time allocated for VR to take place is required clinically to facilitate VR.

Clinically, the specialist team cost approximately £75 more per participant over one year compared to usual care from a health and social care perspective. This equated to one extra community OT visit. For this small additional cost, specialist group participants reported a better quality of life and more were back at work compared to the usual care group at one year. Therefore, providing a specialist TBI team may produce better outcomes for the patient

and, contrary to popular belief, was not prohibitively expensive when compared to the cost of usual care.

6.7 Policy implications

A postcode lottery of service provision for people with TBI meant that not all NHS TBI patients in the region were able to access specialist TBI VR services in this region. This enabled this study to be undertaken. If the findings from this study were replicated in a definitive RCT, the policy implications would be that all TBI patients who were in work or education prior to injury and aim to return to work or education would require access to specialist TBI vocational rehabilitation to increase their chances of returning to work post TBI. This would mean more specialist TBI services with an OT VR component would need to be funded.

The service delivered to the specialist group in this study was NHS funded. However, it resulted in cost savings for the DWP as more people returned to work and contributed to the economy both as taxpayers and as workers. Consequently, fewer people claimed welfare benefits and fewer accessed DWP services targeted at getting people working again. These potential DWP savings from NHS investment infer the need for closer working relationships and partnership funding initiatives between DWP and NHS services.

It is possible that the NHS will also realise a long-term return on their investment into RTW services after TBI as participants in work reported significantly less depression and less anxiety. Enabling people with TBI to work appears to have a positive impact on wellbeing and may infer a reduction in health resource use in the longer term. Health commissioners need to consider these potential savings when commissioning services.

6.8. Conclusion

To date, this may be the only UK study comparing the return to work outcomes and costs of TBI participants receiving specialist OT (either individually or as part of a specialist TBI NHS community team) aimed at returning a person to

work to TBI participants receiving usual care. It is also one of few TBI VR studies, which has measured and described the OT delivered.

Improved acute treatment means more people now survive their TBI and have a normal life expectancy. As employment rates after TBI continue to be lower than pre-injury rates, it is important that research focuses on improving post-TBI employment rates. The mean age of the 94 participants in this study was 35 years old. Therefore, a person with TBI who does not return to work is likely to spend the rest of their life on state benefits. As this study found, at a personal level, not working was related to increased rates of depression, anxiety and a reduced quality of life. On a societal level it is expensive for the state to provide lifelong welfare benefits and lose income in the form of tax.

The UK government wishes to reduce the large number of people claiming disability benefits by increasing the availability of VR (Department for Work and Pensions and Department for Health 2008c). However, the generalist intervention provided by the Department of Work and Pensions commences too late and is not specialised enough for people with TBI. This study found that more people who received the specialist intervention returned to work at all time points and reported coping better at work. The additional cost of the specialist service was relatively small at £75 per person over a year. Liaison between government departments over funding will be required if the model of service delivery used in the study is adopted. This is because the specialist intervention was provided by the NHS but produced savings for the DWP in the form of reduced welfare payments and reduced need for DWP services (Department of Work and Pensions 2010; National Health Service 2010).

As there may be as much as a 90% shortfall in the provision of TBI VR services in the UK, there is a need to understand what type of services and interventions are effective. Equally, the requirement that the NHS provide interventions which are supported by evidence of their cost effectiveness, means that there is a need to ascertain whether TBI VR services are cost effective (Medical Research Council 2000).

This study adds to the limited knowledge of the effectiveness and cost of TBI VR in the UK. The positive results suggest that intervention from a specialist OT and/or specialist team aimed at return to work for people with TBI who were previously employed or in full time education may be effective. However, as the study was not randomised, it cannot be concluded that the increased work rates were the result of the specialist intervention. The low cost difference found between the groups and the development of the proforma as a way of recording intervention suggest an adequately powered study would be both feasible and warranted.

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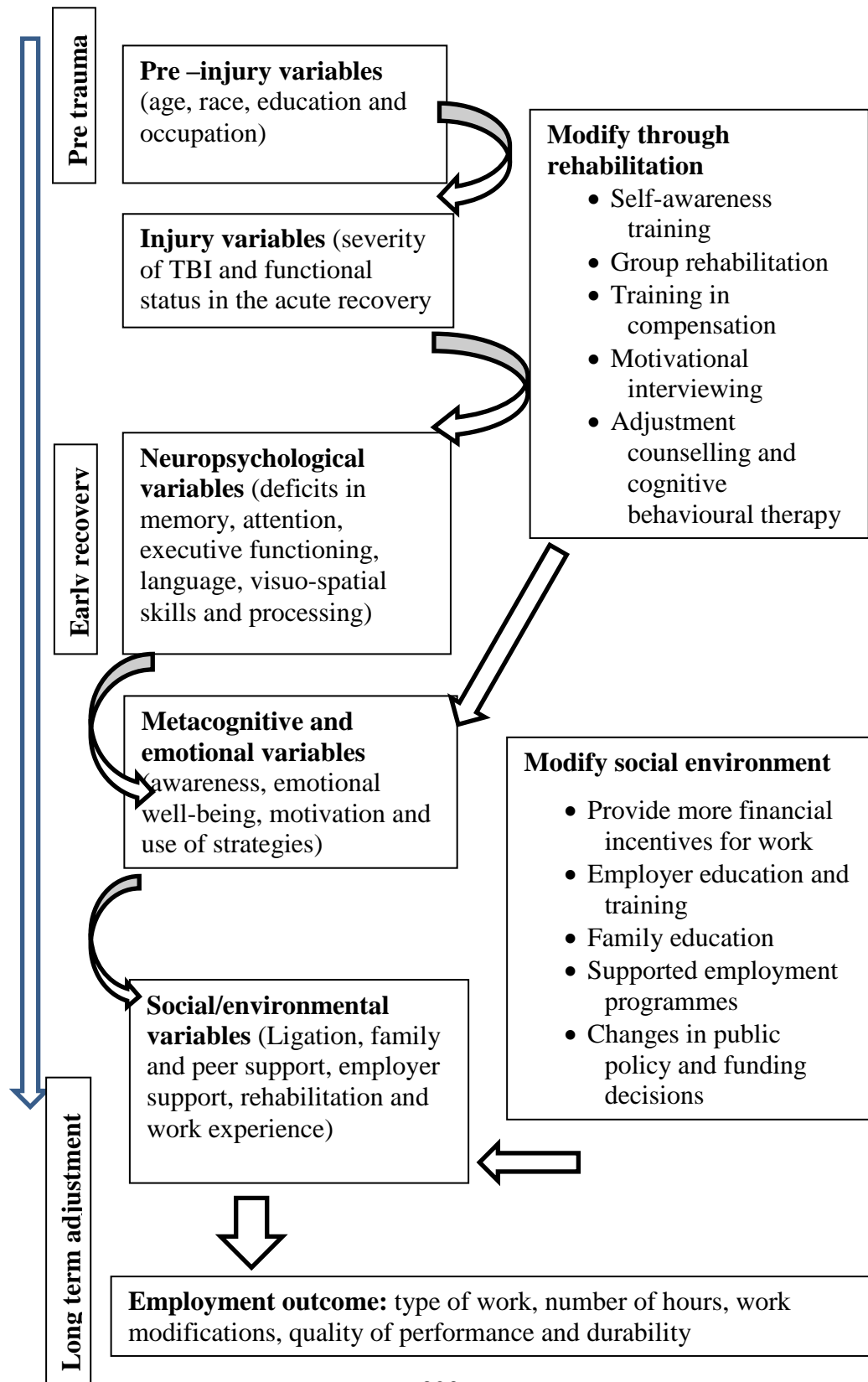
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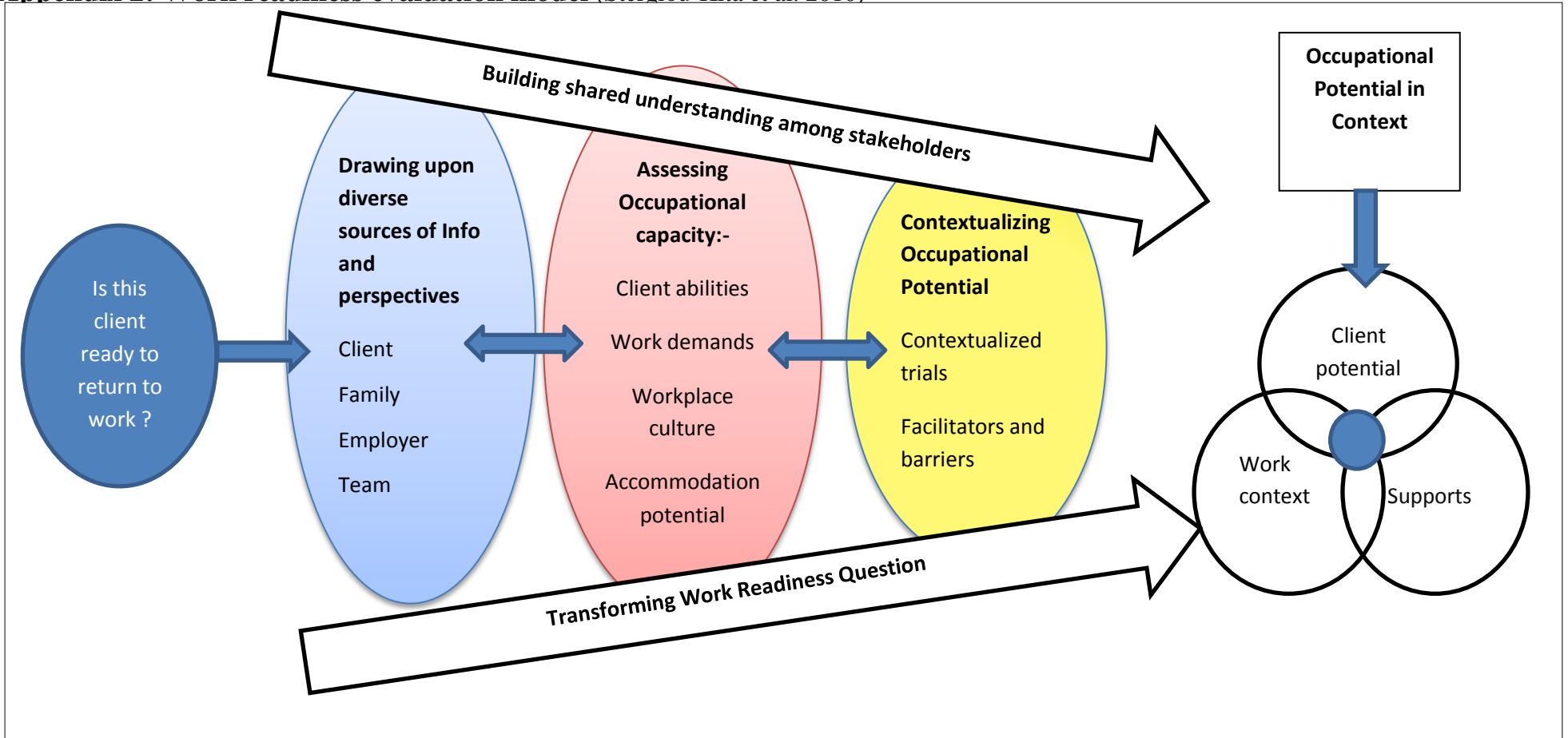
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Appendix 1: A conceptual model of factors related to employment outcomes and interventions for improving employment potential following TBI (Ownsworth et al 2004)



