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**Communication and quality of life outcomes
in people with acquired brain injury
following project-based treatment**

VOLUME 1

Nicholas Behn

**Thesis submitted in fulfilment of the requirements
for the degree of Doctor of Philosophy**

City University London

Division of Language and Communication Science

June, 2016

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Declaration

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Abstract

Communication impairments are common following acquired brain injury (ABI) and have a significant impact on a person's quality of life (QOL) post-injury. While some treatments have improved communication skills, few have measured QOL, and even fewer have shown improved QOL for people with ABI following communication-based treatments. Project-based treatment is an alternative treatment approach that could have an impact on communication skills and QOL for people with ABI who are long-term post-injury. The treatment is embedded in a context of meaningful activities chosen by people with brain injury, whereby, as a group, they work collaboratively to plan and achieve a concrete goal or outcome that contributes others and/or the wider community. Project-based treatment has not been empirically evaluated for people with ABI. More specifically, no research has evaluated whether projects can improve both communication skills and QOL in people with ABI. Therefore, this research aims to evaluate the effectiveness of project-based treatment on the communication skills and QOL for people with ABI.

An exploratory study was designed as a prospective quasi-randomised controlled trial with pre, post and follow-up assessments, using mixed methods, and feasibility testing to investigate the effect of project-based treatment. Twenty-one people with ABI were recruited from community settings, allocated to either a TREATMENT (n=11) or WAITLIST group (n=10). Treatment was completed over 6 weeks and comprised an individual session (to set specific communication goals with the person with ABI and their communication partner), followed by nine sessions conducted in groups of 2-3 people. These sessions involved a range of meaningful activities chosen

by people with ABI that contributed to a tangible end product designed to help others (e.g. video, pamphlet, radio podcast, piece of art).

Mixed methods were used to determine the effect of the treatment on people with ABI. The primary communication outcomes were: (1) Blind ratings of the person with ABI's conversations on the Interaction and Transaction scales of the Adapted Measure of Participation in Conversation (MPC). The secondary communication outcomes were: (1) Blind ratings of the communication partner's involvement in conversations on the Acknowledging and Revealing Competence scales of the Adapted Measure of Support in Conversation (MSC); (2) Blind ratings for the Impression scales that described how appropriate, rewarding, effortful, and interesting a conversation was; (3) La Trobe Communication Questionnaire (LCQ) as rated by the person with ABI, and their communication partner; and (4) Goal Attainment Scaling (GAS). The primary QOL outcome was the Satisfaction With Life Scale (SWLS), and the secondary QOL outcome was the Quality of Life in Brain Injury (QOLIBRI) measure. The qualitative data was drawn from semi-structured interviews conducted post-treatment.

The first set of analyses for the primary and secondary outcome measures, compared the TREATMENT group with the WAITLIST group over two time points, between which only the TREATMENT group had received the treatment. This showed that people with ABI in the TREATMENT group had improved Interaction scores on the MPC, their communication partners had improved Revealing Competence scores on the MSC, and the conversation was perceived as less effortful, compared to the WAITLIST group. No changes were found for the remaining communication outcomes, or the QOL outcomes. The second analyses compared pre-treatment, post-treatment, and follow-up scores across all people with ABI (i.e. scores for both the TREATMENT and WAITLIST group were combined). This showed significant changes for

communication partners on the MSC and LCQ, and significant achievement of communication goals on GAS, as rated by both the person with ABI, and their communication partners. Significant improvement on the QOLIBRI was found, with a trend towards significance on the SWLS. No other significant changes were found. Qualitative data was analysed using content analysis where the content and context of the interview transcripts were analysed and themes identified. People with ABI described overwhelmingly positive experiences of the treatment, the group, the project, and working on goals. They also described a range of positive benefits including improved awareness and skill, and positive feelings.

Project-based treatment made modest improvements to both communication skills, and QOL. Moreover, people with ABI perceived positive experiences, and benefited from inclusion in the treatment. While this study was an exploratory trial, with feasibility testing, the results highlight that this treatment could be a potential alternative to other treatments available to people with ABI.

Chapter 1 Introduction

1.1 Acquired brain injury (ABI)

Acquired brain injury (ABI) is a global health problem that leads to lifelong disability and affects the provision of health and medical resources (Bruns & Hauser, 2003; Corrigan, Selassie, & Orman, 2010; Hyder, Wunderlich, Puvanachandra, Gururaj, & Kobusingye, 2007). The term ABI refers to both non-traumatic and traumatic injuries. Non-traumatic brain injuries include “those caused by strokes and other vascular accidents, tumours, infectious diseases, hypoxia, metabolic disorders (e.g. liver and kidney diseases or diabetic coma), and toxic products taken into the body through inhalation or ingestion” (United Kingdom Acquired Brain Injury Forum, 2015). Traumatic brain injuries (TBI) are defined as “an insult to the brain... caused by an external physical force... which results in an impairment of cognitive abilities or physical functioning. It can also result in the disturbance of behaviour or emotional functioning. These impairments may... cause partial or total functioning disability or psychosocial maladjustment” (Harrison & Dijkers, 1992, p.206).

In the UK, there were 348,934 admissions to hospitals in 2013-14 with a diagnosis of an ABI, which equates to 556 people per 100,000 (Headway, 2015). Since 2005-6, the number of people admitted to UK hospitals with the diagnosis of ABI has risen by 10%. There has been an increase in TBIs alone of 6% from 154,067 admissions in 2005-06, to 162,544 in 2013-14. Overall, over 3 million people have been admitted to UK hospitals with a diagnosis of ABI since 2005-06, traumatic injuries accounting for approximately half. Many of these people will require on-going services, and rehabilitation to address the difficulties that they encounter post-injury.

1.1.1 Classification of ABI

Severity of brain injury can only be classified for traumatic cases. Severity is assessed with indicators that measure depth and duration of coma, and the presence and length of posttraumatic amnesia (PTA). Measurements provide a classification from mild, moderate, severe through to very severe. For the purposes of this study, two indicators of severity were used. The first, PTA refers to the period following emergence from coma where the person can be confused, disorientated and agitated (Russell & Smith, 1961). Assessed either retrospectively or prospectively, periods of less than an hour indicate a mild injury, 1-24 hours a moderate injury, 1-7 days a severe injury and 1-4 weeks a very severe injury (Jennett & Teasdale, 1981). The second indicator used to measure severity was the Glasgow Coma Scale (GCS), which is taken at the time of injury (Jennett & Teasdale, 1981). A person is given a score from 3 to 15 based on their degree of eye opening, motor and verbal responses. An initial score at the time of injury of 8 or less is used to indicate a severe injury, 9-12 a moderate injury and 13-15 a mild injury.

1.1.2 Characteristics of ABI

ABIs give rise to a range of impairments that include communication, cognitive, behavioural, and emotional changes as a result of damage to the brain (Levin & Kraus, 1994; Sohlberg & Mateer, 2001). For 20-83% of people with ABI, these changes post-injury can be permanent resulting in reduced QOL, and poor psychosocial outcomes (Prigatano, 1999). As a result, managing people with ABI can often be difficult as they present as a heterogeneous group. The pattern of deficits can often vary quite considerably amongst individuals. Prigatano (1986) identified six areas of cognitive disturbance that can occur following ABI. These include disorders of attention and

concentration, difficulty in planning goal-directed activities, problems with judgement and perception of others actions, and disorders of learning and memory, information processing and communication. He also classified four broad areas of behavioural disturbance that can have an impact on the rehabilitation process. These include anxiety, lack of self-awareness of difficulties, agitation and affective problems that can result in depression and low self-esteem. The person with ABI can lack initiation, drive and motivation, be disruptive, restless and perseverative, lack self-control and empathy, be concrete, rigid and egocentric with poor self-monitoring and regulation of behaviours (Wood, 2001).

Many of the communication, cognitive, behavioural, and emotional changes associated with brain injury are often the result of damage to the frontal and temporal lobes, and represent the most prevalent problems observed during the rehabilitation process (Wood, 2001). According to Ylvisaker, Turkstra and Coelho (2005), “behavioural and social changes are often judged by family members, teachers, employers, friends and others to be the most problematic consequence of the injury” (p.257). As a result, people with brain injury require rehabilitation to deal with the impact of these changes.

1.2 Communication impairments

Impaired communication can be the result of damage to the brain following ABI. ‘Cognitive-communication disorder’ (CCD) (Hartley, 1995), is an internationally recognised term used to describe communication problems after brain injury (American Speech Language and Hearing Association, 2005; College of Audiologists and Speech-Language Pathologists of Ontario, 2002; Enderby et al., 2009). It distinguishes between communication problems resulting primarily from cognitive impairments, and from

those that result from motor speech and language impairments, as is the case in aphasia from stroke. The incidence of CCDs for people with ABI has been reported to be as high as 80-100% (Halper, Cherney, & Miller, 1991; Sarno, 1980; Sarno, Buonaguro, & Levita, 1986) and these changes in communication persist for years post-injury (Bond & Godfrey, 1997; Knox & Douglas, 2009; Oddy, Coughlan, Tyerman, & Jenkins, 1985; Olver, Ponsford, & Curran, 1996; Shorland & Douglas, 2010; Snow, Douglas, & Ponsford, 1998).

A panel of nine experts from the American Speech and Hearing Association (ASHA) defined CCDs as those that “encompass difficulty with any aspect of communication that is affected by disruption of cognition. Communication includes listening, speaking, gesturing, reading and writing in all domains of language (phonologic, morphologic, syntactic, semantic and pragmatic). Cognition includes cognitive processes and systems (e.g. attention, memory, organisation, executive functions). Areas of function affected by cognitive impairments include behavioural self-regulation, social interaction, activities of daily living, learning and academic performance and vocational performance” (American Speech Language and Hearing Association, 2005, p.2). This definition highlights the importance of non-linguistic cognitive processes, which affect language use. Such processes contrast with the linguistic aspects of communication (i.e. syntax, morphology). While the latter may be impaired following ABI (McDonald, Togher, & Code, 2014), they tend to be a site of relative preservation.

The clinical presentation of a person with a CCD is complex and highly heterogeneous (Snow, Douglas, & Ponsford, 1997), reflecting the cause of injury, severity and extent of fronto-temporal pathology and the diffuse nature of the injury (Prigatano, 1999). In conversation, people with ABI have been described as

overtalkative (Coelho, Liles, & Duffy, 1991b; Galski, Tompkins, & Johnston, 1998; Hartley & Jensen, 1991; Snow, Douglas, & Ponsford, 1995), tangential (Coelho, Liles, & Duffy, 1991a; Mentis & Prutting, 1991), repetitive (McDonald, 1993; Snow et al., 1995), disorganised (Coelho et al., 1991a; Coelho et al., 1991b; McDonald, 1993; Mentis & Prutting, 1991), inefficient (Hartley & Jensen, 1991), and lacking in verbal output (Hartley & Jensen, 1992; McDonald, 1993; Snow et al., 1997). Particular problems in word retrieval have also been identified (Campbell & Dollaghan, 1990; Hartley & Jensen, 1991; King, Hough, Walker, Rastatter, & Holbert, 2006; Snow et al., 1995). Further difficulties arise in social appropriateness (Spence, Godfrey, Knight, & Bishara, 1993) and topic management (Mentis & Prutting, 1991), with the latter including difficulty taking appropriate turns (Coelho et al., 1991a; Mentis & Prutting, 1991; Snow et al., 1995, 1997), initiating, maintaining and extending a conversation (Coelho et al., 1991a; Snow et al., 1997, 1998).

As well as impaired conversational skills, the other aspect of communication frequently affected after an ABI is social perception, which refers to the ability to read social cues to make judgements about the behaviour, attitudes and emotions of others (McFall, 1982). A person with brain injury who has impaired social perception may present as rude and impolite, egocentric and self-centred, lack interest in others, display inappropriate humour and have poor social awareness (McDonald, Honan, Kelly, Byom, & Rushby, 2014). This presentation emerges as people with ABI find it difficult to infer information, be subtle and indirect (Johnson & Turkstra, 2012; McDonald, 1992), recognise emotion in others (Croker, 2005), and interpret the mental state of other people (Bibby & McDonald, 2005; Havet-Thomassin, Allain, Etcharry-Bouyx, & Le Gall, 2006; Henry, Phillips, Crawford, Ietswaart, & Summers, 2006; Saxton, Younan, & Lah, 2013).

Cognitive problems, that are common post-injury, also contribute to problems with communication (McDonald, Togher, et al., 2014; Sohlberg & Mateer, 2001). The specific areas of cognition implicated are impaired working memory and attention, slowed processing time and executive dysfunction (Bibby & McDonald, 2005; Coelho, Ylvisaker, & Turkstra, 2005; Coelho, Liles, & Duffy, 1995; Douglas, 2010b; Havet-Thomassin et al., 2006; Henry et al., 2006; Johnson & Turkstra, 2012; McDonald & Pearce, 1998; Moran & Gillon, 2005; Struchen, Clark, et al., 2008). As the cognitive disturbances can vary amongst people with ABI, so can the communication patterns (Snow et al., 1997). Changes in cognition and behaviour have often been described in terms of deficiencies and excesses (Lane-Brown & Tate, 2011; Tate, 1999), which can be translated into different communication patterns. A person with behavioural *deficiencies* may not initiate conversation, be unable to generate ideas, and have a flat affect exhibiting little interest in the interaction (Sohlberg & Mateer, 2001). A person with behavioural *excesses* may be disinhibited in their verbal responses, talk excessively, be tangential, repetitive and frequently interrupt others during conversation. Deficiencies and excesses have been shown to manifest in verbal communication tasks of information giving (Snow et al., 1997) and discourse (Sim, Power, & Togher, 2013), wherein participants either tended to provide limited information and struggle to contribute to the conversation, or provide excessive information and dominate the conversation.

Changes to communication pose a particular challenge for people with brain injury who face problems developing social networks (Elsass & Kinsella, 1987), forming new friendships and relationships (Zencius & Wesolowski, 1999), and have increased feelings of loneliness, social isolation and low self-esteem (Hoofien, Gilboa, Vakil, & Donovan, 2001; Leith, Phillips, & Sample, 2004; Oddy et al., 1985; Olver et

al., 1996; Shorland & Douglas, 2010). These social participation problems may occur as conversations involving people with ABI have been considered to be less appropriate, rewarding, and interesting (Bond & Godfrey, 1997). For example, increased pragmatic errors during conversation, impaired discourse, and difficulty processing non-verbal cues such as a person's facial expression have been shown to be associated with reduced social integration (Galski et al., 1998; Knox & Douglas, 2009; Snow et al., 1998). Moreover, people with ABI can perceive many of these impairments (Dahlberg et al., 2006). The changes to communication, and conversations have a significant effect on a person's QOL, particularly in areas of social functioning, social integration into the community, and return to work which is now discussed below (Galski et al., 1998; Meulenbroek & Turkstra, 2015; Rietdijk, Simpson, Togher, Power, & Gillett, 2013; Snow et al., 1998).

1.3 Quality of life (QOL) in ABI

The communication, cognitive, behavioural and emotional changes that follow ABI typically impact upon a person's QOL, which researchers have often found difficult to define. Part of the problem lies in the fact that "QOL means different things to different people" (Dijkers, 2004, p.S21). The World Health Organisation has defined QOL as: "...an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns..." (WHOQoL Group, 1993). Although this definition is internationally accepted, researchers still disagree with how QOL should be defined, and operationalised (Dijkers, 2004).

Broadly speaking, there are two approaches to defining QOL. The first, Health-Related QOL (HRQOL), describes the effect of the health condition on a person's QOL

(Bullinger, 2002). Outcomes that measure HRQOL can be described as: (1) generic (i.e. non-condition specific) or disease-specific (i.e. condition specific); (2) multi-dimensional (measuring several dimensions of a person's life) or uni-dimensional (focusing on a single dimension of a person's life); and (3) objective or subjective, despite there being little association between the two (Cicerone, Mott, Azulay, & Friel, 2004; Johnston, Goverover, & Dijkers, 2005). The second approach, subjective well-being (SWB), refers to the "reflection of the way that patients perceive and react to their health status and to other, nonmedical aspects of their lives" (Gill & Feinstein, 1994). In this sense, SWB is viewed as a construct larger than HRQOL where it can be affected independently of the person's medical condition (Figure 1.1)(Johnston & Miklos, 2002). SWB outcomes can describe: (1) overall QOL in a single item; (2) cognitive features e.g. life satisfaction or; (3) affective features e.g. happiness, morale, positive and negative affect. While improved SWB is often treated as the ultimate goal of rehabilitation (Johnston et al., 2005), Gill and Feinstein (1994) would suggest including a measure of HRQOL.

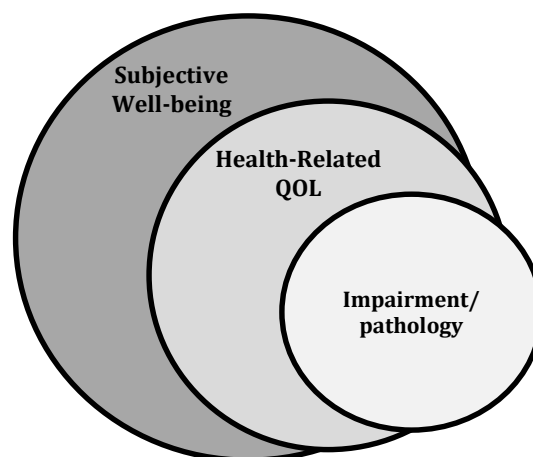


Figure 1.1. Conceptualisation of QOL

Treatment evaluations should include a measure of QOL, which has been proposed as one of the best indicators for the value of health-related treatments (Gill & Feinstein, 1994). Evaluations should include measures of both HRQOL and SWB. While HRQOL outcomes can have implications for the medical, health-related needs of a patient, SWB outcomes can have implications for the non-medical, social and community needs of a patient. Analysis of commonly used outcomes for people with ABI revealed that professionals use a combination of HRQOL and SWB outcomes (Corrigan & Bogner, 2004). HRQOL outcomes commonly being used tend to measure activity and participation levels, while life satisfaction tools being used measure SWB. Studies have shown that the relationship between HRQOL and SWB outcomes is weak-to-moderate (Brown & Vandergoot, 1998; Dawson, Levine, Schwartz, & Stuss, 2000), highlighting that the concepts represent quite distinct and dissociable areas of QOL, and should both be considered when evaluating the effect of rehabilitation.

Both HRQOL and SWB are significantly affected for people many years following their brain injury. Compared to a group of non-injured people, and people with spinal cord injury, Brown and Vandergroot (1998) found that 430 people at 10 years post-injury reported a lower SWB, and furthermore this did not improve over time. Lower life satisfaction was reported for a group of 67 people with ABI, up to 15 years post-injury, compared to a population reference sample (Jacobsson & Lexell, 2013). Similarly, Tomberg, Toomela, Pulver and Tikk (2005) found that people with brain injury reported lower levels of HRQOL compared with a control group at 2 years post-injury, which did not change at 6 years post-injury (Tomberg, Toomela, Ennok, & Tikk, 2007). Some improvements tend to occur early post-injury particularly as physical health improves (Pagulayan, Temkin, Machamer, & Dikmen, 2006). However, QOL remains poor if other effects of the brain injury (e.g. cognitive, emotional) remain

persistent and pervasive (Gould, Ponsford, Johnston, & Schonberger, 2011; Kalpakjian, Lam, Toussaint, & Merbitz, 2004; Whelan-Goodinson, Ponsford, & Schönberger, 2008).

Understanding QOL is particularly important for chronic conditions where there is only partial or temporary amelioration of symptoms (Ebbs, Fallowfield, Fraser, & Baum, 1989). It can help to provide an indicator of the impact of the disease, the treatment regime and the recovery on an individual's life (Bowling, 2001; DePalma, 2001). Moreover, understanding QOL has implications for the provision of services for social and health-related needs. The aim of any medical treatment is not only to increase survival rates, but also add quality to that survival, which relates to patient satisfaction, and how a person feels (Bowling, 2001; Fuhrer, 2000).

Over the last few decades, the importance of measuring QOL for people with ABI has grown, with many researchers investigating the factors that influence QOL. One factor most strongly associated with QOL is a person's emotional state (Steadman-Pare, Colantonio, Ratcliff, Chase, & Vernich, 2001), with depressive symptoms more strongly associated than anxiety symptoms (Stålnacke, 2007). Symptoms of depression have been shown to follow different patterns (e.g. emerging, resolved, and chronic emotional state) that can affect QOL in different ways over time (Hibbard et al., 2004). A second factor consistently shown to be moderately associated with QOL is participation (Burleigh, Farber, & Gillard, 1998; Corrigan & Bogner, 2004; Heinemann & Whiteneck, 1995; Pierce & Hanks, 2006; Steadman-Pare et al., 2001). Improving a person's participation, or community integration (e.g. in social and leisure activities, employment or education), has often been considered an important part of the rehabilitation process involving people with ABI (Corrigan & Bogner, 2004; Dijkers, 2010; Salter, McClure, Foley, & Teasell, 2011; Schipper, Visser-Meily, Hendrikx, &

Abma, 2011). These two factors combined, emotional state and participation, are often referred to in the research as psychosocial factors, and have been focussed in studies that examine QOL in people with ABI (Berger, Leven, Pirente, Bouillon, & Neugebauer, 1999).

There is a range of other factors shown to be less associated with QOL. Levels of activity (Corrigan & Bogner, 2004; Heinemann & Whiteneck, 1995; Johnston et al., 2005; Pierce & Hanks, 2006), and social support (Stålnacke, 2007; Steadman-Pare et al., 2001) are weakly associated with QOL. Little to no association has been found between QOL and indices of impairment including, severity of injury (Heinemann & Whiteneck, 1995), cognitive functioning (Mailhan, Azouvi, & Dazord, 2005; Steadman-Pare et al., 2001), levels of fatigue (Cantor et al., 2008), and mobility post-injury (Steadman-Pare et al., 2001). Fixed factors such as marital status (Pierce & Hanks, 2006; Steadman-Pare et al., 2001), gender (Steadman-Pare et al., 2001), level of education (Brown & Vandergoot, 1998; Pierce & Hanks, 2006; Steadman-Pare et al., 2001), ethnicity (Pierce & Hanks, 2006), and age at time of injury (O'Neill et al., 1998; Steadman-Pare et al., 2001), have also been shown to have little to no association with QOL.

Research examining factors has led researchers to investigate predictive models of QOL. Some found that objective levels of functioning, combined with fixed factors tended to only predict 13-17% of the variance in QOL (Corrigan, Bogner, Mysiw, Clinchot, & Fugate, 2001; Heinemann & Whiteneck, 1995; Pierce & Hanks, 2006). In each of these studies participation alone explained up to 12% of the variance. Other studies have identified factors that can predict 47-55% of the variance in QOL (Cicerone & Azulay, 2007; Rutterford & Wood, 2006; Steadman-Pare et al., 2001). The strongest of these models found that mental health, self-rated health, gender, work and

leisure, and emotional support predicted 55% of the variance (Steadman-Pare et al., 2001). As research into predictive models has developed, other factors not previously considered to influence QOL have emerged including, satisfaction with participation levels (Cicerone & Azulay, 2007), coping (Rutterford & Wood, 2006), perceived self-efficacy (Cicerone & Azulay, 2007; Rutterford & Wood, 2006), and family functioning (Vangel, Rapport, & Hanks, 2011). QOL is clearly underpinned by a range of factors, with no clear consensus to date about which are the most influential. Such a consensus would be extremely valuable for clinicians, in that it would help them to target areas that most impact on QOL. One factor that consistently plays a role is social participation. This in turn suggests that treatments engaging the person in participation in some way may have a greater prognosis for success than treatments focusing purely on a person's impairments.

1.4 Approaches to rehabilitation for people with ABI

There are a range of approaches to rehabilitation that aim to address the communication, cognitive, emotional, and behavioural changes, and QOL of people with ABI post-injury. These include early inpatient rehabilitation, comprehensive holistic rehabilitation programmes which can be administered at various time points in the recovery process, and community-based leisure and social activities. Each approach addresses the impairments, and QOL of people with ABI differently, dependent on the point in time of a person's recovery following an injury (Chestnut, Carney, Maynard, Patterson, & Mann, 1998).

Early inpatient rehabilitation aims to treat people with ABI as soon as they are medically stable and discharged from acute care as recovery in the first 3 months post-injury is greatest (Gentleman, 2001). Therapies typically provide intensive,

multidisciplinary care that focuses on remediating the range of cognitive, physical, emotional, and communication impairments that can occur (Chestnut et al., 1998). To provide this treatment, a range of professionals are involved including, Speech and Language Therapists, Psychologists, Occupational Therapists, and Physiotherapists. Treatment outcomes at this stage tend to be related to functioning, with QOL issues more health-related (Bullinger, 2002). However, impairments are known to persist long-term despite early inpatient rehabilitation (Fleming, Tooth, Hassell, & Chan, 1999; Knight, Devereux, & Godfrey, 1998; Levin & Kraus, 1994; Lippert-Grüner, Kuchta, Hellmich, & Klug, 2006; Oddy & Humphrey, 1980; Olver et al., 1996; Sohlberg & Mateer, 2001; Wood & McMillan, 2001). Of all people discharged from hospital with the diagnosis of an ABI, it is estimated that 43.3% would develop some long-term disability (Selassie et al., 2008). Lippert-Grüner et al. (2006) found that changes such as agitation, inaccurate insight, emotional withdrawal, disinhibition, depressive mood, memory deficits, decreased initiative and poor planning persisted 6-12 months into the future, despite early rehabilitation that lasted between 4 and 78 days. Olver et al. (1996) found that at 5 years post-injury, 103 people with ABI who had on average 9 months of inpatient rehabilitation, felt more irritable, short-tempered or aggressive (66%), forgetful (71%), slower at thinking (69%), had poor concentration (60%), experienced fatigue more often (73%), had inappropriate social behaviours (36%), and were depressed (56%) compared to pre-injury. Family members have reported similar reduced functioning on average 6 years post-injury (Knight et al., 1998). Therefore, services are required to address the problems that can occur long-term post-injury (Hodgkinson, Veerabangsa, Drane, & McCluskey, 2000).

Comprehensive-holistic rehabilitation programmes can produce positive outcomes for people with brain injury both early post-injury, and years later (Cicerone

et al., 2005; Cicerone et al., 2011; Cicerone et al., 2004; Geurtsen, van Heugten, Martina, & Geurts, 2010; Geurtsen et al., 2012; Geurtsen, van Heugten, Meijer, Martina, & Geurts, 2011; Malec, 2001; Sander, Roebuck, Struchen, Sherer, & High, 2001; Worthington, Matthews, Melia, & Oddy, 2006). These programmes provide comprehensive, integrated, and intensive neuropsychological-based treatments to address the range of cognitive, emotional, and communication impairments that occur long-term. The treatments can include a combination of individual and group formats, may be psychosocially or vocationally oriented, and aim to develop a person's awareness of their difficulties, set realistic life goals, and to adjust to their new life having sustained an ABI (Cicerone et al., 2000). The focus of these programmes is less on restoration, and more on learning how to use existing skills and abilities to compensate for residual impairments. These programmes are not successful because of any individual component, but from the programme as a whole (Nilsson, Bartfai, & Löfgren, 2011). Systematic reviews have recommended these programmes as a practice standard for people with ABI, highlighting that they provide some of the best evidence for improvements in health-related outcomes, including social participation and QOL (Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011). Other researchers have highlighted their cost-effectiveness for health authorities (High Jr, 2005; Worthington et al., 2006). However, in the UK the mean cost of these programmes can range from £69-75K per treated individual, if admitted less than 2 years post-injury, to £81K per treated individual, if admitted greater than 2 years post-injury (Worthington et al., 2006), meaning that they are not always financially feasible in some rehabilitation settings (Ownsworth, Fleming, Shum, Kuipers, & Strong, 2008).

After rehabilitation, some services provide community, leisure and social activities to help fill a person's time, reduce social burden, and improve QOL (Douglas,

Dyson, & Foreman, 2006; Fines & Nicholas, 1994; Mitchell, Veitch, & Passey, 2014). Participation in social and leisure activities is increasingly recognised as an important determinant of QOL (Royal College of Physicians and British Society of Rehabilitation Medicine, 2003; Steadman-Pare et al., 2001). Services may include fitness programmes, adventure course programmes, social peer mentoring, leisure education, or individually brokered leisure activities (Tate, Wakim, & Genders, 2014). These programmes are not intended to remediate, or compensate for impairments, but rather provide an opportunity for people to socialise, meet new people, communicate ideas, and improve mental health. A recent systematic review concluded that there is some evidence that leisure and social activities can improve mood and QOL (Tate, Wakim, et al., 2014) however, the evidence base is limited and further well-designed studies are needed. While the key focus for many of these services was on improving QOL, they failed to address impairments in communication, even though there were opportunities for social interaction with others. The authors of the review (Tate, Wakim, et al., 2014) acknowledged that many of the studies they identified had carefully planned out the social and leisure activities being undertaken but, felt that the programmes needed to be even more specific and focused on leisure activity, more structured and goal-driven, and intensive.

The complex effects of CCDs, both on communication with others, and QOL, call for complex treatments, that can make changes to both areas. The evidence base for treatments to remediate communication skills after an ABI is rapidly expanding (Togher et al., 2014). Many systematic reviews have targeted impaired communication skills as the subject of remediation in treatment studies (Blake, Frymark, & Venediktov, 2013; Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011; Coelho, DeRuyter, & Stein, 1996; MacDonald & Wiseman-Hakes, 2010; Rispoli, Machalicek, & Lang, 2010;

Rohling, Faust, Beverly, & Demakis, 2009; van Heugten, Gregório, & Wade, 2012; Ylvisaker et al., 2005; Ylvisaker, Turkstra, et al., 2007). However, many of the studies in these reviews are concerned with remediation of linguistic deficits, rather than remediation of CCDs, and social communication skills. Moreover, few studies have addressed both communication skills, and QOL. The evidence base for treatment of CCDs is currently limited, and needs to be stronger methodologically (Struchen, 2014). Treatments for people with ABI with CCDs should be individualised, with person-centred goals, using techniques that take a person's cognitive and emotional status into account, and view communication within a broader context (Togher et al., 2014).

An alternative treatment approach to the less focused social and leisure activities and thus responds to some of the criticisms of Tate et al. (2014), and could potentially have an impact on both communication skills *and* QOL, is project-based treatment (Ylvisaker, Feeney, & Capo, 2007). This treatment is embedded in a context of meaningful activities chosen by people with ABI, whereby, as a group, they work collaboratively to achieve a concrete goal or outcome that contributes others and/or the wider community. The context of the project produces activities and roles for people where they are recognised as an expert or helper, provide an opportunity to use skills in planning and organisation that results in products useful for others, and offers opportunities for social engagement and communication with others (Feeney & Capo, 2010). The concept of project-based learning is not new. The approach is commonly used in education (Blumenfeld et al., 1991; Kolmos, 1996; Markham, 2011), and has been used therapeutically to improve QOL for people with ABI (Cherney, Oehring, Whipple, & Rubenstein, 2011; Vandiver & Christofero-Snider, 2000; Walker, Onus, Doyle, Clare, & McCarthy, 2005), and older people in residential care settings (Gleibs, Haslam, Haslam, & Jones, 2011; Knight, Haslam, & Haslam, 2010). To date though,

project-based treatment has not been empirically evaluated for people with ABI, as the above studies did not include control groups. More specifically, no research has evaluated whether projects can improve *both* communication skills and QOL in people with ABI. Therefore, the next section of the thesis will examine this treatment approach in more detail.

1.5 Project-based treatment

Project-based treatment is an alternative treatment that offers the opportunity to address the range of cognitive, emotional, behavioural, and communication impairments that occur following an ABI, all of which can impact on a person's QOL. Project-based treatment is not underpinned by a specific theory, but rather describes an approach that addresses a wide range of needs that are common post-injury. Within this approach, Feeney & Capo (2010) define a project as “a personally meaningful activity that results in the accomplishment of a specific and objective personal goal” (p.74). The project is intended to help fill a person's time with activities and tasks that are meaningful, motivating, and engaging for the person with ABI. Projects involve the development of a tangible end product that helps others such as completing a marathon to raise money for a charity, creating an information booklet about an issue of concern, or building a barbeque for a local rehabilitation unit. Moreover, projects provide a context in which people can practise communication skills.

1.5.1 Features of project-based treatment

An early operational definition of project-based treatment contained 10 features for applying the approach to people with ABI (Ylvisaker, Feeney, et al., 2007), that was later synthesised into three main features, that are commonly used (Feeney & Capo,

2010). These include: (1) the development of projects that require skills in planning, organising and executive function, and which result in a product that is considered helpful to others; (2) the identification of activities that create roles for participants where they are considered an expert or helper and; (3) the identification of a project that provides an opportunity for socialising and a context for practising communication skills. Project-based treatment is considered a broad intervention where people with ABI can learn and practise a range of communication, cognitive, behavioural, and emotional skills, which may be impaired following a brain injury (Feeney & Capo, 2010; Ylvisaker, 2006; Ylvisaker, Feeney, et al., 2007).

From a communication perspective, people with ABI are supported to interact and co-operate with others, express their own ideas and opinions, and gain peer feedback within a small group, in order to complete a project. These skills are important for socialising and forming relationships with others. These communication skills are encouraged, in combination with autonomy, choice and control, competence in activities, all factors that positively affect a person's intrinsic motivation and lead to improved QOL (Ryan & Deci, 2000).

From a cognitive perspective, people with ABI are given the opportunity to practise using a range of planning systems, organisational and memory strategies, and scaffolds to solve functional problems. They are encouraged to self-monitor and reflect on their actions, which are important for improving impaired executive function. The process of working on projects involves asking questions, formulating goals and objectives, debating ideas, identifying problems and solutions, making predictions, planning, designing and organising a project or experiment, collecting information, drawing conclusions and communicating ideas and findings with others (Blumenfeld et

al., 1991; Kolmos, 1996). All these processes and strategies are designed to enhance a deeper understanding of learnt information and improve competence in thinking.

From a behavioural and emotional perspective, group projects help to address oppositional and egocentric attitudes, impaired initiation and drive, problems with anxiety and self-esteem, and disinhibited behaviour. They help to enhance motivation and interest within a meaningful and engaging context. Moreover, creating roles within the project may help to reconstruct a person's identity. For example, undertaking expert and helper roles may transform a self-concept dominated by feelings of incompetence, and helplessness. Combined, these roles help to construct a renewed sense of self, which is intrinsically motivating, emotionally satisfying and consistent with their pre-injury understanding of self (Ylvisaker & Feeney, 2000).

1.5.2 Project-based treatment in education

The concept of project-based treatment is not new and is derived from education, and classroom teaching in schools where project-based learning has been popular. This form of learning is an approach that is student-led, collaborative and motivating. Markham (2011) highlights that "project-based learning integrates knowing and doing. Students learn knowledge and elements of the core curriculum, but also apply what they know to solve authentic problems and produce results that matter" (p.38). In that sense, project-based learning is about the real-life application of what the students have learnt. It requires a driving question that is meaningful, generated by the students, that organises the activities of a group and these activities result in a final product or artefact that addresses that driving question (Blumenfeld et al., 1991). Final products tend to involve public events or displays such as a play, writings, art, videos, photography, or a multimedia presentation.

The teacher plays an integral role in facilitating the use of strategies to complete a project by using their enthusiasm and expertise in group facilitation. This expertise is used to provide opportunities for learning through scaffolding instruction and helping students to identify the driving question, to suggest ways to present the information in an end product, and to facilitate the students in planning, organising, executing and evaluating the project tasks. The teacher is critical for supporting the students learning experience to ensure they remain focused, motivated, and have a deep understanding of the taught skills (Blumenfeld et al., 1991).

The interest and value attributed by students to the project will effect their level of motivation and engagement. Project-based learning enhances this by ensuring the project is of personal relevance to the student, is meaningful, has closure with an end product, and has an optimal level of challenge (Blumenfeld et al., 1991). Advances in technology also provide a mechanism for improving student interest and motivation and completion of a more powerful project (Blumenfeld et al., 1991; Markham, 2011). Technology can make information more real and accessible, allow for multiple representations of concepts, and help students to think about the choices they make thus, providing an opportunity for learning. In that sense, technology can help teachers to sustain a student's motivation while completing a project.

1.5.3 Project-based treatment in ageing

To further identify the potential effects of projects, there is some research in other fields including older adults without dementia, where the use of projects has been broadly described. Presented here are a few key examples of studies that have used projects with this group of people, which have demonstrated improved physical health and life satisfaction (Knight et al., 2010), increased perceived social support and

reduced general practitioner calls (Gleibs et al., 2011), and given a sense of purpose and meaning to the people involved (Allen, 2009; Southcott, 2009).

Making collaborative decisions improved QOL for residents in a care home. Knight et al. (2010) found that a group of 27 older people without dementia reported significant improvements in physical health and life satisfaction, when involved in making decisions about the décor in shared rooms within a residential care home for individuals without brain injury, compared to a control group. Residents involved in making decisions about the décor were more engaged with others, and happier, as reported by staff. Moreover, they reported increased identification with staff and other residents. These results were sustained for 4 months after the changes were made to the décor. The authors highlighted how the process had encouraged residents to feel empowered to make their own decisions, to socially interact more frequently with others, and facilitate an activity that gave them a sense of structure and meaning in their lives.

A second study examining older adults reported improved social support and physical health from involvement in a project (Gleibs et al., 2011). The study was designed as a pre-test post-test design in which four conditions were compared (water social club; control social club; water solo; control solo). Improved levels of perceived social support, and fewer general practitioner calls were found for 13 older adults without dementia, in a care home involved in a project group focused on increased water consumption (i.e. water social club). The group met weekly for 20-30 minutes over 8 weeks to share facts about water intake and discuss the problems and benefits of drinking more water. No changes were found for older adults who received a similar treatment (N=11) in a one-to-one setting (i.e. water solo), highlighting the importance of a group context to facilitate communication between participants, and engagement

with, session activities. Fewer general practitioner calls were reported in a control social group (N=12) that didn't focus on water intake (i.e. control social club), but there were no changes to perceived social support. Therefore, the project focus on increased water consumption provided more than the group alone. Participants were able to share information about the benefits of drinking water, and as suggested by the researchers, helped to create a sense of social identity and increased sense of social belonging as evidenced by the increased social support.

A group of older people described improvements to their QOL from being part of a choir group, and actively engaging with others (Southcott, 2009). As part of the choir, older people would voluntarily perform to residents in care facilities and people with dementia. Three members of the group were interviewed and described a sense of purpose from helping others, feeling useful and, making life meaningful for themselves, and the residents they sing to. Members also recognised that the choir provided an environment for forming meaningful relationships with others, and personal growth. Group members were committed and motivated to learn new musical skills, and they reported that the choir helped to maintain their own cognitive abilities (e.g. memory, alertness).

The construction of a lasting memento of a person's life was found to improve the QOL of chronically ill patients and their families (Allen, 2009). The memento, *or project*, was intended to celebrate a person's life and represent something meaningful to the patient. The paper describes three single case studies, a male aged 67 years with poor health after multiple strokes, and two women, aged 68 years and 70 years, both suffering with cancer. The study described the effect of creating mementos that included a scrapbook, cookbook, and audiotaped life story on improving a person's mood, reducing feelings of being a burden, and giving a sense of meaning to the patient.

Improvements to family communication, and reductions in the stress of caregiving were described through working on the project.

These studies highlight that projects can have an impact on the lives of older people, with respect to their QOL. However, no studies have examined whether projects could have an effect on both communication skills and QOL. Similar to the studies for people with ABI, the evidence base is limited, and requires stronger methodological designs, with two of the studies being weak by using qualitative methods only to demonstrate the positive effects of projects.

1.5.4 Project-based treatment in ABI

Several studies provide examples of project-based treatment, and their effects, using the features outlined above (Feeney & Capo, 2010; Ylvisaker, Feeney, et al., 2007), however, they do not offer empirical data as to the effectiveness of project-based treatment. A range of benefits was reported following project-based treatment for people with ABI in a community support programme (Ylvisaker, Feeney, et al., 2007). In an interview about their experiences, 7 people with TBI (1-14 years post-injury), and history of substance abuse and/or a mental health diagnosis, rated projects as highly meaningful, important to helping others, a good use of time, and for 79% of people, led to other meaningful activities. They also highlighted that projects improved their self-esteem, communication skills, sense of competence, specific project-related skills, and reduced anxiety levels. A group of 11 professionals (occupational therapists, speech-language therapists, case managers, social workers and special education teachers) reported on projects that they had completed, as being designed with the goal of helping others (100%), increasing self-insight (100%), creating an expert role for participants

(93%) filling empty time (92%), facilitating organisational abilities (84%) and enhancing motivation (77%). In every project, they identified an end product.

Two further case studies for people with ABI in a community-based programme illustrate the features of project-based treatment (Feeney & Capo, 2010). The first started as a literacy group, where a group of people with moderate-to-severe brain injury, and history of substance abuse and/or a mental health diagnosis, met to help each other learn or re-learn to read, and write functionally. Further demographic details, or details about participants impairments were not provided. Initially, trainers organised tasks to increase the participants' ability to manage the project independently (e.g. setting meeting times, identifying materials to read). Also, trainers facilitated the group to problem-solve when confronted with different ideas and opinions, and remain positive when faced with challenges. As time progressed, and as participants achieved success in specific reading tasks, they started to identify activities themselves (e.g. choosing materials), assume responsibility for the group, and identify expert roles (e.g. leader). The group provided an opportunity for participants to learn how to socialise and collaborate with each other, actively seek input from others, and respond to constructive and positive feedback. As the literacy group progressed and participants became more confident and competent in managing project-activities, new projects were formed such as the book project with the goal of helping group members enjoy classic books, and the current events group which assisted group members to learn about important events by reviewing newspapers, TV and internet sources.

This second project described above also outlined a single case of a man named Tom (Feeney & Capo, 2010), which is worthy of some further explanation here as it highlights the importance of personal relevance. Tom had sustained multiple brain injuries, including a severe brain injury related to substance abuse, and had a history of

multiple arrests. He presented with significant memory problems. Tom was involved in the literacy group described above, but was passive as he had difficulty understanding, missed key pieces of information, and was tangential and confabulatory when he spoke with others. While he was motivated to be a part of the group, he did not feel he contributed to it, received little benefit, did not feel as if he belonged, and felt bad about himself. As a result of these negative feelings, he was encouraged to work on a new group project, which stemmed from his interest in politics. The idea was that participants would identify important political issues that they could discuss and debate as a group. Tom was involved in organising the activities and leading the group. As a result, Tom was described to have improved memory performance, and social competence, increased confidence, and with the support of staff, created a formal presentation about the project for a workshop at a professional conference.