Appendix 2: Work readiness evaluation model (Stergiou-Kita et al. 2010)



Appendix 3: Participant Pre-injury information form

Before	Research No		
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<p>Return to work after brain injury study</p> <p>Confidential</p> <p>Pre-injury information</p>

These questions refer to your situation **BEFORE** your brain injury. This will help us see what changes, if any, occur as a result of your brain injury.

You will only need to fill this questionnaire in once.

Full name				
Full address				
Postcode				
Telephone				
Email address				
Date of birth				
Ethnic Origin				
White:	UK <input type="checkbox"/> ₁	Other <input type="checkbox"/> ₂		
Black:	African <input type="checkbox"/> ₃	Caribbean <input type="checkbox"/> ₄	Other <input type="checkbox"/> ₅	
Asian	Bangladeshi <input type="checkbox"/> ₆	Indian <input type="checkbox"/> ₇	Pakistani <input type="checkbox"/> ₈	Other <input type="checkbox"/> ₉
Male <input type="checkbox"/> ₁	Female <input type="checkbox"/> ₂		Age	
Today's date				

Appendix 3: Participant Pre-injury information form (continued)

Name and address of GP	
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1. Are you filling in the questionnaire yourself?

Yes.....	<input type="checkbox"/> ₁
No, it is being completed for me by:	
My spouse or partner.....	<input type="checkbox"/> ₂
Researcher	<input type="checkbox"/> ₃
Another (Please specify below).	<input type="checkbox"/> ₄

2. Dates

Date of accident	Date of discharge from staying in hospital	How many days were you in hospital?

3. Cause of accident:

Fall <input type="checkbox"/> ₁	Road Traffic Accident <input type="checkbox"/> ₂	Assault <input type="checkbox"/> ₃
Other <input type="checkbox"/> ₄	Please state what:	

4. Lowest recorded Glasgow Coma Score

5. Please give details of any injuries?

6. Have you had a previous brain injury, stroke or any other health problems?

Brain injury	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
Stroke	Yes <input type="checkbox"/> ₃	No <input type="checkbox"/> ₄
Other neurological conditions	Yes <input type="checkbox"/> ₅	No <input type="checkbox"/> ₆
Mental health problems	Yes <input type="checkbox"/> ₇	No <input type="checkbox"/> ₈
Drug problems	Yes <input type="checkbox"/> ₉	No <input type="checkbox"/> ₁₀
Alcohol problems	Yes <input type="checkbox"/> ₁₁	No <input type="checkbox"/> ₁₂

Please give details if you wish.....

Appendix 3: Participant Pre-injury information form (continued)

7. At the time of your injury were you living?

Alone	<input type="checkbox"/> ₁	With parents	<input type="checkbox"/> ₂
With a spouse or partner	<input type="checkbox"/> ₃	With friends	<input type="checkbox"/> ₄
Other <input type="checkbox"/> ₅	Please state		

8. Are you married or have a long term partner?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	I did not have a long term partner <input type="checkbox"/> ₃
---	--	--

Activity Details

9. On the day before your accident, were you? (More than one may apply)

Working	<input type="checkbox"/>	
If so, please state for how many hours per week		
I was on sick leave	<input type="checkbox"/>	
If so, how long for		
I was on an educational course	<input type="checkbox"/>	
If so, how many hours per week?		
I was on a programme aimed at helping me find a job	<input type="checkbox"/>	
I was on the WORKSTEP scheme	<input type="checkbox"/>	
I was doing permitted work	<input type="checkbox"/>	
I attended a day centre regularly	<input type="checkbox"/>	
I was a homemaker/housewife	<input type="checkbox"/>	
I was looking after children	<input type="checkbox"/>	
I was unemployed but actively looking for work	<input type="checkbox"/>	
I was not working but have had a job/been on an educational course in the last 12 months.	<input type="checkbox"/>	
I was doing voluntary work	<input type="checkbox"/>	
Other, please state	<input type="checkbox"/>	

Appendix 3: Participant Pre-injury information form (continued)

10. If you were working or in education, please state what your job or course title was:

.....

Please give a description of your job

.....

11. Please state how long you had worked for your pre-injury employer or had been on your course before your brain injury?

Years.....Months.....

12. Did you enjoy your job/course?

Yes	<input type="checkbox"/> ₁	No	<input type="checkbox"/> ₂	Sometimes	<input type="checkbox"/> ₃
-----	---------------------------------------	----	---------------------------------------	-----------	---------------------------------------

13. In the 12 months before your injury, how many times did you change jobs?

Please state number of times

.....

14. At what age did you leave full time education?

Before 16	<input type="checkbox"/> ₁	At 16	<input type="checkbox"/> ₂
At 18	<input type="checkbox"/> ₃	Had higher education?	<input type="checkbox"/> ₄
Other	<input type="checkbox"/> ₅		

Appendix 3: Participant Pre-injury information form (continued)

15. What is your best estimate of your total household annual income from jobs (before tax and national insurance) and benefits before your injury?

Less than £10,000 per annum <input type="checkbox"/> ₁	£10,000 to £19,999 per annum <input type="checkbox"/> ₂
£20,000 to £29,999 per annum <input type="checkbox"/> ₃	£ 30,000 to £39,999 per annum <input type="checkbox"/> ₄
£ 40,000 to £49,999 per annum <input type="checkbox"/> ₅	£ 50,000 or greater <input type="checkbox"/> ₆

16. What benefits were you or your family claiming before your brain injury? **(This information is only required for this research and will remain completely confidential)**

None <input type="checkbox"/> ₁	Disability Living Allowance <input type="checkbox"/> ₂
Income Support <input type="checkbox"/> ₃	Incapacity Benefit <input type="checkbox"/> ₄
Job Seekers Allowance <input type="checkbox"/> ₅	Working tax credit <input type="checkbox"/> ₆
Other <input type="checkbox"/> ₇	Please specify:

17. Were you driving before your brain injury?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	Not applicable <input type="checkbox"/> ₃
---	--	--

18. Were you receiving any services before your injury e.g. from the NHS, social services, job centre?

Yes ₁ No ₂

If yes, please say what services you were receiving (please specify number of appointments per service received)?

.....

Appendix 3: Participant Pre-injury information form (continued)

BICRO – 39
BRAIN INJURY COMMUNITY REHABILITATION
OUTCOME SCALES

This questionnaire helps us understand how much your life has changed as a result of your brain injury. It will also help us to monitor your progress during treatment.

The questionnaire has eight sections, which ask about your life **before your** brain injury, in relation to your independence in personal care, mobility, self-organisation, contact with your partner and your own children, contact with your parents and siblings, socialising, productive employment and psychological well-being.

Please go through the questionnaire and answer all questions according to how you were BEFORE your brain injury. Please tick responses.

PERSONAL CARE

How much help or assistance from other people did you need with ...

	don't do at all	constant help	a lot of help	some help	prompts only	no help/ prompts
1) getting into and out of bed						
2) moving from room to room						
3) getting to the toilet						
4) using the toilet						
5) reaching and using the phone						
6) reaching and using TV or radio						

Appendix 3: Participant Pre-injury information form (continued)

Mobility

How much help or assistance from other people did you need with ...

	don't do at all	constant help	a lot of help	some help	prompts only	no help/ prompts
7) using public transport						
8) going to local shops						
9) doing laundry (washing, drying, ironing)						
10) cleaning the home (including vacuuming)						
11) shopping (for food, household needs)						
12) go out for a walk or to a park						

SELF-ORGANISATION

How much help or assistance did you need from other people with ...

	don't do at all	constant help	a lot of help	some help	prompts only	no help/ prompt
13) keeping track of money						
14) dealing with your own bank account						
15) paying household bills						
16) writing official letters (e.g. bank)						
17) writing private letters						
18) managing appointments						

Appendix 3: Participant Pre-injury information form (continued)

SOCIALISING

<i>How often did you spend time?</i>						
	not applicable or never	once or twice a year	several times a year	once or twice a month	once or twice a week	most or all days
19) relatives other than immediate family (i.e. not parents, brothers, sisters, partner, own children)						
20) your closest friend						
21) another long-standing friend						
22) a colleague (outside work time)						
23) new acquaintance (since brain injury)						
24) socialising with people and family at home						

PRODUCTIVE EMPLOYMENT

How much time did you spend...?

	Not at all	less than an hour a week	1-4 hours a week	5-10 hours a week	11-20 hours a week	more than 20 hours a week
25) doing paid work						
26) doing unpaid or voluntary work						
27) studying, training, doing courses						
28) looking after children						

Appendix 3: Participant Pre-injury information form (continued)

PSYCHOLOGICAL WELL-BEING

How often did you...

	almost always	very often	often	Some times	hardly ever	never
29) get impatient with yourself?						
30) get angry with other people?						
31) feel hopeless about your future life?						
32) feel lonely?						
33) Feel worn out?						
34) Feel bored?						

Thank you

Appendix 4: Participant Questionnaire

Return to Work Following Traumatic Brain Injury: Case Control Study and Economic Analysis Questionnaire for participants

This booklet contains 4 sections for you to complete. There is a separate section for your partner, parents or carer to fill in (whoever has most contact with you).

The information will be treated confidentially. It will tell us more about the ways your brain injury affects you and the things you do.

For each question, please choose the answer that applies to you and tick ✓ the answers as instructed. If you are unsure which answer to choose, please tick the one that seems most applicable, rather than leaving the question blank. **If you require any help or have any questions, please contact Julie Phillips, Research Assistant 0115 8230243.**

If you are unable to complete the forms yourself, please ask someone who knows you well to do it for you. If someone is filling in the questionnaires on your behalf, it is important that they tick **THE ANSWERS YOU WOULD GIVE** if you were able, even if these are not the ones they would choose for you.

You may feel that some of the questions do not apply to you, for example because you have made a full recovery, but please try to answer them all so we can have an overall picture.

Please return in the enclosed stamp addressed envelope to:

Dr. Kate Radford, Research Fellow
School of Community Health Science
Division of Rehabilitation and Ageing
Medical School B Floor
Nottingham, NG7 2UH
0115 8230244

kate.radford@nottingham.ac.uk

Thank you for filling in the questionnaires

Appendix 4: Participant Questionnaire (continued)

Your name	Today's date

Please put your current address here if it has changed or is not the same as on the envelope:

Telephone:

Are you filling in the questionnaire yourself? box	Please tick <u>one</u>
Yes.....	<input type="checkbox"/> ₁
No, it is being completed for me by:- My spouse or partner.....	<input type="checkbox"/> ₂
Another (Please specify below)	<input type="checkbox"/> ₃

Any comments e.g. about the care received since leaving hospital, the costs incurred as a result of your injury, your work or education, since your injury?

For Official use only

ID no.	Baseline	3 months	6 months	12 months	18 months
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Appendix 4: Participant Questionnaire (continued)

Section 1 = Brain Injury Community Rehabilitation Scales – see Appendix 5; Participant Pre-injury Information form

Section 2

We are trying to find out what you are doing now. Please **tick all** the following statements that apply to you now.

1. Where are you now living?

Is this the same as from before your injury?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
If no, please explain		

2. Are you still married or have the same long-term partner as you did before your injury?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	I did not have a long term partner before my injury <input type="checkbox"/> ₃
---	--	---

3. Driving: If you were driving before your injury:

Have you started driving again?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	Has your ability to work been affected by not driving?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
---------------------------------	---	--	--	---	--

4. What is your current medical situation? (tick all those that apply)

I am fully recovered	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
I am on sick leave at present	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
Since discharge from hospital, do you feel you are getting adequate treatment?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
I believe I can no longer work due to my brain injury	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂

5. Are you planning to return to work or education? If yes, please go to question 6 If no, please go to question 7	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
---	---	--

Appendix 4: Participant Questionnaire (continued)

6. If you are trying to return to work or education, please tick the following statements that apply

I intend to return to what I was doing before my accident?	Yes <input type="checkbox"/> ₁		
I am on a programme to help me find work	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	
I am unemployed and actively looking for work	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	
I am in the process of doing a graded return to work or education	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	
Other			
If you are doing a graded return to work, please fill in the table below or please use the diary sheet at the back of the questionnaire:			
EXAMPLE: Number of hours worked per week since first returned to paid work or education	EXAMPLE: Number of weeks worked at those hours		
12 hours	2 weeks		
20 hours	3 weeks		
30 hours	3 weeks		
Please record the average number of hours worked (or in education) and the number of weeks worked.			
Number of hours worked per week since first returned to paid work or education	Number of weeks worked at those hours		
7.	Are you now working or in education?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
	If yes, please go to question 8 If no, please go to question 17		

Appendix 4: Participant Questionnaire (continued)

8. If you are now working or in education, please tick any of the following statements that apply

I am with the same employer	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am with a new employer	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am doing the same job	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am doing a different job	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
On average, how many hours per week are you in paid employment or in education?			
I am at the same educational college/university	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am at a different educational college/university	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am doing the same educational course	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am doing a different educational course	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
On average, how many hours per week is your course?			
I am on a scheme helping me stay in work	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
If so, please state what it is:			
I do voluntary work	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I look after children	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃
I am a homemaker/ housewife	n/a <input type="checkbox"/> ₁	Yes <input type="checkbox"/> ₂	No <input type="checkbox"/> ₃

9. Please tell us how long it was after your brain injury you returned to paid work or your educational activity (please ignore if you have told us in a previous questionnaire?)

Number of weeks off work or education until I first returned part time.		Number of weeks until I returned to work or education at my previous hours.	
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Appendix 4: Participant Questionnaire (continued)

**10. Why did you return to work or education?
(More than 1 may apply)**

I felt able to cope <input type="checkbox"/> ₁	I wanted to go back to work <input type="checkbox"/> ₂
I felt work needed me <input type="checkbox"/> ₃	I needed the money <input type="checkbox"/> ₄
I thought it would help me recover <input type="checkbox"/> ₅	Other <input type="checkbox"/> ₆

11. Did you tell your employers/college/voluntary work about your brain injury?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
Any comments	

12. Do you feel your employer/tutors are supportive?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
Any comments ₃	

13. Compared to before your accident, how do you feel you are coping?

Better than before <input type="checkbox"/> ₁	Worse than before <input type="checkbox"/> ₂	About the same <input type="checkbox"/> ₃
Please explain.		

14. Are you enjoying your job/course?

More than before <input type="checkbox"/> ₁	Less than before <input type="checkbox"/> ₂	About the same <input type="checkbox"/> ₃
--	--	--

Appendix 4: Participant Questionnaire (continued)

15. Has your employer or tutors made any other of the following adjustments for you?

No adjustments have been made		<input type="checkbox"/> ₁₃
Allowed you more breaks?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
If yes, how many more minutes break a day do you take?		
Reduced the amount of work you have to do?	Yes <input type="checkbox"/> ₃	No <input type="checkbox"/> ₄
Reduced your responsibilities?	Yes <input type="checkbox"/> ₅	No <input type="checkbox"/> ₆
Provided more supervision or support at work?	Yes <input type="checkbox"/> ₇	No <input type="checkbox"/> ₈
Allowed you to work at home?	Yes <input type="checkbox"/> ₉	No <input type="checkbox"/> ₁₀
Used any outside help for you e.g. government schemes, occupational health etc?	Yes <input type="checkbox"/> ₁₁	No <input type="checkbox"/> ₁₂
If yes please provide details		

16. Has your employer/college had to pay for additional support or equipment because of your brain injury?

Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
Please state what.	
If you know, please state approximately how much this has cost?	

<p>17. Have you had to leave or change your job or education?</p> <p>If yes, please go to question 18 If no, please go to question 23</p>	<p>Yes</p> <input type="checkbox"/> ₁	<p>No</p> <input type="checkbox"/> ₂

Appendix 4: Participant Questionnaire (continued)

18. Please state how long you managed to work or study before you left or changed jobs or courses e.g. number of weeks or months

--

19. Please explain why you have changed from your previous job/educational activity. (Tick more than one box if applicable)

Previous employment not kept open <input type="checkbox"/> ₁	Unable to do previous job/course <input type="checkbox"/> ₂
I feel this is a positive step <input type="checkbox"/> ₃	I wanted to change jobs/do this course <input type="checkbox"/> ₄
I feel this is my only choice <input type="checkbox"/> ₅	I feel this keeps me occupied <input type="checkbox"/> ₆
Other. Please explain	

20. If you have started a new job, educational course, training scheme, work placement or voluntary work, please tell us your job title or activity and give a brief description of what you do.

--

21. How many times have you changed jobs/activity since your brain injury or since you last completed one of these questionnaires?

--

22. Please state the jobs or courses you have done since your brain injury

--

Appendix 4: Participant Questionnaire (continued)

With the following questions, we are trying to find out how your income has been affected?