These early examples of project-based treatment using the features described above demonstrate its potential impact on people with ABI. However, the treatment remains relatively new, all of the above treatment research in ABI originates from one single site in North America, and project-based treatment is not commonly used in clinical practice. Some related studies have broadly explored projects where there is an end product, which people with ABI may or may not help to plan and organise, however these are not explicitly framed within the project-based treatment literature of Ylvisaker et al. (2007). These studies offer some empirical data to support the impact of projects, having shown that post-treatment, people with ABI have better mood and communicative ability (Cherney et al., 2011), improved QOL (Thomas, 2004), increased self-efficacy (Vandiver & Christofero-Snider, 2000), and achieved personal goals (Walker et al., 2005), and are expanded upon below.

Improved communication and mood was reported in a group study of 7 people who participated in a drama project with no control group (Cherney et al., 2011). People were on average 57 years old, 8 years post-injury (6 stroke, 1 TBI), with three presenting with a mild aphasia, and four a moderate aphasia. The group met for 90 minutes over 18 weeks with the aim of staging a performance that helped to explain the experiences of communication problems after stroke to other people. During the sessions, group members described their own personal experiences of having communication problems, created their own scripts, and took on different roles within the final performance including, set development, composition of the musical score, and leading a question-answer session with the audience, according to their strengths and weaknesses. Selected subscales from the Burden of Stroke Scale, and Communication Confidence Rating Scale for Aphasia, were administered pre-group, and post-group, with effect sizes calculated to determine the effect of treatment. Post-group, participants had moderate decreases in communicative burden ($d=-0.46$) and distress ($d=-0.51$), and moderate increases in positive feelings ($d=0.61$). Smaller increases were found for communicative confidence ($d=0.38$), smaller decreases in negative feelings ($d=-0.33$), and small increase for the distress associated with those feelings ($d=0.22$).

Improvements in QOL were reported from a project described as an experiential outdoor adventure course (Thomas, 2004). The experimental group consisted of 14 people with ABI (12 severe TBI, 2 other) with a mean age of 32 years, and 6 years post-injury. They were compared with a control group who received nothing, of 8 people with ABI (6 severe TBI, 2 other), who had a mean age of 38 years, and 5 years post-injury. The course consisted of three phases: (1) fund-raising activities that were organised with people with ABI to contribute half the cost of the camping course; (2) nine day outdoor adventure camping course; and (3) regular groups meetings over a 3-4

month period to work on personal goals (e.g. gain employment, develop new leisure pursuits). A significant improvement on the QOL Inventory (QOLI) was found for the experimental group post-course, which was sustained at 6 months, and 2 years follow-up, and no improvements were found within the control group. Further analysis revealed that most of the change in QOL occurred for those people with ABI who regularly attended group meetings in the latter part of the course (n=9) compared to those who did not (n=5). Participants reported in interviews that the course facilitated post-injury adjustment by giving them insight into their strengths, weaknesses, and capabilities, increased self-esteem, acceptance, a new valued sense of self as they re-integrated new and old aspects of themselves, and helped them to restructure, modify, and adapt their pre-injury skills with newly acquired skills from the course.

The same course was also shown to facilitate goal achievement for a group of 11 people with severe TBI who were on average 6 years post-injury, with no control group (Walker et al., 2005). Personal goals were achieved to a high degree (81%) and included gaining work, using public transport, increasing leisure and/or social activities, and taking a holiday. All but one participant achieved at least one goal. Lack of goal achievement reflected impaired awareness, as some participants were over-ambitious when setting goals. There were no significant changes to measures of psychological health (i.e. Depression, Anxiety, and Stress Scales), and QOL (i.e. General Well-Being Questionnaire). While the measures may have lacked sensitivity to change, participants in this study were in the “mild” range for anxiety, depression, and stress pre-course, and the authors acknowledged that some participants were coping with significant psychiatric issues and major life stressors that may have led participants to rate their QOL lower. The sample size in this study was also small with a high degree of

variability, and unlike Thomas (2004), this study did not explore the effect of attendance on QOL.

Involvement in a social club improved self-efficacy for a group of 15 people with mild-severe TBI, with no control group (Vandiver & Christofero-Snider, 2000). The community-based club was designed to provide support and socialisation for its members, and would be considered a project group as its members assumed responsibility for the running of the group which included, bi-monthly meetings, scheduling meeting times, activities, and outreach. Moreover, the members planned and organised events such as group meals, speakers, training, fundraising events, and outings. The impact of the group was evaluated for 15 people taken from a larger cohort with a mean age for men and women, of 39 and 36 years respectively. The mean age for first TBI was 25 years. People with TBI completed the Self-Efficacy Scale, at two time points, each separated by 6 months. Over this time, self-efficacy significantly improved for people with TBI suggesting a positive change in competency. In interviews post-group, members identified examples of social relations as important to their QOL including, meeting and interacting with others, and having community connections, which were both key aims of the group.

The results of the above studies suggest that completing projects (i.e. camping course, community club, staging a performance) could have a positive effect on QOL, the adjustment process following an ABI, and communication skills. However, none of the studies investigated both communication skills and QOL. One study was able to show positive changes to communication and mood, however no control group was included, and a broader measure of QOL was not included (Cherney et al., 2011). Overall, the strength of the evidence supporting the use of projects is limited, with only a single study including a control group (Thomas, 2004). Furthermore, there are several

areas for future investigation that are absent from many of these studies including, consistency of measures used, information about whether the treatment was implemented as intended, and whether outcomes were assessed for maintenance after the treatment was withdrawn.

1.6 Summary

Acquired brain injury (ABI) is a global health problem that can lead to lifelong disability resulting from significant communication, cognitive, emotional, and behavioural changes. These changes can lead to a reduced QOL for people with ABI. In particular, communication impairments, or CCDs, are common sequelae following an ABI, affecting a person's QOL, and ability to integrate into a community and return to work. A range of treatment approaches to rehabilitation exists to remediate communication skills and/or QOL, but each of these have their limitations, which were discussed in this chapter. Effective treatments for people with ABI with CCDs should be individualised, with person-centred goals, using techniques that take a person's abilities into account, and view communication within a broader context (Togher et al., 2014).

Project-based treatment is a broad treatment approach that may have an impact on both communication skills and QOL for people with ABI who are long-term post-injury. Studies have shown that this treatment approach, either for people with ABI or older adults, can have a range of potential benefits including improved QOL, perceived self-efficacy, communication, or achievement of personal goals. Qualitative data has suggested that projects could give people a sense of meaning, purpose, and identity and in the case of people with ABI, also assist the adjustment process post-injury. However, the current evidence base is limited, and the studies that do exist, are not strong

methodologically. Moreover, the studies do not provide conclusive evidence that the treatment could be used to treat both communication skills and QOL, in people with ABI.

The notion of projects does however have some merit as a potential alternative to existing treatment approaches for people with ABI. Each of the studies described above highlighted that people did report positive benefit. This is likely due to each of these studies working towards an end goal whether it was an event (e.g. staging a performance, camping course), a tangible product (e.g. room décor), or behaviour (e.g. increased water intake). Also, each project required people to interact with others, and undertake some degree of responsibility, e.g. for planning, group discussion, giving and receiving feedback, and/or making decisions.

An examination of existing treatment approaches for improving communication skills and QOL, could help to extract the principles important to creating change, to incorporate into project-based treatment. To identify these principles, the following two chapters will examine the effect of behavioural treatments on each of these areas to ensure the treatment can have as great an impact as possible. Treatment reviews in Chapters 2 and 3 will then lead into Chapter 4, which will present a list of the main principles that need to be incorporated to project-based treatment.

Chapter 2 Review of communication treatments

This chapter provides a review of communication-based treatments for people with ABI. This review was completed with three aims. The first was to identify the type of treatments for people with ABI that intend to improve communication skills, and identify the principles that would be important to incorporate to project-based treatment. The second aim was to identify the most suitable method to assess, and measure the change in communication skills for people with ABI who participate in a treatment. The final aim was to examine the effect of existing communication-based treatments on QOL. The information from this review would be used to inform the design of project-based treatment, which would intend to improve the communication skills of people with ABI.

2.1 Method

2.1.1 Eligibility criteria

To investigate the effects of communication treatments for people with brain injury, a review of the literature was conducted. Studies published since 1980, and published in English were included, as it was not possible to translate research from other languages. Eligibility criteria were defined in terms of the type of study, population, treatment, and outcome (Schmidt, Lannin, Fleming, & Ownsworth, 2011):

- Types of studies: the review included all types of studies including, randomised and non-randomised controlled trials, case series and single-case experimental designs. Systematic and non-systematic reviews of the literature were also included.

- Population: participants were over 18 years of age and required a diagnosis of acquired brain injury including traumatic brain injury, brain tumour, stroke and encephalitis. At least 50% of each study sample was required to have sustained an ABI (Schmidt et al., 2011; Teasell et al., 2007). Studies that included people with severe aphasia as reported by the authors of the study were excluded, as their clinical presentation is more related to the impaired linguistic aspects of language, which necessitates a specific focus on improved language functioning rather than CCD.
- Treatments: The review targeted behavioural treatments solely focused on social communication, defined as “treatments that target discourse, pragmatics, conversation, social communication, non-verbal communications (eye contact, facial expression, proxemics or personal space, gesture), and social perception (theory of mind, listener’s perspective etc.)...[and] self-regulation or regulation of communication behaviours” (MacDonald & Wiseman-Hakes, 2010, p.490). Group and individual treatments with the person with ABI and/or their communication partner were included. Studies reporting on lexical-based treatments focused on verbal or written expression, auditory or reading comprehension (at the word or sentence level), and training of total communication strategies (e.g. gesture, drawing) were excluded because they did not target social communication.
- Outcome: studies need to have included at least one outcome measure of communication skills and employed an empirical design.

2.1.2 Search strategy

Studies for inclusion in this review were identified using the ‘Psychological Database for Brain Impairment Treatment Efficacy’ (PsycBITE), a freely available database of treatments for the psychological consequences of ABI (McDonald et al., 2006; Tate et al., 2004). Identifying relevant literature via PsycBITE searching was considered both an efficient and reliable method, because studies archived there are already objectively and externally rated for evidence and meet specific standards for inclusion. It is acknowledged that a PsycBITE search does not constitute a systematic review, however, studies entered into PsycBITE are drawn from comprehensive searches of seven reputable databases: Allied and Alternative Medicine Database (AMED, from 1985), Cumulated Index to Nursing and Allied Health Literature (CINAHL, from 1982), Cochrane Library (from 1991), Excerpta Medica Database (EMBASE, from 1980), Educational Resources Information Centre database (ERIC, from 1966), Medline (from 1966), and PsycINFO (from 1967). Studies are auto-searched using 85 search terms and need to meet 5 selection criteria on the effectiveness of treatments to be considered and logged in PsycBITE: (1) the study needs to be published in a peer reviewed journal; (2) participants are human diagnosed with an acquired brain injury; (3) participants are older than 5 years of age; (4) treatment needs to comprise at least one treatment that is psychologically based and/or target one psychological consequence of ABI; and (5) the study reports empirical data regarding treatment efficacy (Tate et al., 2004). Included studies are then indexed using 73 terms across 5 domains: (1) target area (e.g. pragmatics/social communication); (2) treatment (e.g. community re-entry); (3) neurological group (e.g. TBI/Head Injury); (4) method (e.g. group studies); and (5) age group.

For the purposes of this review, an initial search was conducted in the first year of the PhD, with a final updated search completed on the 20 November 2014, in PsycBITE using the following criteria: all study types including systematic reviews; group studies and single case designs (method); TBI/Head Injury (neurological group); language/communication/speech (target area); adults 18+; and English. Other included studies that met criteria were those identified through a manual hand search (e.g. of the systematic reviews). Titles and abstracts were first reviewed to determine if the studies met the criteria for full review. In cases where the eligibility criteria were unclear from the title and abstract, the full text article was retrieved to review this information. The author of the thesis undertook identification and review of studies.

2.1.3 Data extraction

Once an article was selected for full review, the following data was extracted: authors; date of publication; number of participants in the study; details regarding the population (i.e. mean age, diagnosis); description of treatment; the communication and QOL outcome measures used; the effect of the treatment on outcome measures; and any reported maintenance effects at follow-up. This information is reported on studies included in the final review in Table 2.1 in section 2.2 below.

2.1.4 Rating of study quality

It is essential to consider study quality. A unique and main advantage of using the PsycBITE database is that the methodological quality of randomised and non-randomised controlled studies are already rated and ranked in order of quality following clear guidelines (McDonald et al., 2006; Tate et al., 2004). Controlled studies are rated using the 11-item PEDro scale (Appendix A)(Maher, Sherrington, Herbert, Moseley, &

Elkins, 2003). The first item relates to the external validity of the study (i.e. participant selection criteria). The next 10 items, which contribute to the quality rating score, assess the internal validity of the trial and whether it contains sufficient statistical information to make it interpretable. Items include concealed allocation of participants, comparability of participants at baseline, blinding of subjects and assessors, and measures of variability. A maximum score of 10 out of 10 can be achieved for RCTs. However, non-RCTs can only achieve a maximum score of 8 out of 10, as items 2 and 3 cannot be rated for non-RCTs (i.e. random, and concealed allocation). Two independent raters evaluate each paper using the PEDro scale, and in the case of discrepancy, a third rater provides a rating to achieve reliable scores. The PEDro scale has good inter-rater reliability (ICC=0.68) for total scores across several raters (Maher et al., 2003), including volunteer raters (Murray et al., 2013). For the purposes of this review, the PEDro rating supplied by the PsycBITE database was used.

A second quality rating method was used for studies not rated by the PEDro scale. Studies that were single-case experimental designs (SCED) were rated using the 11-item SCED scale (Appendix B)(Tate et al., 2008). The first item of this scale refers to the specification of clinical history (i.e. age, sex, aetiology) to allow comparability to the PEDro scale, but does not contribute to the method score. The next 10 items, which do contribute to the method quality score, contain items that refer to the target behaviour, baseline sampling, inter-rater reliability of target behaviour, independence of assessors, and statistical analysis. A maximum score of 10 out of 10 can be achieved for SCED's. The SCED scale has excellent reliability for the total score, both for individual raters (ICC=0.84), and for consensus ratings between pairs of raters (ICC=0.88)(Tate et al., 2008). As SCED ratings are not supplied by the PsycBITE database, inter-rater reliability was calculated with two raters (author of this thesis and one doctoral

supervisor, NB and JM respectively) on 3 randomly selected articles, which were rated separately. There was 97% point-to-point agreement on the SCED ratings, across the 3 articles. Inter-rater reliability was excellent, both for the total score (ICC=0.96), and item reliability ($k=0.94$), permitting the thesis author to continue with rating the remaining SCEDs independently.

2.1.5 Determining levels of evidence

Studies were divided into three main levels of evidence according to Cicerone et al. (2000; 2005; 2011). Level 1 evidence included prospective, randomised and quasi-randomised controlled trials. Level 2 evidence included non-randomised case control or cohort studies or studies with controls that allowed for between-subject comparisons of the treatment outcome. Level 3 evidence included studies with no control group and included case series and SCED designs. The use of controlled trials for the evaluation of communication treatments in people with ABI is a relatively new phenomenon and it was not desirable to exclude relevant studies. Therefore, other study designs that included case control, cohort, case series and SCEDs were also included.

Level 1 and 2 studies can be rated using the PEDro scale described in the previous section. Therefore, the strength of these studies can be grouped to help the interpretation of the results. Studies that scored 9-10 on the PEDro scale were considered to be of excellent quality, 6-8 was considered to be of good quality, while studies scoring between 4-5 were of fair quality and scores below four (<4) were poor quality (Teasell et al., 2007). Level 3 single-case designs can be rated using the SCED scale however, case series cannot be rated and are not considered here.

2.2 Results

Initially, 157 articles were identified from the PsycBITE search (n=155) and manual hand search (n=2). Of the articles identified from the PsycBITE search, 17 were review articles, which were manually searched for further articles to screen. Overall, 243 articles were screened for eligibility. Of these, 213 were excluded. Thirty articles met criteria for inclusion. Figure 2.1 shows the search results and the number of articles excluded at each stage of the review. Two articles (Sim et al., 2013; Togher, McDonald, Tate, Power, & Rietdijk, 2013) reported on the same controlled trial. The article by Togher et al. (2013) described the effect of two different treatments (SOLO and JOINT), which have both been included in this review. The article by Sim et al. (2013) examined a sub-group from the same cohort (i.e. JOINT group), but used a different analytic procedure to determine the effect of treatment. The 30 articles that outline 31 studies, are tabulated alphabetically in Table 2.1, and include data extracted as outlined in section 2.1.3, and information regarding study quality as outlined in section 2.1.4. Of these 31 studies, 9 were randomised controlled trials (Level 1 evidence), 3 were non-randomised controlled trials (Level 2 evidence), 4 were case series (Level 3 evidence), and 15 were single-case experimental designs (Level 3 evidence). The methodological quality of the randomised controlled trials (n=9) was poor to good with PEDro scores ranging from 3 to 8 (mean=6). The quality of the non-randomised controlled trials (n=3) was fair with a score of 5. The quality of the single-case designs ranged from 0 to 8, (mean=5) out of a maximum of 10.

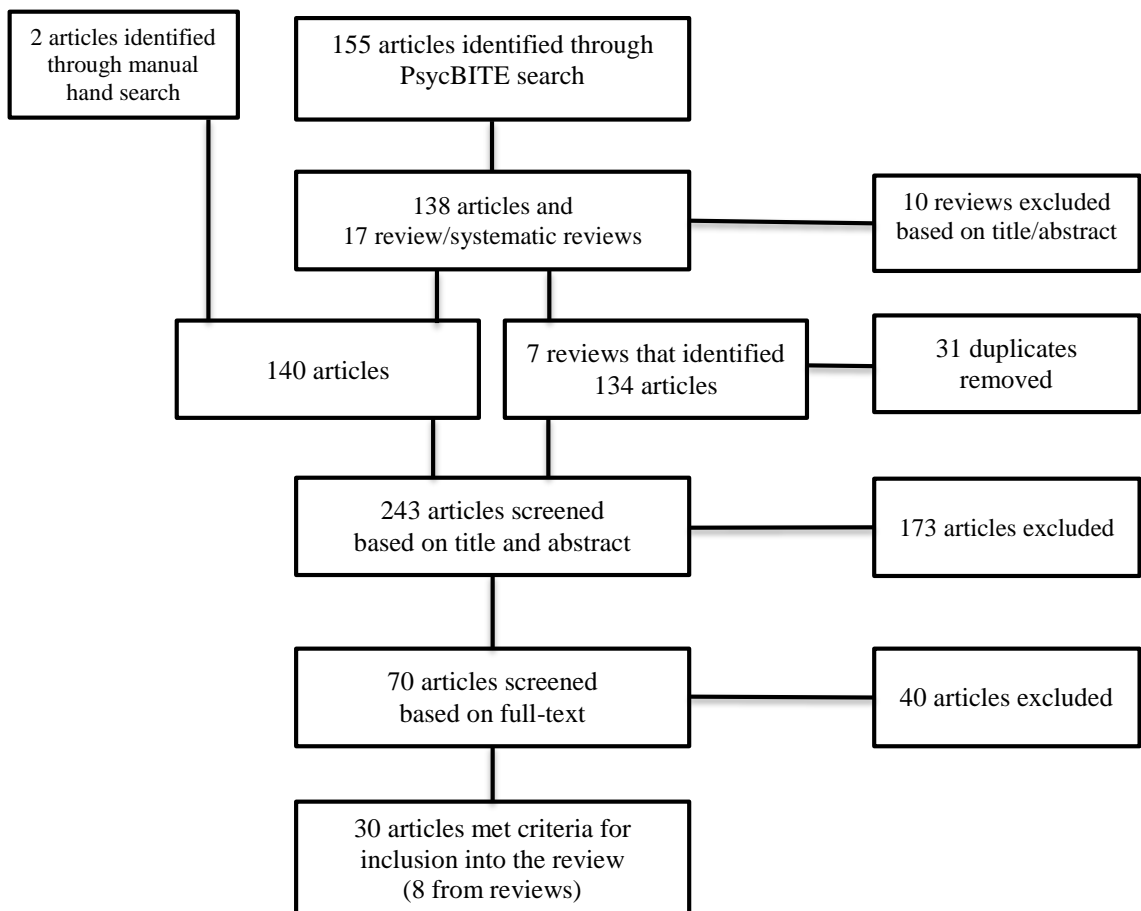


Figure 2.1. Screening studies for eligibility

Table 2.1. Description of studies that met criteria for inclusion into the review

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Behn et al. (2012)	RCT (PEDro 6/10)	n=5 Mean age: 29.2 years Diagnosis: TBI n=10 paid carers	Group treatment for six sessions to paid carers across 8 weeks (17 hours in total). Treatment involved training positive communication strategies using the modified TBI Express programme. Approaches included group discussion, modelling, role-play, feedback, rehearsal and positive reinforcement. Five trained paid carers (n=5) compared to control group (n=5).	Impression Scales; Adapted Kagan Scales (Measure of Participation in Supported Conversation; Measure of Skill in Supported Conversation); La Trobe Communication Questionnaire (LCQ).	None completed.	Significant improvements for the trained group on the Measure of Skill in Supported Conversation and three of the four impression scales (appropriate, interesting, rewarding). No significant changes on the other measures.	Improvements maintained at 6 months post-training.
Bornhofen & McDonald (2008a)	RCT (PEDro 7/10)	n=18 Mean age: 31-43 years Diagnosis: TBI	Group treatment to remediate impaired emotion perception over 10 weeks (and 25 hours) by focusing on different emotions and emotional states. Treatment compared errorless learning (EL: n=6) with self-instruction training (SIT: n=6) and waitlist control (n=6).	The Facial Expression Same/Different Task; The Facial Expression Naming Task; The Facial Expression Matching Task; The Awareness of Social Inference Test (TASIT).	Depression, Anxiety and Stress Scales; Sydney Psychosocial Reintegration Scale.	SIT group made significant improvements on the same/different task, and matching task. The EL group made significant improvements on the matching task, and TASIT. No significant changes on other measures.	Improvements maintained for both groups at 1 month on the matching task, but faded by 6 months. All other gains not maintained.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Bornhofen & McDonald (2008b)	RCT (PEDro 6/10)	n=12 Mean age: 35.1 years Diagnosis: TBI	Group treatment over 8 weeks (and 25 hours) designed to address emotion perception using a range of techniques (errorless learning and self-instruction training). Programme structured hierarchically from static to dynamic stimuli. Treatment group (n=6) compared to waitlist control group (n=6).	The Facial Expression Naming Task; The Facial Expression Matching Task; The Awareness of Social Inference Test (TASIT).	Sydney Psychosocial Reintegration Scale.	Significant improvements for matching task and TASIT (judging emotions and social inferences). No changes for QOL measure, or naming task.	Improvements maintained at 1-month post-treatment.
Braden et al. (2010)	Case series	n=30 Mean age: 42.11 years Diagnosis: TBI	Group treatment for 13 weeks (each 1.5 hours) following the GIST programme to teach social communication skills.	Profile of Pragmatic Impairment in Communication (PPIC); Social Communication Skills Questionnaire-Adapted; La Trobe Communication Questionnaire; Goal Attainment Scaling.	Awareness Questionnaire; Participation Assessment with Recombined Tools; Satisfaction With Life Scale (SWLS).	Significant improvements for all communication measures except PPIC. Only the SWLS showed significant change post-treatment.	Improvements maintained at 6 months post-treatment.
Braunling-McMorrow et al. (1986)	SCED (SCED 6/10)	n=3 Age: 18, 20 & 27 years Diagnosis: TBI	Group treatment focused on teaching social skills (e.g. compliments, politeness and social confrontation) using a game format. Used modelling, faded feedback and social reinforcement.	Percentage of correct responses to game questions; rating scale of social behaviours at meal-times as scored by an independent rater; blinded ratings by house staff.	None completed.	All participants improved in their responses to game questions and on a rating scale for social behaviours. No change on blinded ratings post-treatment. No statistical analysis.	Improvements maintained at 12 days post-treatment for all participants.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Brotherton et al. (1988)	SCED (SCED 8/10)	n=4 Age: 20, 22, 25 & 27 Diagnosis: TBI	Individual treatment focusing on improving social skills using verbal instruction, modelling, behavioural rehearsal, videotaped feedback and social reinforcement.	Videotaped interactions rated for 6 target behaviours (e.g. reinforcing feedback, positive statements) by independent raters.	None completed.	One participant demonstrated improvement on four behaviours. Performance of other three was more variable with some target behaviours demonstrating greater improvement than others. Greater improvement for motoric (e.g. posture) compared with complex verbal behaviours (e.g. reinforcing feedback). No statistical analysis.	Gains maintained for two of the participants at 1 year follow-up.
Brownell et al. (2013)	Case series	n=8 Mean age: 43 years Diagnosis: TBI	Individual treatment for 3-9 sessions (1 hour each) to improve metaphor interpretation. Treatment used simple graphic displays to help people generate and evaluate the semantic associations for nouns that underlie metaphors.	Oral Metaphor Interpretation; The Formulaic and Novel Language Comprehension Test (FANL-C).	None completed.	No group analyses conducted. Six participants made significant improvements on the oral metaphor interpretation. No changes on the FANL-C.	Improvement maintained for the metaphor interpretation for three of six participants at 3-4 months post-treatment.
Burke & Lewis (1986)	SCED (SCED 7/10)	n=1 Age: 21 years Diagnosis: anoxic brain injury	Individual treatment using a behaviour point system to reduce three inappropriate verbal behaviours (i.e. loud verbal outburst, interrupting, nonsensical talk).	Frequency of the three inappropriate verbal behaviours as rated by observer (Independent observer rated 12% of sessions for reliability).	None completed.	Reduction of all three behaviours in response to the treatment. Slight reduction for nonsensical talk and slight increase in verbal outburst and interruptions when the treatment was withdrawn. Reduction in verbal outburst and interruptions when treatment reinstated. No statistical analysis.	All target behaviours reduced to zero levels 2 weeks after the end of the treatment trial.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Cannizzaro & Coelho (2002)	SCED (SCED 4/10)	n=1 Age: 39 years Diagnosis: TBI	Individual treatment for nine 1-hour sessions over 3 weeks to improve discourse production. Treatment used pictures and filmstrip stories to improve story retell and generation with prompts to identify episodes and episode components.	Analysis of story grammar performance.	None completed.	Participant has less incomplete episodes, more complete episodes and greater use of direct consequence components. No statistical analysis.	Improvements not maintained at one and 3 months post-treatment.
Carlson & Buckwald (1993)	SCED (SCED 0/10)	n=1 Age: 24 years Diagnosis: TBI	Group treatment over 12 weeks (2 sessions per week) for people ready for return to work. Sessions focused on work-situations and problems, and involve education, discussion, role-play, videotaping, social reinforcement and modelling. Individuals require communicative awareness.	Ross Test of Higher Cognitive Processes and non-independent observations.	None completed.	Improved performance for use of deductive thinking skills and questioning strategies (on the Ross Test). Qualitative improvements in pragmatics and speech intelligibility. No statistical analysis.	No follow-up.
Dahlberg et al. (2007)	RCT (PEDro 7/10)	n=52 Mean age: 41.17 years Diagnosis: TBI	Group treatment for 12 weeks (1.5 hours each) following the group interactive structured programme. The programme taught social communication skills using strategies such as self-assessment, group feedback, problem solving, skill practise, homework, and video feedback. Treatment group (n=26) compared to waitlist control group (n=26).	The Profile of Functional Improvement in Communication (PFIC); Social Communication Skills Questionnaire – Adapted; Goal Attainment Scaling.	Craig Handicap Assessment and Reporting Technique – Short Form; Community Integration Questionnaire; Satisfaction With Life Scale (SWLS).	A significant improvement for all communication measures. Nine of ten scales for the PFIC showed improvement post-treatment. The SWLS was the only QOL measure to show change post-treatment.	Changes maintained for all measures that improved however, only six of the ten scales were better than baseline at 6 months post-treatment.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Dixon et al. (2004)	SCED (SCED 5/10)	n=4 Age: 21, 20, 48 & 61 years Diagnosis: TBI	Individual treatment of providing different forms of verbal feedback to reduce inappropriate and maintain appropriate verbal behaviours.	Frequency of inappropriate verbal behaviours (e.g. profane, or sexual comments) as rated by observer (reliability checks by independent observer on 25% of sessions).	None completed.	Reduction of inappropriate verbal behaviours for all participants. No statistical analysis.	Reported for 1 participant at 1 month post-treatment. Gains maintained.
Ehrlich & Sipes (1985)	Case series	n=6 Mean age: 24.5 years Diagnosis: TBI	Group treatment focused on 4 target areas (i.e. nonverbal communication, communication in context, message repair and cohesiveness of narrative). Techniques included role-play, group discussion, videotaping, feedback and reinforcement.	Communication behavioural rating scale and non-independent observations by authors.	None completed.	More change on the rating scale for linguistic (i.e. topic maintenance, topic initiation) rather than non-linguistic communication skills (i.e. interruption, facial expression) however, detail of statistical analyses unclear. Qualitative improvements noted.	No follow-up.
Flanagan et al. (1995)	Case series	n=5 Mean age: 31.1 years Diagnosis: TBI	Group treatment that consisted of weekly sessions over 3 months with individualised goals, videotaped role-plays and homework.	Behaviourally Referenced Rating System of Intermediary Social Skills – Revised (BRISS-R).	None completed.	Significant improvement for the Partner-Directed Behaviour Subscale of the BRISS-R.	No follow-up.
Gajar et al. (1984)	SCED (SCED 8/10)	n=2 Age: 22 years Diagnosis: TBI	Group treatment where trainer facilitated conversation and gave feedback for positive or negative communicative behaviours (B), and self-monitoring of behaviours (C).	Frequency of appropriate communicative behaviours rated by independent rater (33% data checked).	None completed.	Behaviours improved to within range of comparison group for both people during the feedback and self-monitoring phases. Behaviours fell to pre-treatment levels at second baseline.	No follow-up.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Giles et al. (1988)	SCED (SCED 3/10)	n=1 Age: 27 years Diagnosis: TBI	Individual treatment of five half-hour sessions per week (over 1 month). Sessions involved social and tangible reinforcement, specific and direct verbal feedback to give “short answers” and TOOTS.	Mean words per minute across three question types (i.e. structured, semi-structured and unstructured).	None completed.	Significant main effect for both question type and time period (pre vs. post vs. follow-up) but not their interaction. Most improvement found on structured question types and least improvement for semi-structured.	Significant improvement at 2 month follow-up compared with pre-treatment across all question types.
Guercio et al. (2004)	SCED (SCED 1/10)	n=3 Mean age: 21.67 years Diagnosis: Mixed brain injury	Individual treatment to teach emotion recognition. Participants attended 5-6 training blocks of a computer-based programme that presented photographs of emotions that needed to be identified.	Label Ekman pictures; Match Ekman pictures to updated pictures; Matching photographs.	None completed.	Improved scores on all measures. No statistical analysis.	No follow-up.
Helffenstein & Wechsler (1982)	RCT (PEDro 4/10)	n=16 Age: 17-35 years Diagnosis: mixed brain injury I	Individual treatment involved 20-hours of interpersonal process recall treatment compared with nontherapeutic attention. Treatment involved a videotaped conversation and structured review with feedback, modelling and rehearsal in collaboration with the person with ABI and their communication partners. Treatment (n=8) compared to control group (n=8).	Interpersonal Communication Inventory (ICI); Interpersonal Relationship Rating Scale (IRRS); Independent Observer Report Scale; Videotape Analysis.	State-Trait Anxiety Scale (STAS).	Reduced proneness to anxiety on the STAS; Improvements on the IRRS and independent observer report scale. No changes on other measures.	Limited follow-up with change maintained for participants that improved post-treatment at 1 month.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Kirsch et al. (2004)	SCED (SCED 2/10)	n=1 Age: Mid-thirties Diagnosis: TBI	Individual treatment to reduce verbose speech by using a recording of 'be brief' delivered at fixed intervals by a personal digital assistant.	Total number of utterances and total utterance time.	None completed.	No substantial difference on utterance frequency. Total utterance time during cues sessions was substantially lower compared with non-cued sessions. No statistical analysis.	No follow-up.
Lennox & Brune (1993)	SCED (SCED 6/10)	n=1 Age: 27 years Diagnosis: TBI	Individual treatment using incidental teaching to train complete and intelligible requesting behaviour.	Percentage of complete requests and independent requests recorded by trainer. Inter-observer agreement assessed by two independent observers for 25% of sessions.	None completed.	Increased number of complete requests and (to a lesser extent) independent requests across three settings (i.e. dining room, hall, bedroom). No statistical analysis.	Anecdotal reports suggest maintenance of improvements.
Lewis et al. (1988)	SCED (SCED 5/10)	n=1 Age: 21 years Diagnosis: anoxic brain injury (same case as Burke & Lewis, 1986).	Individual treatment for improving conversations by providing three forms of verbal feedback: attention and interest, ignoring, and correction. Treatment provided by three therapists.	Frequency of socially inappropriate talk (i.e. unintelligible, foolish or absurd statement) scored by an independent rater (two additional raters did reliability checks for 20% of the data).	None completed.	Irrespective of therapist, correction resulted in greatest reduction, ignoring was only slightly effective than baseline, and attention and interest increased inappropriate talk. No statistical analysis.	Anecdotal reports 6 months post-treatment reported maintained improvement.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
McDonald et al. (2008)	RCT (PEDro 6/10)	n=39 Mean age: 34-35 years Diagnosis: mixed brain injury	Group treatment involved a 12 week social skills programme with 3 hour weekly group sessions (2 hours on training social behaviours and 1 hour on training emotional expressions and social inference). Treatment sessions used role-play, modelling, feedback and repetition, with an additional 1 hour weekly individual session with a clinical psychologist. Social skills treatment (n=13), compared to social activity (n=13) and waitlist control group (n=13).	Behaviourally Referenced Rating System of Intermediary Social Skills – Revised (BRISS-R); La Trobe Communication Questionnaire; The Awareness of Social Inference Test (TASIT).	Depressive, Anxiety and Stress Scale; Sydney Psychosocial Reintegration Scale.	Significant improvements for the Partner Directed Behaviour Scale of the BRISS-R. No changes for other measures.	No follow-up.
McDonald et al. (2013)	RCT (PEDro 8/10)	n=20 Mean age: 45.62 years Diagnosis: Mixed brain injury	Group treatment of graded tasks to improve perception of, and ability, to distinguish between prosodic emotional cues in three 2 hour sessions. Techniques included errorless learning, positive feedback and repeated practise. Treatment group (n=10) was compared to waitlist control group (n=10).	The Awareness of Social Inference Test (TASIT); Prosodic Emotion Labelling Task; Communication Questionnaire.	None completed.	Significant improvement on communication questionnaire. No significant changes on other measures at group level, but analysis of individual performance indicated six of ten participants made improvement on prosodic measures.	Improvement of questionnaire maintained at 1 month. Improved prosodic recognition maintained for four of the six participants.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Radice-Neumann et al. (2009)	RCT (PEDro 3/10)	n=19 Mean age: 43 years Diagnosis: Mixed brain injury	Individual treatment was treatment for 1 hour three times weekly, completed in 6-9 sessions. The treatment included computer-based exercises to compare). Both treatment types incorporated discussion of personal emotional experiences. Treatment compared emotion processing from visual information (n=10) with using short stories/written contexts (n=9).	Levels of Emotional Awareness Scale (LEAS); Diagnostic Assessment of Non-Verbal Affect – Adult Faces (DANVA-AF), and Adult Paralanguage (DANVA-AP); Emotion Evaluation Test from the TASIT.	None completed.	The visual information group improved on emotion recognition from faces (DANVA-AF), and on the LEAS. No other significant changes reported. The written context made no significant changes on any measure from pre to post-treatment.	Changes on DANVA-AF but not LEAS maintained at 2 weeks follow-up for visual information group. Significant improvement on LEAS (comparing pre-treatment and follow-up) for written context group.
Schloss et al. (1985)	SCED (SCED 7/10)	n=2 Age: 21&20 years Diagnosis: TBI	Individual treatment focused on self-monitoring by counting a range of verbal behaviours (e.g. complimenting others, asking others questions about themselves, self-disclosure). No instruction on frequency of behaviours given during conversations with others.	Frequency of 3 target verbal conversational behaviours, as scored by independent raters. Ratings of social competence for seven response categories (e.g. eye contact, intonation, content) were also rated independently.	None completed.	Both people showed an increased frequency of giving compliments and asking questions, within the normal range (of a comparison group). Variable effects for self-disclosure (below the level of the comparison group). Giving participants the instruction to self-monitor consistently produced a higher frequency of compliments and questions and a lower rate for self-disclosure. Significant differences from pre to post-treatment on the ratings of social competence.	No follow-up.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Sim et al. (2013) ^b	Non-RCT (PEDro 5/10)	n=29 Mean age: 30-38 years Diagnosis: TBI	As for Togher et al. (2013).	Exchange structure analysis (ESA) and productivity analysis.	None completed.	Trained communication partners (CPs) significantly reduced use of test questions compared to control group but not rate of information giving/requesting. No significant differences for person with TBI on ESA moves. Productivity analyses showed significant increases in productivity for trained person with TBI post-treatment. No change for CPs.	None reported.
Sohlberg et al. (1988)	SCED (SCED 6/10)	n=1 Age: 38 years Diagnosis: TBI	Individual treatment within a group setting using an external cueing system (i.e. intermittently presented cards) to increase the individual's self-initiation of conversation and response acknowledgement. Behaviours targeted separately.	Frequency count of verbal initiations and response acknowledgement (reliability checks by independent observer for 30% of sessions).	None completed.	Increase in verbal initiation and response acknowledgement when cueing system introduced. Reduction in verbal initiations when treatment applied to response acknowledgement. Some variability in performance noted during training for each behaviour. No statistical analyses.	Anecdotal reports suggest reduction in behaviours following completion of treatment.
Togher et al. (2004)	RCT (PEDro 7/10)	n=20 Mean age: 36-37 years Diagnosis: TBI	Group treatment for six 2 hour sessions to police officers, focused on communication strategy training for commonly occurring telephone enquiries. Sessions examined the generic structure of queries, with role-play, feedback and discussion. Treatment (n=10) compared to waitlist control group (n=10).	Systemic Functional Linguistics – Generic Structure Potential.	None completed.	Trained police officers spent more time establishing the nature of a request and providing answer post-training. Increased proportion of closing remarks. People with brain injury had reduced inappropriate and incomplete responses with trained police officers post-training.	None reported.

Study	Study design	Population	Treatment description	Measure(s) of communication	Measure(s) of QOL	Treatment effect on measures	Maintenance effect
Togher et al. (2013) ^a	Non-RCT (PEDro 5/10)	n=44 Mean age: 30-39 years Diagnosis: TBI	Group treatment involved 10-weekly group sessions (2.5 hours each) with an extra 1 hour individual session. Treatment followed the manual TBI Express programme, which aimed to develop more positive interactions through using collaboration and elaboration strategies and everyday social situations. Treatment compared people with brain injury trained SOLO (n=15), JOINT with a communication partner (n=14), or in a CONTROL group (n=15).	Adapted Kagan Scales (Measure of Participation in Supported Conversation; Measure of Skill in Supported Conversation).	None completed.	Significant interaction effects across all measures from pre-treatment to post-treatment. Post-hoc analyses revealed significant improvements specifically for the JOINT group. No significant changes in the other two groups. No significant difference between CONTROL and SOLO group.	Changes were maintained at 6 months post-treatment for JOINT group.
Zencius et al. (1990)	SCED (SCED 6/10)	n=1 Age: 24 years Diagnosis: TBI	Individual treatment with visual cue (i.e. piece of paper with the word "swearing") to reduce profanity.	Frequency of profanity used in treatment sessions as rated by therapist. (Independent observer rated 30% of sessions for reliability).	None completed.	Reduced occurrences of profanity to near zero levels.	No follow-up.

^aThis articles reports on the effect of two treatment studies (i.e. JOINT and SOLO). ^bThis article reports on a cohort from the Togher et al. (2013) study but with a different analytic procedure.

The following three sections address the three aims of this review. First, the breadth of communication-based treatments provided to people with ABI was examined, for the purpose of selecting common principles to effective treatments that could be incorporated into this study. Second, methods for measuring change in communication skills were explored, to help identify what measures should be chosen in this study. Finally, the effect of communication-based treatments on improving QOL was examined.

2.2.1 Effect of treatment on communication skills

The majority of studies reported some degree of improvement post-treatment for communication skills, thus, illustrating that communication skills are amenable to some degree of change from targeted treatment. The predominant treatment focus, determined by the description of the treatment as reported in each study, for most studies (21 of the 31 studies) was impaired social skills (including discourse). The treatment focus for the other studies included social perception skills (6 of 31), and communication partners (4 of 31). Findings for effectiveness of treatment will be discussed further with respect to treatment type.

The first treatment type focused on impaired social skills, and involved training a range of skills (e.g. starting and maintaining a conversation, asking questions, reducing verbose speech, topic selection, giving compliments) with a range of techniques (e.g. role-play, videotaping, feedback, discussion, repeated practise, modelling, and social reinforcement). Most studies (20 of 21) showed some degree of positive change in communication skills post-treatment. In some studies (12 of 21), the treatment was provided on an individual basis, and nearly all of these studies were single-case experimental designs (n=11). There was a single RCT (Helffenstein &

Wechsler, 1982) that reported improved interpersonal and communication skills for treated people with TBI (n=8) compared to a control group (n=8). Treatment lasted 20-hours and involved regular videotaped interactions with individualised feedback involving a person with TBI, their communication partner and an independent observer. The majority of studies provided on an individual basis (9 of 12) focused on 1-3 individualised target areas, either reducing inappropriate behaviours or increasing positive behaviours. Chosen behaviours tended to be individualised including the reduction of aggressive comments (Dixon et al., 2004) or conversation disruptions (Burke & Lewis, 1986), reduced profanity (Sohlberg, Sprunk, & Metzelaar, 1988), increased production of brief responses (Giles, Fussey, & Burgess, 1988), and increased complete requests (Lennox & Brune, 1993). In other studies (9 of 21), the treatment was provided in a group context. The quality of these studies was also stronger methodologically compared to the individual treatments with randomised controlled trials (n=2), non-randomised controlled trials (n=1), case series (n=3) and single-case experimental designs (n=3). The largest study, with the highest reported level of evidence, involved 52 people with brain injury evenly allocated to either a treatment or delayed treatment group (Dahlberg et al., 2007). Training in social skills was conducted in groups for 1.5 hours per week for 12 weeks and focused on teaching social skills such as presenting oneself successfully, being assertive and setting social boundaries. Blind raters perceived trained people with ABI as having better communication skills post-treatment (e.g. improved general participation in conversation and social style), compared to a control group. For some of the group treatments (4 of 9), setting individualised communication goals was a core principle, and found in studies with higher quality. Goals (e.g. asking more questions, interrupting less in conversations) would be collaboratively set between the therapist, person with ABI and in some cases,

the communication partner. Two of the four studies objectively evaluated goals and reported goal attainment over time for people with ABI (Braden et al., 2010; Dahlberg et al., 2007).