(This information is only required for this research and will remain completely confidential)

23. What benefits are you or your family currently claiming as a result of your brain injury?

None <input type="checkbox"/>	<input type="checkbox"/>	Disability Living Allowance <input type="checkbox"/>	<input type="checkbox"/>
Income Support <input type="checkbox"/>	<input type="checkbox"/>	Incapacity Benefit <input type="checkbox"/>	<input type="checkbox"/>
Job Seekers Allowance <input type="checkbox"/>	<input type="checkbox"/>	Carers allowance <input type="checkbox"/>	<input type="checkbox"/>
Statutory sick pay (SSP) <input type="checkbox"/>	<input type="checkbox"/>	Other: Please specify:	

24. What is your best guess of your household current yearly income from jobs and benefits (before tax and national insurance is taken off)?

Less than £10,000 per annum <input type="checkbox"/>	<input type="checkbox"/>	£10,000 to £19,999 per annum <input type="checkbox"/>	<input type="checkbox"/>
£20,000 to £29,999 per annum <input type="checkbox"/>	<input type="checkbox"/>	£ 30,000 to £39, 999 per annum <input type="checkbox"/>	<input type="checkbox"/>
£ 40,000 to £49,999 per annum <input type="checkbox"/>	<input type="checkbox"/>	£ 50,000 or greater <input type="checkbox"/>	<input type="checkbox"/>
Don't know <input type="checkbox"/>	<input type="checkbox"/>		

25. Do you think you would be better off financially if you returned to paid work?

Yes <input type="checkbox"/>	<input type="checkbox"/>	No <input type="checkbox"/>	<input type="checkbox"/>	Don't know <input type="checkbox"/>	<input type="checkbox"/>
If no, please state why?					

26. Are you pursuing a compensation claim?

Yes <input type="checkbox"/>	<input type="checkbox"/>	No <input type="checkbox"/>	<input type="checkbox"/>	Looking into it <input type="checkbox"/>	<input type="checkbox"/>
What advice have you been given about working from your solicitor?					

27. Please tell us about what other costs or expenses you and your family have had as a result of your brain injury?

--

Appendix 4: Participant Questionnaire (continued)

The following questions are to help us find out if your partner, parents or carers (whoever has most contact with you) work status and income has been affected by your brain injury.

27. How has your partner, carer or parents (i.e. anybody who has a lot of contact with you) work status been affected by your brain injury?

I have no one close that has been affected by my brain injury <input type="checkbox"/> _1	They did not work before my injury <input type="checkbox"/> _2
Their work has not been affected by my injury <input type="checkbox"/> _3	They had to stop work due to my injury <input type="checkbox"/> _4
Had to change jobs <input type="checkbox"/> _5	They have had to reduced their hours due to my injury <input type="checkbox"/> _6

28. How many working weeks or hours have they lost through your injury?

--

29. What was your partner, carer or parents (i.e. anybody who has a lot of contact with you) job at the time of your injury?

--

Appendix 4: Participant Questionnaire (continued)

With these questions, we are trying to find out more about the services you and your family have received since leaving hospital as a result of having a brain injury.

30. What services you have you received in the last 3 months since you left hospital as a result of your brain injury?

Do not include services received while you were an in-patient in a hospital. If unsure, please put in your best guess.

1.	Consultant	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
2.	GP	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
3.	Case Manager	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
4.	Neuro-psychologist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
5.	Cognitive behavioural therapist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
6.	Occupational Therapist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
7.	Physio Therapist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
8.	Speech and Language therapist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
9.	Social worker	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, how many times?	
10.	Other: (please give details)				

Appendix 4: Participant Questionnaire (continued)

31. Medication

	Since your injury (or since the last time you filled in one of the questionnaires) have you started taking any new medication?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂
	If yes, please specify the name of the drug, the dose and how long you have been taking it for.		

32. Please tell us if you have had contact with any of the people listed below since your discharge from hospital.

1.	Benefits advisor	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
2.	Disability employment advisor	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
3.	Other services arranged by the job centre	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
4.	Solicitor	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
5.	Other services aimed at helping you get or stay in work or education?	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
6.	A self-help group: Please state which one:	Yes <input type="checkbox"/> ₁	No <input type="checkbox"/> ₂	If yes, how many times?	
7.	Please say if you have seen anyone else who has helped you since discharge from hospital or since you last completed one of these questionnaires.				

Appendix 4: Participant Questionnaire (continued)

SECTION 3

We should like to know how your health is affecting your mood and how you have been feeling **IN THE PAST WEEK OR SO**. Please answer **ALL** the questions by putting a tick in the box which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

<p>I feel tense or 'wound up':</p> <p>Most of the time</p> <p>A lot of the time</p> <p>Time to time, Occasionally ...</p> <p>Not at all</p>	<p>I feel as if I am slowed down:</p> <p>Nearly all the time</p> <p>Very often</p> <p>Sometimes</p> <p>Not at all</p>
<p>I still enjoy the things I use too:</p> <p>Definitely as much</p> <p>Not quite so much</p> <p>Only a little</p> <p>Hardly at all</p>	<p>I get a sort of frightened feeling like 'butterflies' in the stomach:</p> <p>Not at all</p> <p>Occasionally</p> <p>Quite often</p> <p>Very often</p>
<p>I get a sort of frightened feeling as if something awful is about to happen :</p> <p>Very definitely and quite badly</p> <p>Yes, but not too badly</p> <p>A little, but it doesn't worry me</p> <p>Not at all</p>	<p>I have lost interest in my appearance :</p> <p>Definitely</p> <p>I don't take as much care as I should</p> <p>I may not take quite as much care</p> <p>I take just as much care as ever</p>

Appendix 4: Participant Questionnaire (continued)

I can laugh and see the funny side of things:		I feel restless as if I have to be on the move:	
As much as I always could	<input type="checkbox"/>	Very much indeed.....	<input type="checkbox"/>
Not quite so much now.....	<input type="checkbox"/>	Quite a lot	<input type="checkbox"/>
Definitely not so much now.....	<input type="checkbox"/>	Not very much	<input type="checkbox"/>
Not at all	<input type="checkbox"/>	Not at all	<input type="checkbox"/>
Worrying thoughts go through my mind :		I look forward with enjoyment to things :	
A great deal of the time	<input type="checkbox"/>	As much as I ever did	<input type="checkbox"/>
A lot of the time	<input type="checkbox"/>	Rather less than I used to	<input type="checkbox"/>
From time to time but not too often	<input type="checkbox"/>	Definitely less than I used to ...	<input type="checkbox"/>
Only Occasionally	<input type="checkbox"/>	Hardly at all	<input type="checkbox"/>
I feel cheerful :		I get sudden feelings of panic :	
Not at all	<input type="checkbox"/>	Very often indeed	<input type="checkbox"/>
Not often	<input type="checkbox"/>	Quite often	<input type="checkbox"/>
Sometimes	<input type="checkbox"/>	Not very often	<input type="checkbox"/>
Most of the time	<input type="checkbox"/>	Not at all	<input type="checkbox"/>
I can sit at ease and feel relaxed :		I can enjoy a good book, radio programme or TV :	
Definitely	<input type="checkbox"/>	Often	<input type="checkbox"/>
Usually	<input type="checkbox"/>	Sometimes	<input type="checkbox"/>
Not often	<input type="checkbox"/>	Not often	<input type="checkbox"/>
Not at all	<input type="checkbox"/>	Very seldom	<input type="checkbox"/>

Appendix 4: Participant Questionnaire (continued)

SECTION 4

**I would now like to ask you about your state of health today.
Please could you state which you feel best describes your
health state today.**

Mobility (Tick one box only)

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care (Tick one box only)

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (Tick one box only)

- I have no problems with performing my usual activities
(E.g. work, study, housework, family or leisure activities)
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort (Tick one box only)

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression (Tick one box only)

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

**Compared with my general level of health over the past 12 months, my
health state today is:**

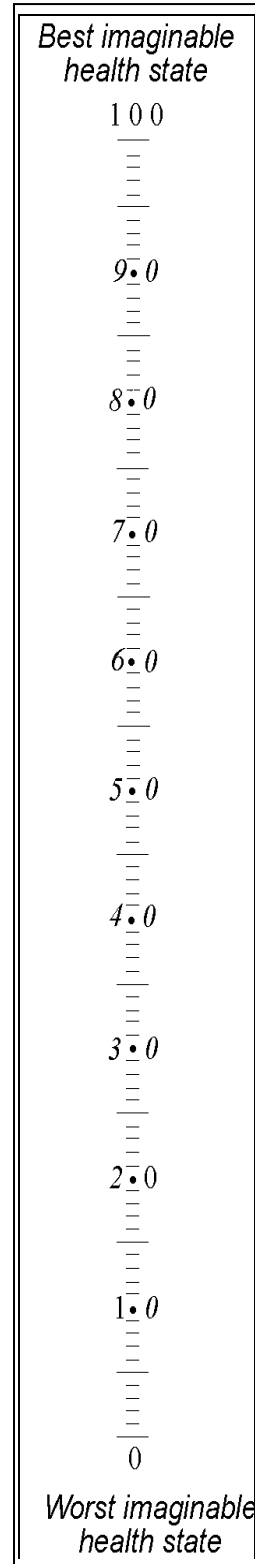
- Better
- Much the same
- Worse

Appendix 4: Participant Questionnaire (continued)

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best health state you can imagine is marked 10.0 and the worst health state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is.

<p>Your health state today</p>



Thank you for completing this questionnaire.
Please check you have completed all the questions

Appendix 5: Comparison of participation measures

	Domains covered	Personal Care	Mobility	Shopping	House work	Money and appointments
Brain Injury Community Rehabilitation Outcome (BICRO) (Powell et al. 1998)	Six sections: - Personal care - Mobility - Self-organisation - Socialising - Productive employment - Psychological well being	In/out bed, Toileting,	Public transport, Walk in the park	Go to local shops	Laundry, Cleaning home, Cooking not mentioned	Keep track of money Deal with bank account Write official letters Appointments
Community Integration Questionnaire (CIQ) (Willer et al. 1994)	Three sections: - Home integration - Social integration - Productive activity	No	Travel outside the home	Household shopping, shopping outside home	Housework, meal preparation	Personal finances
Craig Handicap Assessment and reporting technique- Short form (CHART) (Whiteneck et al. 1992)	Five domains: - Physical independence - Mobility - Occupation - Social Integration - Economic self sufficiency	How many hours assistance is required to do PADL?	Can you use transport independently?	How many hours spend spent per week in active homemaking? How many hours do you spend in home maintenance?		Asks for household income and how much spent on medical costs?
European Brain Injury questionnaire (EBIQ) (Teasell et al. 2007)	Eight domains: - Somatic, - cognitive, - motivation, - impulsivity, - depression and isolation - physical - communication	No	No	No	Asks about problems with household chores	No

Appendix 5: Comparison of measures of participation (continued)						
	Socialising	Work	Psychological	Cognitive problems	Pre-post injury comparison	Carers version
BICRO	Relatives, close friends, new acquaintances	Paid work, voluntary work, studying, looking after children	Impatient with self, get angry, feel hopeless, feel lonely, feel worn out, feel bored	No	Yes	Yes
CIQ	Plan leisure activities Participate in leisure activities Have a best friend	Childcare, Full time, part time, not working but looking for work/not looking for work, School or training programme, volunteer	No	No	No	No
CHART	How many days do you phone people, go out of the house, spend nights away from your home?	How many hours do you spend in paid work, studying or being a volunteer	No but does ask if in a romantic relationship	Assistance with decision making or judgement, being alone	No	No
EQIB	No	No	Yes	Yes	No	Yes

Appendix 5: Comparison of measures of participation (continued)					
	Method of delivery	Number of items	Time to complete	Answers	Training needed
BICRO	Self-administered. Too long to complete over the telephone	39	Approx 25 mins	Varies but usually 6 options: <ul style="list-style-type: none"> - Don't do at all - Constant help - A lot of help - Some help - Prompts only - No help or prompts 	No
CIQ	In person or by telephone interview	15	Approx 15 mins	Varies but often 4 options: <ul style="list-style-type: none"> - Yourself alone - Yourself and someone else - Someone else - Not applicable 	No
CHART	In person or by telephone interview	32	Approx 15 mins	Varies but often 3 options: <ul style="list-style-type: none"> - I almost always have difficulty - Sometimes I have difficulty - I almost never have difficulty 	No
EBIQ	In person	68	Approx 15 mins	Three part answers to all questions: <ul style="list-style-type: none"> - Not at all - A little - A lot 	No

Appendix 5: Comparison of measures of participation (continued)			
	Strengths	Limitations	Other
BICRO	Has pre-post injury comparison. Has carer version for comparison Has psychological and ADL component Recommended in the BRSM basket of measures (British Society of Rehabilitation Medicine 2000a)	The choice of six possible answers is too fine a distinction for some people. Not widely used Too long for completion by phone	Used in one UK RCT (Powell et al. 2002)
CIQ	Recommended in the COMBI list (Centre for Outcome Measurement for Brain Injury 2010) Can be administered by telephone	No comparison of pre and post injury ability No carers component No psychological wellbeing section	In a comparison with other measures Van Baalan et al (2006) did not recommend its use at one year post TBI. Wagner et al (2002) found the productivity subscale correlated with return to work Widely used in other TBI studies (Goranson et al. 2003; Reid-Arndt et al. 2007; Sopena et al. 2007; Willemse-van Son et al. 2009)
CHART	Includes questions about communication	Originally designed for spinal injury patients. No comparison of pre and post injury ability No carers component No psychological wellbeing section	A comparison of CHART with CIQ for measuring community integration in spinal injury patients concluded CIQ was a valid measure as it was brief and simple compared to CHART (Gontkovsky et al. 2009)
EBIQ	Aimed at subjective experience. Has carer's component	No questions about work Not aimed at personal and community activities	Only used in more recent studies (Bjorkdahl et al. 2004; Avesani et al. 2005; Svendsen et al. 2006)

Appendix 5: Comparison of measures of participation (continued)		
	Reliability (Test-retest, Inter-rater, Internal consistency)	Validity (Content, Construct, Sensitivity to change over time)
BICRO	See 3.2.4.2. for details of reliability	See 3.2.4.2. for details of validity
CIQ	Assessed on 16 people with ABI Test –retest reliability =0.91 for people with TBI, 0.97 for TBI carers Inter- rater reliability not formally tested, but a separate sample of 59 TBI patients and carers scores were compared at 1 year post TBI, correlation co-efficients were: home integration 0.81, social integration 0.74, and productive activity 0.96. A review of studies on the CIQ by Dijkers (2000) suggests reliability is mixed with TBI participants rating themselves as more integrated on the home, productivity and 3 of the social integration items	No formal content or face validity studies have been done (Dijkers 2000). Willer et al. assumed high content validity as it was designed by 14 experts in TBI. Principle component analysis reduced the original 47 questions to 15 questions. Willer et al. compared 341 people with TBI to 211 people without TBI. There was a statistically significant difference between the groups on home integration, social integration and productivity sub scales as well as total scores. There is only limited research and evidence that the CIQ shows change of time (Dijkers 2000)
CHART	Norms obtained from 342 spinal injury (SCI) patients. Reliability obtained from 135 SCI patients Overall Test –Retest reliability= 0.93 Overall subject -proxy correlation = 0.83, although low at 0.28 for social integration was statistically significant	Rasch Analysis found CHART to be a well calibrated linear scale. Validity demonstrated by independent classification of significant differences between low and high scores on the total scores and in 4/5 sub sections
EBIQ	Test – test = 0.76 (range 0.55 -0.90) Pearson product moment correlations Internal consistency: median 0.63 Cronbachs coefficient alpha for TBI self-report Patient/carers agreement:= 0.77 Cronbachs' coefficient alpha	Developed by expert opinion from a variety of European experts and developed on 905 TBI patients from seven European countries Significant differences between brain injury population and controls (Mann Whitney U p = 0.5)

Appendix 6: Unemployment rates

During the study period (Jan 2007 –Oct 2009) England underwent an economic recession with both the National and East Midland unemployment rates rising by 2% - see Table below. Leicester showed the greatest percentage increase in unemployment rates over the study period, however only a few usual care participants came from this area. The remaining usual care participants were recruited from North Nottinghamshire, Derby and Derbyshire and Lincolnshire, all of which had a lower percentage increase in unemployment rates during the study period. However specialist group participants were only recruited from Nottingham and South Nottinghamshire, both areas had the highest levels of unemployment, both at the start and end of the study, and the greatest increase in unemployment rates– see Table below.

Percentage employment rates (16+ years)

Using Local labour market indicators by NUTS 3 area sheet 15 (Office for National Statistics 2010)

Unemployment rates	April 2006 – March 2007 (LMSemid 0108)	October 2008 – September 2009 (LMSemid0510)	Percentage difference
UK total	5.3%	7.3%	2%
East Midlands	5.1%	7.2%	2.1%
Nottingham	9.4%	12.6%	3.2%
South Nottinghamshire	4.1%	7.8%	3.7%
North Nottinghamshire	5.8%	5.7%	-0.1%
Derby (+ Derbyshire)	5.5% (4.0% -5.6%)	8.6% (4.6%-7.6%)	3.1% (0.6%-2.0%)
Leicester (+ Leicestershire)	7.9% (3.8%)	11.9% (5.8%)	4.0% (2%)
Lincolnshire	5.1%	5.9%	0.8%

Appendix 7: OT Proforma- Explanatory notes

Category	Explanatory notes i.e. factors to consider
Medical history	Full details may emerge over time. New problems may develop e.g. epilepsy
Social situation/roles	May change over time.
Pre-morbid lifestyle	Include leisure, roles, work, attitudes and behaviors.
Current difficulties/problems	Assess patients and families perception of skill deficits in self-maintenance, productivity and leisure. Difficulties may emerge as awareness increases.
Current abilities	Assess communication, physical, sensory (include smell, taste and neglect), fatigue levels, cognitive, emotional, behavioral functioning and level of insight. Will need constant assessing as abilities change and are challenged.
Family views	Family and friends views, expectations, knowledge of TBI and recovery need to be considered.
Current issues	
Medical	Any other ongoing treatment. Both client and OT need knowledge of TBI and an understanding of the recovery process
Social	Include living arrangements, isolation especially if not driving
Benefits	Benefit claims, sickness entitlement
Family	Change of roles, increased time together
Work	Explain return to work process, check availability of previous employment/course
Other	e.g. compensation– advise to consult solicitor if any queries, housing etc.
Goals	
Identify/set realistic goals	Use specific, measurable, achievable, measured and timed goals (SMART).
Task analysis	Breakdown the goals/activity
Review goals	Encourage client to reflect and judge success of goal.
Modify goals	Encourage client to alter goal if required