The second treatment type was social perception skills, and comprised six of the 31 studies (n=3 individual; n=3 group), wherein treatment focused on reflecting an evolving awareness of the impact of these skills on communicative ability for people with ABI. Five of the six studies involved training emotional cues (Bornhofen & McDonald, 2008a, 2008b; Guercio, Podolska-Schroeder, & Rehfeldt, 2004; McDonald et al., 2013; Radice-Neumann, Zupan, Tomita, & Willer, 2009), and one study involved training the interpretation of metaphors (Brownell et al., 2013). The highest level of evidence was reported for group-based studies but the results in these studies were mixed with some participants showing more improvement than others (Bornhofen & McDonald, 2008a, 2008b; McDonald et al., 2013). People with ABI most likely to benefit from treatment of social perception skills are those with particular difficulty with these skills (McDonald et al., 2008). Bornhofen et al. (Bornhofen & McDonald, 2008b) attempted to explore the issue of who benefits most from treatment by analysing the individual performance of participants. They found that while there was little correspondence between improved social perception skills and pre-treatment cognitive functioning, change was seen most for motivated participants who attended treatment sessions, completed homework and were most engaged in sessions. Those with little improvement tended to have experienced significant life stressors (e.g. court settlement, further medical diagnoses) during the treatment. These findings provide some insight into the issue of candidacy.

Finally, four studies focused on the third treatment type of training the communication partner of the person with brain injury. Communication partners play an important part in conversations and can either promote or hinder the communication skills of the person with ABI (Togher, 2000; Togher, Hand, & Code, 1997a, 1997b; Togher, Taylor, Aird, & Grant, 2006). Also, they can help to create communicative opportunities for the person with ABI to practise and rehearse their newly learnt skills. Two randomised controlled studies found that the interactions of people with ABI were improved when the communication partner of the person with ABI was trained (Behn, Togher, Power, & Heard, 2012; Togher, McDonald, Code, & Grant, 2004). The first study involved training 10 police officers (Togher et al., 2004), and the second, five paid carers in a residential rehabilitation centre (Behn et al., 2012). In each of these studies, communication partners were trained in small groups that did not include the person with ABI. Sessions involved education on the structure of conversational interactions and training a range of strategies and techniques to improve the quality of those interactions. People with ABI can also be trained with their communication partner. A recent non-randomised controlled trial involving 44 people with TBI found that training the communication partner *with* the person with ABI led to improved conversations (Sim et al., 2013; Togher et al., 2013), more than training the person with ABI *alone* (Togher et al., 2013). Each of these studies incorporated individualised goal setting for the person with brain injury. Communication partners therefore play an important role in facilitating positive and successful conversations for people with ABI. In summary, regardless of the treatment approach (i.e. social skills, social perception skills, communication partner training), communication skills improved to some degree across most studies.

2.2.2 Common principles of communication-based treatments

This section describes several principles that were common to effective communication-based treatments, to incorporate into project-based treatment, which is proposed in this study. In addition to this review, further evidence to support specific principles can be found in recommendations that were developed by an international group of researchers and clinicians (known as INCOG) (Togher et al., 2014).

The INCOG group developed a set of best practice recommendations for the treatment of CCD post-ABI following a rigorous process of evaluating the research (Togher et al., 2014). First, they completed a detailed internet and Medline search to identify published clinical practice guidelines. The quality of the development process for each guideline was then evaluated using the Appraisal of Guidelines for Research and Evaluation (II) instrument (AGREE II). Recommendations were extracted from these guidelines, tabulated and distributed to an expert panel. These were then examined with an initial set of recommendations, which were made based on the available evidence. To then ensure that the recommendations reflected current evidence, synopses of large systematic reviews were prepared from several databases including those on cognitive rehabilitation. Reference lists (of more than 600 references) were created and reviewed to help map the current evidence to the recommendations and prioritise (using a Modified Delphi Voting Technique) a set of graded recommendations for the management of people with CCDs.

Three key principles were identified from the current treatment review, similar to recommendations from the expert INCOG panel, and are discussed in turn below. The three principles are then further discussed in Chapter 4 after the QOL review. It is important that where possible, findings from methodologically stronger studies are prioritised in the overall evidence base.

Firstly, a treatment should address setting individualised communication-based goals with the person with ABI. The importance of individualised goal setting was a key focus for 16 of the 31 reviewed treatment studies. While many of these studies were conducted on an individual basis (n=10), the group studies that involved individualised goal setting (n=6), represented higher levels of evidence, with one randomised, and three non-randomised controlled trials. For all these studies the focus of the goal was social skills (e.g. reduction of socially inappropriate behaviours, asking more questions) however, there would be potential to incorporate goals on social perception skills (i.e. emotional cues) dependent on the presenting impairments of the person with ABI.

Secondly, a treatment should consider being group rather than individual based. Of the 31 studies reviewed, 16 were group treatments and 15 were individual treatments. The expert panel acknowledged that while treatment can be provided on an individual or group basis, the strength of the evidence is strongest for group-based treatments (Togher et al., 2014). In the current treatment review, 10 of the 16 group-based treatments were randomised (n=7) and non-randomised treatment trials (n=3). Moreover, group-based treatments, albeit for cognitive not communication impairments, have been recommended in rehabilitation in a recent systematic review (Cicerone et al., 2011).

Finally, treatment should consider providing education, training and support to the communication partner of a person with ABI. Two randomised controlled studies found that the interactions of people with ABI were improved from group training when the communication partner of the person with ABI was trained (Behn et al., 2012; Togher et al., 2004). Furthermore, two non-randomised controlled trials involving 44 people with TBI described in two articles (Sim et al., 2013; Togher et al., 2013), found that training the communication partner *with* the person with ABI was able to improve

conversations more than training the person with ABI *alone*. This highlights the important role communication partners play in facilitating positive and successful conversations.

2.2.3 Measuring change in communication skills

The second aim of the review was to identify the range of communication outcome measures currently used in research, and inform the decision making of the most appropriate method to assess communication skills in the current study. Table 2.1 details the measures of communication used in each study. For this section, the Togher et al. study (2013) that was previously included twice (as it described two different treatment approaches) was only included once in this section. Therefore, this section refers to the 30 articles, which used three different measurement approaches: conversation analysis; communication-based questionnaires (self or other report); and standardised assessment. Of the 30 articles, 7 articles included more than one measurement approach, with a communication-based questionnaire used as one of the approaches (Behn et al., 2012; Braden et al., 2010; Dahlberg et al., 2007; Ehrlich & Sipes, 1985; Helffenstein & Wechsler, 1982; McDonald et al., 2008; McDonald et al., 2013).

Analysis of conversation was the most commonly used method to determine the effects of a treatment. Conversation was used in 24 articles which all reported some degree of improvement post-treatment. For the randomised and non-randomised controlled studies, in 7 of the 11 articles, conversation was the most used form of assessment for detecting change. It was also a common method in the case series and single-case design studies (17 out of 19). There were three main methods of analysing conversation for change: rating specific pre-determined communicative behaviours

(n=22); linguistically analysing the conversation (n=3); or qualitatively describing observations (n=2). Three studies used more than one method to analyse conversation (Braden et al., 2010; Dahlberg et al., 2007; Schloss, Thompson, Gajar, & Schloss, 1985). The most popular method, rating specific communicative behaviours, was completed in one of two ways. The first involved the completion of a scale (n=12) such as the Adapted Kagan Scales (Behn et al., 2012; Togher et al., 2013) or Profile for Functional Impairment in Communication (Braden et al., 2010; Dahlberg et al., 2007), and was the chosen method for the controlled trials where conversations were scored by blind and independent raters. The second way was by rating specific individualised behaviours (n=10) using Goal Attainment Scaling (Braden et al., 2010; Dahlberg et al., 2007), or frequency count of observable behaviours (Burke & Lewis, 1986; Dixon et al., 2004; Giles et al., 1988; Kirsch et al., 2004; Lennox & Brune, 1993; Schloss et al., 1985; Sohlberg et al., 1988; Zencius, Wesolowski, & Burke, 1990).

Communication-based questionnaires were used in seven studies, all of which reported group treatment. Four of these studies demonstrated improvement post-treatment (Braden et al., 2010; Ehrlich & Sipes, 1985; Helffenstein & Wechsler, 1982; McDonald et al., 2013), however there was no measure consistently used with six different questionnaires applied across the four studies. The most commonly used questionnaires were the La Trobe Communication Questionnaire (LCQ) (Douglas, O'Flaherty, & Snow, 2000) and the Social Communication Skills Questionnaire – Adapted (SCSQ-A)(Dahlberg et al., 2006). One study used both of these questionnaires and reported improvements in each questionnaire post-treatment (Braden et al., 2010). One advantage of the LCQ over the SCSQ-A is that it was specifically developed for people with ABI, and the validity and reliability of the questionnaire is more widely

reported (Douglas, 2010c; Douglas, Bracy, & Snow, 2007a, 2007b; Douglas et al., 2000; Struchen, Pappadis, et al., 2008).

Standardised assessment was used in eight studies to determine the treatment outcome. In seven of these studies, an assessment of social perception skills was used. This was in line with the treatment content, which focused on the improvement of social perception skills (e.g. emotion recognition and social inference). While mixed results were reported, it is difficult to know whether these assessments are not sensitive to change, or whether these impaired skills are difficult to treat. The most commonly used assessment in five of the studies (Bornhofen & McDonald, 2008a, 2008b; McDonald et al., 2008; McDonald et al., 2013; Radice-Neumann et al., 2009) was The Assessment of Social Inference Test (TASIT) (McDonald, Flanagan, Rollins, & Kinch, 2003).

The review of outcome measures highlights the importance of using conversation as an outcome of the treatment. Conversation should be analysed using a valid and reliable scale, which is scored by blind and independent raters. In addition, a communication-based questionnaire may also provide information about the improvement in communication skills post-treatment.

2.2.4 Effect of treatment on QOL

The third aim of this review was to determine the impact of a change to communication skills, on the QOL of people with ABI. QOL was examined as an outcome in six of the 30 articles, and five of these studies were randomised controlled trials of poor to good quality. It is worth noting that the measurement of QOL in communication-based treatments is a relatively new phenomenon with five such studies published after 2007.

From the six studies that examined QOL post-treatment, three studies demonstrated a positive change following the treatment (Braden et al., 2010; Dahlberg et al., 2007; Helffenstein & Wechsler, 1982). Helffenstein and Wechsler (1982) found people with ABI were less anxious (n=16, psychological health measure), and Dahlberg et al. (n=52)(Dahlberg et al., 2007) and Braden et al. (n=30)(Braden et al., 2010) found people with TBI had greater life satisfaction. These three studies were focused on training social skills, with two of the three studies being group treatments (Braden et al., 2010; Dahlberg et al., 2007). Of the three studies that did not show improvement, two of these were focused on training social perception skills (Bornhofen & McDonald, 2008a, 2008b), and one on training social skills (McDonald et al., 2008), with them all being group treatments.

This review highlights that currently very few studies consider the impact of communication treatments on improving QOL. However, if communication changes are known to have an impact on a person's social integration and QOL then these areas should be considered a treatment outcome in future research studies, and further reflection on treatment type, delivery and choice of outcome measure are warranted.

2.3 Summary

This chapter aimed to understand more about the treatment of communication skills to inform the process for implementing project-based treatment. Three aims were achieved from this treatment review.

First, the review of 31 treatment studies revealed that communication skills are amenable to change. The treatment focus for most studies was impaired social skills, with other studies focusing on impaired social perception skills, and training communication partners. Each treatment type was well represented by Level 1 or 2

evidence (i.e. randomised or non-randomised controlled trials) with four studies in each treatment type of this level of evidence. Single-case designs, of varying quality, were mainly reported for studies targeting impaired social skills. Three principles emerged from all treatment studies that could be considered important for project-based treatment: setting individualised communication-based goals targeting social or social perception skills; group treatment; and involvement of communication partners. Each of these principles was drawn from the evidence presented within this review, and supported by a set of best practice recommendations from the INCOG group (Togher et al., 2014).

Second, the review showed that communication skills could be assessed and measured to determine the effect of a treatment. Several methods for measuring communication skills were identified: conversation; communication-based questionnaires; and standardised assessment. Conversation was most widely used to analyse change post-treatment either by rating specific communicative behaviours, linguistic analysis, or qualitative describing observations. More specifically, Level 1 and 2 evidence used conversation that was blindly, and independently rated using a valid and reliable scale. In addition, measuring specific individualised communicative behaviours was widely used to measure conversation particularly, in single-case designs. Almost a quarter of studies used more than one approach to demonstrate change in communication skills post-treatment. In all these studies, a communication-based questionnaire was used, with over half of these studies showing change. The most commonly used communication questionnaires assessed perceived communicative ability as rated by the person with ABI and/or a communication partner.

Third, the treatment review intended to examine the effect of communication-based treatments on QOL for people with ABI. While few communication treatment

studies measured QOL, half of those showed improvement following treatment. The majority of studies reported improvement on a measure of life satisfaction.

This review aimed to better understand the impact of communication treatments, their effect on QOL, and principles that could be extracted to incorporate to project-based treatment. The review highlights that QOL is rarely considered in communication-based treatments despite there being good evidence for the relationship between communication skills, and QOL. To further inform the treatment chosen in this research, the following chapter examines the literature on behavioural treatments, with a specific focus of their effect on QOL, in order to identify additional principles to be considered in the development and outcome measurement of the treatment approach selected.

Chapter 3 Review of QOL treatments

The chapter provides a review to determine the effectiveness of behavioural treatments for improving the QOL of people with ABI. As few studies have examined QOL as an outcome of communication treatments for people with ABI, considering another field of the literature (i.e. behavioural treatments) was important for providing guidance on the principles of a treatment that improve QOL, and the measures that are most likely to show change. The first aim was to identify and describe the range of behavioural treatments reported, and thereby determine what behavioural treatments for people with ABI produce a change in QOL. This information could then be used to extrapolate which principles may be important to incorporate into project-based treatment. The second aim was to identify the QOL measures, used in studies that demonstrate improvement. This information could then be used to inform decision making in the current treatment study, which intends to improve both communication skills and QOL.

3.1 Method

3.1.1 Eligibility criteria

To investigate the effects of behavioural treatments for people with ABI, a review of the literature was conducted. A constrained time frame was set to include the most recent studies published since 2000, and published in English, as translation resources were not available. Other eligibility criteria were defined in terms of the type of study, population, treatment, and outcome (Schmidt et al., 2011):

- Types of studies: studies included had at least an evidence of Class IV (i.e. randomised-controlled and non-randomised controlled trials, case series, cohort and case-controlled studies). Systematic reviews and discussion articles were excluded.
- Population: participants were over 18 years of age and required a diagnosis of ABI including TBI, brain tumour, stroke and encephalitis. At least 50% of each study sample was required to have sustained a brain injury (Schmidt et al., 2011; Teasell et al., 2007). Participants were required to have been discharged from an acute inpatient or residential rehabilitation programme. Community dwelling participants or participants attending an outpatient setting were included in this review.
- Treatments: treatments were required to be behavioural and not include any pharmacological or medical treatments (e.g. brain stimulation). Group and individual treatments were included. Post-acute comprehensive-holistic neuropsychological rehabilitation programmes were excluded as these programmes have already been proven to be a practice standard in the rehabilitation of people with acquired brain injuries (Cicerone et al., 2011). Such programmes include integrated treatments directed at multiple areas (greater than 2) of impairment (e.g. cognitive, emotional, motivational and interpersonal impairments).
- Outcome: studies need to have included at least one QOL outcome that measured HRQOL and/or SWB. For HRQOL, four dimensions were included based on the Berger et al. seminal paper (a review of 16 studies between 1991 and 1998 involving people with ABI): physical, psychological, social and cognitive health (Berger et al., 1999). While it is acknowledged that some of the HRQOL

outcomes could be considered broader measures of outcome, they would be considered measures of HRQOL under the Berger et al. (1999) definition.

- Measures were required to be completed by the person with ABI (not significant other) at pre- and post-treatment (including follow-up). For the purposes of this review, statistical significance rather than clinical significance was used as a guide.

3.1.2 Search strategy

Studies for inclusion in this review were identified using PsycBITE, a free database of treatments for the psychological consequences of ABI (McDonald et al., 2006; Tate et al., 2004). This database has been described in detail in section 2.1.2. An initial search was conducted in the first year of the PhD, with a final updated search completed on the 18 May 2014, for the period 2000 to the current date (to obtain the most recent evidence) on PsycBITE under the criteria: group studies (method); TBI/Head Injury (neurological group); adults 18+; and English. Other included studies that met criteria were those identified through a manual hand search. Titles and abstracts were first reviewed to determine if the studies met the criteria for full review. In cases where the eligibility criteria were unclear from the title and abstract, the full text article was retrieved to retrieve this information. The author of the thesis undertook identification and review.

3.1.3 Data extraction

Once an article was selected for full review, the following data was extracted: authors; date of publication; study design; number of participants in the study; details regarding the population (i.e. diagnosis); description of treatment including length of

treatment in hours and weeks where indicated; the QOL outcome measure used; and the effect of the treatment on QOL. This information is reported on studies included in the final review in Table 3.1 in section 3.2 below.

3.1.4 Rating of study quality

Similar to the previous review (see section 2.1.4), studies identified on the PsycBITE database had been rated and ranked in order of methodological quality. Rating the quality and strength of the studies has become important in recent years particularly, when making conclusions and clinical recommendations about best practice in ABI (Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011; Schmidt et al., 2011; Teasell et al., 2007). Research designs considered in the current review were randomised-controlled trials, non-randomised controlled trials, case control or cohort studies, and case series. Randomised and non-randomised controlled trials can be rated using the 11-point PEDro scale (Appendix A) described in section 2.1.4 (Maher et al., 2003). This scale does not rate case series. For the purpose of this review, the PEDro rating supplied by the PsycBITE website was used.

3.1.5 Determining levels of evidence

Studies were divided into three main levels of evidence according to Cicerone et al. (2000; 2005; 2011). These three levels of evidence were described in the previous review (see section 2.1.5). For the purposes of this review, Level 1 evidence included prospective, randomised, and quasi-randomised controlled trials. Level 2 evidence included non-randomised case control or cohort studies or studies with controls that allowed for between-subject comparisons of the treatment outcome. Level 3 evidence included studies with no control group and include case series, either post-test or pre-

test/post-test studies. Level 1 and 2 studies can be rated using the PEDro scale and the strength of these studies can be grouped to help the interpretation of results (Teasell et al., 2007). The PEDro scale and how to interpret the quality of the evidence was detailed in section 2.1.5.

3.1.6 Defining treatment type

To further explore the effect of treatment on QOL, studies were grouped according to treatment type. Decision-making about treatment type was achieved by reviewing the techniques outlined in the paper, which were used to create a change in behaviour, or determined by the content of the treatment. Behavioural change techniques are not well defined in ABI treatment studies, and often researchers need to go beyond the published article and access information on published treatment descriptions, protocols and manualised programmes (Dombrowski et al., 2012). For the purposes of this study, this process (and level of detail) was not possible. Subsequently, more emphasis was placed on reviewing treatment content, as this information was more consistently available from published articles alone. Treatment content was most commonly reported in the methods section of each article with some articles providing a session-by-session description of the content and delivery method (individual, group or combination). Where the content of the treatment was unclear or varied, reference was made to the aims and theoretical underpinnings of the treatment to make the final decision. Treatment content types were determined by grouping like treatments together. The process of determining and agreeing classification of studies is referred to later in section 3.2.1.

3.2 Results

Overall, 396 potential articles (391 through PsycBITE and 5 through hand searching) were identified, and a total of 316 excluded for various reasons, leaving 80 articles eligible for inclusion in the review. Figure 3.1 summarises the search results and the number of articles excluded at each stage of the review. Two articles, one by Ownsworth et al. (2008), and one by D'Antonio, Tsaousides, Spielman, & Gordon (2013), each report on two treatment studies. The study by Ownsworth et al. (2008) reports on a psychological treatment, and meaningful activity treatment. The study by D'Antonio et al. (2013) reports on a psychological treatment, and cognitive treatment. Therefore, the 80 articles collectively reported on 82 different treatment studies. Of these 82 studies, 43 were randomised controlled trials (Level 1 evidence), 16 were non-randomised control trials, case control or cohort studies (Level 2 evidence), and 23 were case series (Level 3 evidence). The methodological quality of the randomised controlled trials (n=43) was poor to good with PEDro scores ranging from 1 to 8 (mean=1.8). The quality of the non-randomised controlled trials (n=16) was also poor to good with PEDro scores ranging from 1 to 7 (mean=3.2). Core information regarding each study and its quality for each of the 82 studies is reported in Table 3.1 below. Studies are reported in groups according to treatment type. QOL measures are referred to by their typical acronyms, and full titles of each measure can be found in Table 3.2. This table lists 102 different QOL measures. In addition, a further 14 were used. These further measures were variants of the original measures. For example, Douglas et al. (2006) used the social integration subscale from the Community Integration Questionnaire to determine treatment outcome. Variant forms of a measure are clearly indicated in the Table 3.1.

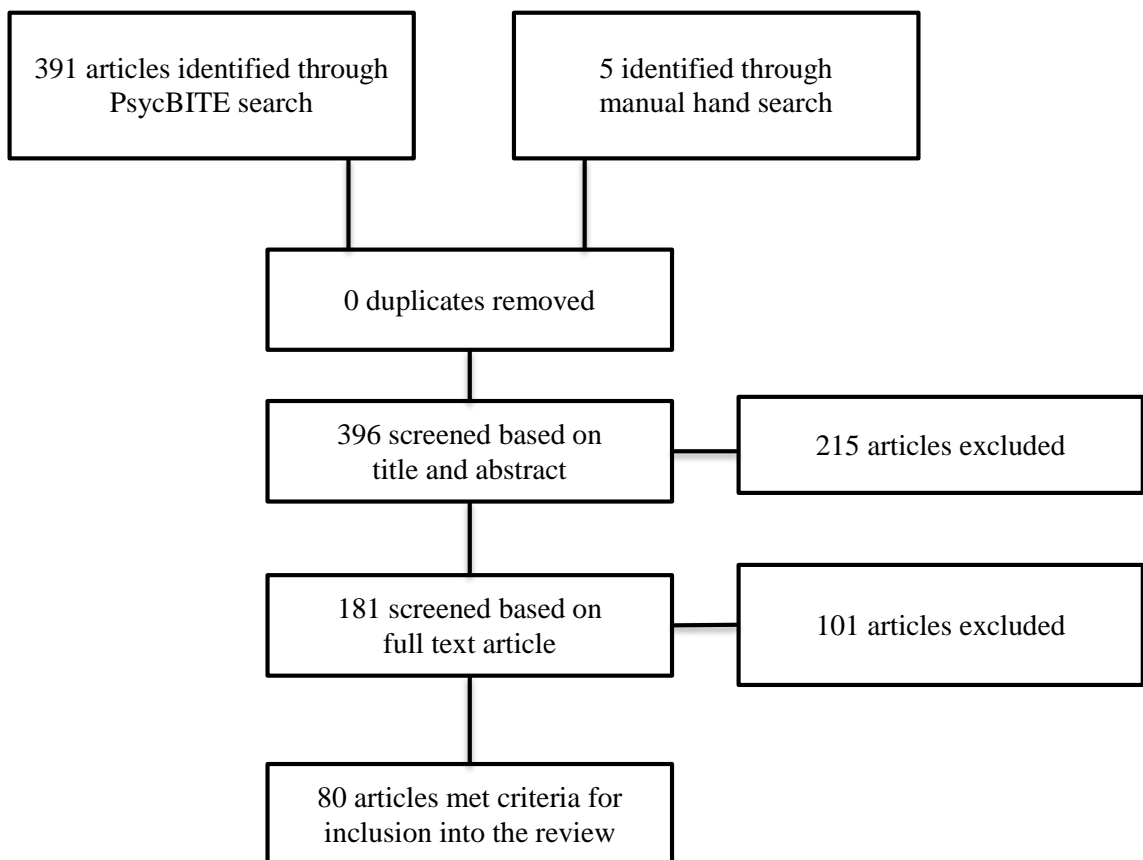


Figure 3.1. Screening of studies for eligibility

Table 3.1. Summary of studies that investigated the effect of a behavioural treatment on QOL.

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Bornhofen & McDonald (2008a)	Communication	RCT (PEDro 7/10)	18 people Diagnosis: TBI		DASS		SPRS		
Bornhofen & McDonald (2008b)	Communication	RCT (PEDro 6/10)	12 people Diagnosis: TBI				SPRS		
Braden et al. (2010)	Communication	Case series	30 people Diagnosis: TBI			AQ	PART		SWLS*
Dahlberg et al. (2007)	Communication	RCT (PEDro 7/10)	52 people Diagnosis: TBI				CHART-SF; CIQ		SWLS*
McDonald et al. (2008)	Communication	RCT (PEDro 6/10)	51 people Diagnosis: TBI		DASS		SPRS		
Aboulaflia-Brakha et al. (2013)	Psychological	Case series	10 people Diagnosis: TBI	SF-36	AQ-12*; HADS; IBS	FrSBe			
Anson & Ponsford (2006a)	Psychological	RCT (PEDro 3/10)	31 people Diagnosis: TBI	SIP	HADS; RSES				

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Arundine et al. (2012)	Psychological	Non-RCT (PEDro 4/10)	17 people Diagnosis: Mixed brain injury		SCL-90-R*; DASS*		CIQ*		
Backhaus et al. (2010)	Psychological	RCT (PEDro 6/10)	20 people Diagnosis: Mixed brain injury		BSI-I8				
Bedard et al. (2003)	Psychological	Non-RCT (PEDro 2/10)	13 people Diagnosis: TBI	SF-36*	BDI-II*; PSS*; SCL-90-R		CIQ		
Bedard et al. (2014)	Psychological	RCT (PEDro 2/10)	105 people Diagnosis: TBI		BDI-II*; SCL-90-R; PHQ-9				
Bradbury et al. (2008)	Psychological	Non-RCT (PEDro 4/10)	20 people Diagnosis: Mixed brain injury		SCL-90-R*; DASS*		CIQ		
Carnevale et al. (2006)	Psychological	RCT (PEDro 5/10)	37 people Diagnosis: Mixed brain injury	NFI-R					

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Coetzer & Corney (2001)	Psychological	Case series	22 people Diagnosis: Mixed brain injury		BDI-II*	AQ			
D'Antonio et al. (2013)	Psychological	RCT (PEDro 3/10)	44 people Diagnosis: TBI		BDI-II*				
Gurr & Coetzer (2005)	Psychological	Case series	20 people Diagnosis: TBI	NHP	HADS			HANA*; CPI*; HDI*	
Henry et al. (2012)	Psychological	Non-RCT (PEDro 3/10)	24 people Diagnosis: Mixed brain injury					THI	
Hodgson et al. (2005)	Psychological	RCT (PEDro 5/10)	12 people Diagnosis: Mixed brain injury		SPAI; HADS*; POMS*; CSEI				
Hofer et al. (2010)	Psychological	Case series	11 people Diagnosis: Mixed brain injury		BDI-II*				

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Johansson et al. (2012)	Psychological	RCT (PEDro 5/10)	29 people Diagnosis: Mixed brain injury		CPRS			MFS*	
Medd & Tate (2000)	Psychological	RCT (PEDro 6/10)	16 people Diagnosis: Mixed brain injury		STAXI*; HADS; PCRS ^a ; CSEI				
Muenchberger et al. (2011)	Psychological	Case series	52 people Diagnosis: Mixed brain injury	RAND-36	DASS				
Owensworth et al. (2000)	Psychological	Case series	21 people Diagnosis: Mixed brain injury	SIP*	HIBS				
Owensworth et al. (2008)	Psychological	RCT (PEDro 7/10)	35 people Diagnosis: Mixed brain injury			PCRS*			
Simpson et al. (2011)	Psychological	RCT (PEDro 8/10)	17 people Diagnosis: TBI		BHS*; BSS; HADS; RSES	SPSI-R			

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Sinnakaruppan et al. (2005)	Psychological	RCT (PEDro 5/10)	49 people Diagnosis: Mixed brain injury		HADS; GHQ-28*; RSES*				
Topolovec-Vranic et al. (2010)	Psychological	Case series	21 people Diagnosis: TBI		CES-D*; PHQ-9*				
Vungkhanching et al. (2007)	Psychological	RCT (PEDro 3/10)	117 people Diagnosis: TBI						PANAS*
Walker et al. (2010)	Psychological	Case series	52 people Diagnosis: TBI		STAXI**				
Wolf et al. (2012)	Psychological	Case series	10 people Diagnosis: TBI		BDI-II*; PCL-M*				
Akerlund et al. (2013)	Cognitive	RCT (PEDro 5/10)	47 people Diagnosis: Mixed brain injury		HADS	DEX			

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Bergquist et al. (2009)	Cognitive	Non-RCT (PEDro 4/10)	20 people Diagnosis: TBI				CIQ		
Bjorkdahl et al. (2013)	Cognitive	RCT (PEDro 3/10)	38 people Diagnosis: Mixed brain injury			DEX; WMQ*		FIS*	
Boman et al. (2004)	Cognitive	Case series	10 people Diagnosis: Mixed brain injury	EBIQ					QOL-A
Bourgeois et al. (2007)	Cognitive	RCT (PEDro 3/10)	38 people Diagnosis: TBI			CDQ	CIQ		
Cantor et al. (2014)	Cognitive	Non-RCT (PEDro 7/10)	98 people Diagnosis: TBI		BDI-II; STAXI	PSI*; FrSBe*	POPS		Life-3
Chandrashekar & Benshoff (2007)	Cognitive	Non-RCT (PEDro 3/10)	36 people Diagnosis: TBI	WHSSQOL I*		AQ			

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
D'Antonio et al. (2013)	Cognitive	RCT (PEDro 3/10)	44 people Diagnosis: TBI		BDI-II*				
das Nair & Lincoln (2012)	Cognitive	RCT (PEDro 7/10)	72 people Diagnosis: TBI		MABD; GHQ-12; WSRS	EMQ	NEADL		
Huckans et al. (2010)	Cognitive	Case series	21 people Diagnosis: TBI		PCL-C; BDI-II*; SDS	MSNQ*; PRMQ*	CIQ		SWLS*
Johansson & Tornmalm (2012)	Cognitive	Case series	18 people Diagnosis: Mixed brain injury			CFQ*			
Lundqvist et al. (2010)	Cognitive	Non-RCT (PEDro 4/10)	21 people Diagnosis: Mixed brain injury	EQ-5D; EQ-5D VAS*					
Miotto et al. (2009)	Cognitive	Non-RCT (PEDro 2/10)	30 people Diagnosis: Mixed brain injury			DEX			

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Quemada et al. (2003)	Cognitive	Case series	12 people Diagnosis: TBI			MFE*			
Raskin et al. (2012)	Cognitive	Case series	8 people Diagnosis: Mixed brain injury			PMQ; EMQ*	CIQ		
Rath et al. (2000)	Cognitive	Case series	34 people Diagnosis: Mixed brain injury			PSI*			
Rath et al. (2003)	Cognitive	RCT (PEDro 1/10)	46 people Diagnosis: TBI		BSI ^a ; RSES*	PC; PSI*; PSQ*	CIQ; SIP ^a		
Serino et al., (2007)	Cognitive	Case series	9 people Diagnosis: TBI			PCRS*	RHFUQ*		
Spikman et al. (2010)	Cognitive	RCT (PEDro 7/10)	75 people Diagnosis: TBI	QOLIBRI		DEX*			

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Thaut et al. (2009)	Cognitive	Non-RCT (PEDro 1/10)	54 people Diagnosis: Mixed brain injury		BSI-18*; MAACL*				
Thickpenney-Davis & Barker-Collo (2007)	Cognitive	Non-RCT (PEDro 2/10)	14 people Diagnosis: Mixed brain injury			MEL			
Tiersky et al. (2005)	Cognitive	RCT (PEDro 6/10)	20 people Diagnosis: TBI		SCL-90-R*	AttQ	CIQ		
Vas et al. (2011)	Cognitive	RCT (PEDro 6/10)	28 people Diagnosis: TBI	FSE			CIQ*		
Bell et al. (2005)	Supportive Management	RCT (PEDro 7/10)	171 people Diagnosis: TBI	DRS*; NFI; EQ*; FSE; PQOL-M*; SF-36*	BSI*		CIQ		
Bell et al. (2011)	Supportive management	RCT (PEDro 6/10)	433 people Diagnosis: TBI	DRS; EuroQOL; PQOL-M; SF-12	BSI-18		PART ^a ; CIQ		

Study	Treatment type	Study design	Number of participants	Type of measure						
				Multi	Psych	Cognitive	Social	Physical	SWB	
Bombardier et al. (2009)	Supportive management	RCT (PEDro 6/10)	171 people Diagnosis: TBI		BSI ^{a*} ; NFI ^{a*} ; SF-36 ^{a*}					
Hanks et al. (2012)	Supportive management	RCT (PEDro 3/10)	96 people Diagnosis: TBI		BSI-18*		CIM		SF-12 ^{a*}	
Heinemann et al. (2004)	Supportive management	Non-RCT (PEDro 2/10)	319 people Diagnosis: TBI	SF-36			CIQ			SWLS*
Kelly et al. (2013)	Supportive management	Case series	41 people Diagnosis: Mixed brain injury		HADS; RSES					
Perlick et al. (2013)	Supportive management	Case series	11 people Diagnosis: TBI		PHQ*; PCL-C		SPRS*			
Struchen et al. (2011)	Supportive management	RCT (PEDro 3/10)	30 people Diagnosis: TBI		CES-D; UCLA		CHART-SF			SWLS

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Dawson et al. (2013)	Meaningful activity	Non-RCT (PEDro 3/10)	13 people Diagnosis: TBI			DEX	M2PI*		
Doig et al. (2011)	Meaningful activity	RCT (PEDro 3/10)	14 people Diagnosis: TBI	MPAI-4*			SPRS*		
Douglas et al. (2006)	Meaningful activity	Case series	25 people Diagnosis: TBI		NFI ^{a*} ; SF-12 ^{a*}		CIQ ^{a*}		QOL-GR
Goverover et al. (2007)	Meaningful activity	RCT (PEDro 5/10)	20 people Diagnosis: Mixed brain injury			AQ	CIQ		
Owensworth et al. (2008)	Meaningful activity	RCT (PEDro 7/10)	35 people Diagnosis: Mixed brain injury			PCRS			
Thomas (2004)	Meaningful activity	Non-RCT (PEDro 5/10)	22 people Diagnosis: Mixed brain injury	QOLI*					

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Walker et al. (2005)	Meaningful activity	Case series	11 people Diagnosis: TBI	GWB	DASS				
Blake & Batson (2009)	Physical exercise	RCT (PEDro 6/10)	20 people Diagnosis: TBI			GHQ-12*			PSDQ
Driver & O'Connor (2003)	Physical exercise	RCT (PEDro 2/10)	Unknown Diagnosis: Mixed brain injury						PSDQ ^{a*} PAAS*
Driver et al. (2006)	Physical exercise	RCT (PEDro 3/10)	18 people Diagnosis: Mixed brain injury						PSDQ ^{a*}
Driver & Ede (2009)	Physical exercise	RCT (PEDro 3/10)	16 people Diagnosis: TBI			POMS*			
Evans et al. (2009)	Physical exercise	RCT (PEDro 6/10)	19 people Diagnosis: Mixed brain injury					DTQ	

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Gemmell & Leathem (2006)	Physical exercise	RCT (PEDro 3/10)	18 people Diagnosis: TBI	SF-36	VAMS*; RSES				
Hassett et al. (2009)	Physical exercise	RCT (PEDro 7/10)	62 people Diagnosis: TBI		DASS; POMS		SPRS; BICRO-39		
Hoffman et al. (2010)	Physical exercise	RCT (PEDro 4/10)	84 people Diagnosis: TBI	SF-12; PQOL	BDI-II		CHART-SF	BPI*; PittSI; HISC; APS	
Mumford et al. (2012)	Physical exercise	Case series	9 people Diagnosis: TBI	NFI					
Thornton et al. (2005)	Physical exercise	Non-RCT (PEDro 2/10)	27 people Diagnosis: TBI					LEFS	
Wise et al. (2012)	Physical exercise	RCT (PEDro 3/10)	40 people Diagnosis: TBI	PQOL*; SF-12*	BDI-II*		CHART-SF	APS; BPI; PSQI	
Brenner et al. (2012)	Lifestyle	RCT (PEDro 6/10)	74 people Diagnosis: TBI	SRAHP; SF-12; NFI; PWS			PART ^a		SWLS

Study	Treatment type	Study design	Number of participants	Type of measure					
				Multi	Psych	Cognitive	Social	Physical	SWB
Cooper et al. (2009)	Lifestyle	Case series	7 people Diagnosis: Mixed brain injury	SF-36*	HADS			BIFS; ESS	
Fleming et al. (2009)	Lifestyle	Non-RCT (PEDro 3/10)	36 people Diagnosis: Mixed brain injury		HADS*; BICRO-39 ^a psych			SPRS*	

Note. Multi=multi-dimensional; Psych=psychological; SWB=subjective well-being; RCT=Randomised controlled trial; Non-RCT=Non-randomised controlled trial.

^aThis outcome measure is a variant of the original

*denotes statistically significant change on that measure

Table 3.2. *A list of all the different QOL measures used.*

APS	Analog Pain Scale
AQ*	Awareness Questionnaire
AQ-12	Aggression Questionnaire-12
AttQ	Attention Questionnaire
BDI-II	Beck Depression Inventory-II
BHS	Beck Hopelessness Scale
BICRO-39 ^a	Brain Injury Community Rehabilitation Outcome Measure
BIFS*	Brain Injury Fatigue Scale
BPI	Brief Pain Inventory
BSI-18	Brief Symptom Inventory 18
BSI ^a	Brief Symptom Inventory
BSS	Beck Scale for Suicide Ideation
CDQ	Cognitive Difficulties Questionnaire
CES-D	Centre for Epidemiological Studies – Depression Scale
CFQ	Cognitive Failures Questionnaire
CHART-SF	Craig Handicap Assessment and Reporting Technique – Short Form
CIM	Community Integration Measure
CIQ ^{a*}	Community Integration Questionnaire
CPI	Chronic Pain Index
CPRS	Comprehensive Psychopathological Rating Scale
CSEI	Coppersmith Self-Esteem Inventory
DASS	Depression, Anxiety and Stress Scale
DEX*	Dysexecutive Questionnaire
DRS*	Disability Rating Scale
DTQ	Dual Tasking Questionnaire
EBIQ*	European Brain Injury Questionnaire
EMQ*	Everyday Memory Questionnaire
EQ	EuroQol Questionnaire
EQ-5D	EQ-5D (EuroQol group)
EQ-VAS	EQ Visual Analogue Scale (EuroQol group)
ESS	Epworth Sleepiness Scale
FIS	Fatigue Impact Scale
FrSBe	Frontal System Behaviour Scale
FSE*	Functional Status Examination
GHQ-12	General Health Questionnaire-12
GHQ-28	General Health Questionnaire-28
GWB	General Well-Being Questionnaire
HADS	Hospital and Depression Scale
HANA	Headache Needs Assessment
HDI	Headache Disability Inventory
HIBS	Head Injury Behaviour Scale
HISC*	Head Injury Symptom Checklist
IBS	UPPS Impulsive Behaviour Scale (selected scales)
LEFS	Lower Extremity Functional Scale
M2PI*	Mayo-Portland Participation Index
MAACL	Multiple Affect Adjective Checklist
MABD	Mental Adjustment to Brain Damage Scale
MEL	Memory in Everyday Life
MFS	Mental Fatigue Self-Assessment
MFE	Memory Failures in Everyday Memory Questionnaire
MPAI-4*	Mayo-Portland Adaptability Inventory-4
MSNQ	Multiple Sclerosis Neuropsychological Screening Questionnaire

NEADL	Nottingham Extended Activities of Daily Living
NFI ^{a*}	Neurobehavioural Functioning Inventory
NFI-R*	Neurobehavioural Functioning Inventory - Revised
NHP	Nottingham Health Profile
PAAS	Physical Activity Affect Scale
PANAS	Positive Affect Negative Affect Scale
PART*	Participation Assessment of Recombined Tools
PC	Problem Checklist (selected scales)
PCL-M	Post-traumatic Stress Disorder Checklist – Military Version
PCL-C	Post-traumatic Stress Disorder Checklist – Civilian Version
PCRS ^a	Patient Competency Rating Scale
PHQ	PHQ (selected scales)
PHQ-9	Patient Health Questionnaires-9
POMS	The Profile of Mood States
POPS*	Participation Objective, Participation Subjective
PMQ	Prospective Memory Questionnaire
PQOL	Perceived Quality of Life Scale
PQOL-M	Perceived Quality of Life Scale - Modified
PRMQ	Prospective-Retrospective Memory Questionnaire
PSDQ ^a	Physical Self-Description Questionnaire
PSQI	Pittsburgh Sleep Quality Index
PSI	Problem Solving Inventory
PittSI	Pittsburgh Sleep Inventory
PSQ	Problem Solving Questionnaire
PSS	Perceived Stress Scale
PWS	Perceived Wellness Scale
QOL-A	Quality of Life – Analog Scale
QOL-GR	Quality of Life – Global Rating
QOLI	Quality of Life Inventory
QOLIBRI*	Quality of Life in Brain Injury Questionnaire
RAND-36	RAND-36 Health Survey (selected items)
RHFUQ*	Rivermead Head Injury Follow-Up Questionnaire
RSES	Rosenberg Self-Esteem Scale
SDS	Severity of Dependence Scale
SF-12 ^a	Short Form Health Survey
SF-36 ^a	Short Form-36
SCL-90-R	Symptom Checklist 90 - Revised
SIP ^a	Sickness Impact Profile
SPAI	Social Phobia and Anxiety Inventory
SPSI-R	Social Problem Solving Inventory - Revised
SPRS*	Sydney Psychosocial Reintegration Scale
SRAHP	Self-Rated Abilities for Health Practices Scale
STAXI ^a	Stait-Trait Anger Expression Inventory
SWLS	Satisfaction With Life Scale
THI	Tinnitus Handicap Inventory
UCLA	UCLA Loneliness Scale – Version 3
VAMS	Visual Analogue Mood Scales
WHSSQOLI	Wisconsin HSS Quality of Life Questionnaire
WMQ	Working Memory Questionnaire
WSRS*	Wimbledon Self-Report Scale

^aThe measures, which had an original, and variant form (n=14). The BSI, NFI, SF-12 and PSDQ each had an original and two variant forms.