Appendix 7: OT - Explanatory notes (continued)

Personal Activities of Daily Living	
Dressing	Include choosing appropriate clothing
Toileting	Including managing menstruation
Bathing	Including frequency of washing
Other	Fine motor activities
Education re TBI	
Client	Explain TBI, the rehabilitation and return to work process
Family/friends	Concerns, needs and expectations, knowledge of TBI
Employer	As above. Include likely timescales and risk of epilepsy
Other	e.g. Disability Employment Advisor
Instrumental Activities of Daily Living	
Making drinks/meals	Consider pre morbid functioning
Housework/ laundry	Including use of prompts
Money/ Budgeting	e.g. can they work out correct change, work out a weekly budget, buy realistic gifts, control impulse buys.
Shopping	Consider pre morbid functioning
Correspondence	Use of written information, phone or email
Use of phone	Answering phone, alarm, use of calendar
Managing appointments	Use of diaries, calendars, mobile phone, other people, notice boards
Being left alone	How long do family feel comfortable leaving them alone e.g. a few hours, days, weeks etc.
Leisure activities	Encourage people to restart both new and old activities. Include use of Headway
Encourage socializing	Encourage people to keep in contact with friends, family, work colleagues.
Other	
Mobility	
Walking to shops	Alone or accompanied
Crossing roads	Consistent use of pedestrian lights, choosing safe places
Using public transport	Buses, trams, trains etc. Obtain bus pass
Driving	Notification to DVLA, assessment at a mobility driving center
Other	Can they organize lifts?

Appendix 7: OT - Explanatory notes (continued)

Cognitive/Executive skills	
Education about cognitive/executive skills	Memory, attention, problem solving, slower speed of processing and insight. Factors affecting it e.g. fatigue, food, alcohol, routine
Memory aids/strategies	As in managing appointments. Plus use of lists, routine. Look at medication etc.
Attention skills	Recognition of type of attention problem and use of strategies e.g. turn off TV; plan plenty of breaks, do not multi-task.
Problem solving activities	Organizing and planning activities e.g. night out. Encourage self-monitoring by predicting/evaluating success/failure of activity
Standardized tests	Use of standardized tests e.g. Behavior memory test
Other	
Psychological factors	
Confidence Building	Graded activities, use of errorless learning
Low mood	Encourage leisure activities, consider medication
Motivation	Set very specific tasks, use of routine
Anxiety	Teach anxiety management/relaxation techniques
Behavioural problems	Increased irritability, use of pacing, fatigue management, refer for Cognitive Behavioral Therapy
Dealing with others	Identify specific problems and work out relevant strategies. Discuss what to say about TBI.
Work Preparation	
Teach pacing/fatigue management	Plan a home practice routine e.g. regular meals, activity, rest periods, different types of activity
Use of routines/time keeping	Encourage regular time keeping activities e.g. get up by x o clock,
Discuss work options	E.g. graded return
Patient contact with employer	Encourage client to keep in contact with work place
Detailed job analysis	Obtain job description if possible
Identify potential problems/solutions	Encourage clients to think of problems and solutions. Practice work type activity as much at home as possible
Other	
Miscellaneous	
Sleep	Sleep hygiene and sleep routines
Family/carer involvement	Support family/carer/friends as necessary

Appendix 7: OT - Explanatory notes (continued)

Return to work (RTW) process	
Return to work planning meeting	<p>Agree with client before the meeting what can be disclosed. Encourage honesty.</p> <p>Assess job, potential problems and possible solutions Ensure client, OT and employer have the same awareness of employer's sickness policy, return to work procedure and expectations.</p> <p>Agree plan of action e.g. patient/OT to notify them when patient nearly ready to go back to work and/or set up regular appointments to monitor progress. Inform GP of proposed plan</p>
Work Assessment meeting	<p>Provide guidance on what to assess for.</p> <p>Following assessment, formulate return to plan with employers and clients covering hours, days, duties, pay, feedback and a contingency plan.</p>
Monitoring/grading meeting	Worksite meeting to monitor and grade return to work. Stress honest feedback needed
Maintenance meeting	Monitor situation.
Written information given to employers	All work visits should be written up with a copy for patient, employer and whoever else attends. Possibly GP.
Advice/education given	This category will be used if additional information is given to employer, work mates, human resources, OH
Statutory issues	Cover insurance, benefits, risk of epilepsy, driving and working at heights, pay,
Liaison face to face, by letter, telephone call or email	
Case manager	<p>Record whether the liaison has been face to face, by letter, telephone or email. Class providing the client with a written summary of visit is written liaison. Record 'other' if not on list.</p>
Cognitive Behavioral Therapist	
Psychologist	
Consultant	
General Practitioner	
Family	
Employer	
Human Resources/Occupational Health	
Disability Employment Adviser	
DWP Work provider	
Carer/partner	

Appendix 7: OT - Explanatory notes (continued)

General issues	
Identifying problems	Any additional problems identified that cannot be classed under any other heading
Written information given	Any written information given excluding work site visit letter
Homework tasks set	Record that they were set
External feedback in place	Use of partners, parents, employers
Use of internal/external strategies	Record if used
Pay when returning to work	
Patient return to work whilst on Statutory Sick pay (SSP)	Tick as applicable. Record 'other' if not on list
Patient returned to work on incapacity benefit (IB)	
Patient on full pay but reduced hours	
On permitted work	
No benefits, pay cut for graded return	
Concessions agreed	
Decreased hours	Tick as applicable. Record 'other' if not on list
Reduced days	
Reduced duties/ responsibility	
Provision of mentor/extra support	
Flexibility to take extra breaks	
Flexible start/finish times	
Provision of special conditions e.g. no heights if epileptic	
Being supernumerary	
Work at home	
How got to work	
Walk	Tick as applicable
Lifts	
Public transport	
Drive	
Access to work scheme	
Client engagement	
Very good	Fully engages, well-motivated
OK	Does what asked but no more
Poor	Has difficulty engaging
Attitude of employer	
Very good	Goes out of their way to be helpful
OK	Does what is asked but no more
Cautious	Very cautious

Appendix 7: OT - Explanatory notes (continued)

Use of other services	
DEA	Tick as applicable
Permitted work	Allows a person to work up to 15.99 hours per week and earn up to a set amount per week whilst claiming incapacity benefit
Work Preparation Scheme	Government funded scheme helping people have a taster of a job.
Work psychologist	Psychologist provided by the DWP
Other work provider	E.g. Remploy.
Social Services	
Headway	Self-help support group
Support workers	Provided by compensation process or in higher education
Other	Access to work scheme
OT activity with employer	
General advice re TBI	Advice that applies to most people with a TBI
Specific advice/education re the individual person in relation to their job	Specific advice about how the person's injury is likely to impact on their ability to work e.g. fatigue level, specific memory problems, how to give feedback etc. Explain return to work process and likely recovery rates for that person.
Information about rehabilitation process	Inform employer what the rehabilitation process consists of for that person e.g. the need for the person to build up their activity levels. Explain why the person may not be ready for work even though they may be seen out (regularly).
Advice/support re work assessment	Ascertain with patient and employer minimum level of ability the person needs before returning to work. Explain what to look out for and potential ways around any obvious problem. Pay, benefits and insurance need to be addressed.
Advice/monitoring/support re graded return to work including pacing, work load, supervision, skill level	With employer and client, carry out a graded return to work covering hours at work, rest breaks, level of responsibility, supervision, feedback and review schedule. Include contingency plans if necessary. Pay, benefits and insurance need to be addressed.
Advice re an specific work based problems	Any problems that become apparent need addressing. May include advice re any new job or new skill required
General support/monitoring	Once person has reached their maximum level at work, maintain contact with employer (in person, phone or email) to provide ongoing support to ensure person is able to sustain employment until patient and employer no longer require it.
Information and liaison with statutory provision	e.g. DEA's, Access to Work

Appendix 8: OT Proforma

OT Content Analysis
Record in 10 min units

Patient number

Treatment session date.....

Treatment session number.....

Length of session (10 min)

Return travel time from base (10 min)).....

Where seen		5. Education re TBI and/or RTW	9. Dealing with psychological issues	13. Return to work process
Home		Client	Confidence building	RTW planning meeting
Work		Carer	Low mood	Work Assessment meeting
Job centre		Employer	Motivation	Monitoring/grading meeting
Other		Other	Anxiety	Maintenance meeting
			Behavioural problems	Written info given to employers
1. Assessment		6. Instrumental ADL	Dealing with others	Advice/education given
Medical history		Making drinks/meals	Relaxation techniques	Statutory issues covered
Social situation/roles		Housework/laundry		
Current difficulties/problems		Money/budgeting	10. Cognitive/executive skills	14. Liaise by face to face. letter, phone, email
Pre-morbid lifestyle		Shopping	Educate re cognitive/executive skills	Case manager
Current abilities		Correspondence	Memory aids/strategies	CBT
Family views		Use of phone	Attention skills	Psychologist
		Managing appointments	Problems solving	Consultant
2. Current Issues		Being left alone	Standardized tests	GP
Medical		Leisure activities	Other	Family
Social		Other		Employer
Benefits			11. Work prep	HR/Occupational health
Family		7. Mobility	Teach pacing/fatigue management	DEA
Work		Walking outside home	Use of routines/time keeping	Work provider
Other		Road safety	Discussing work options	Carer/partner

Appendix 8: OT proforma (continued)									
			Using public transport			Patient contact with work place			Patient
3. Goals			Route finding			Detailed job analysis			Other
Identify/set realistic goals			Driving			Identify potential problems/solutions			
Task analysis			Other			Other			15. General issues
Reviewing/modifying goals									Identifying problems
			8. Physical						Written info given
4. Personal ADL			Transfers			12. Miscellaneous			Homework tasks set
Dressing			Splinting			Sleep			External Feedback system in place
Toileting			Wheelchairs			Family/carers support			Use of in/external strategies
Bathing			Aids and adaptations						
Other									

OT proforma: Page 2

OT Content Analysis 2

Pay		Use of other services	
Patient returned to work on statutory sick pay		DEA	
Patient returned to work on incapacity benefit		Permitted work	
Patient on full pay but reduced hours		Work step	
On permitted work		Work prep	
No benefits, pay cut for graded return		Work psychologist	
Other		Other work provider	

Appendix 8: OT proforma (continued)			
			Social services
Concessions agreed			Headway
Decreased hours			Support workers in education
Decreased days			Support workers/compensation
Reduced duties/responsibilities			Other
Provision of mentor			
Flexibility of extra breaks			Client engagement
Flexibility start/finish times			Very good
Provision of special provisions			OK
Being supernumerary			Poor
Work at home			
Other			
How patient got to work			
Walk			
Lifts			
Public transport			
Drive			
Access to work			
Attitude of employer			
Very helpful			
OK			
Cautious			

Appendix 9: Total annual household income

(Taken from SSPS data base)

Baseline total annual household income

	Specialist group (40)	Usual care group (54)
Less than £10,000 p.a. ¹	11 (27.5%)	20 (37.0%)
£10,000 to £19,999 p.a.	15 (37.5%)	14 (25.9%)
£20,000 to £29,999 p.a.	5 (12.5%)	8 (14.8%)
£30,000 to £39,999 p.a.	4 (10.0%)	6 (11.1%)
£40,000 to £49,999 p.a.	2 (5.0%)	2 (3.7%)
£50,000 p.a. and over	3 (7.5%)	4 (7.4%)
Don't know	0 (0.0%)	0 (0.0%)

¹ per annum

12 month total annual household income

	Specialist group (25)	Usual care group (36)
Less than £10,000 p.a.	7 (28.0%)	7 (19.4%)
£10,000 to £19,999 p.a.	7 (28.0%)	8 (22.2%)
£20,000 to £29,999 p.a.	4 (16.0%)	12 (33.3%)
£30,000 to £39,999 p.a.	4 (16.0%)	2 (5.6%)
£40,000 to £49,999 p.a.	2 (8.0%)	2 (5.6%)
£50,000 p.a. and over	0 (0%)	3 (8.3%)
Don't know	1 (4.0%)	3 (8.3%)

Percentage change from baseline in total annual household income at 12 months

	Specialist group (25)	Usual care group (36)
Less than £10,000 p.a.	+0.5% ¹	-17.6% ²
£10,000 to £19,999 p.a.	-9.5%	-3.7%
£20,000 to £29,999 p.a.	+3.5%	+18.5%
£30,000 to £39,999 p.a.	+6%	- 5.5%
£40,000 to £49,999 p.a.	+3%	+1.9%
£50,000 p.a. and over	-5.0%	+0.9
Don't know	4.0%	8.3%

¹ Plus sign = more than at baseline

² Minus sign = less than at baseline

Appendix 10: Household income index score

Baseline household income index score¹

Score	Baseline Household income band	Specialist group (n= 40)	Index sum	Usual care group (54)	Index sum
1	Less than £10,000 pa	11	11 x 1 = 11	20	20 x 1 = 20
2	£10,000 to £19,999 pa	15	15 x 2 = 30	14	14 x 2 = 28
3	£20,000 to £29,999 pa	5	5 x 3 = 15	8	8 x 3 = 24
4	£30,000 to £39,999 pa	4	4 x 4 = 16	6	6 x 4 = 24
5	£40,000 to £49,999 pa	2	2 x 5 = 10	2	2 x 5 = 10
6	£50,000 p.a. and over	3	3 x 6 = 18	4	4 x 6 = 24
	Total	40	100	54	130
	Index score	100/40 = 2.50		130/54 = 2.40	

12 month Household income band¹

Score	12 month Household income band	Specialist group (n= 25)	Index sum	Usual care group (n=36)	Index sum
1	Less than £10,000 pa	7	7 x 1 = 7	7	7 x 1 = 7
2	£10,000 to £19,999 pa	7	7 x 2 = 14	8	8 x 2 = 16
3	£20,000 to £29,999 pa	4	4 x 3 = 12	12	12 x 3 = 36
4	£30,000 to £39,999 pa	4	4 x 4 = 16	2	2 x 4 = 8
5	£40,000 to £49,999 pa	2	2 x 5 = 10	2	2 x 5 = 10
6	£50,000 p.a. and over	0	0 x 6 = 0	3	3 x 6 = 18
	Total	24	59	37	103
	Don't know	1	n/a	3	n/a
	Index score	59/24 = 2.45		103/37 = 2.78	

¹Index score = Allocation of a number to each income category, multiply the income category score by the number of people in that category thus giving a total category score. Add up the total category scores and divide by the total number of people in each group to obtain the index score.

Appendix 11: Baseline resource use: Imputed data set

Health perspective	Specialist group (n=33)		Usual care group (n=45)		Mean difference (95% CI)	
	Mean	Std Dev	Mean	Std ev	Mean	95% CI
No. of appts						
Medical Appts						
Consultant	0.18	0.53	0.36	0.77	-0.17¹	(-0.47, 0.12)
GP	1.00	1.09	1.20	1.24	-0.20	(-0.74, 0.34)
Specialist team						
Case manager	0.82	-1.04	0.00	0.00	0.82	(0.45, 1.19)²
CBT	0.18	0.73	0.00	0.00	0.18	(-0.80, 0.44)
Psychologist	0.03	0.17	0.04	0.21	-0.01	(-0.10, 0.08)
OT (NTBIS)	1.09	1.01				
Total NTBIS	2.12	2.16				
Health appts						
OT (other)	0.18	1.04	0.20	0.76	-0.02	(-0.42, 0.39)
Physio	0.18	0.53	0.42	1.23	-0.24	(-0.65, 0.17)
SALT	0.03	0.17	0.02	0.15	0.01	(-0.65, 0.81)
Social worker	0.00	0.00	0.13	0.40	-0.13	(-0.25,-0.01)
Other	0.12	0.70	0.09	0.36	0.03	(-0.22, 0.27)
Total Therapy appointments	2.64	3.23	0.91	1.89	1.73	(0.46, 2.99)
Total health and social care appointments	3.82	3.40	2.47	2.23	1.35	(0.08, 0.62)
Total OT appointments ³	1.27	1.57	0.20	0.76	1.07	(0.48, 1.67)
Societal perspective	Specialist group		Usual care group		Mean difference	
Health appointments	3.82	3.40	2.47	2.23	1.35	(0.08, 0.62)
Participant weeks lost wages	5.64	4.17	7.44	7.36	-1.81	(-4.65, 1.03)
Carers weeks lost wages	1.45	4.08	2.73	7.69	-1.28	(-4.21, 1.65)
DWP appointments	0.18	0.58	0.04	0.21	0.14	(-0.08, 2.87)
Total health and societal appointments	4.00	3.47	2.51	2.23	1.49	(0.10, 2.87)
Weeks lost wages	7.09	7.72	10.18	14.32	-3.09	(-8.56, 2.39)

¹Minus mean difference score = more appointments in the usual care group

²Red text= statistically significant

³Total OT appointments are listed separately because the Specialist group OT appointments are totalled as part of the specialist team appointments which does not allow an overall total OT figure to be obtained. The total OT appointments are not included in the total figures for therapy and health appointments as this would be double counting.

Appendix 12: Baseline costs: Imputed data set (UK£2007)

Health perspective	Specialist care (n=33)		Usual care (n=45)		Mean difference	
Mean cost (£) per participant	Mean £	Std Dev £	Mean £	Std Dev£	Mean £	95% CI £
Medical Costs						
Consultant	35.64	103.42	65.36	150.66	-29.72¹	(-90.35, 30.91)
GP	34.00	37.05	40.80	42.02	-6.80	(-25.06, 11.46)
Medication	22.13	70.58	36.68	78.71	-14.55	(-48.96, 19.86)
Specialist team						
Case manager	67.91	86.69	0.00	0.00	67.91	(37.17, 98.65)²
CBT	12.18	48.70	0.00	0.00	12.18	(-5.09, 29.45)
Psychologist	2.03	11.66	2.98	13.96	-0.95	(-6.90, 5.00)
OT (NTBIS)	75.27	69.78				
Total NTBIS	157.39	160.88				
Other health appointments						
OT (other)	12.55	72.07	13.80	52.22	-1.25	(-29.26, 26.76)
Physio	7.27	21.11	16.89	49.35	-9.62	(-26.05, 6.82)
SALT	2.09	12.01	1.53	10.29	0.56	(-4.48, 5.60)
Social worker	0.00	0.00	16.80	50.97	-16.80	(-32.11,-1.49)
Other	2.30	13.23	6.67	35.21	-4.36	(-17.21, 8.48)
Total therapy	181.61	205.33	58.67	111.17	122.94	(43.62, 202.26)
Total health and social care costs	273.37	220.85	201.50	197.66	71.87	(-22.95,166.70)
Total OT ³	87.82	108.10	13.80	52.22	74.02	(74.02, 20.36)
Societal perspective						
Health perspective	Specialist group £		Usual care group £		Mean difference £	
Health costs	273.37	220.85	201.50	197.66	71.87	(-22.95, 166.70)
Participant costs	2362.87	1514.30	2931.80	3763.51	-568.92	(-2166.56, 1028.71)
Carers costs	299.22	589.81	806.96	1659.09	-507.74	(-1043.76, 28.27)
Employers costs	0.00	0.00	0.00	0.00	0.00	0
DWP costs	6.73	21.60	1.64	7.71	5.08	(-2.88, 13.04)
Total health & societal costs	2942.19	3327.79	3941.91	5089.22	-999.71	(-3023.51, 901.76)

¹Minus score = more costs in usual care group, ²Red text= statistically significant

³ Total OT appointments are listed separately as they are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained. Total OT appointments are listed separately for additional detail.