*Brain injury specific measures.

3.2.1 Effect of treatment on QOL

The treatment studies were reviewed in several ways to examine their effect on QOL. The studies were reviewed according to their level of evidence, treatment type, the number of participants according to the level of evidence and treatment type, improvement on a QOL measure according to treatment type, and the intensity and delivery of treatment according to treatment type and improvement on a QOL measure. Amongst the 82 behavioural treatment studies (as per Table 3.1 above), 116 QOL measures were used (as per Table 3.2 above), and 224 effects of the treatment were investigated (hereafter referred to as 'QOL measures' for ease). For many studies, more than one QOL measure was used. Overall, positive effects of behavioural treatment were found for 91 of the 224 QOL measures (41%).

Considering methodological strength of treatment studies, 59 of the 82 studies represented Level 1 or 2 evidence, as highlighted earlier in this chapter. There were 43 RCTs and 16 non-RCTs reported on, and PEDro ratings provided a further grading of study quality (Table 3.3). From within these studies, positive effects of treatment were found for 62 of the 166 QOL measures (37%). A breakdown according to study strength revealed positive treatment effects in 26% of Good evidence studies, 41% of Fair evidence studies, and 48% of Poor evidence studies.

Table 3.3. *Analysis of positive treatment effect of Level 1 and 2 evidence studies according to PEDro ratings (N=59)*

Strength of evidence	Number of studies	Number of measures	Positive treatment effect reported
Excellent (9-10)	0	0	0
Good (6-8)	21	69	18 (26%)
Fair (4-5)	12	32	13 (41%)
Poor (<4)	26	65	31 (48%)
Total	59	166	62

Positive treatment effects were subsequently considered according to treatment type, and the content of treatment (as outlined in each article) determined the allocation of the study to one of seven treatment types (see Table 3.4). Initially, the 82 studies were classified into six treatment types as identified and defined by the author of the thesis (NB) and comprised: communication; psychological; cognitive; supportive management; physical exercise; and meaningful activity treatment types. The allocation of studies into treatment type was checked and verified independently by a member of the supervision team (MC), who agreed with the treatment type definitions and the allocated treatment type for 62 of the 82 studies. The remaining 20 studies were reviewed in further detail and discussed for consensus agreement. Of the 20 studies, 15 remained in their allocated treatment type, two studies were re-grouped to a different treatment type, and three were considered to represent a new treatment type, namely lifestyle. The initial 62 grouped studies were then re-checked to ensure none represented this new treatment type, and none were re-grouped.

Table 3.4. *Description and number of treatment types amongst reviewed studies (N=82)*

Treatment type	Number of studies	Description
Psychological	25	Treatments focused on teaching strategies to address emotional distress (e.g. anxiety and depression), coping and anger issues. These treatments included CBT or mindfulness.
Cognitive	23	Treatments focused on specific cognitive-related skills (e.g. attention, memory, executive function, problem solving) and/or helping the person with ABI to understand the impact of their cognitive impairments.
Physical	11	Treatments focused on physical exercise (e.g. local gym, fitness, Tai Chi, aquatic) or structured physical exercise (e.g. for upper limbs).
Supportive	8	Treatments focused on supportive management either by a trained professional (e.g. psychologist), case manager or peer (i.e. person with ABI). These treatments included both face-to-face or distance contact (e.g. telephone support).
Meaningful activity	7	Treatments focused on meaningful activities either chosen by the person with ABI or provided in a structured format (e.g. IADLs).
Communication	5	Treatments focused on targeting social communication skills (as defined in section 2.1.1).
Lifestyle	3	Treatments focused on teaching strategies or providing suggestions for broad life issues (e.g. managing fatigue in life, benefit of exercise, managing environmental problems).

Note. CBT = cognitive-behavioural therapy; IADL = instrumental activities of daily living

Table 3.5 shows participant numbers according to treatment type and the quality of the evidence. In two studies, the same participants had been reported in an earlier study that was also included in this review, but at a different time point (Arundine et al., 2012; Bombardier et al., 2009). That is, in the Arundine et al. study (2012) the participants were also reported in the Bradbury et al. study (2008), and the participants from the study by Bombardier et al. (2009) were also reported in the study by Bell et al. (2005). Therefore, each group of participants were only included once in Table 3.5. In addition, one study did not report sample size (Driver & O'Connor, 2003). Aggregation of participants from across the remaining 79 studies revealed that 3,432 people with ABI were included in the treatment studies. Treatments most widely researched for people with ABI (i.e. supportive management, psychological and cognitive treatments) comprised the largest sample sizes.

Table 3.5. *Participant numbers according to treatment type and strength of evidence (N=79).*

Treatment type	Level 1 + 2			Level 3	Total
	Good	Fair	Poor		
Supportive	604	0	445	52	1101
Psychological	88	164	334	219	805
Cognitive	293	88	300	112	793
Physical	101	84	119	9	313
Communication	133	0	0	30	163
Meaningful	35	42	27	36	140
Lifestyle	74	0	36	7	117

QOL measures were scrutinised for improvement, and considered according to treatment type (Table 3.6). Across the 224 QOL measures, more of the meaningful activity treatments (50%) and psychological treatments (49%) showed improvement, followed by supportive management (41%) and cognitive treatments (40%). The least change was found for treatments of the physical (32%), lifestyle (23%) and communication types (18%). Caution should be exercised with the interpretation of these results for two reasons. First, this table should not be interpreted as an indication of the relative efficacy of different treatment types. The purpose of grouping similar treatments based on content and aims was to extract core principles important to project-based treatment. Not all studies within each treatment type examined the same treatment over a similar period of time and so can't be explicitly compared. Second, caution also needs to be exercised when the results are compared with Tables 3.1 and Table 3.5, as the meaningful activity, and psychological treatments that showed improvement are from a low quality evidence base (i.e. poor quality level 1 or 2 evidence, and level 3 evidence). Meaningful activity treatments showed improvement in 5/7 studies, with four of these being of low quality, and psychological treatments showed improvement in 20/25 studies, with 12 of these being of low quality.

Table 3.6. *Improvement on QOL measures according to treatment type*

Treatment type	Number of times measure used	Improvement
Meaningful	14	7 (50%)
Psychological	63	31 (49%)
Supportive	33	13 (41%)
Cognitive	59	25 (40%)
Physical	31	10 (32%)
Lifestyle	13	3 (23%)
Communication	11	2 (18%)
Total	224	91

To further describe the treatments that have an effect on QOL, treatment intensity and delivery was also investigated. Treatment intensity refers to the number of hours and weeks of therapy; treatment delivery refers to the format of therapy (i.e. individual, group, or combined).

For treatment intensity, 78 studies described the number of weeks of treatment, and 60 studies reported the number of hours of treatment (Table 3.7). Most studies lasted from 5 weeks to 15 weeks (53/78), with improvement occurring more in treatments that lasted 4 months to a year. Most studies reported less than 14 hours treatment (25/60), and 42% of QOL measures showing improvement, however more QOL measures (46%) showed improvement in treatments that lasted 21-30 hours. Extreme caution should be exercised as to what conclusions can be drawn from these results, as there was considerable variability in the data and the difference between treatments lasting less than 14 hours compared to 21-30 hours is marginal (i.e. 42% cf. 46%). Moreover, the data extracted from the studies only indicated the number of

measures that showed statistically significant change. The magnitude of change is not explored. The purpose of this level analysis was to guide the appropriate length and delivery of project-based treatment. To draw more definitive conclusions with implications for clinical practice, further research would need to explicitly compare specific and identical treatments of varying lengths and delivery.

Table 3.7. *The effect of treatment intensity (in weeks and hours) on QOL measures*

	No. of studies	No. of measures	Improvement (%)
Weeks of treatment:			
< 4 weeks	8	14	5 (36%)
5-8 weeks	27	61	28 (46%)
9-15 weeks	26	89	28 (31%)
4 months - 1 year	14	39	23 (59%)
> 1 year	3	12	2 (17%)
Total	78	215	86
Hours of treatment:			
< 14 hours	25	73	31 (42%)
15-20 hours	13	37	8 (22%)
21-30 hours	16	24	11 (46%)
> 31 hours	6	25	7 (28%)
Total	60	159	57

For treatment delivery, the majority of studies (i.e. 45/79) were individual treatments (Table 3.8). One study did not report treatment delivery type (Bedard et al., 2014), and two studies did individual treatment for some participants and group treatment for others without an analysis of the difference (Bradbury et al., 2008; Arundine et al., 2012), and were excluded. From those examined, improvement

occurred more in treatments that combined individual with group treatment (n=5).

However, improvement was also seen in the individual and group treatments separately.

Table 3.8. *The effect of treatment delivery on QOL measures*

Treatment approach	No. of studies	No. of measures	Improvement (%)
Combined	5	13	6 (46%)
Individual	45	114	50 (44%)
Group	29	88	29 (33%)
Total	79	215	

3.2.2 Measures that show change in QOL

The second aim of this review was to identify the range and type of QOL measures that are utilised in research studies in general, and specifically identify the measures that show improvement. QOL measures were classified as multi-dimensional HRQOL, uni-dimensional HRQOL (i.e. cognitive, physical, psychological or social health), or subjective well-being. Each HRQOL dimension was defined using the descriptors (Table 3.9) used for a systematic review of QOL measures for people with ABI (Berger et al., 1999). Initially, the overall aim and theoretical underpinning of the measure was identified, and then items were compared against the descriptors for the dimensions. Classification was undertaken by the thesis author, and checked with a member of the supervisor team (MC).

Table 3.9. *HRQOL dimensions*

HRQOL dimension	Description
Psychological	Problems regarding personality and behavioural alterations, affective disorders e.g. anxiety, depression, aggressivity, loneliness and self-esteem
Cognitive	Neuropsychological impairments, e.g. memory, attention, concentration deficits, executive function and awareness
Physical	Neurological impairments, pain, sleep problems, problems with functional independence and mobility in daily life
Social	Problems regarding the social network and social and/or community integration

One hundred and sixteen (116) different QOL measures were used across the 82 treatment studies. There was much variability amongst the type of measure chosen for psychological, physical, cognitive and multi-dimensional health measures, and much less variability for the social health and subjective well-being measures (Table 3.10).

Table 3.10. *Occurrence of QOL measures according to measure type*

QOL measure type	Different type of measures
Multi-dimensional	22
Psychological	39
Social	13
Physical	17
Cognitive	19
Subjective Well-Being	6
Total	116

Improvement was considered according to type of QOL measure (Table 3.11). Subjective well-being measures (55%) detected the most change, followed by psychological health measures (48%), physical health measures (45%), and cognitive health measures (44%).

Table 3.11. *Type of QOL measures to show most change post-treatment*

Measure type	Number of times measure used	Improvement
Subjective Well-Being	11	6 (55%)
Psychological	86	41 (48%)
Physical	20	9 (45%)
Cognitive	32	14 (44%)
Multi-dimensional	38	13 (34%)
Social	8	37 (22%)
Total	224	91 (41%)

Finally, to complete the review of treatment studies, respondent burden for completing QOL measures was evaluated. The number of measures (and number of items per QOL measure) was calculated for each study as administered to people with ABI across the 80 articles. While most studies contained QOL measures, some studies also included other measures (e.g. coping and self-efficacy) used by the studies' authors to evaluate treatment outcome, but not considered QOL measures by this thesis author. These additional measures were included in the evaluation for respondent burden. Studies typically administered three measures (mean=3.3, SD=2.2, range 1-10) with an average of 77 items (SD=56, range 12-250) across the measures, to evaluate QOL measures in the treatment study.

3.3 Summary

The two aims of this review was to determine the effect of behavioural treatments on improving QOL for people with ABI, and identify the type of QOL measures that show change. Eighty articles that described 82 studies, seven treatment types, and used 116 different QOL measures were examined following a review that was systematically conducted. Overall, 41% of measures showed improvement on QOL measures post-treatment. A large proportion of these studies were randomised or non-randomised controlled trials. This summary will examine the relationship between changes in QOL and treatment type, the effect treatment intensity and delivery may have on outcome, and how to measure QOL. The limitations of this review will also be discussed, with some concluding comments.

There is a potential pattern between changes in QOL as associated with treatment type. The type of treatment can have an impact on how a person perceives their QOL. More of the meaningful activity and psychological treatment studies showed

improvements in QOL. Meaningful activities are often chosen by the individual so are personally meaningful and motivating to them. However, such treatments are under-researched, i.e. to date there have been only seven studies reporting on 140 participants. Conversely, psychological treatments are more widely researched and typically focus on giving feedback and strategies to address emotional distress, which are common following an ABI. The feedback and strategies given may be individualised, or if given in a group context, given to people with ABI that have particular problems in that area. The aim of psychological treatments is to provide a person with ABI with a set of strategies that enable increased self-monitoring and regulation of a person's own skills and emotional state. Given the success of both treatment types in achieving positive treatment effects on QOL, key principles or aspects of both treatments would ideally be integrated into the design of project-based treatment in the current study. These principles will be further discussed in the next chapter.

Treatment intensity and delivery is often a dilemma faced by researchers conducting treatment studies for people with ABI. This review highlighted that there is much variability in both, and that the impact on QOL is mixed. The intensity of treatment needs to reflect both what is practical, with what is necessary to create change for a person with ABI. While one may have assumed that an increased number of hours and weeks may have a better effect on QOL, the results are less clear. In fact, some of the least positive results were found in treatments greater than 31 hours and/or more than a year. The results of this review suggest that treatments greater than 4 weeks and up to 30 hours may have some degree of success for improving QOL, but these should be interpreted cautiously as other factors such as the type of treatment are likely to have a greater impact on outcome. For treatment delivery, the most change was derived from a combined approach that included both individual and group treatment. However,

individual and group treatments separately also produced a large proportion of change on QOL measures. Whilst these findings do not present a definitive picture for treatment intensity and delivery, the main overall findings were considered in the development of project-based treatment in this study.

While treatment content, intensity and delivery affect treatment outcome, QOL is a difficult construct to measure in people with ABI. The choice of measure and its responsiveness to change can be considered just as important. Von Steinbuechel, Richter, Morawetz, & Riemsma (2005) highlighted the methodological challenges for measuring a construct such as QOL in people with cognitive deficits and recommended an assessment of neuropsychological status for reasons of validity. As a result, careful consideration should be given to the measure chosen. Across the 80 articles, 116 different QOL measures were used, and great variability was noted within domains of QOL. In cognitive health for example, 19 different measures were used on the 32 occasions cognitive health was measured. While less variability was observed in other areas of QOL (e.g. subjective well-being and social health), there is no clear picture of a preferred QOL measure in ABI, and international consensus for QOL outcome measures used in treatment effectiveness and efficacy research in ABI is urgently needed. The review does provide helpful guidance to researchers as to the number of measures (and items) that could be administered to ensure respondent burden is considered. Essentially though, the choice of measure should correspond closely with the aims of the treatment. For example, psychological treatments mainly used psychological health measures, and cognitive treatments mainly used cognitive health measures. Whilst the most popular measures can be identified, the most popular measures are not necessarily the ones to show the most change. For example, a popular social health measure was the CIQ however, on the 16 occasions it was used, it

demonstrated improvement on only 3 occasions. This limited change may indicate the treatment was not effective, however, it can equally indicate the measure may lack sensitivity to change. Many researchers have often pointed out in their discussion of non-significant results that the problem may have related to the sensitivity of the measure (Bornhofen & McDonald, 2008a; Cooper, Reynolds, & Bateman, 2009; Trombly, Radomski, Trexel, & Burnett-Smith, 2002; Walker et al., 2005). Thus, there is no definitive suggestion to choose one QOL measure over another on the basis of this review.

A major finding of this review is the degree of low and poor quality evidence in the field of ABI treatment literature, and the subsequent need to design more methodologically stronger studies to ensure a stronger evidence base. There was much variability in the levels of evidence with almost 60% being of poor quality (Level 1 and 2 evidence) or case series design (Level 3 evidence). Participant numbers for the poor quality Level 1 and 2 studies, and Level 3 studies combined was greater than 50% of participants in this review. The quality of the evidence is important for making clear conclusions about the effectiveness of particular treatments and should be integral to the design of future studies.

One of the limitations of this review was that it described the effect of different treatment types defined according to content rather than behavioural change techniques (Michie et al., 2011). While improvement on QOL may be more related to the techniques used, defining a treatment according to behavioural change techniques would constitute a separate line of enquiry, which is beyond the scope of this study. This review has shown that the majority (59%) of QOL measures reported in the studies were non-significant and showed no effect of treatment. Whilst various reasons can be proposed for this, it may be that quantitative measures don't always reveal change, and

mixed method assessment may help illuminate what happens and changes in a treatment for people with ABI. Increasingly, ABI treatment studies are using mixed methods to better understand the experience of participants during the treatment. Of the 80 articles described in this review, 13 used mixed methods (Aboulafia-Brakha, Buschbeck, Rochat, & Annoni, 2013; Anson & Ponsford, 2006a; Backhaus, Ibarra, Klyce, Trexler, & Malec, 2010; Cooper et al., 2009; Douglas et al., 2006; Fleming, Kuipers, Foster, Smith, & Doig, 2009; Gurr & Coetzer, 2005; Henry et al., 2012; Johansson & Tornmalm, 2012; Struchen et al., 2011; Thickpenney-Davis & Barker-Collo, 2007; Thomas, 2004; Thornton et al., 2005). The nature of ABI treatments is that they are complex, and designed to address a range of concerns, problems and needs in a heterogeneous group of people. What may work for one person may not work for another. Mixed methods can help to obtain a richer source of information about the participant's experience of the complex treatment. Moreover, negative quantitative findings may be related to poor choice of measure, so mixed methods help to identify sources of change that may not be captured by the chosen measures.

This review set out to identify the type of treatments that impact on QOL, in order to identify potential principles that should be incorporated to project-based treatment. Principles from both meaningful activity and psychological treatments could have an impact on QOL. Moreover, the use of mixed methods may help to describe the participant experience of the treatment. The following chapter aims to synthesise what has been learnt thus far from the first three chapters, and describes a set of principles that would be important to the design of project-based treatment, if it intends to have an effect on both communication skills and QOL.

Chapter 4 Principles of project-based treatment

The aim of the previous two chapters was to further understand the treatments that improve communication skills and QOL, and to help identify what are deemed to be some of the core principles to treatments. Already, in Chapter 2 (i.e. communication treatment review), three principles were discussed in a preliminary manner (see section 2.2.2), which will be further discussed here, with reference to best practice recommendations (Togher et al., 2014). These principles were the need to set individualised goals that the person with ABI can work towards during the treatment period; the need to make use of groups; and the need to involve a person's communication partner. In Chapter 3, two treatment types (i.e. meaningful activity and psychological) showed more change on QOL measures than the other treatment types. Therefore, two further principles were identified; the need to employ activities and tasks that are meaningful, and the need for treatment to take account of a person's existing cognitive abilities. This last principle is partly derived from the psychological treatments and partly from what is considered to be integral to any treatment involving people with ABI, regardless of its specific aims. People with ABI present with a range of cognitive impairments that impact treatment delivery (Cicerone et al., 2011). These impairments should be taken into account for any treatment that intends to make changes (Prigatano, 1999; Togher et al., 2014; Velikonja et al., 2014). Each of these five principles will be discussed below, with reference to how they were incorporated into the project-based treatment design.

4.1 Account for existing cognitive abilities

A treatment for people with ABI needs to take a person's cognitive ability into account, irrespective of the treatment content. Cognitive impairments are common, long-standing, and pervasive post-injury (Levin & Kraus, 1994; Prigatano, 1999; Sohlberg & Mateer, 2001), and can have an impact on treatment delivery, and the uptake or development of target skills (Anson & Ponsford, 2006b; Bornhofen & McDonald, 2008a; Cicerone et al., 2011). In particular, there may be impairments in memory, concentration, new learning, executive function, and awareness. Even if treatments are not intended to improve cognitive ability, treatments must accommodate a person's existing cognitive ability, and make adjustments to the treatment in order for people to get the most benefit (Togher et al., 2014; Velikonja et al., 2014).

Several studies have provided practical suggestions on how to make such accommodations. Difficulties with attention, concentration and fatigue can be overcome by limiting the duration of sessions to no more than 2 hours and incorporating frequent breaks (Hodgson, McDonald, Tate, & Gertler, 2005). Impairments in new learning and memory can be addressed by increasing the intensity of sessions, involving family members (Khan-Bourne & Brown, 2003), giving frequent repetitions of information, and using visual aids and session summaries (Hodgson et al., 2005; Ponsford, Sloan, & Snow, 1995). Elements of these were incorporated into project-based treatment with respect to session duration and structure, and use of supportive visual aids.

More recently, technologies have emerged to overcome impaired recall of treatment goals and session information. In particular, there has been an increase in the use of mobile assistive technologies to support cognition including good evidence for technologies that call attention to goals (Gillespie, Best, & O'Neill, 2012). Recall is important for treatment success and reiterating goals can increase the chance of

achievement (Miller & Rollnick, 2002). While studies have shown improved goal recall from a range of electronic devices (Dowds et al., 2011; Hart, Hawkey, & Whyte, 2002), these devices often require many hours of training (Svoboda, Richards, Leach, & Mertens, 2012). Mobile phones address this problem, as they are commonplace, socially acceptable and unlikely to require training. Culley and Evans (2010) found that 11 people with TBI had better goal recall from daily text reminders of their goals compared to a group that did not receive text reminders. The only ‘training’ requirements were to make sure the goal could be understood and expressed in a single sentence, and that the person with brain injury knew how to receive and read a text. Text reminders prompt the person with ABI to remember and think about their goals and prompt engagement in goal-directed behaviour thus, reducing the need for clinician-led monitoring. Other studies have demonstrated the benefit of text-based systems as a reminder for specific information and/or to engage in specific behaviours (Fish et al., 2007; McDonald et al., 2011; Wilson, Emslie, Quirk, & Evans, 2001). This study incorporated frequent text reminders of a person’s goals, and homework-related tasks, sent to both the person with ABI and their communication partner, to help improve recall and completion of tasks.

Impaired executive function and limitations in goal-directed behaviour can effect recovery. These areas can be partially addressed by conducting sessions in a structured and routine format (Hodgson et al., 2005; Khan-Bourne & Brown, 2003). In addition, strategies that use step-by-step procedures, with metacognitive skills training, can also help to deal with impaired executive function (Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011; Kennedy et al., 2008). A systematic review of treatments for executive function (Kennedy et al., 2008) found that many studies use step-by-step procedures to improve everyday problem solving, which could be supported by visual scaffolds, such as the goal-obstacles-plan-do-review framework

(Ylvisaker, Sellers, & Edelman, 1998), or the traffic light system (Miotto, Evans, de Lucia, & Scaff, 2009). In addition, Chapter 3 highlighted that psychological treatments that give strategies to help improve a person's ability to self-monitor and self-regulate their skills, is important to improving QOL. Metacognitive skills training, which refers to improving a person's ability to self-monitor, evaluate and regulate their performance on tasks, can be built into the step-by-step procedures described above (Cicerone et al., 2011; Kennedy et al., 2008; Ponsford et al., 2014). This training helps to build self-awareness, increase strategy use, and transfer and generalise skills to everyday situations (Cicerone et al., 2011; Kennedy et al., 2008; Ownsworth et al., 2008). Prigatano and Wong (1999) suggest that getting a person to predict and evaluate task performance should be emphasised for repeated tasks. Several studies have demonstrated the positive effects of treatments that have included self-prediction and evaluation on goal achievement (Kreutzer, Stejskal, Godwin, Powell, & Arango-Lasprilla, 2010), self-regulation skills (Goverover, Johnston, Toglia, & Deluca, 2007; Ownsworth, McFarland, & Young, 2000), psychosocial functioning (Ownsworth et al., 2000) and functional task performance (Goverover et al., 2007; Ownsworth, Fleming, Desbois, Strong, & Kuipers, 2006; Ownsworth, Quinn, Fleming, Kendall, & Shum, 2010). More recently, the use of metacognitive skills training has been advocated for working with people with ABI with communication impairments (Togher et al., 2014). The use of a structured session, visual scaffold for problem solving, and metacognitive skills training for tasks within sessions and working on goals, was built into the design of project-based treatment as a result.

Treatments for people with ABI need to address impaired awareness, which can affect response to treatment (Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011; Fleming, Strong, & Ashton, 1998; Ownsworth et al., 2008; Ownsworth et al.,

2000; Prigatano & Wong, 1999; Thomas, 2004). Impaired awareness or impaired acceptance of difficulties can reduce the motivation to engage in treatment, i.e. there may be poor compliance with strategies and techniques to remediate impairments if the person with ABI does not acknowledge that those impairments exist (Fleming et al., 1998; Katz, Fleming, Keren, Lightbody, & Hartman-Maeir, 2002; Sohlberg & Mateer, 2001; Trahan, Pépin, & Hopps, 2006). As a result, treatment approaches need to reflect the underlying cause of a person's impaired awareness whether it is neurocognitive, psychological or socio-environmental (Fleming & Ownsworth, 2006). For example, if the underlying cause is neurocognitive, then approaches may include selecting key tasks to develop awareness, providing clear feedback and opportunities for a person to evaluate their performance and group therapy. In reality, a person with ABI may have a combination of contributing factors that require a range of treatment approaches that address impaired awareness. As a result, some people with ABI may respond more favourably to some treatments than others. As a result, a range of strategies that address awareness were incorporated into project-based treatment (e.g. non-confrontational treatment environment, video-taping, feedback, involvement of communication partners).

4.2 Meaningful activity

The creation of meaning during the treatment process is considered essential, if people with ABI are to engage with the rehabilitation process (Douglas, 2010a; Häggström & Lund, 2008; Ylvisaker, Feeney, et al., 2007). The review of QOL treatment studies highlighted that more of the meaningful activity treatments showed change, with 50% of QOL measures showing improvement post-treatment. Moreover, people with ABI who have previously engaged in project-based treatment, described

projects as “meaningful to them” (Ylvisaker, Feeney, et al., 2007, p.228). Ylvisaker, Feeney et al. (2007) suggests that “in the absence of meaningful engagement in chosen life activities, all interventions ultimately fail” (p.207). People with brain injury want to take part, give something back and be someone (McColl et al., 1998; Schipper et al., 2011). They want to make decisions and exert influence, be engaged in meaningful activities, do things for others and develop a sense of belonging (Häggström & Lund, 2008). For these reasons, ‘meaning’ is commonly referred to when describing goals (Doig, Fleming, Kuipers, Cornwell, & Khan, 2011; Ownsworth et al., 2008; Trombly et al., 2002), activities (Fleming, Lucas, & Lightbody, 2006; Häggström & Lund, 2008; McColl et al., 1998; Schipper et al., 2011; Ylvisaker, Feeney, et al., 2007), participation (Häggström & Lund, 2008; Hammel et al., 2008), engagement (Douglas, 2010a; Ylvisaker, Feeney, et al., 2007), and roles (Schipper et al., 2011; Ylvisaker, Jacobs, & Feeney, 2003) for people following an ABI.

In designing a treatment for people with brain injury, how meaning is defined and the context in which meaning will be derived needs to be considered. Hence, good consideration of the basis of meaning is explained here. Meaning can be difficult to define due to its complex, fluid and multifaceted nature (Heintzelman & King, 2013; Leontiev, 2013). However, three features commonly exist across definitions of meaning: connectedness, coherence, and subjectivity (Heintzelman & King, 2013). Connectedness refers to the linking of experiences, so that they can be understood and interpreted (Baumeister & Vohs, 2002). There also needs to be a sense of coherence to the experience of meaning. That is, meaning involves the person making an evaluation of their life or experiences as making sense or being coherent (Baumeister & Vohs, 2002) within a superordinate context (e.g. a goal, motivation, from life at large) (Leontiev, 2013). Both these features relate to meaningfulness. Conversely, a life that is

disconnected and fragmented (incoherent) is meaningless. Subjectivity refers to the subjective experience of connectedness and coherence. It acknowledges that the experiences in a person's life have no meaning unless they are meaningful to someone. Overall, the ability of a person to derive meaning from their life is related to their QOL, irrespective of disability (Emmons, 2003; Roepke, Jayawickreme, & Riffle, 2014; Steger, Oishi, & Kesebir, 2011).

Meaning can be derived from many contexts. Treatments for people with ABI and particularly meaningful activity treatments aim to provide an individualised context for a person with ABI to derive meaning. Many of these treatments have emerged from the occupational therapy literature, which suggests that the meaningful activities a person engages with can predict their QOL (Eakman, 2013, 2014). However, actions or activities alone cannot create meaning. The affective response to those activities and the superordinate link between the activities and the purpose (or goal), or the motivation for the goal, is also important to derive meaning (Leontiev, 2013). In fact, there are several contexts (or sources) from which to derive meaning (Emmons, 2003; Yalom, 1980). In addition, having multiple contexts beyond the activity alone is important to protecting someone from leading a meaningless life (Baumeister & Vohs, 2002). Therefore, in order to increase engagement, and create improvement, project-based treatment considered multiple contexts in which the person with ABI could derive meaning.

Meaningful contexts can be described according to the level of involvement of the person with brain injury and the goals of the activity. Levasseur, Desrosiers, and Whiteneck (2010) proposed a 6-level taxonomy, derived from a detailed literature search that describes a person's involvement in social activities (alone through to interaction with others) and the goal of the activity (to satisfy basic needs through to helping others and contributing to society) (Figure 4.1). This taxonomy is useful for

understanding meaningful activity treatments for people with ABI as most treatments described in the previous review occurred alone (level 1) and involved activities related to oneself (level 1 and 2) for the purpose of fulfilling basic needs such as cooking, managing finances and shopping (levels 1 and 2). No studies examined meaningful activities at Levels 3-6 including the goal of helping others, which can increase the contexts for a person with ABI to derive meaning. Project-based treatment could be considered situated across Levels 4 and 5.

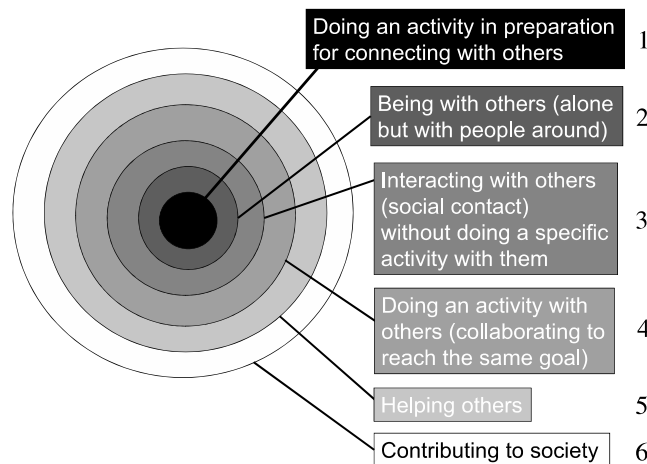


Figure 4.1. Proposed taxonomy of social activities

Project-based treatment is considered to involve a project designed to help others (Ylvisaker, Feeney, et al., 2007). It refers to a situation whereby a person perceives value and meaning through their work, which is considered to make a positive impact on others. This suggests a context larger than the individual themselves to create meaning. Research with other groups has underscored the benefits of philanthropic activity. For example, helping others has been shown to be an important source of meaningfulness in business (Cardador, 2009), has improved mood in university students (Sprecher, Fehr, & Zimmerman, 2007), and can help to advance a person's career

(Rosopa, Schroeder, & Hulett, 2013). As highlighted above, meaningful activity treatments from the previous review focussed primarily on the treatment of personally meaningful activities for people with ABI, with less attention directed to the act of helping others. No studies to date have explored the combination of helping oneself and others while interacting with others, thereby, increasing the contexts from which meaning can be derived, which is explored with project-based treatment.

4.3 Set individualised goals

Goal setting is an important aspect of rehabilitation (Barnes & Ward, 2000; Bovend'Eerdt, Botell, & Wade, 2009; Ownsworth et al., 2008) and results in improved outcomes and increased satisfaction (Leach, Cornwell, Fleming, & Haines, 2010; Ownsworth et al., 2008). The review of communication studies highlighted that there were 16/31 studies that included a goal, or target behaviour that was individualised to the person with ABI, and achieved post-treatment. The INCOG expert panel also recommend that treatments should address goals set by the person with ABI to target communication skills (Togher et al., 2014). Achievement of individualised goals has been reported in many studies involving people with ABI, where a measure to quantify progress has been included (Dawson, Binns, Hunt, Lemsky, & Polatajko, 2013; Doig et al., 2011; Ownsworth et al., 2008; Spikman, Boelen, Lamberts, Brouwer, & Fasotti, 2010; Trombly et al., 2002; Walker et al., 2005).

Goal setting is considered to be a fundamental part of the rehabilitation process (British Society of Rehabilitation Medicine, 2009; Togher et al., 2014). Goal setting should be client centred and individualised, completed collaboratively engaging the 'expertise' of the person with brain injury and be meaningful (Cott, 2004; Gentleman, 2001; Prescott, Fleming, & Doig, 2015). Setting goals in this way will help to integrate

motivation, emotion and personal identity into the rehabilitation process (Siegert, McPherson, & Taylor, 2004). Involvement of the person with ABI is also crucial for goal formulation as it increases their potential for participation in treatment (Cott, 2004; Ownsworth et al., 2008), and leads to more successful outcomes (Bergquist et al., 2012; Malec, 1999; Webb & Glueckauf, 1994). In addition, family involvement can occur during goal setting (Foster et al., 2012; Prescott et al., 2015), which is considered important to the rehabilitation process (British Society of Rehabilitation Medicine, 2009). However, only three Level 1 and 2 studies from the previous reviews explicitly reported inclusion of family members or significant others during the goal setting process (Dahlberg et al., 2007; Doig et al., 2011; Togher et al., 2013). Better outcomes have been reported for people with ABI with engaged families, through active participation or by establishing a working relationship with rehabilitation professionals (Sherer et al., 2007). Family involvement was incorporated into the goal setting process with people with ABI for project-based treatment.

Further factors are known to contribute to the degree of goal achievement, and would need to be addressed if individualised goals are set. These include goal recall (Culley & Evans, 2010), awareness and acceptance of impairments (O'Callaghan, McAllister, & Wilson, 2012), and executive function, which can affect a person's ability to self-monitor and regulate their skills thus affecting maintenance and generalisation of skills. Strategies to address some of these factors were discussed in section 4.1 and include text message reminders of a person's goal (Culley & Evans, 2010), the use of video-taping to improve awareness (Schmidt, Fleming, Ownsworth, & Lannin, 2013), and metacognitive skills training to help improve self-monitoring of goal performance (Ownsworth et al., 2008).

There are both formal and informal approaches to setting goals with people with ABI (Prescott et al., 2015). Formal approaches include Goal Attainment Scaling (GAS) (Malec, Smigielski, & DePompolo, 1991), the Canadian Occupational Performance Measure (COPM)(Law et al., 1994), or a combination of the two (Doig et al., 2011; Trombly et al., 2002). Each of these approaches involves setting goals collaboratively with the person with ABI, and provides a method for quantitatively rating the level of goal achievement. Informal approaches to setting goals are either done collaboratively with the person with ABI, or are therapist-driven, and are based on informal observations, as was the case for many of the single-case studies in the communication review (Burke & Lewis, 1986; Dixon et al., 2004; Giles et al., 1988; Kirsch et al., 2004; Lennox & Brune, 1993; Lewis, Nelson, Nelson, & Reusink, 1988; Schloss et al., 1985; Sohlberg et al., 1988; Zencius et al., 1990). A recent scoping review of 86 studies that examined goal planning approaches revealed that the majority of research studies (77%) used formal approaches (Prescott et al., 2015), which will be used in this study.

4.4 Treatment delivery

Choosing the appropriate delivery method for a treatment can often be difficult. The evidence for group-based treatments were strongest in the communication review, with 10 of the 16 group-based treatments being of Level 1 or 2 evidence (i.e. randomised or non-randomised controlled trials). In comparison, only two individual treatments (2/15) were of Level 1 evidence, with most being single-case designs (12/15). The QOL review showed equivocal evidence for group versus individual treatment, however the study by Ownsworth et al. (2008) which directly compared individual, group, and combined treatment (i.e. group and individual), suggested that groups may offer an advantage that cannot be achieved from the other delivery

methods. They argued that treatment which was concentrated in a group setting might have assisted learning for a broad range of strategies beyond personal goal areas where peer support and feedback is available. For example, groups could help to provide social support, and may confer benefits from meeting others in a similar situation (Sinnakaruppan, Downey, & Morrison, 2005). Whilst there can be many challenges associated with conducting group-based treatments such as logistical and practical issues, and unpredictability of the group, therapists have reported that the positive outcomes from a group outweigh these challenges (Patterson, Fleming, Doig, & Griffin, 2015).

Group-based treatments are increasingly recommended for people with ABI. The INCOG expert panel of researchers and clinicians recognise that the evidence is strongest for group-based treatments of CCD (Togher et al., 2014), as has a recent review of communication treatments for people with ABI (Struchen, 2014). Moreover, this delivery of treatment has been recommended in a systematic review which focused on the cognitive rehabilitation of people with ABI that included people with CCD (Cicerone et al., 2011). Group-based treatments have also been recommended more specifically in a range of cognitive impairments including memory (Velikonja et al., 2014), and executive function and awareness (Tate, Kennedy, et al., 2014). Therefore, this study used groups to deliver project-based treatment.

The number of people in a group can vary. A review of the group studies in Chapters 2 and 3 highlights that groups can have from 2-3 people (Bornhofen & McDonald, 2008a, 2008b; Gajar, Schloss, Schloss, & Thompson, 1984; McDonald et al., 2013; Simpson, Tate, Whiting, & Cotter, 2011) up to 10-14 people (Backhaus et al., 2010; Fleming et al., 2009; Kelly, Ponsford, & Couchman, 2013; Miotto et al., 2009). Previous studies suggest that when there are individualised goals, sufficient time needs

to be allocated for each goal to be focused upon during the group (Brenner et al., 2012). Moreover, a smaller group of no more than 2-3 people allows each person an opportunity to receive feedback and develop individual skills (Brenner et al., 2012; McDonald et al., 2013; Simpson et al., 2011). As this study was part of a PhD with limited resources, which was to be facilitated by a single therapist (NB), smaller groups of 2-3 people was determined to be the most feasible.

4.5 Involvement of the communication partner

Communication partners are known to have a significant impact on conversations involving people with ABI. Their skills can both promote and hinder the communication skills of people with ABI (Togher et al., 1997a, 1997b; Togher et al., 2006). The increased use of positive communication strategies by communication partners (e.g. use of short, simple direct sentences and questions)(Shelton & Shryock, 2007), and regular social contact and opportunities for interaction (Bellon & Rees, 2006), can improve conversations involving people with ABI. As a result, involving communication partners in the treatment process has long been argued as helping to improve the conversational skills of people with ABI (Ylvisaker, Feeney, & Urbanczyk, 1993; Ylvisaker, Sellers, et al., 1998). The communication review highlighted four studies, two randomised controlled trials, and two non-randomised controlled trials, that all showed improvement in conversations involving people with ABI post-treatment. Furthermore, the INCOG expert panel suggest that a treatment for people with CCD should involve education and training of a communication partner (Togher et al., 2014).

The well-designed studies from the communication review demonstrated improved conversations from training a communication partner, with partners including police officers (Togher et al., 2004), family members or significant others (Sim et al.,

2013; Togher et al., 2013), and paid caregivers (Behn et al., 2012). These improvements were perceived to have a positive impact on interactions by both communication partners, and people with ABI (Behn, Togher, & Power, 2015; Togher et al., 2012). Involvement of the communication partner is considered important to help maintain any improvements made, and generalise to other types of conversation (Togher et al., 2013). It is important to note however that in these studies referred to here, that the communication partner was the target of treatment and attended all sessions, as opposed to the model adopted in the current study.

Project-based treatment is focused on achieving a tangible end product, and is intended to improve skills of the person with ABI, without attendance from a communication partner. Given the strength of the evidence for communication partner involvement, this aspect needs to be incorporated to the treatment to promote gains in a person's communication skills. Struchen (2014) suggests that the training of communication partners could occur as an adjunct to more typical treatments of communication skills. As already highlighted in this chapter, the involvement of communication partners has been suggested as important during the goal setting process. Another study made more practical suggestions for the involvement of communication partners which included, giving feedback to the goals of an individual, providing feedback about homework tasks, and practising communication with the person with ABI at home and in the community (Dahlberg et al., 2007). Further to this, communication partners reported that post-training, information about using a positive question style was particularly useful for their interactions with people with ABI (Behn, 2011). Many of these suggestions that aim to increase the involvement of the communication partner were incorporated into the trial of project-based treatment.

4.6 Summary

Behavioural treatments for people with ABI are complex with many components that can make them difficult to define. The success of treatments is made more complex by the heterogeneous presentation of people with ABI. Project-based treatment is both complex and multi-faceted, and evidence to date of its effectiveness is limited. In this thesis the benefits of project-based treatment for both communication skills, and QOL was explored. Therefore, this section aimed to elucidate principles that were accommodated into the design of a treatment that intends to make changes to both areas. These principles included accounting for a person's existing cognitive abilities, exploiting meaningful tasks and activities, setting individualised goals, using groups as a delivery method, and involving communication partners. The treatment, with use of these principles, is comprehensively described in the following chapter.

4.7 Aims and hypotheses

This study was an exploratory trial with feasibility testing to investigate the effect of project-based treatment for improving communication skills and QOL in people with ABI. The aims and hypothesis were examined and evaluated in a quasi-randomised controlled trial comparing a TREATMENT group with a WAITLIST control group using mixed methods. As this treatment is an alternative to existing treatment approaches, there is a need to adequately define the treatment, and perform fidelity checks to ensure the treatment was delivered as intended for participants.

4.7.1 Aims

The seven main aims are:

1. To develop and define project-based treatment for people with ABI.
2. To develop a mechanism for checking treatment fidelity against the treatment definition and to evaluate the fidelity of the treatment as delivered.
3. To evaluate the effect of project-based treatment on communication skills and QOL for people with ABI in a TREATMENT group compared to a WAITLIST control group.
4. To evaluate the change over time in communication skills and QOL for all people with ABI from pre-treatment to follow-up, following project-based treatment.
5. To determine the feasibility of conducting a trial of project-based treatment with people with ABI.
6. To describe the experiences of people with ABI who have participated in the project-based treatment.
7. To explore and identify factors that may affect a person with ABI's ability to respond positively to project-based treatment.

To address the first two aims, a process will be developed to define project-based treatment and to check the fidelity of that treatment. This will aim to ensure that the treatment was implemented as intended. To address the final aim, five areas were identified which might relate to treatment outcomes (i.e. demographics; cognitive, emotional and social functioning; coping ability). These were correlated with gains to explore their associative value. Hypotheses for the remaining four aims are shown below.

4.7.2 Hypotheses

1. People with ABI in the TREATMENT group will have improved communication skills and QOL following project-based treatment compared to a WAITLIST control group.
2. All people with ABI, from pre-treatment to follow-up, will have improved communication skills and QOL following project-based treatment.
3. Feasibility of project-based treatment for people with ABI will be demonstrated, in terms of demand, implementation, practicality, acceptability, and initial efficacy.
4. People with ABI will identify and describe positive experiences and changes following involvement in project-based treatment.

4.8 A brief overview of the thesis

Chapter 1 discussed the nature of ABI, the impairments that can occur post-injury and the effect of an ABI on QOL. Project-based treatment was introduced as a treatment approach for the remediation of communication skills and QOL. For the purposes of grounding this thesis in current evidence and to ensure that the design of project-based treatment reflected current evidence, two reviews were completed systematically to understand existing treatment approaches for the remediation of communication skills (Chapter 2), and improvement of QOL (Chapter 3). These reviews were used in part to extract and discuss principles that project-based treatment would need to include, in the light of best evidence (Chapter 4).

Chapter 5 presents the method, results, and discussion for defining and checking the fidelity of project-based treatment. This treatment is considered a complex behavioural treatment and so needs to be adequately defined and checked. Chapter 6

presents the methodology for testing the effectiveness of project-based treatment for improving communication skills, and QOL in people with ABI. The study design involved a quasi-randomised controlled trial (with WAITLIST control group) with mixed methods to test the research aims described above.

The quantitative and qualitative results of the study are presented over three chapters that describe the main quantitative results (Chapter 7), follow-up results and individual level analysis (Chapter 8), and the qualitative results (Chapter 9).

Chapter 10 provides a comprehensive discussion of the findings and factors that may have impacted on treatment success. This chapter also highlights the limitations of the study, clinical implications, and future research that should be undertaken in this field. Some final concluding remarks are also made.

Chapter 5 Treatment definition and fidelity

5.1 Background

Complex behavioural treatments are becoming increasingly more common in brain injury studies. Treatments are considered complex when they contain several “active ingredients” or components that can make the treatment difficult to define. These may include “...behaviours, parameters of behaviours (e.g. frequency, timing), and methods of organising and delivering those behaviours (e.g. type(s) of trainer, setting and location)” (Medical Research Council, 2000). Complex treatments are also hard to define because they are frequently tailored to the specific problems and goals of the individual or group (Spillane et al., 2007), particularly, for people with ABI where treatments need to be individualised and contextualised to have some effect on behaviour (Ylvisaker, Hanks, & Johnson-Greene, 2002).

Complex brain injury treatments can often be defined in terms of specificity and flexibility (Hart, 2009). A large proportion of treatment studies tend to be specific, using a treatment manual to prescribe a session-by-session plan of the treatment delivery. However in reality, treatments for people with ABI require some degree of flexibility for individualisation to the specific problems or concerns for the person with ABI. One of the biggest challenges for researchers is to determine the source of any significant effects (Medical Research Council, 2000), which is made more difficult when the treatment is more flexible.

Project-based treatment is a highly individualised and flexible complex behavioural treatment. As a result, the treatment and its active ingredients needed to be accurately defined (i.e. treatment definition) and an assurance made that the treatment

was implemented as intended across all groups (i.e. treatment fidelity). Both of these will be discussed below.

5.1.1 Treatment definition

Identifying the active ingredients was considered essential for better understanding the components by which the treatment should work. The Medical Research Council (MRC) describes a process for the development of complex treatments (Medical Research Council, 2008), however Hart (2009) breaks this down further to describe a specific process for treatments for people with ABI, comprising three steps addressing: (1) the theory level (i.e. proposing the active ingredients); (2) translating the active ingredients into behavioural operations; and (3) translating the active ingredients into treatment materials and/or manual.

The MRC (2000) defines the first step in two phases: understanding the theory that underpins the treatment (i.e. pre-clinical or theoretical phase); and developing an understanding of the treatment and its possible effects (i.e. modelling phase). The previous chapter has provided guidance as to the important principles of a treatment for people with ABI. Other methods that can be used to help refine the active ingredients for project-based treatment may include case studies (such as those described in section 1.5.4) and focus groups (Medical Research Council, 2000).

The second step proposed by Hart (2009) involves translating the active ingredients into behavioural operations on behalf of the trainer and/or patient. That is, describing the actual behaviours that should be observed to indicate that the active ingredients are present during the treatment. External coders can then use these behavioural operations or codes to identify the presence or absence of active ingredients within treatment sessions. Such a process is important for establishing fidelity of the

treatment. Behaviours can be broadly classed as having common or specific treatment elements (Hart, 2009). Common treatment elements are those that are important active ingredients to several treatments regardless of the content of the treatment. However, specific treatment elements are those that are intentionally added and specific to a particular treatment type.

The third and final step is translating the active ingredients into materials and/or a manual to use during the treatment. Hart (2009) presents a continuum of specificity to flexibility through which to conceive the development of a treatment manual. Specific manuals provide a session-by-session script for a therapist to use with each patient while a flexible script enables adaptation to an individual's needs.

These three steps for defining the active ingredients of a complex treatment are essential to establishing treatment fidelity. This in turn influences the therapist behaviours, which in turn may be measured during or after treatment sessions. Treatment definition should not be a process that is completed after the treatment, but rather it should occur prior to and during the treatment delivery to help establish reliability and replication. This guidance was followed in the development of the treatment in this study.

5.1.2 Treatment fidelity

Treatment fidelity refers to the “methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions” (Borrelli et al., 2005, p.852). Establishing treatment fidelity ensures that the treatment was implemented as intended, and is important to being able to make decisions about treatment efficacy and replication of a treatment. However, few treatment studies report fidelity. A recent review of aphasia treatment studies across three journals (2002-2011) revealed that only

14% (21/149) of studies explicitly reported on treatment fidelity, and furthermore, only 9% (13/149) used *independent* raters (Hinckley & Douglas, 2013). For the brain injury studies reported in Chapter 3, 12% (10/80) reported fidelity using raters (Bell et al., 2011; Bornhofen & McDonald, 2008a; Bourgeois, Lenius, Turkstra, & Camp, 2007; Brenner et al., 2012; Cantor et al., 2014; D'Antonio et al., 2013; das Nair & Lincoln, 2012; Perlick et al., 2013; Rath, Simon, Langenbahn, Sherr, & Diller, 2003; Vungkhanching, Heinemann, Langley, Ridgely, & Kramer, 2007).

As fidelity practices become more critical, there is a greater need to prove fidelity at the outset of a treatment. To assist researchers in understanding how to implement fidelity, the treatment fidelity workgroup of the National Institute of Health Behavior Change Consortium has developed a comprehensive description of treatment fidelity practices and recommendations for their implementation in behavioural interventions (Bellg et al., 2004). These have been used to operationalise treatment fidelity for an RCT of a complex treatment (Spillane et al., 2007). While these recommendations provide a guide to demonstrate fidelity, there remain practical issues with conducting checks. These relate to the amount of data required to conduct an adequate fidelity check, the timing of fidelity checks (i.e. prospective or retrospective), and the process through which the fidelity check is conducted.

The first consideration for conducting fidelity checks relates to the amount of data to be used. Independent raters checked 10-20% of the data in aphasia treatments (Hinckley & Douglas, 2013) however, the amount of data checked by raters tended to range from 16% (Bourgeois et al., 2007) to 40% (Bornhofen & McDonald, 2008a) in the brain injury studies. In one study, 100% of the data was checked by a single rater, with inter-rater reliability calculated for approximately 10% of the data (Hart et al.,

2013). As a general rule, Borrelli (personal communication, 18 December, 2013) suggests that 10% is considered the “bare minimum” when conducting fidelity checks.

A fidelity check can be conducted either prospectively or retrospectively, and will depend on the aims of the treatment. Retrospective fidelity checks are conducted to explain significant or non-significant results and help determine whether the treatment was delivered as intended. Checks of this type are common (Hinckley & Douglas, 2013) and tend to be conducted on video- or audiotaped sessions following the end of the treatment (Bornhofen & McDonald, 2008a; Hart et al., 2013). Prospective checks are conducted to prevent ‘therapist drift’³ and to make treatment protocol changes during the study period. Typically, these checks involve the use of a manual and/or therapist training before treatment (Hinckley & Douglas, 2013). Brenner et al. (2012) did independent prospective fidelity checks with “occasional feedback...to group leaders on the basis of the fidelity ratings” (E63). Of the 10 brain injury treatment studies that examined fidelity, prospective checks were conducted in all but one study (Bornhofen & McDonald, 2008a).

A final consideration is the process of how to conduct a fidelity check. Hinckley and Douglas (2013) reported that the majority of studies reported fidelity (13/21) by having raters review videotaped treatment sessions and indicate whether steps from a treatment protocol were observed. Thus, a percentage of the treatment steps completed from the protocol could be reported. Bornhofen and McDonald (2008a) comprised a fidelity checklist that related to specific and desirable treatment elements which were then rated for their presence by two independent assessors on a scale from 1 (“not at all”) to 5 (“very much”). Hart (2009) and Hart et al. (2013) described a more detailed

³ Therapist drift refers to small or gradual changes of a treatment protocol by a trainer, unintentionally or unknowingly, in response to a person’s behaviour (Hinckley & Douglas, 2013).

process where the active ingredients of a treatment are identified and translated into actual observable behaviours, which can be used prospectively to assess their presence (or absence) during the course of the treatment. The latter approach to assessing treatment fidelity is preferable. This process was used in a study that scored audiotaped conversations for fidelity to elements of problem solving, goal setting, therapeutic alliance, and structure (Bell et al., 2011; Hart, 2009). These were then used during supervision of the treatment to provide feedback.

Establishing treatment fidelity is important, as this study is the first to empirically evaluate the principles of project-based treatment. This is made more important by the fact that project-based treatment is a highly flexible and individualised treatment that is adaptive not prescriptive, and the goals of both the individual and the group will be different according to the participants in the treatment. The next section of this chapter will examine the process of treatment definition and fidelity as specifically applied to project-based treatment.

5.2 Process of treatment definition and fidelity for project-based treatment

The process of treatment definition and fidelity are important concepts that involve several processes. Prior to conducting a fidelity check, the active ingredients for the treatment should be identified and described, fidelity practices operationalised and a treatment manual created. These processes needed to be completed before the treatment could commence with further fidelity checks to ensure the treatment was conducted as intended. The steps involved in this process have been outlined in Figure 5.1.

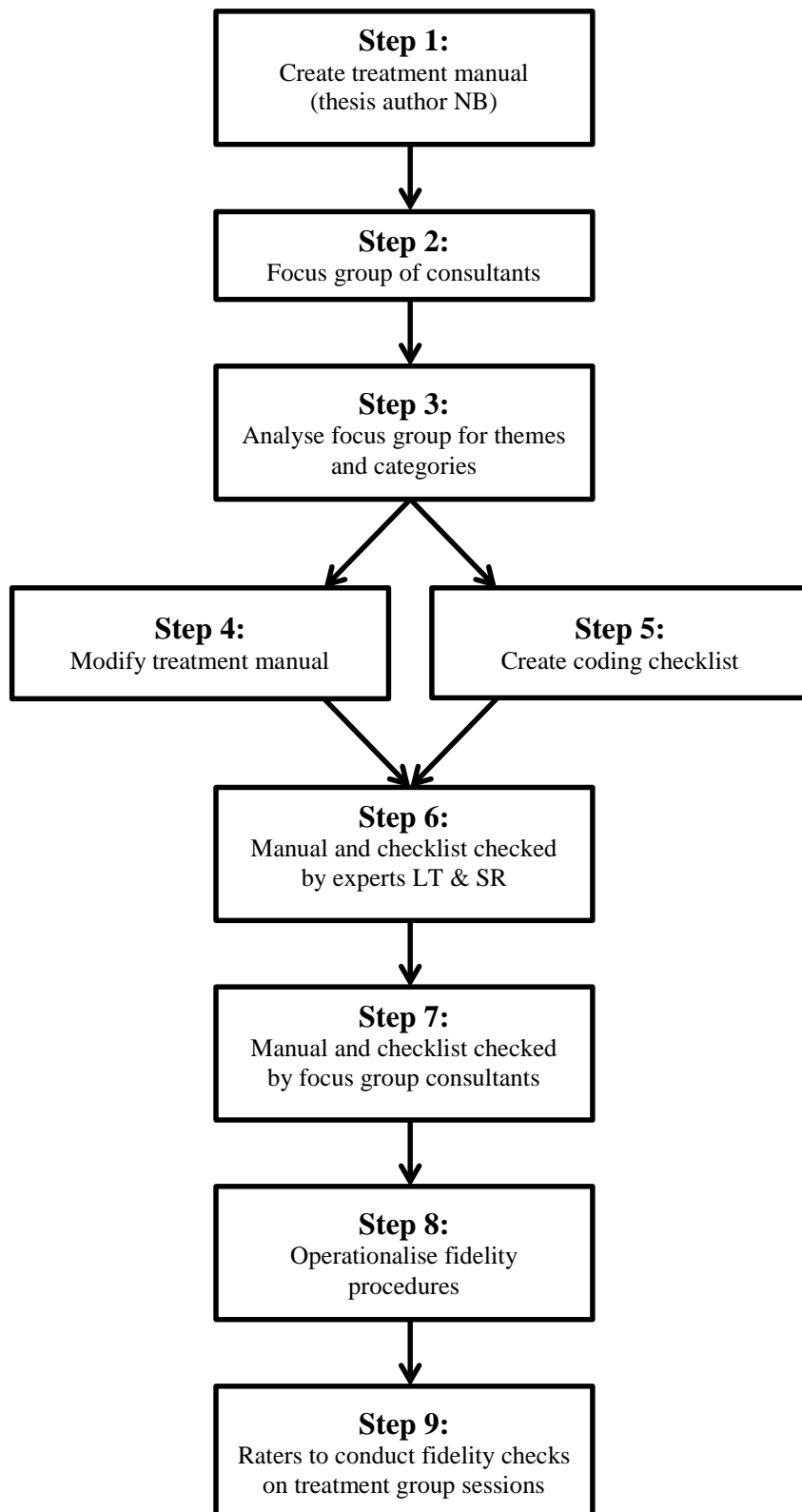


Figure 5.1. Procedure for treatment definition and fidelity

5.2.1 Experts and consultants

Several consultants were recruited to help define the active ingredients of project-based treatment and inform the development of the treatment manual. However, the author of the thesis (NB) was responsible for first drafting the treatment manual (prior to the involvement of the consultants), and drew on his expertise as a qualified Speech and Language Therapist (SLT) with 15 years' experience of working with people with ABI and over 8 years' experience of conducting project-based treatment. Experts and consultants were then recruited to participate.

Two experts were recruited. The first expert was a Professor from The University of Sydney, Australia (LT) who was a SLT with over 20 years' experience of both working with people with ABI and conducting research in the field. In addition, she was chosen as she had extensive experience of writing treatment manuals for research studies. The second expert was a practising Speech and Language Therapist from Australia (SR) who had 12 years' experience in working with people with ABI and in conducting project-based treatment. She was chosen due to her experience in proof reading manuals for publication.

Three groups of consultants were further recruited at different stages to: (1) attend a focus group; and (2) code fidelity of treatment sessions. All consultants were approached through local brain injury professional networks to voluntarily participate in this part of the study. Inclusion criteria were: (1) practising health professional (e.g. Occupational Therapist, SLT, Clinical Psychologist); (2) have more than 2 years' experience of treating people with ABI; and (3) experience of conducting project-based therapy.

For the focus group, the consultants needed to attend two focus group sessions. Six people expressed an interest to participate (C1-C6), and in health research, the appropriate size of a focus group is considered 5-8 (Krueger & Casey, 2009). Five of these consultants were Speech and Language Therapists and one was an Occupational Therapist (Table 5.1). The average age of consultants were 32.83 (30-36 years), amount of time working with people with ABI was an average 7.83 years (3-13 years) and an average of 5.67 years (2-13 years) for conducting project-based treatment. Consultants were from a range of work settings including inpatient, residential and community based services.

Table 5.1. *Characteristics of Consultants*

Consultant	Profession	Age (y)	Work (y)	Work in ABI (y)	Work in PBT (y)	Description of current work setting
C1	SLT	36	13	13	13	Inpatient acute/rehabilitation
C2	SLT	33	4	4	2	Community based services
C3	SLT	33	10	10	5	Community based services
C4	SLT	30	8	8	6	Community based services
C5	OT	35	13	9	6	Residential rehabilitation
C6	SLT	30	6	3	2	Inpatient and community
C7	SLT	36	10	10	8	Inpatient acute/rehabilitation
C8	SLT	38	12	12	12	Community based services
Mean		33.88	9.5	8.63	6.75	

Note. y = years; ABI = acquired brain injury; PBT = project-based treatment; SLT = speech and language therapist; OT = occupational therapist.

For coding fidelity of treatment sessions, two sub-groups within the consultants' group volunteered to participate. The first group (C1, C2 and C7) attended two sessions. The second group of consultants (C4 and C8) attended a single session.

5.2.2 Procedure

The procedure used to define and check fidelity of the treatment was guided by the procedure described by Hart (2009) and Hart et al. (2013) as this was specific for complex treatments involving people with ABI. Figure 5.1 describes the procedure. Steps 1-7 refer to treatment definition and identification of the 'active ingredients'; steps 8 and 9 refer to treatment fidelity and the prospective and retrospective checks.

The first two steps of treatment definition identified the active ingredients. Fieldwork (or clinical experience) and a focus group were the methods chosen to define project-based treatment (Medical Research Council, 2000). The author of the thesis (NB) had experience of conducting project-based treatment, which combined with theoretical principles proposed by Ylvisaker, Feeney et al. (2007) and Feeney and Capo (2010), were used to create a first draft of the treatment manual. The second step chosen to identify and confirm the active ingredients was a focus group facilitated by NB. Consultants in the focus group were asked a series of questions that probed their thoughts and opinions as to what components they felt were important to project-based treatment for people with ABI and what materials they would expect to see in a treatment manual. A topic guide of the questions asked is in Appendix C. Efforts were made by the facilitator (NB) to not influence the opinions of the consultants but rather probe and encourage elaboration and examples of what was being said. The focus group was audio and videotaped for later transcription.

Results from the focus group (step 3) were used to modify and change the treatment manual and create a behavioural checklist (steps 4 and 5). Each of the items on the behavioural checklist is scored using a 3-point scale: (1) absent; (2) present to some/a slight degree; or (3) present to a substantial degree (Hart, 2009). The two experts (LT and SR) checked the treatment manual and behavioural checklist to confirm the content and make any preliminary changes (step 6). The consultants from the focus group then attended a second session to review, discuss and make any further changes to both the treatment manual and behavioural checklist (step 7). This check was completed to ensure that the manual and checklist reflected the active ingredients of project-based treatment as identified by the focus group consultants.

The final two steps of the procedure involved checking fidelity of the treatment. The first was a prospective fidelity check (step 8) to operationalise fidelity practices using the five categories described by Bellg (2004). This involved the identification of strategies to monitor the implementation of the treatment across all treatment groups. This process has been described elsewhere for a complex health treatment (Spillane et al., 2007). The second was a fidelity check of the treatment sessions. Consultants were recruited into two groups and rated three treatment sessions in total (each 2 hours in length). The first group of three consultants checked two randomly selected treatment sessions, and the second group of two consultants checked one randomly selected treatment session (step 9). These sessions were selected from each of the first three treatment groups conducted. Consultants were required to determine the absence or presence of behaviours from the checklist to establish fidelity of the treatment. No prior training was provided on the use of the checklist to rate treatment sessions.

5.2.3 Data analysis

Qualitative data from the initial focus group was transcribed verbatim and analysed to identify meaningful codes of information using a generic 6-step analysis procedure described by Creswell (2013). These meaningful codes were re-read and re-coded before categories were identified (Saldana, 2009). A constant comparative analysis technique was used to compare codes and categories (Corbin & Strauss, 2008; Fram, 2013; Glaser & Strauss, 1967). As similarities and differences emerged within codes and categories, data was rearranged and re-categorised for themes to then be generated. Steps were undertaken to validate the accuracy of the findings. Firstly, themes, categories and codes of meaningful data were checked and verified by the author's primary supervisor (MC). Some data was re-coded and re-arranged following this check. Secondly, member checking was conducted with the consultants of the focus group during the second session. No changes were made to the data following this check.

Fidelity for the treatment was analysed by two groups of consultants who checked randomly selected treatment sessions from each of the first three treatment groups. To determine the level of agreement between consultants for each treatment session rated, Cohen's kappa was used (Cohen, 1960; Hallgren, 2012). A kappa can range from -1 to +1. A negative value suggests that the agreement between the two raters was less than chance. A kappa of 1 indicates that there was perfect agreement between the two raters. A kappa greater than 0 can be classified according to the strength of agreement (Landis & Koch, 1977): less than 0.2 is slight, 0.21 to 0.40 fair, 0.41 to 0.60 moderate, 0.61 to 0.80 substantial, and 0.81 to 1 which is perfect agreement.

5.3 Results

The focus group with the six consultants lasted 90 minutes. The analysis of the focus group revealed four themes and 18 categories that defined and described the behaviours required for conducting project-based treatment groups. The themes were: (1) project-based treatment; (2) group therapy; (3) therapeutic clinical skills for running project-treatment groups; and (4) project-based treatment manual. Table 5.2 outlines the themes and categories. The consultants highlighted that conducting project-based treatment groups included behaviours not specific to projects but also to facilitating groups. They provided valuable information that would inform the treatment manual and behavioural checklist. Each of the themes that emerged from the transcripts described in turn below.

Table 5.2. *Themes and categories from focus group*

Theme	Category	Description
Project-based treatment	Choosing a meaningful project	<ul style="list-style-type: none"> Participants need to agree a project they are all interested in
	Target a range of cognitive skills	<ul style="list-style-type: none"> The project must involve a range of planning and organisational skills, flexibility and problem solving skills
	Roles	<ul style="list-style-type: none"> The project should involve the allocation of different roles (e.g. minute-taker, manager)
	Positive outcome of group projects	<ul style="list-style-type: none"> The group should be positive and enjoyable
	Group composition and session duration	<ul style="list-style-type: none"> Type of people in group, and length of sessions
	Completion of homework	<ul style="list-style-type: none"> Homework needs to be done but can often be a challenge

Theme	Category	Description
Group treatment	Peer support and motivation	<ul style="list-style-type: none"> Group participants are able to give each other support and feedback within and outside the group
	Goal setting	<ul style="list-style-type: none"> Focus on setting an individual and group goal
	Group membership	<ul style="list-style-type: none"> The group should be voluntary with pre-group discussions about the content of the group
	Address barriers	<ul style="list-style-type: none"> Barriers may be individual (e.g. fatigue) or group-related (e.g. tension between participants)
Therapeutic skills for running project-based treatment groups	Motivating participants	<ul style="list-style-type: none"> The therapist needs to be energetic, enthusiastic and motivating
	Facilitate group interaction	<ul style="list-style-type: none"> Need to be facilitative and not directive when encouraging interaction between group participants
	Support organisational skills	<ul style="list-style-type: none"> Suggestions for supporting organisation (e.g. session plans)
	Flexible thinking	<ul style="list-style-type: none"> Need to be less rigid, flexible and allow group members to generate ideas
	Communicate reasons clearly	<ul style="list-style-type: none"> Be clear about the aims and rationale of each session
Project-based treatment manual	Resources and materials	<ul style="list-style-type: none"> Needs some background literature, case studies and session plans
	Running a group	<ul style="list-style-type: none"> Needs some information on how to run a good group (e.g. group rules, troubleshooting suggestions)
	Goal setting and outcomes	<ul style="list-style-type: none"> Information about how to write goals and outcome measures for measuring progress

5.3.1 Project-based treatment

The first theme that emerged from the data described features that the consultants reported were core to project-based treatment. Meaningful projects, teaching a range of cognitive skills, and creating roles for people with ABI, were considered important features of the treatment. Such features have also been described by Ylvisaker et al. (2007) and should be carefully considered when conducting projects. Consultants reported that a project should be meaningful and interesting to the entire group, and enable people with ABI to have different roles and experiences such as leading a group. The project also provides an environment where people with ABI can develop cognitive skills that improve their planning and organisation, flexibility, and problem solving. The projects also enable an understanding of a person's level of insight and awareness into their difficulties post-injury. Examples of these features include:

Choosing something [a project] they are all interested in (C3).

Flexibility because it, that level of problem solving is quite crucial to planning a project (C4)

Overall, there was a positive feeling that consultants had experienced when conducting projects with people with ABI. They reported that people with ABI were “really pleased with what we produced” (C6), “they are having fun” (C5) and the end product was a “really positive project” (C2).

The consultants then provided some insights into their own experiences of running project-based groups. These experiences highlighted more practical issues of conducting projects. For example, consultants reported that group sessions should run

for no longer than 2 hours and should not have more than 4-6 people with ABI.

Completion of homework was another category that emerged within this theme with discussion about the challenges of getting people with ABI to do homework and practical solutions to the problem.

5.3.2 Group treatment

This theme emerged from data that described the consultant's experiences of conducting groups. This theme is distinctively different from the previous theme in that the data described experiences specific to conducting groups irrespective of whether the group was project-related or not. Consultants identified that a group is a context where people with ABI can receive support, and feedback from others.

Another positive of the group is I think that the peer support can be brilliant so when a group works I think they can support each other in that group and out of the group, which is really nice (C1).

The group members started to learn that they could comment on other group members and how this was a really good job (C5).

Consultants also highlighted the positive effect of group treatment for working towards both individual and group goals and receiving feedback on those goals.

So a group setting can be a good way of keeping the, keeping up the, flagging up the goals and what people and other people are working towards and giving each other feedback as well as yourself (C6).

You gotta have the ability to be able to balance an individual with the group goal (C6).

While groups can be supportive and facilitative for people with ABI to achieve their goals, consultants reported several challenges for conducting groups. One challenge was group dynamics and forming a group of people who interact well with one another. A solution suggested by consultants was to be open, and offer the choice for people to withdraw if they would like. Other reported challenges were more specific to people with ABI. Consultants highlighted that therapists should have an awareness of individual factors that may affect outcomes such as reduced motivation, fatigue or physical problems that may effect an individual's participation (e.g. accessing a computer). Any professional conducting a group with people with ABI should consider these factors.

5.3.3 Therapeutic clinical skills for running project-treatment groups

Consultants reported that a range of clinical skills is required by a therapist to facilitate a project within a group context. This theme was generated from data describing those skills and was distinctive from other themes that described the features of project-based groups or the benefits and challenges of groups for people with ABI. One of those skills was the ability for a therapist to instil enthusiasm and motivation for group participants and to facilitate interaction rather than direct it. This is important when choosing a project that is motivating and meaningful to the group.

You have to sell the idea, you have to...to get people to buy into it (C5).

Addressing this whole kind of being too directive because I think when I see other people run groups, who are maybe other professionals I think sometimes that's the big difference in their directing rather than facilitating something (C1).

The other set of clinical skills consultants reported are required by a therapist during group sessions are the ability to support planning and organisational skills whilst remaining flexible. People with ABI require a level of structure and routine due to impaired executive function, which incorporates planning and organisational abilities. Consultants reported that methods for supporting structure such as "a schedule" or "flow chat" could assist this. Consultants also highlighted that being flexible is important and involves managing the different expectations of group members and not being excessively rigid in following an agenda or plan. A therapist needs to strike a balance between providing enough structure while remaining flexible. Examples of this include:

At the beginning of each session is, what we're going to do that group and this is what needs to be achieved (C3).

We have to have a plan, but still be flexible, you have to be confident you have to know what you're doing (C5).

But you still have to be that person who recognises, this isn't working so I got to do something different and if you haven't that flexibility of thinking then I don't think it's, I don't think it will work (C4).

The last important skill consultants reported that a therapist requires is the ability to clearly communicate the rationale for the session to people with ABI. One consultant indicated that it could affect the successful running of project-based treatment groups.

They didn't have such a clear rationale of what the point of the project was and so they lost some of the goal focus in getting the project done (C6).

Overall, there is a range of skills that consultants reported are important for a therapist who conducts a project-based treatment group. One comment in particular neatly summarises this range:

You almost also need to teach people how to have a 50-50 approach, you need to be directive but facilitative, you need to have structure but be flexible, you need to be motivated but stand back and let them come up with ideas (C5).

5.3.4 Project treatment manual

Consultants were able to provide specific information about what needs to be included in a treatment manual. Much of this information was derived from discussion about core features of project-treatment groups, and group treatment more generally. Consultants wanted 'a bit of literature' on project-based treatment and what it is. One consultant reported:

I just think there needs to be a lot of transparency to stop people getting scared of doing projects. Got to be really simple hasn't it? Useable to stop people being scared of it (C3).

Consultants wanted the treatment manual to provide some direction on how to troubleshoot different problems that could occur during the project-treatment group. Problems included how to choose a meaningful project, how to form a cohesive group, how to encourage people that are reluctant to join a group, and how to facilitate group interaction.

I almost wanna put the structure in for people who don't actually know where to start (C5).

And also potentially how to identify when you're not doing a good job, rough example (C5).

Almost a bit of a maybe, what not to do...maybe some nice video examples (C1).

More practical suggestions from consultants included 'session plans', 'case studies', 'a DVD [of examples]' and 'references'. Goal setting and outcomes of treatment were also discussed. Guidance for how to discuss goal setting with a person with ABI, and systems of measurement, were identified by consultants as important in a rehabilitation context and an important feature of a treatment manual.

And something about writing up your goals as well in there (C6).

How you might talk about goals (C1).

5.4 Treatment content and manual

The treatment manual had been drafted prior to the focus group, based on the features of project-based treatment as proposed by Ylvisaker, Feeney et al. (2007). The principles identified as important in Chapter 4 were also incorporated, with themes from the focus group used to make further amendments to the manual. Checks were then performed to confirm the content and ensure that it corresponded with the active ingredients. The two experts (LT and SR) checked the treatment manual first, and then the focus group consultants reviewed the manual. While consultants made slight amendments, the content of the manual was largely confirmed as addressing the active ingredients of project-based treatment.

The final treatment manual provided guidance for 10 group treatment sessions that were flexible and highly individualised. The manual needed to accommodate the different projects each group would choose, as well as the specific communication goals of each person with ABI. The final version contained an introduction to project-based treatment and guidance for treatment sessions to help the therapist facilitate the group through to completion. This included direction and guidance to facilitate the development and implementation of a project and the setting of participant's communication goal. Several handouts were provided (e.g. minutes, goal planning framework, visual scaffolds) to people to help them plan and organise project-related tasks. Initial treatment sessions were described in detail (i.e. sessions 1-3), with the remainder of sessions described in less detail to accommodate the project chosen by the participants.

Despite the inherent flexibility in the manual, there were three components that were common to most treatment sessions. First, at the beginning of each session there was a discussion of each participant's communication goals. This discussion involved

the participant identifying their own goal, providing examples of how they achieved their goal outside of the treatment environment between sessions, and self-rating their performance for the current treatment session. At the end of each treatment session, participants rated their performance against their own communication goals again, and discussed any discrepancies and changes they could make for successive sessions. Giving this feedback, which is known as metacognitive skills training, intends to improve self-monitoring and self-regulation skills, and has been utilised in other treatment studies involving people with ABI (Ownsworth et al., 2008; Schmidt et al., 2013). The second component common to most sessions was the generation of a plan. This involved writing down the tasks to be completed, and prioritising and ranking them in the order to be achieved during the session. This plan was constantly reviewed with identification and discussion of any problems that may have arisen during the group. The final component was to write 'minutes' for the session (i.e. summary) and to identify any action points to be achieved for the next session. These action points were texted as a reminder to both the person with ABI and their communication partner 1-2 times between each treatment session. The study utilised an online text messaging service (www.textanywhere.net), which has successfully been used to help improve recall for people with ABI (Culley & Evans, 2010).

Sessions in the treatment manual were described as follows:

Background. This section of the manual provided the therapist with information about the core principles of the treatment, which the consultants requested be in the manual. These principles were drawn from those described in Chapter 4 and existing literature (Feeney & Capo, 2010; Ylvisaker, Feeney, et al., 2007), and adapted for projects conducted in a group context in a discrete time period. Positive communication

strategies were also described to help the therapist(s) facilitate conversation within groups, and to help define areas of improvement when setting individual communication goals for people with ABI. These strategies were adapted from a published treatment manual (Togher et al., 2011) that focused on training to communication partners of people with ABI. All of the information in this section was intended to provide the therapist with background information about how to conduct project-based treatment.

Session 1. The first session is conducted between the therapist, person with ABI, and their communication partner. There are two purposes to this session. Firstly, to set individual communication goals for the person with brain injury, and secondly to provide strategies and techniques that may improve their conversational interactions.

Guidance is provided in the treatment manual on how to facilitate a discussion with people with ABI and their communication partner, to set individual, meaningful communication goals for the person with ABI. Involving the communication partner in the goal setting process is important as people with ABI often have persistent difficulties in setting realistic goals for themselves (Ownsworth et al., 2000). The goal setting session involved setting no more than two goals, as more success has been reported with fewer goals (McDonald et al., 2011; Wade & Troy, 2001; Wilson, Evans, Emslie, & Malinek, 1997). To facilitate this process, a conversation between the person with ABI, and their communication partner (i.e. family member, significant other, friend or carer) was video-recorded and then watched back immediately to identify communication strengths and weaknesses. Collaboratively, a discussion was conducted to identify what would constitute change and improvement, and then set about to

establish an agreed goal. The goals were then written in simple and accessible terms for the person with ABI to understand, using a goal attainment scale that will be described in detail in the methods section of the thesis. Text messaging was used to improve recall and achievement during the treatment. Each person received a daily text message during the course of the treatment to remind them of their communication goal(s). An identical text was sent to the communication partner weekly.

The second part of the session was to provide both the person with ABI and their communication partner with strategies and techniques to improve their conversational interactions. As already established, communication partners play a vital role in the success of conversational interactions that involve people with TBI (Togher et al., 1997a, 1997b; Togher et al., 2006) and are an important influence on social participation and QOL for people with ABI (Fleming et al., 2009). Training involved teaching strategies and techniques that help the communication partner to speak in an adult-like and sensitive manner while increasing opportunities for the person with brain injury to communicate. The use of a positive questioning style (Togher et al., 2011) has previously been highlighted as important to conversations (Behn, 2011), so these were individualised and related to each person's communication goal(s). For example, if the person was passive and quiet, questions and strategies to encourage maximal participation for the person with brain injury would be discussed. Providing individualised strategies enables the communication partner to help the person with ABI to achieve and generalise their communication goal(s) to settings external to the therapeutic environment. Also, both people will be able to better communicate about activities related to the treatment and actions that need to be completed for future sessions.

Session 2. This session was the first occasion where the group met and involved a discussion about each person's personality, strengths, weaknesses, hobbies and interests. This discussion was facilitated to identify areas of common interest and potential avenues for a collaborative group project. This section of the manual provided information to establish group rules, defined what projects were, and provided examples of projects and methods to start brainstorming projects for the group. There was also information about common concerns that may arise during group sessions and possible solutions. Concerns may include difficulty choosing a meaningful project, people wanting to withdraw from the group, conflicts between group members, and if a person feels they have little to offer the group. Suggestions for alleviating these concerns were provided in the manual. In addition, there was information about the core features of the session described earlier (i.e. self-rating individual goals, taking minutes, and reviewing individual goals at the end of the session).

Session 3. This session was mainly focused on the development of a project idea. Goal planning frameworks and visual scaffolds were utilised to provide structure to plan and organise project-related tasks for group participants. The framework used for goal planning was the goal-obstacles-plan-do-review framework suggested by Ylvisaker et al. (1998). This framework involves 5 steps:

- Goal: Identification of the goal (i.e. what do I need to do?)
- Obstacles: Identification of obstacles and barriers (i.e. who/what is standing in my way?)
- Plan: Discussion of the plan and prediction of how the group feels they will go (i.e. what options do I have? what things do I need to help? how do I think I will go?)

- Do: Carrying out the plan
- Review of performance: (i.e. did it work? If not, what do I need to do for next time?)

This information was represented using the visual scaffold of a traffic light system or ‘stop, think, go’ strategy (Miotto et al., 2009). Other visual scaffolds (e.g. storyboards) were also introduced to highlight the importance of generating a session-by-session, week-by-week plan of what needed to be achieved in order to complete the project within the time frame of the group. These scaffolds were used in each session as a core component. In addition, this session discussed equipment needs for the project and the allocation of roles (*or jobs*), which were highlighted by focus group consultants as an important feature of project-based treatment. The session also contained the core components described earlier (i.e. self-rating individual goals, taking minutes, and reviewing individual goals at the end of the session).

Sessions 4-10. The remaining sessions were structured and prescribed in terms of what needed to be done for a project to be identified and completed. As a result, these sessions were less structured and more flexible to accommodate the complexity of the idea chosen and the individual needs of the group participants. Tasks included videotaping, writing scripts, taking photographs or recording voice-overs. However, each session consistently contained core components. These involved participants self-rating their individual communication goals at the start and end of session, making written plans for each session (and prioritising tasks), reflecting on the overall week-by-week plan for achieving the project, discussing problems and options to solve them, and

taking minutes at the end of the session (including identifying actions for future sessions). A group celebration of the projects completion comprised part of session 10.

5.4.1 Behavioural checklist

Translating the active ingredients into behavioural operations on a checklist was important to establish fidelity of the treatment. Themes from the focus group were reviewed against the features of project-based treatment (Feeney & Capo, 2010; Ylvisaker, Feeney, et al., 2007). As the consultants also described group facilitation skills, reference was made to behavioural descriptors of group-work for adults (Ewing, 2007). These included a range of techniques to help facilitate group dynamics and group participation (e.g. starting, seeking and giving information, focusing, summarising, and modelling).

These themes and information were then translated into coding behaviours. Table 5.3 demonstrates how the coding behaviours were derived from the focus group themes and categories. Behaviours were separated into essential (i.e. specific treatment elements) and desirable criteria (i.e. common treatment elements) in order to distinguish between elements that are required in a project-treatment session, and those that are not required but would enhance the delivery of the treatment if present (i.e. group facilitation skills). In addition, elements were separated into project, therapist, and participant behaviours to delineate the difference between behaviours. Before the checklist was checked and confirmed by consultants, a process of review and deletion occurred where the author of the thesis (NB) and the supervisory team (MC and JM) re-phrased and deleted behaviours. Initially, 18 behaviours were identified (12 essential and 6 desirable behaviours). A 3-point scoring scale as suggested by Hart (2009) was adopted to rate each treatment session: (1) absent; (2) present to some degree; or (3)

present. This checklist was first checked and confirmed by the two experts, and then presented to the focus group consultants. Some revisions were made with a final checklist comprising 13 essential and 6 desirable behaviours made up of 4 project-therapy behaviours, 10 therapist behaviours (4 essential, 6 desirable), and 5 participant behaviours (see Appendix D).

Table 5.3. *List of coding behaviours, as derived from focus group themes, and categories.*

Essential Criteria – Project-behaviours	Theme	Category
People make reference to what the end goal is during the session (i.e. it is easy to identify what the project is)	Project-based treatment	<ul style="list-style-type: none"> • Choose a meaningful project to participants
Each of the participant’s roles in the project can be clearly identified during the session	Project-based treatment	<ul style="list-style-type: none"> • Roles
Each participant’s individual goal(s) can easily be identified in the session	Group treatment	<ul style="list-style-type: none"> • Goal setting
The rationale for the session can be identified and a plan for how it will be organised is clear throughout	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Communicate reasons clearly
Essential criteria – Therapist behaviours	Theme	Category
The therapist facilitates and supports identification of problems and a range of options/actions to solve them	Project-based treatment Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Target a range of cognitive skills • Support organisational skills
The therapist uses appropriate tools and strategies to support the session (e.g. visual scaffolds)	Project-based treatment Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Target a range of cognitive skills • Support organisational skills

Essential criteria – Therapist behaviours (continued)	Theme	Category
The therapist supports group participants to reflect on plans and performance (e.g. “how will you know if it’s working?” or “what could you do if it doesn’t work?”)	Project-based treatment	<ul style="list-style-type: none"> • Target a range of cognitive skills
The therapist is flexible during the session (i.e. able to listen to different ideas and opinions and able to modify in-line through negotiation)	Project-based treatment Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Target a range of cognitive skills • Flexible thinking
Essential criteria – Participant behaviours	Theme	Category
The project appears meaningful and motivating to participants within the group	Project-based treatment Group treatment Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Choose a meaningful project • Peer support and motivation • Motivating participants
In order to achieve the project, participants initiate interaction with other group members	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Motivating participants • Facilitate group interaction
Participants demonstrate an understanding of the plan for the session	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Communicate reasons clearly
Participants contribute to the plans and/or any problems that may arise in the session	Project-based treatment Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Target a range of cognitive skills • Facilitate group interaction • Communicate reasons clearly
The participant demonstrates an understanding of their goal	Group treatment	<ul style="list-style-type: none"> • Goal setting

Desirable criteria – Therapist behaviours	Theme	Category
The therapist communicates respect to participants in a non-patronising and sensitive manner (e.g. by acknowledging difficulties that they may have)	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction
The therapist asks questions in a supportive and non-demanding manner (i.e. open questions that encourage participants to share their thoughts, feelings and opinions)	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction
The therapist can re-direct and focus the group back to the project when the conversation goes off topic	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction • Support organisational skills
The therapist seeks and gives information and/or encourages discussion without dominating	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction
The therapist gives positive feedback (i.e. to reward interaction and suggestions made by participants)	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction
The therapist seeks agreement from all participants when making decisions	Therapeutic skills for running project-based treatment groups	<ul style="list-style-type: none"> • Facilitate group interaction • Flexible thinking

5.4.2 Operationalising project-based treatment

Strategies for monitoring treatment fidelity were operationalised using the procedures proposed by the National Institute of Health Behavior Change Consortium (Bellg et al., 2004). These procedures were used to monitor the implementation of the treatment and ensure it was consistently completed in an identical way for each treatment group. The procedures described by Bellg et al. (2004) include treatment design, training providers, treatment delivery, treatment receipt and treatment enactment, and have previously been operationalised for a complex behavioural treatment (Spillane et al., 2007), and are outlined in Table 5.4. A brief outline of this information is presented below.