Appendix 13: 12 month resource use: Imputed data set

(Mean number of appointments per participant)

12 month	Resource use				Imputed data set	
Health perspective	Specialist group (n=33)		Usual care group (n 45)		Mean difference	
	Mean £	Std Dev	Mean £	Std Dev	Mean £	95% CI
Medical Appointments						
Consultant	3.2	5.0	3.2	3.3	0.0	(-1.89, 1.86)
GP	7.1	7.5	7.4	9.6	-0.3	(-4.31, 3.69)
Specialist team						
Case manager	4.8	-7.2	1.0	3.5	3.8	(1.05, 6.53) ²
CBT	1.4	4.5	0.2	0.9	1.3	(-0.36, 2.89)
Psychologist	1.3	2.2	1.5	3.1	-0.2 ¹	(-1.48, 1.05)
OT (NTBIS)	6.6	8.1				
Total NTBIS	14.1	16.7				
Other health appointments						
OT (other)	0.7	2.8	2.0	5.2	-1.4	(-3.21, 0.45)
Physiotherapy	4.7	8.8	6.3	20.0	-1.6	(-9.01, 5.81)
SALT	0.5	1.5	1.7	6.8	-1.2	(-3.60, 1.21)
Social worker	0.0	0.0	0.2	0.8	-0.2	(-0.43, 0.03)
Other	1.0	5.9	1.3	4.7	-0.3	(-2.66, 2.14)
Total therapy appointments	21.0	20.0	14.2	32.8	6.8	(-6.02, 19.65)
Total health and social care appointments	31.2	25.0	24.8	37.6	6.5	(-8.53, 1.50)
³ Total OT appointments	7.3	8.1	2.0	5.2	5.2	(2.01, 8.45)

¹Minus score = more costs in usual care group, ²Red text= statistically significant

³ Total OT appointments are listed separately because the specialist OT appointments are totalled as part of the specialist team appointments. Totalling the OT appointments as part to the specialist team appointments allows a total figure for therapy and health appointments to be obtained. Total OT appointments are listed separately for additional detail.

Appendix 13: 12 month resource use: Imputed data set
(continued)

12 month	Resource use				Imputed data set	
Societal perspective	Specialist group (n=33)		Usual care group (n=45)		Mean difference	
	Mean £	Std Dev	Mean £	Std Dev	Mean £	95% CI
Health appointments	31.2	25.0	24.8	37.6	6.5	(-8.53, 21.50)
Participant weeks lost wages	13.6	17.6	20.5	22.0	-6.8	(-15.78, 2.12)
Carers weeks lost wages	2.2	6.9	6.9	17.0	-4.8	(-10.3, 0.85)
DWP appointments	1.9	3.3	1.5	2.1	0.4	(-0.80, 1.66)
Total health and societal appointments	33.2	26.4	26.3	37.9	6.9	(-8.39, 22.22)
Weeks lost wages	15.8	21.4	27.4	32.5	-11.6	(-23.77, 0.59)

¹Minus mean difference score = more appointments in the usual care group

Appendix 14: 12 month costs: Imputed data set

12 months	Mean cost (UK£2007) per participant				Imputed data set	
Health perspective	Specialist group (n=33)		Usual care group (n=45)		Mean difference	
	Mean £	Std Dev	Mean £	Std Dev	Mean £	95% CI
Medical costs						
Consultant	623.64	976.88	627.20	653.54	-3.56¹	(-371.31, 364.19)
GP	241.09	255.62	251.60	325.75	-10.51	(-146.64, 125.62)
Medication	28.07	96.28	81.30	237.59	-53.23	(-131.57, 25.10)
Therapy costs						
Specialist team						
Case manager	397.39	598.43	83.00²	290.77	314.39	(86.86, 541.93)
CBT	95.42	303.37	10.42	60.53	85.00	(-23.89, 193.89)
Psychologist	85.27	144.35	99.76	210.72	-14.48	(-99.24, 70.28)
OT (NTBIS)	455.82	560.01	0.00	0.00	455.82	(257.2, 654.39)
Total NTBIS	1033.91	1237.19				
Other therapy						
OT (other)	46.00	196.43	141.07	357.92	-95.07	(-221.42, 31.29)
Physio	186.67	350.95	250.67	799.25	-64.00	(-360.41, 232.41)
SALT	35.55	106.51	118.07	469.51	-82.52	(-248.61, 83.57)
Social worker	0.00	0.00	25.20	95.36	-25.20	(53.85, 3.45)
Other	39.15	224.91	57.42	177.55	-18.27	(-109.0, 72.50)
Total therapy	1341.27	1317.92	785.60	1684.99	555.67	(-147.79, 1259.13)
Total health and social care costs	2234.07	1810.30	1745.70	2098.09	488.37	(-416.35, 1393.08)
³ Total OT	501.82	557.44	141.07	357.92	360.75	(138.42, 583.08)

Appendix 14: 12 month costs: Imputed data set (continued)

12 months	Costs				Imputed data set	
Societal perspective	Specialist group (n=33)		Usual care group (n=45)		Mean difference	
	Mean £	Std Dev	Mean £	Std Dev	Mean £	95% CI
Health costs	2234.07	1810.30	1745.70	2098.09	488.37	(-416.35, 1393.08)
Participant costs	5202.80	6891.48	8009.98	9585.72	-2807.18	(-6798.69, 1184.32)
Carers costs	747.20	3027.13	1479.29	3847.68	-732.09	(-2341.36, 877.18)
Employers costs	75.79	435.19	14.61	65.78	61.18	(-69.73, 192.09)
DWP costs	77.85	131.23	57.49	79.78	20.36	(-27.38, 68.09)
Total health and societal costs	8337.70	10175.67	11307.07	12352.34	-2969.37	(-8212.37, 2,273.63)

¹Minus score = more costs in usual care group

Appendix 15: Benefit status

Reported benefit status at baseline

	Specialist group (n=40)		Usual care group (n=54)	
	No.	%	No's	%
In work, no benefits	8	20.0	0	0.0
Benefits only	0	0.0	3	6.1
In work and benefits	20	50.0	28	51.9
No wages or benefits	12	30.0	23	42.6

Reported benefit status at 12 months

	Specialist group (n=34)		Usual care group (n=45)	
	No.	%	No's	%
In work, no benefits	22	64.7	25	55.6
Benefits only	6	17.7	14	31.1
In work and benefits	3	8.8	2	4.4
No wages or benefits	3	8.8	4	8.9

Percentage change from baseline in benefit status at 12 months

	Specialist group (n=34)	Usual care group (n=45)
In work, no benefits	+44.7% ¹	+55.6%
Benefits only	+17.7%	+25.0%
In work and benefits	-41.2% ²	-47.5%
No wages or benefits	-21.2%	-33.7%

¹ Plus sign = more than at baseline

² Minus sign = less than at baseline

Appendix 16: Cost of increased length of hospital stay

National Schedule of Reference Costs 2007-8 give the costs for national average unit cost of a person with varying severity of TBI staying in a National Health Service bed for a day (Department of Health 2009). For example, the cost of a hospital day for a person with:

- A head injury without complications (HD37A) is £440 (£252, £423). This was used to calculate the minor TBI length of stay (LOS) difference
- A head injury with complications (HD37B) is £388 (£238, £442). This was used to cost the moderate/severe TBI LOS difference.
- A head injury with major complications (HD37C) is £380 (£238, 453). As this is the lowest figure, this was used to calculate the cost of the extra days for the whole cohort.

In order to give the lowest conservative estimate, both the mean and median difference in length of hospital stay (LOS) was examined and the least difference in bed days were used for the calculation – see table below.

	Mean LOS		Difference in LOS (days)		LOS used to calculate costs (days)	Cost of hospital day	Cost of difference in LOS per person
	Specialist group n=40	Usual care group n=54	Mean	Median			
Whole Cohort (n=94)	12.33	22.93	10.6	10.5	11	380	£4,180
Moderate/severe TBI (n=54)	17.66	30.57	12.91	14.5	13	388	£5,044
Minor TBI (n=40)	4.17	15.16	10.99	7.5	8	440	£3,520

Therefore, the average cost of a day in hospital in 2007 due to traumatic brain injury (TBI) was between £380 -£440 depending on the severity of injury – see above table. The difference between groups in length of hospital stay was between 8-13 days depending on severity of injury. Using the lowest difference in LOS, the health and social care costs of the usual care group needed to be increased by £3,520 to £5,044 to account for the longer hospital stay. If the cost of the length of hospital stay were included in the economic evaluation, the difference would alter the cost effectiveness analysis in favour of the specialist group – see 5.4.1.5.