Treatment design refers to factors to consider when designing a trial to enable adequate replication of the treatment. Information about the intensity and length of treatment sessions, the use of a focus group to identify the active ingredients of project-based treatment, the use of a manual, and monitoring of contact (both face-to-face and telephone) were conducted for this study.

Training providers refers to the training and on-going support to the treatment providers to ensure systematic implementation of the treatment. As the same therapist conducted all treatment sessions, this aspect was less of concern, however, all sessions were videotaped with fidelity checks (as described in section 5.2.2) to ensure there was no therapist drift.

Treatment delivery refers to processes that monitor and improve the delivery. Use of a manual, the videotaping of sessions, fidelity checks, and qualitative interviews with participants was strategies enforced to ensure the treatment was delivered as intended.

Treatment receipt, means ensuring that participants understand the information that is presented to them during the treatment. This is particularly important for people with ABI who present with cognitive impairments (i.e. memory, attention). Obtaining participant feedback, and monitoring and reviewing tasks that needed to be achieved, minimising the amount of written material provided, post-treatment interviews, and the review of treatment sessions, were strategies that indicated participant comprehension.

Treatment enactment relates to the monitoring and improvement of skills and strategies in relation to real-life everyday settings. That is, the extent with which a person actually implemented a skill or strategy in their life. While there was limited opportunity to adequately assess enactment, all communication between the researcher and participant from post-treatment and follow-up was monitored with a follow-up assessment conducted at 6 weeks post-treatment.

Table 5.4. *Strategies for monitoring fidelity for project-based treatment*

Theoretical element	Operational element
Treatment design	<ul style="list-style-type: none"> • Sessions will be of a fixed length (in hours and weeks) across treatment and control conditions. • Session attendance for all participants will be recorded (both assessment and treatment sessions). • A focus group of consultants contributed to identifying the active ingredients of the treatment. • Use of a treatment manual. • Sent text messages sent to participants will be monitored. • Completion of homework will be monitored. • The number of face-to-face, email and telephone contacts with each participant during the treatment will be recorded. • All assessment and treatment sessions will be videotaped.
Training providers	<ul style="list-style-type: none"> • A behavioural checklist of therapist and participant behaviours was created. • Fidelity checks will be done at the beginning of treatment by having treatment sessions rated by external observers using the above checklist.

(continued)	<ul style="list-style-type: none"> • The same therapist will provide all treatment sessions (with no exception). • Treatment sessions will be conducted using a treatment manual. • All treatment sessions will be videotaped.
Delivery of treatment	<ul style="list-style-type: none"> • Treatment sessions will follow the instructions in the manual (where appropriate). • Participants will all receive the same information sheets from the treatment manual. • Where sessions may be individualised or flexible, the content of these sessions will be recorded in detail. • A behavioural checklist of therapist and participant behaviours will be completed at the end of each session. • Qualitative interview will be conducted with all participants at the end of treatment. • External observers to rate the presence/absence of active ingredients in a selection of treatment sessions using the behavioural checklist • Treatment will occur across several sites in the UK. • Control and treatment conditions will not attend a testing site on the same day to minimise contamination.
Receipt of treatment	<ul style="list-style-type: none"> • Use of written material will be minimised to ensure maximum comprehension. • Participants will be invited to contribute to the plan of sessions. • Participant's understanding of session content and level of engagement will be recorded and externally observed on the behavioural checklist. • Participant's comments of the treatment during sessions will be recorded. • Participant's individual goals will be monitored within each session and at the end of treatment. • Each participant will receive a daily text reminder of their communication goal during the treatment and a homework reminder text after each session. • Post-treatment assessment using a videotaped conversation and questionnaires will be conducted. • Qualitative interview of all participants post-treatment to explore their experiences of the treatment.
Enactment of treatment skills	<ul style="list-style-type: none"> • Follow-up assessment at 6 weeks - videotaped conversation and self-report and significant other questionnaires completed. • All telephone and email contact between post-treatment and follow-up will be recorded for each participant.

5.5 Fidelity check

Consultants rated three treatment sessions. Across all groups, there were 27 videotaped treatment sessions in total with each session lasting 120 minutes. Due to technical problems, not all treatment sessions were fully recorded; and as a result, a treatment session was only included in the randomisation if 70% of the session (or 84 minutes) was recorded. This criterion captured 19 of the 27 treatment sessions (six from the first two groups and seven from the third). This meant that 15.7% (3/19) of the available data was checked by the consultants. The treatment sessions from each group were numbered according to the session number (i.e. session 1, 2, 3, 4, 6, 9) and randomised using a list randomiser (Haahr, 1998). The first number from each list corresponded to the session shown to the consultants to conduct the fidelity check.

The results from the fidelity checks are shown in Table 5.5. In four of the seven checks between consultants, there was fair to excellent agreement. For the first treatment session, agreement was fair for one consultant pair ($\kappa = 0.34, p < .05$). Sources of disagreement related to whether the behaviour was “present” or “present to some degree”. The three consultants then reached consensus on the number of observations that should be made for each category. Agreement then increased to moderate ($\kappa = 0.44, p < .05$) through substantial ($\kappa = 0.64, p < .01$) for the second treatment session. The level of agreement was excellent for the third treatment session ($\kappa = 1.0, p < .001$). There were several non-significant findings but this was unsurprising with such a small sample size.

Table 5.5. Fidelity checks for treatment sessions

Treatment group	% agreement	Kappa	95% CI	<i>p</i>
Group 1 (session 6)				
C1 + C2	57.9%	-0.03	[-0.35, 0.41]	0.89
C1 + C7	73.7%	0.34	[0.03, 0.71]	0.05
C2 + C7	84.2%	0.33	[-0.26, 0.92]	0.16
Group 2 (session 3)				
C1 + C2	94.7%	0.64	[0.002, 1.0]	<0.01
C1 + C7	89.5%	0.44	[-0.21, 1.0]	0.05
C2 + C7	84.2%	-0.08	[-0.19, 0.04]	0.73
Group 3 (session 3)				
C4 + C8	100%	1.0	[0.99, 1.0]	<0.001

Note. C1, C2, C4, C7 and C8 refer to the particular consultant who is described in Table 5.1.

Despite agreement between some consultant pairs, there was evidence of disagreement (e.g. C1 and C2 in treatment session 1). The source of disagreement between consultants was in the definition of “present” and “present to some degree”. Hart (2009) initially suggested a three response category for defining treatment behaviours, however similar difficulty for achieving substantial agreement was subsequently reported by Hart et al. (2013). As a result, categories were reduced from three to two (present vs. absent) (Hart et al., 2013), which should be a consideration for future studies conducting fidelity checks using a behavioural checklist. Importantly though, no behaviours were reported as absent for the three treatment sessions rated above. This finding suggests that all behaviours described as important to project-based treatment were observed to some degree by all consultants for all rated treatment sessions.

5.6 Summary

This chapter provided a detailed and comprehensive description of the process of treatment definition and fidelity for this study. The process draws extensively on previous guidance papers (Medical Research Council, 2008) and research that has described the process of definition and fidelity in complex behavioural treatments for people with ABI (Hart, 2009; Hart et al., 2013).

As this behavioural treatment was individualised and flexible, there was an inherent need to adequately define the treatment, achieved using experts and consultants to participate in a focus group, to review the treatment manual content and help create and review a behavioural checklist. The use of consultants with extensive experience of conducting project-based treatment with people with ABI served to strengthen this study.

As the end-project for each group could be different from the next, there was a need for fidelity checks to ensure the features of project-based treatment were upheld. Having the same therapist for all treatment groups enhanced fidelity, and inclusion of additional independent checks by the consultants for a random selection of treatment sessions further increased this validity. These checks confirmed that the treatment behaviours were observed for the first three treatment groups. Overall, confidence can be assumed in the delivered treatment, and will enable subsequent replication in future research.

Chapter 6 Method

6.1 Study Design

This thesis describes a study designed as a prospective quasi-randomised controlled trial with pre, post and follow-up assessments, using mixed methods, and feasibility testing, to investigate the effect of project-based treatment on people with ABI. In total, the study was conducted over 20 months. Participants were allocated into an immediate treatment (TREATMENT) or deferred treatment arm (WAITLIST). A control group and follow-up measures were included, as they are both considered important to improving the methodological validity of studies particularly, for people with ABI (Boelen, Spikman, & Fasotti, 2011). A waitlist control group was chosen as it represents a more ethically accepted option for conducting randomised or non-randomised controlled trials (Malec & Basford, 1996).

Mixed-methods were used as they have been shown to be increasingly important for the evaluation of behavioural treatments for people with brain injury (Fleming et al., 2009; Kreutzer et al., 2010; Togher, Power, Rietdijk, McDonald, & Tate, 2012). Mixed-method outcomes provide additional information to complement and explain quantitative results as well as provide unique sources of information not provided by the quantitative data alone. Creswell (2012) highlights that mixed-methods provide a “better understanding of the research problem and question than either method by itself” (p.535). The conclusions that can be drawn are also extended beyond the data provided by the quantitative information alone. In this study, the main design was quantitative, with a smaller qualitative component.

As this was an exploratory study of a treatment with little evidence for people with ABI, assessment of its feasibility was crucial to determining whether it should be considered for further trials (Bowen et al., 2009). Establishing feasibility helps to identify whether the ideas and findings of project-based treatment are relevant, and whether any changes need to be made to the research methods or protocol. Bowen et al. (2009) describe a range of criteria for assessing feasibility, of which five are relevant to the current study, and have been described in a study testing the feasibility of a treatment for people with ABI (Aboulafia-Brakha et al., 2013). These criteria include demand (to what extent was it used?), implementation (was it delivered as planned?), practicality (could it be administered to the intended population?), acceptability (was it satisfying for the intended participants?), and initial efficacy (is it likely to be successful with the intended population?). The chosen methods, and analysis of data, take these criteria into account to help determine the feasibility of the project-based treatment, which will be discussed comprehensively in Chapter 10.

6.2 Ethics

Three ethics committees approved this study. The Language and Communication Science Proportionate Review Research Ethics Committee from City University London approved the first phase of the study (treatment definition) on the 23 January 2013. The Brain Injury Rehabilitation Trust's Research Ethics Committee granted full ethical approval on the 21 May 2013 (Appendix E). City University's School of Health Sciences Research Ethics Committee granted full ethical approval on the 6 June 2013.

6.3 Participants

6.3.1 People with ABI

As this study would be considered an exploratory trial, the sample size was therefore determined through reference to other group treatment studies for people with ABI (Kennedy et al., 2008). Social skills treatment trials have produced significant treatment effects and large effect sizes (0.89) with as few as 8 people per group (Helffenstein & Wechsler, 1982; Medd & Tate, 2000). More recently, a social skills training study produced an effect size of 0.70 with 13 in each group (McDonald et al., 2008) while a communication partner training study produced effect sizes of 0.53-0.82 with 5 in each group (Behn et al., 2012). As a result, an appropriate sample size of 24 people was chosen: with 12 in the immediate TREATMENT group and 12 in the WAITLIST control group.

People with ABI were recruited from three sources: Brain Injury Rehabilitation Trust, a private non-for-profit brain injury organisation which has residential rehabilitation centres in Cambridgeshire, West Sussex and West Yorkshire; Headway, a charitable organisation for people with brain injury in East Sussex; and a local stroke support group in London. Each of these centres were approached and agreed to be involved. Consultant Psychologists, Speech and Language Therapists and managers identified participants who were considered to have capacity and a cognitive-communication disorder. The author of the thesis (NB) then approached each participant to conduct a formal capacity assessment that determined his or her ability to consent to inclusion into the study. As part of this assessment, the study information sheet was shown and discussed. The person with brain

injury was then supported to answer questions about study commitments, how many sessions they would need to attend and potential benefits. If a person was not able to give capacity to participate in the study, they were not included. If they were deemed to have capacity, they also needed to meet the following inclusion and exclusion criteria.

Inclusion criteria for participants with ABI were: (1) aged over 18; (2) a diagnosis of ABI; (3) a moderate-to-severe injury based on period of post-traumatic amnesia (PTA) as determined by a qualified psychologist or neuropsychologist, Glasgow Coma Scale at time of injury, or clinical presentation based on the extent of cognitive and physical impairments (if the diagnosis was TBI); (4) occurrence of injury at least 6 months earlier; (5) discharged from post-acute/residential rehabilitation at least 6 months earlier; (6) presence of cognitive-communication disorder as diagnosed by a speech and language therapist/psychologist and/or reported by family member or significant other, and/or identification of some aspect of impairment in social communication skills on the La Trobe Communication Questionnaire (LCQ) (Douglas et al., 2000); (7) able to identify a family member, friend or paid carer to attend assessment sessions; (8) able to travel to treatment venue; (9) time available to attend assessment and treatment sessions; (10) a mobile phone that is able to receive text messages; (11) able to consent to participate in the study as determined by capacity checks administered by the author of the thesis (NB); and (12) sufficient English to participate in the study.

Exclusion criteria for participants with ABI included: (1) poor speech intelligibility that would affect their ability to be understood by others in the group or severe aphasia as diagnosed by a speech and language therapist; (2) people receiving speech and language therapy for the duration of the study; (3) diagnosis of an active mental health disorder; and

(4) significant behavioural problems that would disrupt group participation (Backhaus et al., 2010).

Across these three sources, 100 potential participants were identified. Of these, the Brain Injury Rehabilitation Trust identified 91; Headway identified 6; and local stroke support groups in London identified 3. Participants were recruited between July 2013 and October 2014 (16 months). Of the total 100, 19 people declined to participate; 3 further people declined after eligibility assessment; 6 people were initially contacted but then did not respond to further attempts of contact; 47 participants were unable to be contacted; and 4 people wanted to be included but were unable to participate, as they did not live close to a treatment location; and 21 participants agreed to participate and were eligible. A thorough description of participant characteristics is detailed in Chapter 7 (section 7.2). Once a person was deemed to have met the inclusion and exclusion criteria, the person was allocated to a group (of 2-3 people with ABI) on their availability to attend the treatment sessions. Alternate allocation of groups to either the WAITLIST or TREATMENT group was then conducted throughout the course of the study. Treatment groups occurred in six locations across London (2 participants), Sussex (8 participants), Cambridgeshire (6 participants), and Yorkshire (5 participants). Intention-to-treat analyses were used. Recruitment and allocation to groups is shown in the CONSORT diagram (Figure 6.1).

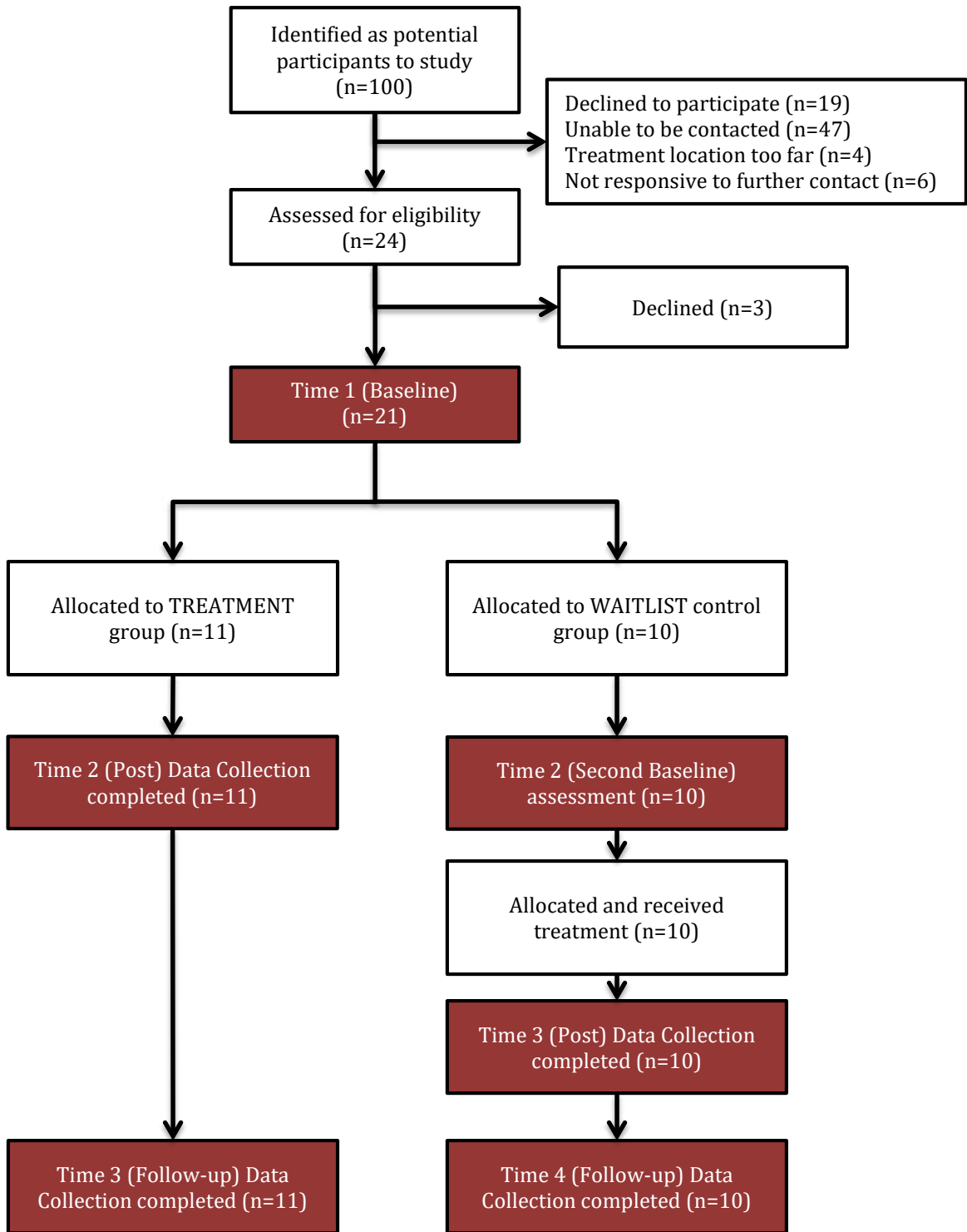


Figure 6.1. CONSORT diagram illustrating participant allocation and treatment design

6.4 Treatment Process

Treatment commenced within 1 week of the assessment being conducted. The treatment was conducted over a period of 6 weeks and involved 10 sessions in total. Section 5.4 (in Chapter 5) described the delivery and content of the treatment programme. In brief, the first session involved the person with ABI, their communication partner, and the therapist, to identify individualised communication goals, and discuss specific strategies that would improve conversations for each dyad. The next nine sessions were conducted in small groups of 2-3 people with ABI that were flexible and individualised to each group according to the project they chose to create. A treatment manual was used to guide the treatment process. The communication partner did not attend these sessions.

6.5 Procedure

Data was collected at three time intervals for participants: (1) one to two weeks prior to the commencement of the treatment; (2) one to two weeks after the end of training; and (3) six to eight weeks after the completion of training. Data was collected for participants in the WAITLIST group four times as they underwent assessment twice prior to the treatment, each separated by a 6 week gap in which they received no treatment.

At each time point, people with ABI attended between one and two sessions to complete assessments dependent on attention and fatigue levels, and to accommodate availability of a communication partner. At each time point, they participated in a videotaped conversation with a communication partner, and completed three questionnaires. The number of items across the three questionnaires was carefully considered in terms of respondent burden. The QOL review in section 3.2.2 highlighted that

an average of 77 items (\pm 56 items) could be considered an appropriate number of items for people with ABI to complete. In addition, a range of profiling assessments was conducted in the first assessment session, and a focused interview in the post-treatment session. The author of the thesis (NB), who was not blind to treatment condition, completed all assessment sessions. A detailed description of the communication and QOL treatment outcomes, profiling assessments (Table 6.1), and focused interview, is presented next.

Table 6.1. *List of profiling assessments, and communication and QOL treatment outcome measures*

Area of assessment	Outcome	Description
PROFILING ASSESSMENTS		
Cognitive functioning	<ul style="list-style-type: none"> • Repeatable Battery of the Assessment of Neuropsychological Status (RBANS) • Wisconsin Card Sorting Test (WCST) 	<p>Measures attention, language, visuospatial/constructional and immediate and delayed memory.</p> <p>Measures executive function abilities.</p>
Social functioning	<ul style="list-style-type: none"> • Participation Assessment of Recombined Tools – Objective (PART-O) • Interpersonal Support Evaluation List – Short Form (ISEL-SF) 	<p>Measures social participation.</p> <p>Measures the degree of social support in a person’s life.</p>
Emotional functioning	<ul style="list-style-type: none"> • Hospital Anxiety and Depression Scale (HADS) • Rosenberg Self-Esteem Scale (RSES) 	<p>Measures anxiety and depression in two separate scales.</p> <p>Measures level of self-esteem</p>
Personal factor	<ul style="list-style-type: none"> • Coping Scale for Adults (CSA) 	<p>Measures coping strategies – productive, non-productive, optimism and sharing.</p>

Area of assessment	Outcome	Description
COMMUNICATION OUTCOME MEASURES		
Primary outcome measure	<ul style="list-style-type: none"> • Measure of Participation in Conversation (MPC) 	Measures participation of the person with ABI on two scales (interaction & transaction)
Secondary outcome measures	<ul style="list-style-type: none"> • Impression Scales • Measure of Support in Conversation (MSC) • La Trobe Communication Questionnaire (LCQ) • Goal Attainment Scaling (GAS) 	<p>Measures overall impression of a conversation on 4 scales (appropriate, effort, interesting, rewarding)</p> <p>Measures the support provided by the communication partner on 2 scales (acknowledging and revealing competence)</p> <p>Measures perceived communicative ability</p> <p>Measures perceived achievement towards an individualised communication goal</p>
QUALITY OF LIFE OUTCOME MEASURES		
Primary outcome measure	<ul style="list-style-type: none"> • Satisfaction With Life Scale (SWLS) 	Measures subjective well-being
Secondary outcome measure	<ul style="list-style-type: none"> • Quality of Life in Brain Injury (QOLIBRI) 	Measures health-related quality of life (HRQOL) across 7 scales.

6.6 Profiling assessments

The profiling assessments helped define the range of functioning of people with brain injury. Obtaining as much information about a person's level of functioning helps to determine who benefits most from project-based treatment. The profiling assessments included aspects of a person's cognitive, social, and emotional functioning and were all completed by the person with ABI.

6.6.1 Cognitive functioning

Cognitive functions are disrupted following a brain injury, and cognitive impairments post-injury can have a large impact on treatment outcomes (Anson & Ponsford, 2006b; Bornhofen & McDonald, 2008a). As a result, the majority of treatment studies involving people with ABI will routinely conduct an assessment of cognitive function before commencing treatment.

The first chosen assessment of cognitive functioning was the Repeatable Battery of the Assessment of Neuropsychological Status (RBANS). The RBANS is considered a suitable assessment of cognitive functioning for people with cognitive-communication disorders (Turkstra, Coelho, & Ylvisaker, 2005), and has been previously used in treatment studies to describe the cognitive abilities of participants (Arundine et al., 2012; Bergquist et al., 2009; Bradbury et al., 2008). This assessment is a brief, valid and reliable screening test that measures five domains: attention, language, visuospatial/constructional abilities and immediate and delayed memory for adults aged 20-89 (Lezak, Howieson, Bigler, & Tranel, 2012). The advantage of this test over other tests of cognitive function specific to TBI is

that it can be administered to, and has been standardised for a range of people with neurological conditions including dementia, degenerative disorders (e.g. Parkinson's disease), stroke, and TBI. It can be administered in 20-30 minutes, and the raw scores from all subtests can be converted into total index scores for each of the five domains, and for the total test. The index scores range from 40-160 with a higher score reflective of greater cognitive functioning. The RBANS provides useful information about a person's cognitive functioning that will help to determine the rate and complexity of speech, and amount of repetition and summarisation that might be required to organise retention of information for each person during the treatment (Bradbury et al., 2008). One of the limitations of this test is that it does not assess executive function, which is also known to be impaired following an ABI therefore, an additional test was included in the baseline measures.

To assess executive function, the Wisconsin Card Sorting Test (WCST) (Heaton, Chelune, Talley, Kay, & Curtiss, 1993) was used. This test is the most frequently used measure of executive function by neuropsychologists (Rabin, Burton, & Barr, 2007) and recommended by others for people with ABI (Cicerone, Levin, Malec, Stuss, & Whyte, 2006). It is a generalised measure that assesses a person's ability to show abstract thinking and display flexibility of thought. The test is both reliable and valid (Miller, McIntire, & Lovler, 2011; Strauss, Sherman, & Spreen, 2006), and generates a number of scores of which the 'categories achieved' and 'perseverative errors' are two of the most widely used (Lezak et al., 2012), which were used in this study.

6.6.2 Social functioning

Social functioning, often considered the ultimate aim of rehabilitation for people with ABI (Corrigan & Bogner, 2004; Dijkers, 2010), can be described in terms of the number of activities a person is doing (i.e. social participation) and the number of people in a person's life (i.e. social support). However, the review of QOL treatment studies (see section 3.11) revealed that few treatment studies show change on these measures, suggesting social functioning is unlikely to change over a short treatment period (Ownsworth et al., 2008). Despite this, a person's existing level of social functioning may affect the treatment outcome, for example, those with a high degree of social participation and support may respond more positively to project-based treatment; and for this reason, these measures were included pre-treatment.

The measure of participation used was the recently developed Participation Assessment with Recombined Tools–Objective (PART-O) (Bogner et al., 2011; Whiteneck, Bogner, & Heinemann, 2011). This questionnaire objectively measures participation levels as reported by the person with ABI. The questionnaire is not as commonly used as the Community Integration Questionnaire (CIQ) (Willer, Ottenbacher, & Coad, 1994), however the items of the PART-O were drawn from three existing measures, including: the CIQ, both the original (Willer et al., 1994) and revised version (CIQ-2) (Johnston et al., 2005); Participation Objective, Participation Subjective (POPS) (Brown et al., 2004); and the Craig Handicap and Assessment Reporting Technique (CHART) (Whiteneck, Charlifue, Gerhart, Overholser, & Richardson, 1992). In addition, there is good self-proxy agreement on the objective items of this measure (Hart et al., 2010), and the measure has been used in TBI, spinal cord injury, stroke, and the general population (Bogner et al.,

2011). Most items are scored on a 5-point Likert scale ranging from 0 (never participate in these type of activities) to 5 (almost always participate in these type of activities) with four items having dichotomous scoring (0=no; 5=yes). A total score for participation can range from 0-120 where a higher score reflects higher participation (Bogner et al., 2011). The PART-O has adequate to strong correlations with other measures of participation and functional ability (Whiteneck et al., 2011). The internal consistency of the measure is excellent and the authors have concluded that the measure stands as a uni-dimensional measure of participation (Whiteneck et al., 2011).

The measure of social support chosen was The Interpersonal Support Evaluation List (ISEL-SF), which is a shortened version of the original 40-item ISEL and contains two items each from the tangible, belonging and appraisal social support factors (Cohen, Mermelstein, Kamarck, & Hoberman, 1985). While other more comprehensive assessments of social support exist (Ensel & Woelfel, 1986), the intention of using a shortened version was to simply identify the level of social support people have, rather than describe the different types of support. This measure has been used for people with ABI (Struchen et al., 2011), older adults (Newsom & Schulz, 1996; Williamson & Schulz, 1992), and people with other medical conditions (Williamson, 2000). Each item is measured using a 4-point Likert scale (definitely true, probably true, probably false, and definitely false). The measure ranges from 6-24 where a higher score is indicative of greater social support. This measure has been shown to have adequate internal consistency (Cronbach alpha ranged from 0.73 to 0.82) (Cohen et al., 1985).

6.6.3 Emotional functioning

Emotional functioning refers to a person's level of anxiety, depression, and self-esteem following an ABI (Morton & Wehman, 1995). Similar to social functioning, measures of emotional functioning were not used as an outcome of treatment as relatively short treatment programmes are unlikely to make significant changes to long-term emotional issues (Anson & Ponsford, 2006b). However, a person's emotional functioning pre-treatment may have an impact on the success of treatment (Fleming et al., 2009; Simpson et al., 2011; Tiersky et al., 2005), wherein a person who has low emotional functioning prior to the commencement of treatment may benefit less (Sinnakaruppan et al., 2005). Researchers in the QOL review (Chapter 3) frequently used the chosen measures.

The first measure used was the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), which is a questionnaire of psychological distress for people with psychological and psychiatric symptoms and the general population. The measure has been extensively used for people with ABI (Anson & Ponsford, 2006a; Appleton et al., 2011; Cooper et al., 2009; Fleming et al., 2009; Hodgson et al., 2005; Medd & Tate, 2000; Simpson et al., 2011; Sinnakaruppan et al., 2005). The HADS consists of 14 items that can be equally divided into an anxiety and depression scale. Participants rate each item on a 4-point Likert scale that ranges from 0 (absence) through to 4 (extreme presence). Five of the items are reversed scored. Each scale is scored out of 21. Higher scores are indicative of greater levels of anxiety or depression with a cut-off point of 8/21 (Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS has well-established psychometric properties with adequate to excellent internal consistency, moderate-strong correlations with other

measures of anxiety and depression and was commonly used following a review of 747 papers (Bjelland et al., 2002).

The second measure was the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965). This measure of self-esteem has been extensively used with people with ABI (Anson & Ponsford, 2006a; Gemmell & Leathem, 2006; Mitchell et al., 2014; Rath et al., 2003; Simpson et al., 2011; Sinnakaruppan et al., 2005). The RSES has 10-items which are rated on a 4-point Likert scale (strongly agree, agree, disagree, and strongly disagree). There are an equal proportion of positively and negatively worded items. The measure ranges from 0-30 where a higher score is indicative of higher levels of self-esteem. Scores below 15 suggest a low level of self-esteem. This measure has moderate internal consistency (Cronbach $\alpha = 0.77-0.88$) and good test-retest reliability with correlations ranging from 0.82-0.88 (Blascovich & Tomaka, 1993; Rosenberg, 1986).

6.6.4 Personal factors

Personal factors can affect treatment outcome particularly, QOL. A coping measure was chosen as a person's ability to cope, particularly adaptive coping, has been suggested as a precursor to better adjustment and overall well-being (Bradbury et al., 2008) and has been successfully used in behavioural treatments for people with brain injury (Anson & Ponsford, 2006b). The Coping Scale for Adults – Short Form (CSA-SF) (Frydenberg & Lewis, 1996) is a measure that examines a person's own coping behaviours. The person is required to rate the frequency with which they use 19 coping behaviours using a 5-point Likert scale (i.e. doesn't apply or don't do it, used very little, used sometimes, used often, used a great deal). The coping behaviours are divided into four sub-scales: (1) dealing with

the problem; (2) non-productive coping; (3) optimism; and (4) sharing. Total adjusted scores for each sub-scale range from 21-105 for adaptive and non-productive coping, and 20-100 for optimism and sharing. Higher scores indicate more frequent use of a particular coping strategy. The adaptive coping behaviours and non-productive coping behaviours have acceptable reliability with Cronbach alpha α of 0.65 and 0.73, respectively. However, the optimism and sharing sub-scales should be interpreted with caution as they have low reliability with a Cronbach alpha of 0.45 and 0.42, respectively.

6.7 Communication skills assessment

Conversational discourse has often been utilised as an outcome of treatment for people that present with communication impairments (Behn et al., 2012; Bloomberg, West, & Iacono, 2003; Dobson, Upadhyaya, & Stanley, 2002; Hickey, Bourgeois, & Olswang, 2004; Kagan, Black, Duchan, Simmons-Mackie, & Square, 2001; Legg, Young, & Bryer, 2005; Rayner & Marshall, 2003; Togher et al., 2013). Variability in elicitation procedures can often make obtaining an accurate and reliable sample problematic (Correll, Steenbrugge, & Scholten, 2010; Turner & Whitworth, 2006), however casual conversations are typically used when investigating conversational discourse in people with brain injury (Behn et al., 2012; Coelho, 1999; Galski et al., 1998; Togher et al., 2013).

For the purposes of this study, people with ABI were videotaped at each time point of the study. For the videotaped conversation, the person with ABI sat with a family member, friend or paid carer in a quiet room either at their own home or at a local residential rehabilitation centre. Where possible, the same communication partner was used at each time point, and was possible for 19 participants. The remaining two people with

ABI (from the WAITLIST group) had two different communication partners. For one participant, one communication partner was used for the first two pre-treatment conversations, and a different communication partner for the final two conversations. For the second participant, one communication partner was used for the first pre-treatment conversation and a different communication partner for the remaining three conversations. For all 21 participants, the dyad was asked to ‘speak about a topic of interest for 10 minutes’. Previous studies involving people with ABI have used a similar elicitation method for a casual conversation sample (Behn et al., 2012; Coelho et al., 1991b; Galski et al., 1998; Togher et al., 2013). The researcher left the room during this time and no further guidance or support was provided. Assessment sessions were videotaped using a Flip Video Camera HD mounted on a tripod.

Research supports that 10 minutes conversation yields adequate and representative data for analysis, as rated by blind raters. A recent study involving paid caregivers and people with ABI reported change in communicative behaviour for 10-minute conversations (Behn et al., 2012). Boles and Bombard (1998) also reported that 10-minute conversations “rarely missed the mark” (p.557). Change has been documented for shorter conversations lasting 3-5 minutes involving people with aphasia (Correll et al., 2010) and for conversations lasting 5 minutes involving people with ABI (Togher et al., 2013). However, in both of these studies the communication partner was a family member or friend. Given that communication partners in this study were a mixture of family members, significant others, friends and paid caregivers, 10-minutes were considered an appropriate length to capture any change from the treatment. Blinded raters then scored the videotaped conversations on the measures described below, and all videotaped conversations were

reviewed and edited to delete inadvertent references to training or times of the year that would have revealed the time of videotaping.

6.7.1 Primary outcome measure of communication skills

The primary measure used to blindly rate the videotaped conversations of people with ABI was The Adapted Measure of Participation in Conversation (MPC) (Togher, Power, Tate, McDonald, & Rietdijk, 2010). The original measure rated conversations involving people with aphasia (Kagan et al., 2001; Kagan et al., 2004), and the Adapted MPC contains two scales (Interaction and Transaction) that rate the level of participation of the person with ABI in a conversation. Interaction (social connection) refers to how the person with ABI engages and shares the conversation, and Transaction refers to how the person with brain injury exchanges information and understands the content of the conversation. Measures are scored on a 9-point Likert scale ranging from 0 to 4 with 0.5 intervals. The MPC scale ranges from 0 (no participation) to 4 (full participation). The original version of the MPC and the Measure of Support in Conversation (MSC) have well-established inter-rater reliability and construct validity (Kagan et al., 2004), and the adapted measures have excellent inter-rater and strong intra-rater reliability (Togher, Power, et al., 2010), and furthermore, have been shown to be responsive to change for conversations involving people with ABI following communication training (Behn et al., 2012; Togher et al., 2013).

6.7.2 Secondary outcome measures of communication skills

As this study is considered an exploratory study, other measures that rate conversations were included, to identify which ones are most appropriate to test responsiveness to change from the treatment. The Impression Scales assess broader, more global aspects of social skills (Bond & Godfrey, 1997). In doing so, they rate the overall impression of the conversation taking into account the skills of both the person with ABI and their communication partner. Having a conversation perceived as socially reinforcing is likely to be important for forming and maintaining friendships and relationships. For these scales, the rater is required to score how appropriate, effortful, interesting and rewarding they perceived the interaction to be. Scoring is conducted on a 9-point Likert scale ranging from 0 (not present) to 4 (present throughout) with 0.5 intervals. Reverse scoring is applied to the Effort scale where a high score reflects less effort. The Impression Scales have been utilised to evaluate the effects of communication partner training for people with TBI (Behn et al., 2012; Togher, McDonald, Tate, Power, & Rietdijk, 2010) and have been shown to have excellent inter-rater reliability ($r = 0.89 - 0.92$) (Bond & Godfrey, 1997).

The Adapted Measure of Support in Conversation (MSC) (Togher, Power, et al., 2010) rated the conversation skills of the communication partner. This measure was adapted from one intended for the communication partners of people with aphasia (Kagan et al., 2001; Kagan et al., 2004). The Adapted MSC contains two scales (Acknowledge and Reveal Competence) that rate the skill of the communication partner and the support they provide to the person with ABI. Acknowledging Competence (AC) refers to how the communication partner is able to create a natural adult-like conversation that is non-patronising and sensitive to the communication difficulties of the person with ABI.

Revealing Competence (RC) is further divided into 3 subscales that describe strategies and techniques a communication partner may use to ensure the adult understands, ensure the adult has a means of responding, and to provide verification of what has been understood. Measures are scored on a 9-point Likert scale ranging from 0 (not supportive) to 4 (highly skilled support) with 0.5 intervals. The three subscales of the RC scale for the MSC are scored separately and then averaged to give a total RC score. The reliability and validity of the MSC is presented above with the primary outcome measure (MPC).

The La Trobe Communication Questionnaire (LCQ) is a questionnaire that measures perceived communicative ability for a person with ABI (Douglas et al., 2000). Assessing perceived communicative ability is important as some people with ABI can perceive changes to communication as having a negative impact on their conversations with others including a reduced ability to express a range of emotions, be tactful, empathic, or a confident communicator (Shorland & Douglas, 2010). Also, we are interested in whether any changes observed by blind raters on the rating scales are reflected in the self-ratings of the person with ABI, or their communication partner. The LCQ was chosen as it is a reliable, valid, and commonly used measure (see section 2.2.3). The person with ABI (LCQ-Self) and their communication partner (LCQ-Other) completed this questionnaire separately. The LCQ contains 30 questions rated on a 4-point Likert scale (never or rarely, sometimes, often, usually or always) with reverse scoring for six items to prevent response bias. Twenty of the items are based upon normal communicative behaviours, and 10 upon commonly reported cognitive-communication difficulties post-injury. The questionnaire gives a total score from 30-120 where a lower score indicates better communication skills. The questionnaire has strong test-retest reliability (Douglas et al., 2007b) and established

discriminant validity for people with brain injury and their close others (Bracy & Douglas, 2005; Douglas et al., 2007b; Struchen, Pappadis, et al., 2008; Watts & Douglas, 2006). The questionnaire has acceptable internal consistency (Douglas et al., 2007b; Struchen, Pappadis, et al., 2008), established construct validity that demonstrates the interaction of cognition and language function on communication (Douglas et al., 2007a; Struchen, Pappadis, et al., 2008), and has been shown to be responsive to change (Braden et al., 2010).

Goal Attainment Scaling (GAS) is a method for quantifying clinically meaningful change towards rehabilitation goals that are highly individualised for people with ABI. Initially introduced by Kiresuk and Sherman (1968), GAS has been widely reported in goal setting for people with ABI (Bovend'Eerd et al., 2009; Hurn, Kneebone, & Crompton, 2006; Malec, 1999; Malec et al., 1991; Turner-Stokes, 2009). GAS goals have the advantage of being “measurable, attainable, desired by all, and socially, functionally, and contextually relevant” (Ottenbacher & Cusick, 1990, p.520), and can be used to improve self-awareness for people with ABI (Malec, 1999). In the current study, goals were formulated in collaboration with both the person with ABI and their communication partner, on the session immediately before the group treatment sessions (see section 5.4).

Several studies provide guidance as to the development and implementation of GAS goals (Bovend'Eerd et al., 2009; Malec, 1999) with careful articulation of the level of desired outcome, which can be important for making it easier to define remaining outcome levels (Turner-Stokes, 2009) (i.e. over or under achievement of goal). Multiple members of a team usually rate achievement of goals, however in this study, the person with ABI and their communication partner rated goals and did so separately. This was done to identify

whether people with ABI could recognise change post-treatment in their own communication skills, and whether they are as reliable in rating change as their communication partner. Achievement of goals was rated on a 5-point outcome scale, “much less than expected” (-2), “less than expected” (-1), “expected” (0), “better than expected” (+1) and “much better than expected” (+2). The baseline or pre-treatment score is usually rated as -1 and the “expected level of outcome” is 0. Malec (1999) suggests the use of numbers 0-4 rather than -2 to +2 as many people with ABI have indicated distress at being ‘negatively’ rated. Thus, people with ABI were presented with the 0-4 scale, and the data was re-considered thereafter by the researcher.

There is strong evidence from a systematic review (based on 11 studies) for the reliability, validity and sensitivity of GAS (Hurn et al., 2006). The measure has excellent inter-rater reliability when goals were rated by multiple members of a team (ICC>0.90), satisfactory concurrent validity, and sensitive to the needs of people with ABI while being responsive to change (Malec, 1999). Positive outcomes have been reported from the use of GAS for people with ABI (Doig et al., 2011; McPherson, Kayes & Weatherall, 2009; Trombly et al., 2002), including those with CCDs (Braden et al., 2010; Dahlberg et al., 2007). However, as GAS is highly individualised, Malec (Malec, 1999) suggests the measure is employed as part of a comprehensive set of outcome measures.

6.7.3 Establishing inter-rater reliability for measures rating videotaped conversations and scoring procedures

Four raters were recruited to score the videotaped conversations on the MPC, MSC (Adapted), and Impression Scales. The use of independent raters enabled blinding of the

data. The raters were practising Speech and Language Therapists who were completing a post-graduate masters degree at City University London. All raters were trained in the use of the MPC, MSC (Adapted), and Impression Scales. Training lasted 18 hours across five sessions and was modelled on other effective studies (Behn et al., 2012; Togher, Power, et al., 2010). Training involved raters familiarising themselves with the scales, scoring videotaped conversational interactions, and discussing any discrepancies. During the training process, the four raters watched 22-videotaped conversations involving 17 different people with ABI. Of these 22 conversations, 13 were used to calculate inter-rater reliability on the scales (training videos), before the raters were given the study samples. Three of the training sessions (12 hours) were conducted with all four raters and the author of the thesis (NB). The remaining sessions were conducted in pairs (6 hours) owing to the practical constraints of organising training sessions amongst all four raters, and were not attended by NB. Pairs were chosen according to the geographical proximity of raters to each other, and were conducted to allow the raters additional time to practise rating videotaped conversations.

In total, there were 73 videotaped conversations to be scored, three conversations from each participant in the TREATMENT group (n=11), and four conversations from each participant in the WAITLIST group (n=10). Figure 6.2 presents how the conversations were divided and rated by the four raters. The 73 conversations were divided into two groups. The first contained conversations from the first four treatment groups (i.e. 2 WAITLIST and 2 TREATMENT). The second group contained conversations from the last four groups. The conversations (from each group) were then randomised so raters were blind to group assignment, and the time at which the videotaped conversations occurred. Raters were not

blind to the purpose of the study. All raters were responsible for individually scoring the first 11-12 videotaped conversations from each group (23 conversations in total). These scorings from both pairings (32% of the total data) were used to calculate inter-rater reliability.

Each pair was then responsible for rating the remaining conversations from their group. Within each pair, and for each video, one rater was identified as the primary rater and one as the secondary rater. The primary rater was chosen at random using a list randomiser (Haahr, 1998). The analysis of treatment outcomes only used the scores from the primary raters.

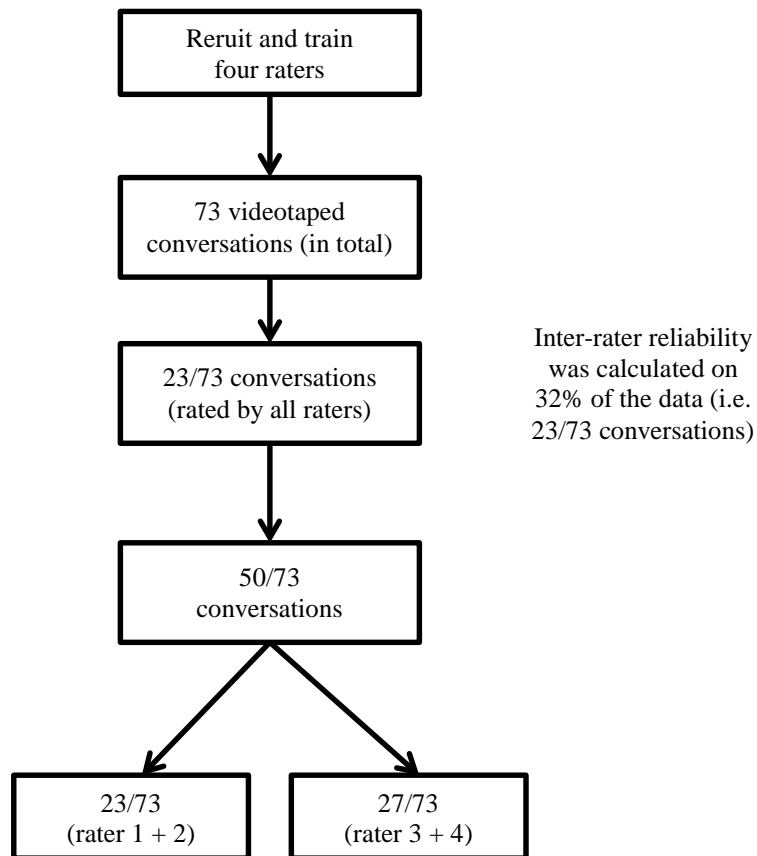


Figure 6.2. Division of videotaped conversations between the four blind raters

6.8 Quality of life assessment

Two measures were chosen to measure subjective well-being (SWB), and health-related QOL (HRQOL). These were chosen to reflect information gained from the review of QOL treatment studies (Chapter 3) and reference to the literature. The Satisfaction With Life Scale (SWLS) was chosen to measure SWB as researchers frequently chose it (i.e. on 6 of 11 occasions) and it showed change in 4/6 studies. There was greater variability for HRQOL with 22 different multi-dimensional measures used across the 38 occasions. The most commonly chosen measure was the SF-36 (used on 6 occasions) and it showed change in 3/6 studies. However, the SF-36 is not easily accessible, is not entirely subjective as some items are objective in nature, a total score is unable to be generated, and there are concerns about sensitivity to different severities of ABI (Salter, Teasell, & Jutai, 2013). These problems are overcome with The Quality of Life in Brain Injury (QOLIBRI) (von Steinbüchel et al., 2010), which has been described in the literature as an emerging disease-specific measure of HRQOL (Wilde et al., 2010), which is entirely subjective, and easily accessible. Both the SWLS and QOLIBRI will be discussed below.

6.8.1 Primary outcome measure of QOL

The Satisfaction With Life Scale (SWLS) is a global measure of life satisfaction (Diener, Emmons, Larsen, & Griffin, 1985). Life satisfaction is a cognitive judgement of the construct of SWB. The SWLS has five items that are rated on a 7-point scale ranging from 1 (strongly disagree) through 4 (neither agree nor disagree) to 7 (strongly agree). A total score of 5-35 can be obtained where a higher score reflects greater life satisfaction. This measure has good to strong internal consistency (Cronbach alpha = 0.79 to

0.89)(Pavot & Diener, 1993), good test-retest reliability (Cronbach alpha=0.82)(Diener et al., 1985) and has been shown to have construct and concurrent validity (Diener et al., 1985; Pavot & Diener, 1993; Pavot, Diener, Colvin, & Sandvik, 1991). The measure has been widely used to assess a person's life satisfaction following ABI (Corrigan et al., 2001), and is responsive to change following treatment (Braden et al., 2010; Dahlberg et al., 2007; Huckans et al., 2010).

6.8.2 Secondary outcome measure of QOL

The Quality of Life in Brain Injury (QOLIBRI) (Truelle et al., 2010; von Steinbüchel et al., 2010) is a disease-specific measure developed to assess HRQOL of people after a brain injury. The measure has been tested extensively on people with ABI in the UK and Europe and has satisfactory internal consistency and good test-retest reliability for people with impaired cognition including, severely injured people (von Steinbüchel et al., 2010). The measure contains 37 items that are divided into six scales. The first four scales assess a person's satisfaction with their cognitive abilities (7 items), self (7 items), daily life and autonomy (7 items), and social relationships (6 items). The next two scales assess how bothered a person is with their emotions (5 items) and physical problems (5 items). Responses to the satisfaction items are scored by a person with ABI on a 5-point scale ranging from "not at all" through "moderately" to "very" satisfied. Responses to the bothered items are reverse scored by a person with ABI on a 5-point scale ranging from "very" through "moderately" to "not at all" bothered. Responses for all 37 items can be averaged to give a total QOLIBRI score scale which can then be converted to a 0-100 scale where 0 = worst possible QOL and 100 = best possible QOL. The QOLIBRI total score has

been shown to have good validity, good internal consistency, good test-retest reliability (von Steinbüchel et al., 2010; von Steinbuchel et al., 2010), and has been shown to be responsive to change (Lin, Chu, Liang, Chiu, & Lin, 2014).

6.9 Semi-structured interview

Structured interviews were conducted with each participant to explore their experiences of being involved in the treatment. The participant's voice should form part of the evidence when evaluating treatment effectiveness. The unique information provided by the participant can help to "provide deeper insight into the meaning and quality of the evidence being generated" (Kovarsky & Curran, 2007, p.60). Thus, helping to illuminate change that has occurred from participation in the treatment. For example, in a training programme for people with aphasia, Simmons-Mackie et al. (2007) found that participants and their caregivers reported the group format to be helpful in enabling them to learn skills about a range of topics (e.g. solving problems effectively, better managing stress and how to be more patient). Information such as this could not be obtained from quantitative data alone.

Increasingly, treatments are becoming more complex with active ingredients that can be hard to define. Qualitative data can provide a rich source of information for identifying these ingredients and the components that may or may not be related to the treatment effect (Behn et al., 2015; Medical Research Council, 2000; Togher et al., 2012). This data is important for exploratory studies testing the feasibility of a treatment, such as the one under investigation in this thesis. The data can help to identify which aspects of the treatment were most important to participants, which aspects facilitated and/or hindered

their learning, and what improvements or changes they would make to the treatment. For example, providing specific feedback about conversations, role-plays, a combination of individual and group sessions and the social component of training were considered valuable components of a communication training programme for people with brain injury (Togher et al., 2012). Participants in this study also identified challenges and the need for improvements that included more real-life examples, more interesting course content, and involvement of other family members. Kreutzer et al., (2010) were able to use qualitative data to identify that specific sessions on ‘solving problems and setting goals’ and ‘strategies for optimal recovery’ were perceived more strongly than other training sessions. This finding would have implications for future training for people with ABI and their caregivers. Qualitative data can provide information on what the most important “active ingredients” are of a complex treatment, which has implications for the design of future treatment studies for people with ABI.

The interview was semi-structured and conducted with people with ABI in a quiet room post-treatment. Each interview was audio and videotaped. An interview topic guide was utilised to ensure consistency across the interviews (Creswell, 2007). The topic guide contained the opening probe question “your experiences with the treatment are important to us. We’d like to know more about your opinion on how it has been to participate in the treatment”. Further questions were asked to probe their feelings and impressions of particular components of the treatment. Prompts were given for people with brain injury to explain, clarify, and give examples of comments they made during the interview. These prompts ensured that the information given was as accurate and unambiguous as possible without unnecessarily influencing their opinions. The protocol is outlined in Appendix F.

Further specific questions were asked to identify any improvements or changes that could be made to the treatment.

The focused interview was also used to obtain qualitative information about the assessment process. Questions were asked to gauge a participant's opinion on the content of questionnaires and whether they helped to explain changes post-treatment. The purpose of asking questions about the assessment process was two-fold. First, to determine whether participants could identify what may have changed as a result of the treatment based on the questionnaires that they completed at each time point; and second, to assess respondent burden for the assessment sessions and whether participants felt that the number of questionnaires administered was too excessive.

The author of the thesis (NB) conducted the interviews, and was experienced in working with people with ABI (15 years), as well as delivering the treatment. Being the interviewer and therapist could be advantageous as there is shared knowledge and experience, which could lead to more meaningful data being collected during interviews (Johnson, 2006). However, being in the role of therapist, interviewer and person responsible for analysis may have led participants to respond in a socially desirable way, and affected the degree of objectivity during the interview and analysis. The study was an exploratory study that included feasibility testing with limited funding to recruit independent therapists and interviewers. Therefore, validation of the findings was important, including independent verification of the data with supervisory team, and member checking where each interview was transcribed and given to the individual participant to check and verify the content of the interview.

6.10 Data Analysis: Quantitative Analyses

A series of quantitative analyses were conducted to evaluate the aims of the study, as elaborated on below. These included: (1) preliminary analyses; (2) analyses to determine the effect of the treatment on the TREATMENT group compared to the WAITLIST group; (3) change over time comparisons for all participants; and (4) follow-up analyses to determine whether scores on the profiling assessments were associated with response to treatment, and which participants benefited most from the treatment. All analyses were computed using SPSS, Version 22.0.

6.10.1 Preliminary analyses

Preliminary analyses assessed the inter-rater reliability of the outcome measures and comparability of the groups at baseline. First, inter-rater reliability was calculated for the conversation rating scores. Inter-rater reliability was established for two scales of the Adapted MPC (interaction and transaction) and MSC (AC and RC), and the four Impression Scales (appropriate, effortful, interesting, rewarding). The reliability of these outcome measures is integral to determining the effectiveness of the treatment. Tests of inter-rater reliability seek to evaluate the degree of variability between different judges' ratings. Intra-class correlations (ICCs) are widely accepted as the method for establishing inter-rater reliability (Field, 2009). In particular, the ICC (3,1) procedure was the method chosen for the purposes of this study (Shrout & Fleiss, 1979). Reliability was established for 32% of videotaped interactions as scored by the four raters.

The second set of preliminary analyses assessed the comparability of the groups at baseline. Independent samples t tests were used to compare the TREATMENT and

WAITLIST control group on the demographic characteristics, profiling assessments, and primary and secondary outcome measures pre-treatment. This test requires that the dependent variable be approximately normally distributed within each group. All methods for determining normality (i.e. visual inspection of the histogram, skewness and kurtosis values, Shapiro-Wilk statistic) are affected by small sample sizes (Lund & Lund, 2013; Razali & Wah, 2011) however, the Shapiro-Wilk statistic is considered the best choice (Field, 2009; Ghasemi & Zahediasl, 2012; Razali & Wah, 2011). In cases where the Shapiro-Wilk statistic was significant (i.e. the data is not normally distributed), the non-parametric equivalent, Mann-Whitney U was conducted. An independent samples t test also assumes that the variances are equal (homogeneity of variance). If the variances are unequal, this result can have an effect on the type I error rate. Homogeneity of variance was tested with Levene's test. If the result was significant, the non-parametric Mann-Whitney U was again used.

The difference between scores within the WAITLIST control group at time 1 (baseline) and time 2 (second baseline) were compared using a paired samples t test. This aimed to confirm that change did not occur on the measures prior to the treatment. This test was used given the one independent variable (i.e. time) and one dependent variable (i.e. treatment outcome). Similar to other parametric tests, the paired samples t test assumes normal distribution of scores. In cases where the data was not normally distributed, the non-parametric equivalent, the Wilcoxon Signed Ranks Test was used.

6.10.2 Effect of treatment on outcomes

The first analyses used mixed ANOVAs to determine the effect of treatment. Data were drawn from time points 1 and 2 (see Figure 6.1), from both the TREATMENT and the WAITLIST control group. These analyses, therefore, compared participants who had and who had not received treatment. A treatment effect was demonstrated if the interaction between group and time was significant.

To complete the mixed ANOVAs, several assumptions must be upheld. First, the data were checked to detect any outliers. Second, the data needs to be normally distributed. Similar to the preliminary analyses, the Shapiro-Wilk statistic was used as this test is considered the best choice with sample sizes under 50 (Field, 2009; Ghasemi & Zahediasl, 2012; Razali & Wah, 2011). To confirm any significant results, non-parametric tests were conducted on data that was not normally distributed. Testing was discontinued if results of the ANOVA were insignificant. Third, the mixed ANOVA also assumes that there was homogeneity of variances and covariances. That is, there are equal variances and covariances between the two groups at each time point for each dependent variable. Levene's test of the equality of error variances tested the assumption of homogeneity of variances. The Box's M test of equality of covariance matrices tested the assumption of homogeneity of covariances. If the result is significant for Levene's test ($p < 0.05$) or Box's M ($p < 0.001$), then the variances (or covariances) are unequal and the assumption has been violated (Field, 2009; Lund & Lund, 2013). In these cases, either removing the outliers, or applying a transformation to the data can deal with the data.

Effect sizes quantify the difference between two groups against the total variance within the data. They therefore illuminate the meaning and, potentially, the practical

significance of that difference. Choosing the correct method for calculating effect size is problematic, with a range of approaches existing (Bakeman, 2005; Morris & Fritz, 2013; Olejnik & Algina, 2003). Partial eta squared was chosen as this statistic is commonly used by researchers in psychology (Morris & Fritz, 2013), was used in several treatment studies described earlier (Bornhofen & McDonald, 2008a; McDonald et al., 2008; McDonald et al., 2013; Mumford et al., 2012), and is computed by SPSS (Kinnear & Gray, 2009).

6.10.3 Change over time comparisons

The second analyses examined whether test scores improved after treatment for all participants, and whether any gains were maintained at follow-up. These analyses combined data from the TREATMENT and WAITLIST Group. Three time points were entered into the analysis: pre-treatment (time 1 for the TREATMENT group and time 2 for the WAITLIST group), post-treatment (time 2 for the TREATMENT group and time 3 for the WAITLIST group), and follow-up (time 3 for the TREATMENT group and time 4 for the WAITLIST group); see the CONSORT diagram (Figure 6.1) for time points. Treatment gains would be identified by a significant main effect of time, with post hoc comparisons showing that this was derived from the pre-treatment to post-treatment comparison. Maintenance of gain would be suggested when the post-treatment and follow-up comparison was not significant.

To complete these analyses, several assumptions must be upheld. Firstly, there cannot be any outliers in the group, which can be identified from a boxplot of the data. Secondly, the data needs to be normally distributed. If the Shapiro-Wilk test was significant, data were analysed first with Repeated measures ANOVA, and then with the

non-parametric Friedman's test. The Friedman's test was only used to confirm a significant result on the ANOVA. Testing was discontinued if results of the ANOVA were insignificant. Finally, the variances between related groups (or time points) must be equal, as tested by Mauchly's Test of Sphericity. If the assumption of equal variances was violated, the Greenhouse-Geisser correction was applied (Field, 2009).

The above were calculated for all treatment outcomes except for the GAS scores, which were analysed separately as they were only taken at three time points for both the TREATMENT group (time 1, 2, 3) and WAITLIST group (time 2, 3 and 4). Also, the nature of GAS is such that all participants' start at the same baseline level (i.e. "less than expected" = 1.0) so there is no range in the data at this time point. For that reason, a non-parametric Friedman's test was used to determine the effect of treatment on goal attainment, with post-hoc comparison showing that this was derived from the pre-treatment to post-treatment comparison. Maintenance of gain was suggested when the post-treatment and follow-up comparison was not significant. As both the person with ABI and their communication partner rated the GAS scores independently of each other, they were analysed separately, with pairwise comparisons at post-treatment, and follow-up, to determine the level of agreement between participants at each of the time points.

6.11 Data analysis: Qualitative analysis

The post-treatment interviews were transcribed verbatim using the videotaped records of the interview. The interviews were transcribed within a month, and all identifying information removed. Each participant was provided with a copy of their transcript within 2 months of their treatment being completed. They were asked to check

and verify that the information given in the transcript reflected a complete and accurate recount of their experience of the treatment. This form of member checking was done as one form of data validation (Creswell, 2013). Analysis began after all transcripts had been collected and checked by the participants. The time that elapsed between the interview and the analysis ranged between 5 and 14 months. Transcripts were entered into NVivo version 12.0, which was used to manage the data and reflect on codes, categories and themes.

The data was analysed using content analysis (Ritchie, Spencer, & O'Connor, 2004a) where the content and context of the interview transcripts were analysed and themes identified. Transcripts were initially read and re-read to familiarise with the data. Then, transcripts were read individually, and units of data were identified and coded with labels used by the participants or determined by the researcher. Five transcripts were read and reviewed independently by the primary supervisor (MC), and coding subsequently discussed to help validate the analysis. Validation was critical as the author of the thesis was the interviewer, therapist, and person responsible for the initial analysis (Creswell, 2013), and aimed to reduce potential bias that may arise during the process of analysis.

The data were then organised into a series of main themes subdivided with sub-themes and categories (Ritchie, Spencer, & O'Connor, 2004b), with use of constant comparative analysis where areas of commonality, differences and relationships across and within transcripts were identified (Fram, 2013). The remaining 16 interview transcripts were read and independently coded by the researcher. As this process evolved, some of the data was re-coded into a different category, sub-theme or theme. NVivo 12.0 was used to organise the data. The final list of themes, sub-themes, and categories was then tabulated and described. The coded and categorised data, and tabulated descriptions were then

reviewed and further validated by MC. Differences in the categories and themes were discussed with consensus reached between NB and MC.

6.12 Summary

This chapter described the methodology for a prospective quasi-randomised controlled trial investigating the effect of project-based treatment for people with ABI, as an exploratory trial and incorporating feasibility testing. People were recruited from three non-for-profit and/or charitable organisations across the UK and allocated to either an immediate TREATMENT or WAITLIST control group. Data were collected for all participants at three time intervals: pre-treatment, post-treatment, and at follow-up. Pre-treatment assessments were conducted twice for participants in the WAITLIST control group, each separated by a 6 week period in which they received no treatment.

This study used a mixed methods approach to evaluate the effects of the treatment, with primary emphasis on quantitative analyses. At each time point, participants were involved in a videotaped conversation that was blindly rated on a set of conversational rating scales, completed communication and QOL questionnaires, and reflected on goal achievement. A semi-structured interview with each participant was conducted post-treatment. Quantitative data was analysed using mixed ANOVAs, and repeated measures ANOVA, to determine the effect of the treatment, and change over time from pre-treatment to follow-up for all participants. Qualitative data was analysed using content analysis to explore the participants' experience of the treatment. The results of both analyses are described in the next three chapters.

**Communication and quality of life outcomes in
people with acquired brain injury following
project-based treatment**

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Chapter 7 Quantitative results

This chapter examines the first two aims of this study to evaluate the impact of a project-based treatment on the communication skills and QOL for people with ABI. The main quantitative results are presented including; (1) Attendance and compliance; (2) Preliminary analyses; and (3) Analysis of treatment effects.

7.1 Attendance and compliance

Twenty-one people with ABI received the treatment, conducted via eight treatment groups. Five groups contained three people with ABI, and three groups contained two people with ABI. Thirteen people attended 100% of sessions (i.e. 10 sessions), and eight people attended 90% of sessions (i.e. 9 sessions).

Data on the completion of homework-related tasks were also recorded. With the exception of one person, all people with ABI attempted homework at least once. Variability in compliance ranged from 14% to 100%, with 18/21 people completing homework-related tasks more than 67% of the time. Tasks completed for homework often depended on the progress of the project and how many tasks were completed within group treatment sessions. Messages of goals, and actions from individual sessions were sent using www.textanywhere.net, which was a practical method for sending a high volume of messages. Most people with ABI were able to access messages. The one person who didn't, was able to read messages, but rarely checked his phone as he did not often receive messages prior to the treatment, which would need to be addressed in the future.

Each group's project is accessible on YouTube at the following link: <https://goo.gl/LhzOCz> (Table 7.1). Each project was chosen by the group, and completed within the 6 weeks, and within session time. Each group had to generate an idea, identify tasks, and resources required to complete the project. To date, the projects completed by the eight groups have been viewed internationally by almost 2,000 people.

Table 7.1. *Description of the eight group projects.*

Name of project	People in group	Group	Description of project
We're no different	3	TREATMENT	Video highlighting what people can still do in spite of their injury, and the desire to be treated no differently to others, despite their impairments.
Memories are made of this	2	WAITLIST	Two individual podcasts that use music to tell each person's story of their brain injury, and how they have continued with their lives.
Respect and privacy	2	TREATMENT	Video examining respect and privacy issues, through the personal experiences of people with ABI where they felt their respect and privacy was affected.
Time for change	3	WAITLIST	Pamphlet about how to communicate with people following a brain injury.
Better future	3	TREATMENT	Video created to tell others what is important to creating a better, more positive future post-injury.
Inspiration	2	WAITLIST	Pamphlet about how to move forward and what is important following a brain injury.
Phoenix: re-birth from the ashes	3	TREATMENT	Video describing strategies to help with memory problems, build confidence, and move on post-injury.
ABI Life-line	3	WAITLIST	Art project showing the ups and downs of life post-injury, and how life is variable, with suggestions for moving forward.

7.2 Preliminary analyses

Three sets of preliminary analyses were conducted prior to the calculation of the interaction effects and change over time comparisons: (1) Inter-rater reliability for the scales that evaluated communication skills; (2) Comparability of the TREATMENT and WAITLIST control group on the demographic variables, profiling assessments, primary and secondary outcome assessments and; (3) Comparability of the two baselines in the WAITLIST control group for the primary and secondary outcome measures.

The intention-to-treat principle requires all people with ABI from the controlled trial to be included in the analyses. However, there is missing Time 2 data for three people in the WAITLIST control group. These data points relate to the videotaped conversation outcomes (i.e. MPC, MSC, Impression Scales). This is due to technical problems leading to loss of the data. As a result, the sample size reported for these outcomes is N=18 and the effect of the missing data on the quantitative analyses has been dealt with separately (see section 7.5). In addition, there is missing LCQ (Other) data at Time 1 for one person in the WAITLIST control group, which has affected the sample size for LCQ (Other). Changes to sample size have been indicated in the result tables, where applicable.

Inter-rater reliability was calculated for the communication rating scales (i.e. MPC, MSC, Impression Scales) using two-way mixed ICCs with consistency for both training and study samples. Reliability coefficients below 0.4 were considered to have poor clinical significance, 0.40 - 0.59 fair clinical significance, 0.60 - 0.74 good clinical significance, and 0.75 - 1.0 excellent clinical significance (Cicchetti, 1994). In most instances, the single measure ICC is reported with the exception of the Revealing Competence score where the average measure ICC is reported, as this scale is an average of three individual scales.

Table 7.2 reports the ICCs for the training and study samples. For the trained samples, four of the scales had *excellent* ICCs (0.76-0.95) and four of the scales had *good* ICCs (0.61-0.65) with the confidence intervals ranging from poor through excellent. For the study samples, the majority of the scales had *good* ICCs (0.60-0.73) with the Revealing Competence ICC in the *excellent* range (0.90). Confidence intervals for the scales were fair through to excellent.

Table 7.2. *Intra-class correlations and 95% confidence intervals for communication rating scales*

Outcome	Trained samples (n=13)		Study samples (n=23)	
	ICC	95% CI	ICC	95% CI
MPC				
Interaction	0.65	[0.40, 0.86]	0.73	[0.56, 0.86]
Transaction	0.63	[0.40, 0.85]	0.66	[0.48, 0.82]
MSC				
AC	0.65	[0.40, 0.86]	0.71	[0.54, 0.85]
RC	0.83	[0.66, 0.94]	0.90	[0.80, 0.95]
Impression Scales				
Appropriate	0.85	[0.70, 0.95]	0.63	[0.44, 0.80]
Effortful ^a	0.82	[0.64, 0.93]	0.60	[0.40, 0.78]
Interesting	0.61	[0.35, 0.83]	0.63	[0.44, 0.80]
Rewarding	0.76	[0.54, 0.91]	0.71	[0.54, 0.85]

Note. ^aNote scale reversal for Effort. ICC = intra-class correlations; CI = confidence interval; MPC = Measure of Participation in Conversation; MSC = Measure of Support in Conversation; AC = Acknowledge Competence; RC = Reveal Competence

Table 7.3 reports the demographic variables of people with ABI. No significant differences were found between groups for age, or time post-injury. However, as the variable of time post-injury was not normally distributed for the TREATMENT and WAITLIST control group (Shapiro-Wilk's test $p < 0.01$), a Mann Whitney U was conducted, which confirmed the non-significant result, $U = 54.00$, $z = -0.071$, $p = 0.973$. As other demographic variables (i.e. gender, injury type, injury severity) were dichotomous, the Fisher-Exact statistic was used to determine the difference between groups. No significant differences were found.

Table 7.3. *Demographic variables*

	ALL people with ABI (n=21)	TREATMENT (n=11)	WAITLIST (n=10)	<i>p</i>
Age	45.80 ± 14.47	43.55 ± 14.39	48.30 ± 14.91	0.47
Gender				1.0*
Male	12 (57%)	6 (55%)	5 (50%)	
Female	9 (43%)	5 (45%)	5 (50%)	
Years post-injury	11.95 ± 12.69	12.27 ± 12.54	11.60 ± 13.52	0.91
Injury type				0.39*
Trauma	13 (62%)	8 (73%)	5 (50%)	
Non-trauma	8 (38%)	3 (27%)	5 (50%)	
Injury severity (n=8)				1.0*
Severe	12 (93%)	7 (88%)	5 (100%)	
Moderate	1 (7%)	1 (12%)	0 (0%)	

*Fisher-exact statistic. *Note.* Values are mean ± SD.

Other factors that describe the people with ABI who participated in the study include, living arrangements, employment status, other services being received, time post residential rehabilitation and type of communication partner involved. For living arrangements, 5 people were living alone and independently, 11 independently with a family member or spouse, 4 independently with carer support and 1 in a residential care home. The majority of people were not employed (n=18) however, 1 person was in full-time paid work, 1 person in part-time paid work and 1 person in part-time voluntary work. Most people (n=12) were not receiving any other services however, 3 people were known to a local community rehabilitation team (but not for the duration of their inclusion in the study) and 6 people (three in each of the TREATMENT and WAITLIST group) were part of the national Headway program, which provides a day program for people with ABI. Of the 21 people with ABI in the study, 13 were recruited from a residential rehabilitation service (i.e. BIRT). All these people had been discharged from the service for a mean of 2.85 years (range 1-6 years). There was also a wide range of communication partners involved who included parents (n=6), spouses (n=4), paid carers (n=3), close friends (n=3), daughters (n=2), siblings (n=2), and aunt (n=1).

Table 7.4 reports the means and standard deviations for the profiling assessments. Some data was not normally distributed, as determined by Shapiro Wilk's test, in the TREATMENT group for the measure of social support (i.e. ISEL; p=0.03), executive function (i.e. WCST categories subtest; p=0.002), and CSA (optimism; p=0.046). Therefore, the non-parametric Mann Whitney U test was conducted on each of these assessments to confirm the results. No significant differences (see Table 7.4) were detected between groups for all profiling assessments with non-significant results confirmed on non-

parametric tests for the ISEL, $U = 47.00$, $z = -0.572$, $p = 0.61$, WCST categories subtest, $U=47.50$, $z=-0.542$, $p=0.61$, and CSA (optimism), $U=48.00$, $z=-0.503$, $p=0.65$. The assessment of participation violated the assumption of homogeneity of variances but a Mann-Whitney U revealed no significant difference between groups, $U=53.50$, $z=-0.106$, $p=0.92$.

Table 7.4. *Profiling assessments*

	ALL people with ABI (n=21)	TREATMENT (n=11)	WAITLIST (n=10)	TREATMENT vs. WAITLIST		
				t	df	p
RBANS						
Total Score	70.85 ± 15.27	70.63 ± 15.80	71.10 ± 15.51	0.06	1,19	0.95
Immediate memory	71.10 ± 17.13	72.73 ± 20.22	69.30 ± 13.83	-0.45	1,19	0.66
Visuo-spatial	78.38 ± 18.35	78.27 ± 18.38	78.50 ± 19.31	0.03	1,19	0.98
Language	84.33 ± 15.83	84.00 ± 16.32	84.70 ± 16.15	0.10	1,19	0.92
Attention	75.10 ± 16.29	75.82 ± 20.06	74.30 ± 11.89	-0.21	1,19	0.84
Delayed memory	76.24 ± 17.52	73.45 ± 16.44	79.30 ± 19.01	0.76	1,19	0.46
WCST						
Categories	3.62 ± 1.78	3.45 ± 1.70	3.80 ± 1.93	0.44	1,19	0.67
Per. Errors	25.24 ± 15.47	29.18 ± 18.65	20.90 ± 10.25	-1.24	1,19	0.23
PART-O	37.52 ± 9.22	36.91 ± 5.70	38.20 ± 12.32	0.30	1,19	0.77 ^a
ISEL	20.71 ± 2.76	20.64 ± 3.56	20.80 ± 1.69	0.13	1,19	0.90

	ALL people with ABI (n=21)	TREATMENT (n=11)	WAITLIST (n=10)	TREATMENT vs. WAITLIST		
				t	df	p
CSA						
Productive	59.43 ± 17.79	55.36 ± 19.60	58.80 ± 14.98	0.45	1,19	0.66
Non-productive	50.29 ± 19.85	53.45 ± 19.39	51.30 ± 22.60	-0.24	1,19	0.81
Optimism	56.90 ± 19.40	56.82 ± 19.40	59.50 ± 18.77	0.32	1,19	0.75
Sharing	52.38 ± 29.98	53.64 ± 35.85	47.00 ± 23.12	-0.50	1,19	0.62
HADS						
Anxiety	6.52 ± 4.72	7.27 ± 4.29	5.70 ± 5.25	-0.76	1,19	0.46
Depression	6.71 ± 3.59	7.00 ± 3.58	6.40 ± 3.78	-0.37	1,19	0.71
RSES	17.24 ± 5.37	16.45 ± 5.68	18.10 ± 5.15	0.69	1,19	0.50

Note. Values are mean ± SD. RBANS = Repeatable Battery of Assessment of Neuropsychological Status; WCST = Wisconsin Card Sorting Test; PART-O = Participation Assessment of Recombined Tools – Objective; Per. Errors = Perseverative errors; ISEL = Interpersonal Social Evaluation List; CSA=Coping Scale for Adults; HADS = Hospital Anxiety and Depression Scale; RSES = Rosenberg Self-Esteem Scale. ^aLevene’s test of equality of variances significant so “equal variances not assumed” p value reported

Table 7.5 reports the means and standard deviations for the communication assessments at baseline for the TREATMENT and WAITLIST control group. There is a slightly lower sample size for the LCQ, as one person's communication partner in the WAITLIST group did not complete the LCQ (Other) at this time point. Of the 10 treatment outcomes, four were not normally distributed at baseline, as determined by a Shapiro-Wilk's test ($p < 0.05$). The outcomes not normally distributed were the MPC (Transaction) score in the WAITLIST group ($p = 0.001$), MSC (AC) scores in the WAITLIST group ($p = 0.04$), Appropriateness scores in the TREATMENT ($p = 0.003$) and WAITLIST group ($p = 0.001$), and Effort scores in the TREATMENT group ($p = 0.04$). For each treatment outcome where scores were not normally distributed, a Mann Whitney U test was conducted to confirm the result. No significant differences were found between groups for 9 of the 10 outcomes at baseline (see Table 7.5). There was a significant difference in mean LCQ (Other) scores between the TREATMENT and WAITLIST group, $t(18) = 0.54$, $p = 0.03$, wherein communication partners perceived people with ABI in the TREATMENT group to have more communicative difficulty than in the WAITLIST group. Non-significant results for data not normally distributed were confirmed using a Mann Whitney U for MPC (transaction) scores ($U = 29.00$, $z = -0.951$, $p = 0.43$), MSC (AC) scores ($U = 30.50$, $z = -0.748$, $p = 0.48$), Appropriateness scores ($U = 30.00$, $z = -0.833$, $p = 0.48$), and Effort scores ($U = 28.50$, $z = -0.940$, $p = 0.38$).

Table 7.5. *Communication outcome assessments at baseline*

	TREATMENT (n=11)	WAITLIST (n=7)	TREATMENT vs. WAITLIST		
			t	df	p
MPC					
Interaction	2.72 ± 0.47	3.07 ± 0.45	1.55	1,16	0.14
Transaction	2.77 ± 0.41	2.86 ± 0.63	0.35	1,16	0.73
MSC					
AC	2.55 ± 0.82	2.79 ± 0.57	0.68	1,16	0.51
RC	2.32 ± 0.78	2.69 ± 0.61	1.07	1,16	0.30
Impression Scales					
Appropriate	2.91 ± 0.74	3.21 ± 0.27	1.05	1,16	0.31
Effortful ^a	2.73 ± 0.75	2.50 ± 0.58	-0.68	1,16	0.51
Interesting	2.91 ± 0.86	2.79 ± 0.49	-0.34	1,16	0.74
Rewarding	2.69 ± 0.98	2.36 ± 0.56	-0.79	1,16	0.44
LCQ					
Self (n=21)	63.45 ± 15.60	60.10 ± 20.54	-0.42	1,19	0.66
Other (n=20)	71.09 ± 16.36	55.56 ± 12.32	-2.35	1,18	0.03

Note. Values are mean ± SD. ^aNote scale reversal for Effort. MPC = Measure of Participation in Conversation; MSC = Measure of Support in Conversation. AC = Acknowledging competence; RC = Revealing competence; LCQ = La Trobe Communication Questionnaire

Table 7.6 reports the means and standard deviations for the outcome assessments of QOL for the TREATMENT and WAITLIST control group. All data were normally distributed and no significant differences were found between groups at baseline.

Table 7.6. *QOL outcome assessments at baseline*

	TREATMENT (n=11)	WAITLIST (n=10)	TREATMENT vs. WAITLIST		
			t	df	p
SWLS	19.09 ± 7.44	19.30 ± 7.93	0.06	1,19	0.95
QOLIBRI	53.50 ± 22.22	62.97 ± 20.56	1.01	1,19	0.33

Note. Values are mean ± SD; SWLS = Satisfaction With Life Scale; QOLIBRI = Quality of Life in Brain Injury.

Baselines of all primary and secondary outcome measures for the WAITLIST control group were compared using a paired-samples t-test (Table 7.7). These tests were conducted to determine whether there was any significant difference between the outcome measures from the two pre-treatment assessments. No significant differences were detected.

Table 7.7. Comparison of two pre-treatment baselines for WAITLIST control group

	Time 1 (n=7)	Time 2 (n=7)	Time 1 vs. Time 2		
			t	df	p
MPC					
Interaction	3.07 ± 0.45	2.86 ± 0.48	1.16	1,6	0.29
Transaction	2.86 ± 0.63	2.93 ± 0.19	-0.42	1,6	0.69
MSC					
AC	2.79 ± 0.57	2.93 ± 0.35	-1.00	1,6	0.36
RC	2.69 ± 0.61	2.64 ± 0.46	0.27	1,6	0.79
Impression Scales					
Appropriate	3.21 ± 0.27	3.21 ± 0.64	<0.001	1,6	1.00
Effortful ^a	2.50 ± 0.58	2.29 ± 0.57	1.16	1,6	0.29
Interesting	2.79 ± 0.49	2.93 ± 0.45	-0.55	1,6	0.60
Rewarding	2.36 ± 0.56	2.71 ± 0.49	-1.37	1,6	0.22
LCQ					
Self (n=10)	60.10 ± 20.54	57.30 ± 18.73	1.78	1,9	0.11
Other (n=9)	55.56 ± 12.32	54.00 ± 10.36	0.72	1,8	0.50
SWLS (n=10)	19.30 ± 7.93	19.30 ± 7.93	1.29	1,9	0.23
QOLIBRI (n=10)	62.97 ± 20.56	62.97 ± 20.56	-0.58	1,9	0.58

Note. Values are mean ± SD. ^aNote scale reversal for Effort. MPC = Measure of Participation in Conversation; MSC = Measure of Support in Conversation; AC = Acknowledging competence; RC = Revealing competence; LCQ = La Trobe Communication Questionnaire; SWLS = Satisfaction With Life Scale; QOLIBRI = Quality of Life in Brain Injury.

7.3 Analysis of treatment effects

7.3.1 Effect of treatment on outcome

The first set of interaction effects evaluated group (TREATMENT vs. WAITLIST) by time (Time 1 vs. Time 2). Means, standard deviations and interactions effects for communication skills are shown in Table 7.8. As highlighted earlier, the LCQ sample size is slightly lower for LCQ (Other).

The distribution of data was not normal for 6 of the 10 outcomes of communication skills. The scales affected were: MPC (Transaction), MSC (AC), Appropriate, Interesting, Effort, and Rewarding. Any significant results for these scales from parametric analyses were checked with non-parametric analyses.

For the 10 interactions measuring the effect of project-based treatment on communication skills, three were significant. The significant findings were MPC (Interaction)(Figure 7.1), which measured the skills of the person with ABI ($F_{1,16}=5.11$, $p=0.04$), MSC (Revealing Competence) (Figure 7.2) that measured the skills of the communication partner ($F_{1,16}=6.64$, $p=0.02$) and Effort (Figure 7.3), which related to an overall impression of the conversation ($F_{1,16}=5.43$, $p=0.03$). Data were normally distributed for MPC (Interaction) and MSC (Revealing Competence), but not Effort in the TREATMENT group at Time 1 ($p=0.039$) or Time 2 ($p=0.037$). Therefore, a Wilcoxon Signed Ranks test was used on the Effort scores. There was a significant increase in Effort scores from Time 1 to Time 2 in the TREATMENT group ($z=-2.124$, $p=0.034$) and a significant difference between groups at Time 2 ($U=8.5$, $z=-2.183$, $p=0.004$), wherein Effort scores were higher for the TREATMENT compared to the WAITLIST control group. No other significant differences were found.

As there were multiple comparisons, a Bonferroni correction was made. Type I error rate was set at 0.005, for a family-wise error rate of 0.05. Under the corrected Bonferroni level, none of the above findings was significant.

Table 7.8. Mean scores, standard deviations, and interaction effects, on communication outcomes for the two groups.

Outcome	Time 1		Time 2		Interaction effects			
	TREATMENT (n=11)	WAITLIST (n=7)	TREATMENT (n=11)	WAITLIST (n=7)	F	df	p	ES ^a
MPC								
Interaction	2.72 ± 0.47	3.07 ± 0.45	3.09 ± 0.63	2.86 ± 0.48	5.11	1,16	0.04*	0.24
Transaction	2.77 ± 0.41	2.86 ± 0.63	3.14 ± 0.50	2.93 ± 0.19	1.23	1,16	0.28	0.07
MSC								
AC	2.55 ± 0.82	2.79 ± 0.57	2.95 ± 0.88	2.93 ± 0.35	0.77	1,16	0.39	0.05
RC	2.32 ± 0.78	2.69 ± 0.61	3.00 ± 0.66	2.64 ± 0.46	6.64	1,16	0.02*	0.29
Impression Scales								
Appropriate	2.91 ± 0.74	3.21 ± 0.27	3.32 ± 0.40	3.21 ± 0.64	2.12	1,16	0.17	0.12
Effortful ^b	2.73 ± 0.75	2.50 ± 0.58	3.23 ± 0.52	2.29 ± 0.57	5.43	1,16	0.03*	0.25
Interesting	2.91 ± 0.86	2.79 ± 0.49	3.14 ± 0.55	2.93 ± 0.45	0.06	1,16	0.81	0.004
Rewarding	2.69 ± 0.98	2.36 ± 0.56	3.09 ± 0.49	2.71 ± 0.49	0.02	1,16	0.89	0.001
LCQ								
Self (n=21)	63.45 ± 15.60	60.10 ± 20.54	64.64 ± 17.81	57.30 ± 18.73	1.64	1,19	0.22	0.08
Other (n=20)	71.09 ± 16.36	55.56 ± 12.32	68.09 ± 15.42	54.00 ± 10.36	0.11	1,18	0.74	0.01

Note. Values are mean ± SD. ^aES=effect size (η_p^2). ^bscale reversal for Effort. MPC = Measure of Participation in Conversation; MSC = Measure of Support in Conversation; AC = Acknowledging competence; RC = Revealing competence; LCQ = La Trobe Questionnaire. *p<0.05.

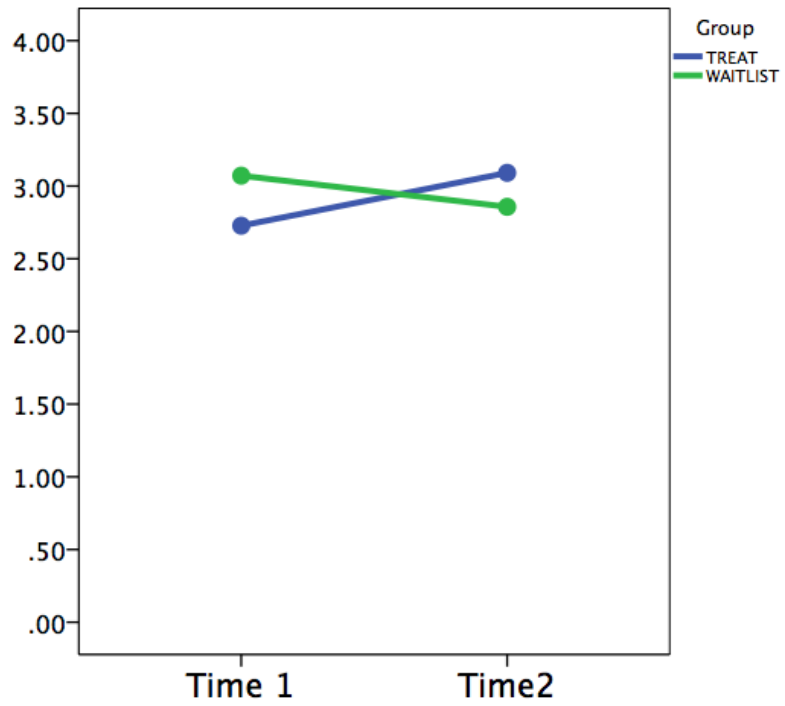


Figure 7.1. Mean MPC (Interaction) scores pre-treatment and post-treatment for the TREATMENT and WAITLIST group

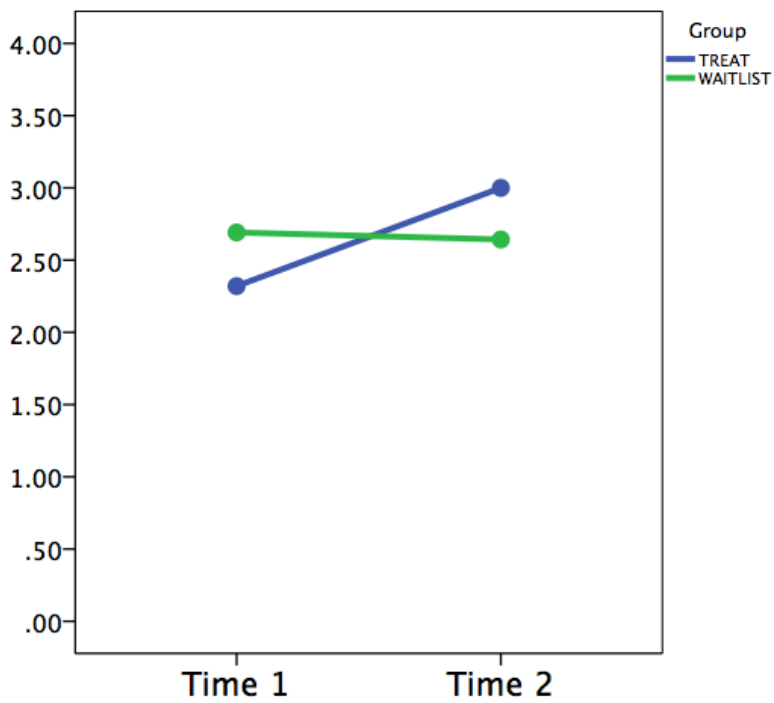


Figure 7.2. Mean MSC (Revealing Competence) scores pre-treatment and post-treatment for the TREATMENT and WAITLIST group

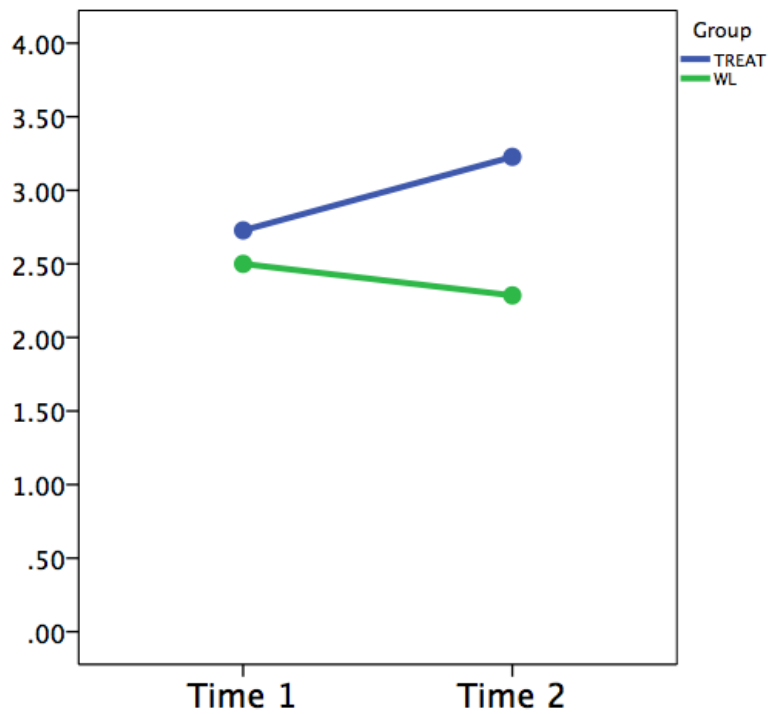


Figure 7.3. Mean Effort scores pre-treatment and post-treatment for the TREATMENT and WAITLIST group

Means, standard deviations and interactions effects for QOL treatment outcomes are shown in Table 7.9. The QOLIBRI total score was not normally distributed for the TREATMENT group at Time 2, as determined by Shapiro-Wilk's test ($p=0.032$). No significant differences were found for these outcomes.

Table 7.9. Mean scores, standard deviations, and interaction effects, on QOL outcomes for the two groups.

Outcome	Time 1		Time 2		Interaction effects			
	TREATMENT (n=11)	WAITLIST (n=10)	TREATMENT (n=11)	WAITLIST (n=10)	F	df	p	ES ^a
SWLS	19.09 ± 7.44	19.30 ± 7.93	21.73 ± 5.55	17.70 ± 7.48	2.281	1,19	0.147	0.11
QOLIBRI	53.50 ± 22.22	62.97 ± 20.56	60.13 ± 20.00	64.93 ± 14.24	0.629	1,19	0.438	0.03

Note. . ^aES=effect size (η_p^2). SWLS = Satisfaction With Life Scale; QOLIBRI = Quality of Life in Brain Injury.

7.3.2 Change over time comparisons

The second set of effects evaluated the change over time from pre-treatment through post-treatment to follow-up, with both groups combined into one sample. Means, standard deviations and interaction effects for communications skills are shown in Table 7.10.

The distributions of data were not normal for 8 of the 10 outcomes of communication skills. The scales affected were: MPC (Transaction), MPC (Interaction), Appropriate, Interesting, Effort, Rewarding, LCQ (Self), and LCQ (Other). Any significant results for these scales from parametric analyses were checked with non-parametric analyses.

The treatment elicited significant improvements over time for MSC (Acknowledging Competence)($F_{2,34}=3.78$, $p=0.03$)(Figure 7.4) and MSC (Revealing Competence)($F_{2,34}=7.4$, $p=0.002$)(Figure 7.5). Significant changes were also found for LCQ (Other)(Figure 7.6) wherein the communication partner perceived more communicative ability in the person with ABI over time ($F_{2,40}=3.48$, $p=0.04$). As the data for LCQ (Other) were not normally distributed, the non-parametric Friedman's Test was used to check the results. The LCQ (Other) scores remained significantly different over all three time points, $X^2(2)=6.66$, $p=0.04$.

A set of planned comparisons was then conducted to determine the source of the significant effects. There was a significant increase in scores from pre-treatment to post-treatment for both MSC (AC), $t(17)=-2.32$, $p=0.03$, and MSC (RC), $t(17)=-3.76$, $p=0.002$. However, this was followed by a significant decrease in scores from post-treatment to follow-up for both MSC (AC), $t(17)=2.75$, $p=0.01$, and MSC (RC), $t(17)=2.765$, $p=0.01$.

No significant difference between pre-treatment and follow-up scores was found for either the MSC (AC) or MSC (RC). The LCQ (Other) scores did not significantly change from pre-treatment to post-treatment, $t(20)=-0.06$, $p=0.95$ however, significant differences in scores were found between post-treatment to follow-up, $t(20)=2.84$, $p=0.01$, and pre-treatment and follow-up scores, $t(20)=2.34$, $p=0.03$. In other words, communication partners perceived more communicative ability for the person with ABI from pre-treatment to follow-up with the source of this significant change in scores occurring between post-treatment to follow-up, which suggests that effects are delayed and manifest at a later point post-treatment.

As there were multiple comparisons, a Bonferroni correction was made. Type I error rate was set at 0.005, for a family-wise error rate of 0.05. Under the corrected Bonferroni level, none of the above findings was significant.

Table 7.10. *Change over time comparisons for all people with ABI (N=18)*

	Pre-treatment	Post-treatment	Follow-up	F	df	p	ES ^a
MPC							
Interaction	2.78 ± 0.46	3.06 ± 0.57	2.97 ± 0.63	1.75	2,34	0.19	0.09
Transaction	2.83 ± 0.34	3.06 ± 0.48	2.89 ± 0.53	1.81	2,34	0.18	0.10
MSC							
AC	2.69 ± 0.69	3.06 ± 0.76	2.72 ± 0.71	3.78	2,34	0.03*	0.18
RC	2.45 ± 0.68	2.98 ± 0.63	2.60 ± 0.64	7.40	2,34	0.002*	0.30
Impression Scales							
Appropriate	3.03 ± 0.70	3.19 ± 0.57	2.86 ± 0.61	2.37	2,34	0.11	0.12
Effortful	2.56 ± 0.70	2.94 ± 0.82	2.72 ± 0.71	1.78	2,34	0.19	0.10
Interesting	2.92 ± 0.71	3.03 ± 0.70	2.92 ± 0.60	0.27	2,34	0.77	0.02
Rewarding	2.69 ± 0.81	2.89 ± 0.65	2.67 ± 0.61	1.00	2,34	0.38	0.06
LCQ							
Self (n=21)	60.52 ± 17.01	61.95 ± 17.11	58.81 ± 15.62	1.67	2,40	0.20	0.08
Other (n=21)	62.95 ± 16.08	63.14 ± 16.10	57.19 ± 14.92	3.48	2,40	0.04*	0.15

Note. ^aES=effect size (η_p^2). MPC = Measure of Participation in Conversation; MSC = Measure of Support in Conversation; AC = Acknowledging competence; RC = Revealing competence; LCQ = La Trobe Communication Questionnaire. *p<0.05

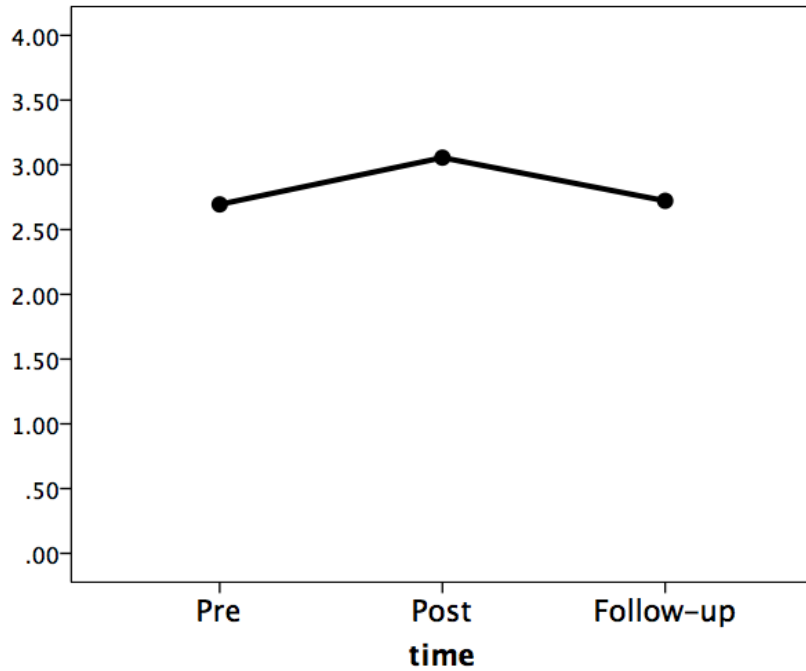


Figure 7.4. Mean MSC (Acknowledging Competence) scores pre-treatment, post-treatment, and follow-up, for all people with ABI

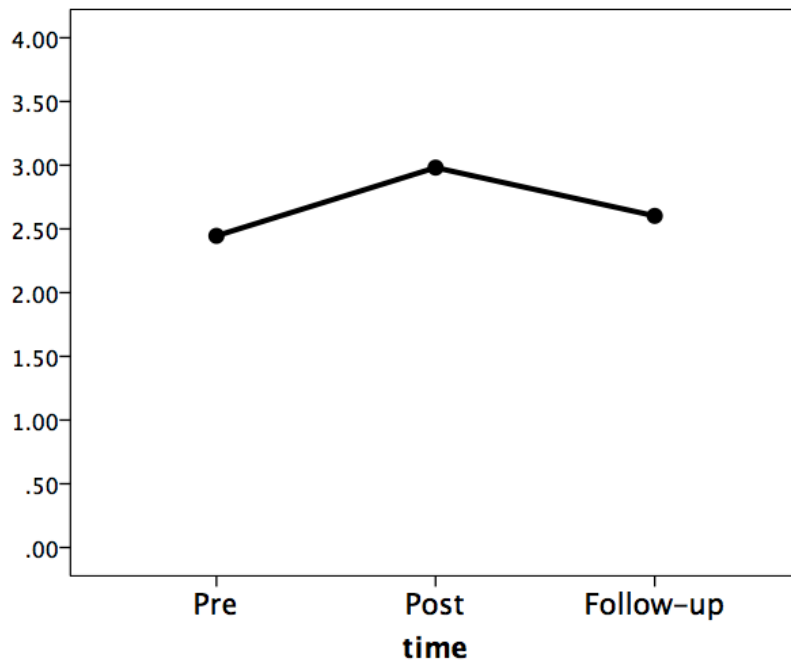


Figure 7.5. Mean MSC (Revealing Competence) scores pre-treatment, post-treatment, and follow-up, for all people with ABI

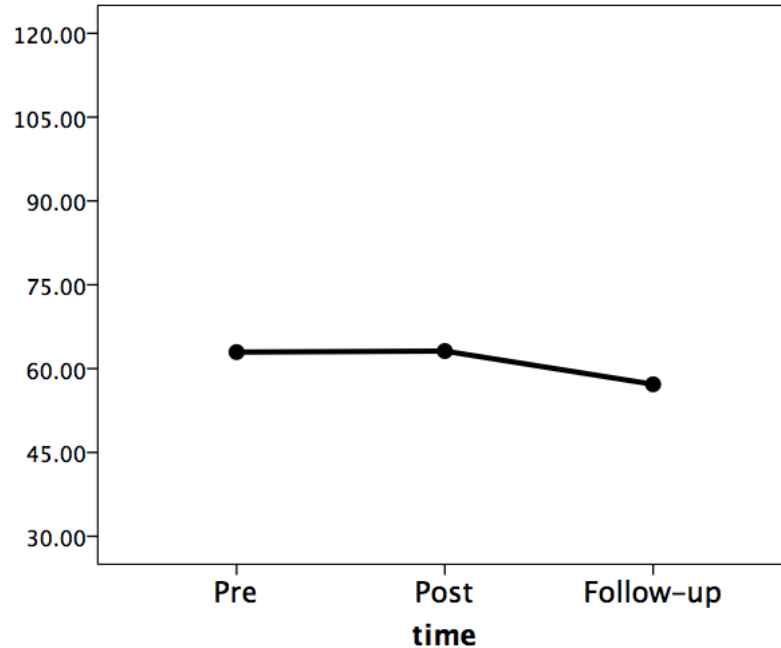


Figure 7.6. Mean LCQ (Other) scores pre-treatment, post-treatment, and follow-up, for all communication partners

Means, standard deviations and main effects for change over time comparisons for QOL outcomes are shown in Table 7.11. All data were normally distributed. There was a significant improvement for the QOLIBRI ($F_{1,46,29.15}=3.622$, $p=0.05$)(Figure 7.7), and trend towards significance for the SWLS ($F_{2,40}=2.972$, $p=0.06$)(Figure 7.8).

To explore this trend further, a set of planned comparisons was then conducted. No significant differences were found between pre-treatment and post-treatment scores, *or* post-treatment and follow-up scores for either the SWLS or QOLIBRI. However, there was a significant difference between pre-treatment and follow-up scores for both the SWLS, $t(20)=-2.3$, $p=0.04$, and QOLIBRI, $t(20)=-2.42$, $p=0.03$. In other words, people with ABI perceived a greater QOL at follow-up compared to pre-treatment.

Table 7.11. *Change over time comparisons for all people with ABI (N=21)*

	Pre-treatment	Post-treatment	Follow-up	F (2, 40)	<i>df</i>	<i>p</i>	ES
SWLS	18.43 ± 7.30	20.76 ± 7.20	21.48 ± 6.88	2.972	2,40	0.06	0.13
QOLIBRI	58.94 ± 19.29	63.16 ± 19.25	65.89 ± 18.24	3.622 ^a	1.46, 29.15	0.05*	0.15

Note. Values are mean ± SD. SWLS = Satisfaction With Life Scale; QOLIBRI = Quality of Life in Brain Injury.

^aGreenhouse-Geisser reported here as Mauchly's test of sphericity was significant at <0.05. *p<0.05

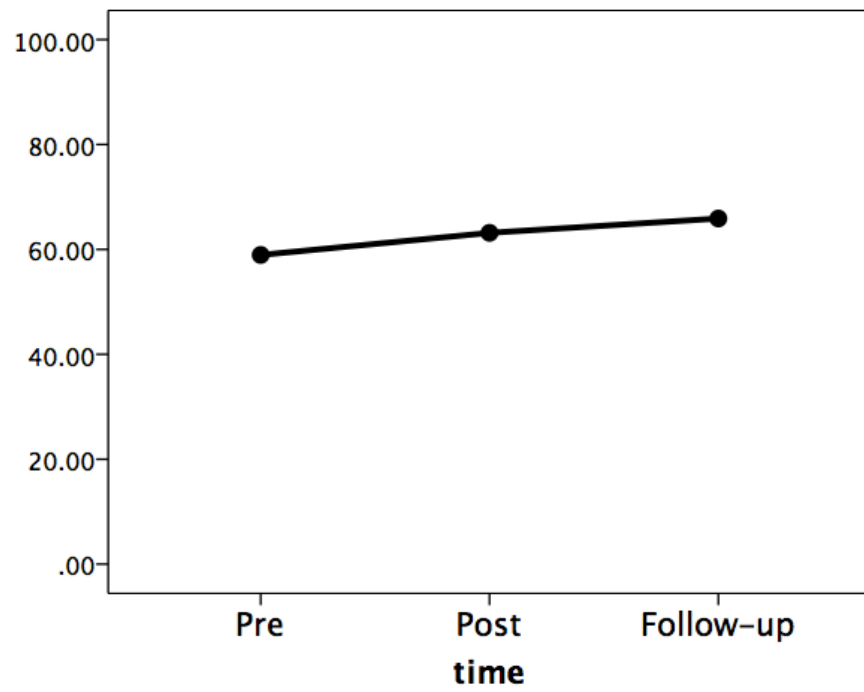


Figure 7.7. Mean QOLIBRI scores pre-treatment, post-treatment, and follow-up, for all people with ABI

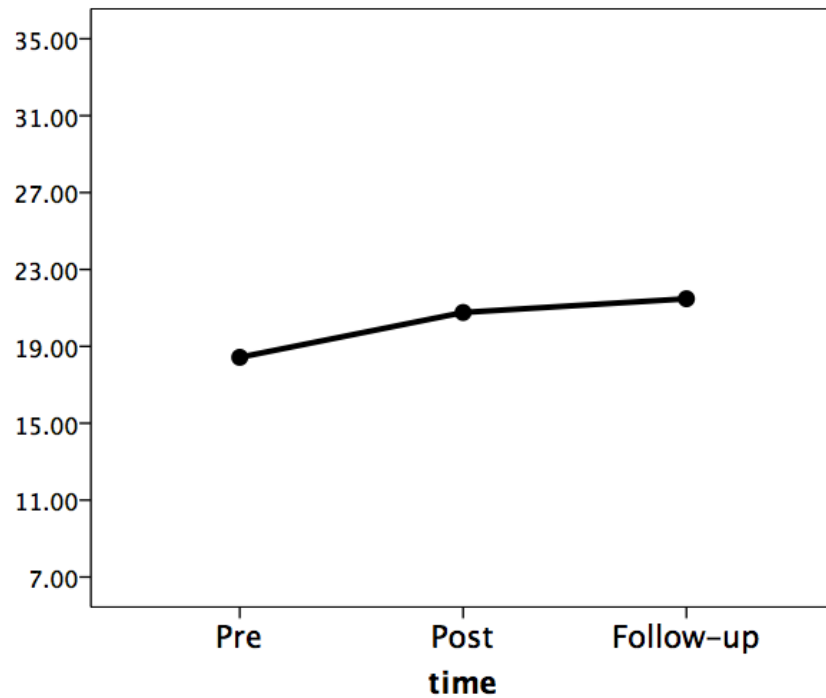


Figure 7.8. Mean SWLS scores pre-treatment, post-treatment, and follow-up, for all people with ABI

7.4 Effect of treatment on goal attainment

The effect of the treatment was also evaluated for a person's ability to recall, and achieve an individualised communication goal set at the beginning of the treatment.

Table G1 (in Appendix G) lists the individual goals. The goals were set using Goal Attainment Scaling (GAS), which is a measure of goal achievement as perceived and rated by the person with ABI and their communication partner.

Goal recall was examined as being able to remember the goal was important to goal achievement. A person's independent recall of their individual communication goal varied across the duration of the treatment. Each person with ABI was asked to recall his or her goal at the beginning of each session. The number of occasions each person could recall his or her goal independently across attended sessions was calculated as a percentage. One person was unable to recall their goal for the duration of the treatment. The remaining 20 people with ABI could recall their individual goal 25% to 100% of the time. For 15/20 of these people, once a person could recall their goal, they could retain this information for the remaining treatment sessions. Figure 7.9 shows the first session in which a person could recall their individual communication goal independently. Fifteen people could recall their goal independently within 5 sessions, with recall improving in the later treatment sessions. A detailed analysis of goal attainment was then conducted.

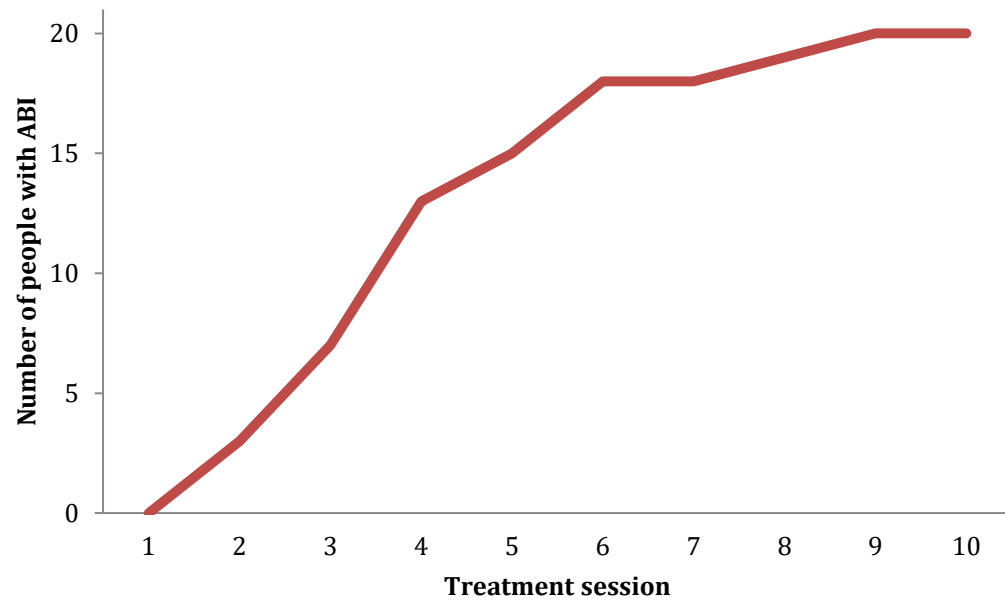


Figure 7.9. First session in which a person with ABI could independently recall their communication goal

A series of analyses were conducted to determine the effect of the treatment on goal achievement: (1) Change over time comparisons to determine whether there is change from pre-treatment to follow-up as rated by both the person with ABI and their communication partner; (2) Planned comparisons to identify the source of a significant effect from pre-treatment to post-treatment, and post-treatment to follow-up; and (3) Comparison of ratings at post-treatment and follow-up for both the person with ABI and communication partner to determine whether both respondents are as reliable as each other in reporting progress towards individualised communication goals.

The nature of setting GAS goals means that all people with ABI start at the same baseline level (i.e. “less than expected” = 1.0) so there is no range in the data at this time point. Also, the data was not normally distributed for the other time points (i.e. post-treatment, follow-up) for either respondent (i.e. person with ABI, communication partner). For both these reasons, only non-parametric analyses were conducted to determine the effects of the treatment on GAS goals.

Table 7.12 shows the means, standard deviations, and change over time comparisons for GAS goals. The treatment found a significant increase over time in GAS scores as rated by the person with ABI, $X^2(2)=28.71$, $p<0.001$ (Figure 7.10), and their communication partner, $X^2(2)=25.48$, $p<0.001$ (Figure 7.11). In other words, both respondents perceived achievement of individualised communication goals over time.

Table 7.12. *Change over time comparisons for GAS goals*

	Pre-treatment	Post-treatment	Follow-up	$X^2(2)$	p
GAS					
Self (n=21)	1.0 ± 0.00	2.33 ± 0.91	2.47 ± 0.93	28.71	<0.001
Other (n=19)	1.0 ± 0.00	2.05 ± 0.78	2.25 ± 0.91	25.48	<0.001

Note. GAS=Goal Attainment Scaling

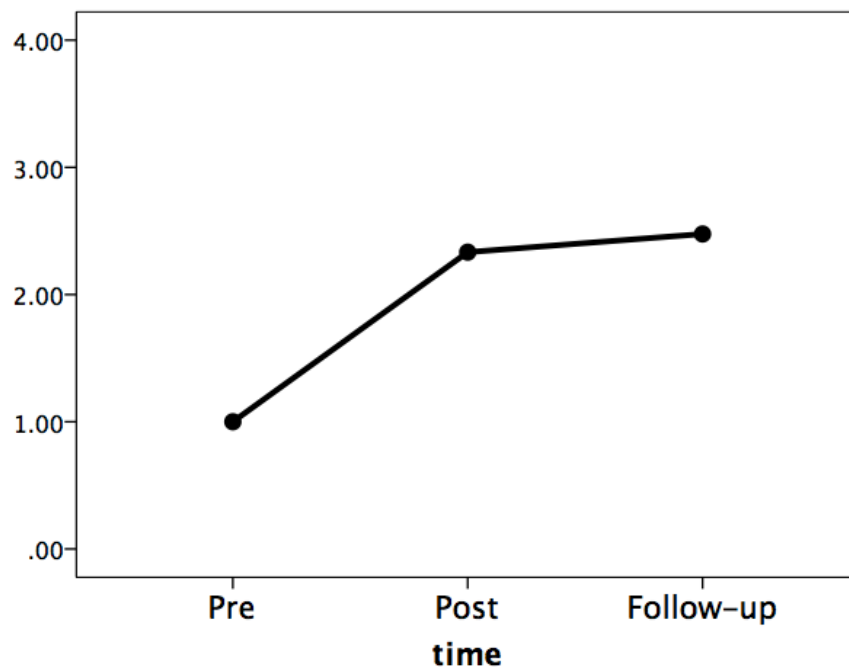


Figure 7.10. Mean GAS (Self) scores pre-treatment, post-treatment, and follow-up, as rated by the person with ABI.

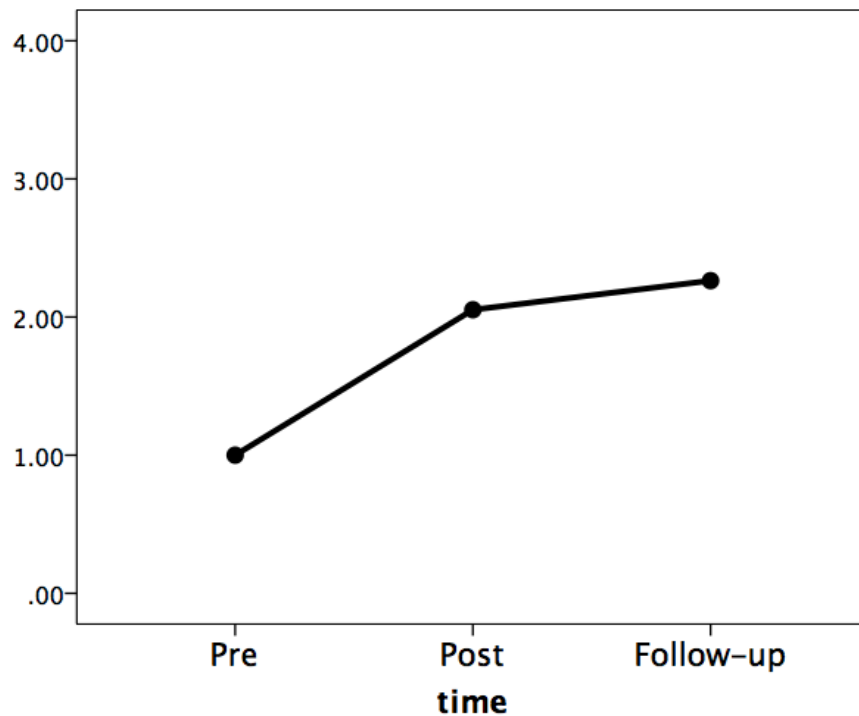


Figure 7.11. Mean GAS (Other) scores pre-treatment, post-treatment, and follow-up, as rated by the communication partner

Planned comparisons demonstrated that the source of the significant change occurred between pre-treatment and post-treatment for both the person with ABI ($z=3.83$, $p<0.001$) and their communication partner ($z=3.40$, $p=0.001$). No significant change was found between post-treatment and follow-up for either the person with ABI ($z=0.78$, $p=0.44$) or communication partner ($z=1.19$, $p=0.23$), indicating that post-treatment improvement was maintained.

Comparison of ratings between the person with ABI and their communication partner demonstrated no significant difference at either critical time point, post-treatment ($z=-1.73$, $p=0.08$), or follow-up ($z=-0.78$, $p=0.44$). This finding means that the person with ABI was as reliable as their communication partner in rating the degree of goal attainment using GAS for individualised communication goals.

7.5 Dealing with missing data

The intention-to-treat principle requires all people with ABI from the controlled trial to be included in all analyses. However, there are missing data points for three people in the WAITLIST control group due to technical problems where data was lost. These data points relate to the videotaped conversation outcomes (i.e. MPC, MSC, Impression Scales) at Time 2 (second baseline). This time point was critical to both calculating the interaction effects of the treatment and the change over time comparisons. White, Horton, Carpenter and Pocock (2011) has proposed a number of strategies for intention-to-treat analyses with missing data of which one is relevant to this controlled trial.

The strategy proposed was to perform the analysis of all valid observed data under a plausible assumption about the missing data. Firstly, the WAITLIST control and TREATMENT group were compared on all demographic variables and profiling assessments with the three people with ABI (with missing data) removed from the analysis. There was no significant difference between the WAITLIST control (n=7), and TREATMENT group (n=11), for any of the variables or assessments.

Second, the missing data was replaced with the last data point carried forward data at Time 1 (das Nair & Lincoln, 2012). This had no effect on the number of interactions that reached significance. From the eight interactions that measured conversational skills, the same three reached significance, MPC (Interaction)($F_{1,19}=5.745$, $p=0.03$), MSC (RC) ($F_{1,19}=9.266$, $p=0.007$) and Effort ($F_{1,19}=6.444$, $p=0.02$). As replacing the data with the last data point carried forward can be controversial, Time 3 (i.e. post-treatment data) was carried back to Time 2 for the same three people with ABI. This could be considered a more conservative option as the data is post-treatment and the scores could possibly be higher as a result of the

treatment. There continued to be no changes in the scales that reached significance, MPC (Interaction)($F_{1,19}=6.806$, $p=0.02$), MSC (RC)($F_{1,19}=9.901$, $p=0.005$) and Effort ($F_{1,19}=5.193$, $p=0.03$).

For the change over time comparisons, the same process was followed for replacing the missing data. Similar to the main results, a significant improvement over time was found for MSC (RC) irrespective of whether Time 1 data ($F_{2,40}=6.183$, $p=0.005$) or Time 3 data were used ($F_{2,40}=6.597$, $p=0.003$). Significance was also found for MSC (AC) when Time 3 data was carried back ($F_{2,40}=3.516$, $p=0.04$), but not when Time 1 data was carried forward ($F_{2,40}=2.836$, $p=0.07$).

7.6 Summary

Over the duration of the study, 21 people with ABI participated in eight treatment groups (in triads or pairs), with a minimum 90% attendance. Homework arising from sessions was attempted 14-100% of the time, and most people could independently recall their individualised communication goal by the end of the treatment. Projects were successfully achieved within the timescales of the treatment, and uploaded to YouTube.

Raters of the primary and secondary communication outcome measures achieved primarily *excellent* reliability on training videos, and subsequently yielded primarily *good* reliability on the study samples. Both the TREATMENT and WAITLIST groups were comparable at baseline on all demographic variables and profiling assessments. There was no significant difference between groups for most measures.

The significant difference between the TREATMENT and WAITLIST group indicates treatment effects for three measures: MPC (Interaction scores), MSC

(Revealing Competence), and Effort. In the change over time comparisons, including scores from all people with ABI for pre-treatment, post-treatment, and follow-up, there was a significant difference over time for MSC (Acknowledging Competence), MSC (Revealing Competence), LCQ (Other), QOLIBRI, and a trend towards significance for the SWLS. People with ABI and their communication partners rated GAS goals as significantly higher (pre-treatment to follow-up). Both respondents rated the GAS goals the same.

The following chapters contain post-hoc quantitative results for all people with ABI, and analysis of the results at an individual level, with a focus on the primary communication outcomes (i.e. MPC – Interaction and Transaction scores), and both QOL outcomes (i.e. SWLS and QOLIBRI).

Chapter 8 Follow-up analyses

The previous chapter provided the main group-based analyses of the treatment outcomes, and this chapter examines change post-treatment in greater detail. People with ABI are heterogeneous, and some people may have responded more favourably to the treatment than others with treatment effects masked by group analyses. Therefore, this chapter explores the amount of change made by individuals post-treatment, and describes the type of people with ABI who respond most to project-based treatment. This chapter explores change in three ways, by examining: (1) the degree of change that occurred for outcome measures, and whether there was a relationship between those outcomes; (2) the relationship between change on outcome measures, and the demographic variables (i.e. age, sex, nature of injury, time post-injury), and profiling assessments (i.e. cognitive, emotional, and social functioning); and (3) descriptive data will be presented, which shows the degree of change achieved by each person on each measure. Two case descriptions will be briefly presented to further illuminate the characteristics of these people.

Firstly, to understand change post-treatment, change was calculated for the outcomes being considered in this analysis, and calculated in a manner that could be compared across participants. For the purposes of analyses in this chapter, the primary communication (i.e. MPC – Interaction and Transaction), and QOL outcomes (i.e. SWLS) were under investigation. The secondary QOL outcome, the QOLIBRI was also included so a measure of SWB could be compared with a measure of HRQOL. In addition, in the first set of analyses (see section 8.1), percentage change was calculated for the remaining communication outcomes (i.e. MSC, Impression Scales) to better understand the relationship between scales, which has not been explored to date.

For individuals in the WAITLIST group, percentage change from Time 2 (i.e. second baseline) to Time 3 (i.e. post-treatment) was used. To convert scores to a percentage, the post-treatment score, minus the pre-treatment score was divided by the total score of the outcome being calculated, and multiplied by 100. For the MPC, MSC, and Impression Scales, the highest total score a person could achieve was 4, and for the SWLS the highest score a person could achieve was 35. The same calculation was not used for the QOLIBRI as the scores are already expressed as a percentage. Definitions of percentage change are shown in Table 8.1 for each treatment outcome.

Table 8.1. *Definition of percentage change for each treatment outcome*

Treatment outcome	Definition of percentage change
(a) MPC, MSC, and Impression Scales	$\left[\frac{(Post - treatment\ score) - (Pre - treatment\ score)}{4} \right] \times 100$
(b) SWLS	$\left[\frac{(Post - treatment\ score) - (Pre - treatment\ score)}{35} \right] \times 100$
(c) QOLIBRI	$[(Post\ treatment\ score) - (Pre - treatment\ score)]$

Note. MPC=Measure of Participation in Conversation; MSC=Measure of Support in Conversation; SWLS=Satisfaction With Life Scale; QOLIBRI=Quality of Life in Brain Injury

Table 8.2 gives the means, standard deviations, and range of percentage change for the outcomes. A positive percentage means that there was improvement, and a negative percentage, deterioration in that treatment outcome.

The mean percentage change for each of the outcomes was generally small, ranging from 2.78% to 13.39%. However, the range of change was extreme. For example, the range of percentage change for the SWLS was -28.57% to 65.71%. The smallest range of percentage change was shown for MPC Transaction, -12.50% to 37.50%.

Table 8.2. Means, standard deviations, and range of percentage change for outcomes.

Treatment outcome	Mean	SD	Minimum	Maximum
MPC Interaction (N=18)	6.94	15.59	-25.0	37.5
MPC Transaction (N=18)	5.56	13.71	-12.5	37.5
MSC AC (N=18)	9.03	16.50	-25.0	37.5
MSC RC (N=18)	13.39	15.11	-8.50	45.8
Appropriate (N=18)	4.17	15.46	-25.0	50.0
Effort (N=18)	9.72	20.81	-37.5	50.0
Interesting (N=18)	2.78	17.45	-25.0	50.0
Rewarding (N=18)	4.86	19.71	-25.0	50.0
SWLS (N=21)	6.67	20.29	-28.6	65.7
QOLIBRI (N=21)	4.21	14.04	-24.3	45.3

Note. MPC=Measure of Participation in Conversation; MSC=Measure of Support in Conversation; AC=Acknowledging Competence; RC=Revealing Competence; SWLS=Satisfaction With Life Scale; QOLIBRI=Quality of Life in Brain Injury.

8.1 Analyses of outcome measures

The first part of this chapter further examines the relationship between percentage changes on those outcomes. To achieve this, four sets of correlational analyses were conducted using Pearson Product Moment Correlations: (1) between the Adapted MPC scales and Adapted MSC scales and; (2) between each of the four Impression Scales; (3) between the two QOL outcomes; and (4) between the Adapted MPC scales and QOL outcomes.

First, the percentage change scores for the MPC scales (i.e. Interaction and Transaction), and MSC scales (i.e. Acknowledge and Reveal Competence) were correlated with each other (see Table 8.3). Three significant correlations were found. Two strong positive associations were found between Transaction and Interaction percentage change scores, and Acknowledge and Reveal Competence percentage change scores. A moderate positive association was found between the Reveal Competence and Transaction percentage change scores.

Table 8.3. *Pearson's correlation coefficient for MPC and MSC*

	% change in Interaction	% change in Transaction	% change in AC
% change in Interaction	1		
% change in Transaction	0.67**	1	
% change in AC	0.35	0.25	1
% change in RC	0.40	0.48*	0.91**

*p<0.05, **p<0.01

Next, percentage changes for the four Impression Scales were correlated with each other. Strong, positive associations were found among all scales (Table 8.4).

Table 8.4. *Pearson's correlation coefficients for Impression Scales*

	% change in Appropriate	% change in Effort	% change in Interesting
% change in Appropriate	1		
% change in Effort	0.67**	1	
% change in Interesting	0.77**	0.63**	1
% change in Rewarding	0.65**	0.71**	0.84**

**p<0.01

As QOL is a main focus of this study, the relationship between the SWB outcome (i.e. SWLS) and the HRQOL outcome (i.e. QOLIBRI) was examined. A moderate positive association was found to exist between the degrees of percentage change in these two outcomes ($r=0.49$, $p=0.03$).

Finally, percentage changes for the MPC scales were correlated with the QOL outcomes. There was no significant association between either of the MPC scales, with the QOL outcomes (Table 8.5).

Table 8.5. *Pearson's correlation coefficients for MPC, and QOL outcomes*

	% change in Interaction	% change in Transaction	% SWLS
% change in Interaction	1		
% change in Transaction	0.67**	1	
% change in SWLS	0.23	0.02	1
% change in QOLIBRI	0.23	0.29	0.49*

*p<0.05, **p<0.01

8.2 Factors associated with change

To determine what factors were most associated with effect on treatment outcomes, percentage change was correlated with the four demographic variables (i.e. age, sex, nature of injury, time post-injury), and 12 profiling assessments (i.e. cognitive, emotional, and social functioning). For these and subsequent analyses, the primary communication (i.e. MPC – Interaction and Transaction), and both QOL outcomes (i.e. SWLS and QOLIBRI) were examined. Type I error rate was set at 0.003, using Bonferroni corrections for a family-wise error rate of 0.05.

Table 8.6 shows the results of the correlational analysis. Three significant correlations were found between percentage change in Transaction scores, and ISEL scores, CSA-optimism, and CSA-sharing. However, none of these three correlations was significant at the corrected Bonferroni level. No other correlations were significant, even at the 0.05 level. Two dichotomous demographic variables (i.e. gender, trauma/non-trauma) were analysed separately using independent samples t test. There was no significant difference in mean percentage change between either men and

women, or between people who had sustained a traumatic compared to non-traumatic injury, for any of the four treatment outcomes at the 0.05 level, or corrected Bonferroni level.

Table 8.6. *Pearson's correlation coefficients for percentage change in the communication skills, and QOL measures with the demographic variables, and profiling assessments.*

Variables	Communication skills		Quality of life	
	% change in interaction	% change in transaction	% change in SWLS	% change in QOLIBRI
Demographic variables:				
Age (current)	0.42	0.12	0.13	-0.12
Time since injury (yrs)	-0.05	-0.10	-0.11	<0.001
Profiling assessments:				
RBANS (Total)	-0.14	0.01	-0.33	0.08
WCST (categories)	-0.01	0.17	-0.35	-0.20
WCST (Per. Errs)	-0.07	<0.001	0.29	-0.03
ISEL	-0.29	-0.50*	0.37	-0.08
HADS-anxiety	0.05	0.31	-0.09	-0.02
HADS-depression	0.42	0.37	0.12	0.21
PART-O	-0.13	-0.19	-0.15	-0.03
RSES	-0.40	-0.30	-0.01	<0.001
CSA-Productive	-0.18	-0.43	-0.23	-0.23
CSA-Non-productive	0.18	0.45	-0.10	-0.13
CSA-optimism	-0.40	-0.51*	-0.34	-0.24
CSA-sharing	-0.39	-0.57*	-0.31	-0.30

*p<0.05.

Note. RBANS=Repeatable Battery of the Assessment of Neuropsychological Status; WCST=Wisconsin Card Sorting Test; Per.Errs=Perseverative Errors; ISEL=Interpersonal Social Evaluation List; HADS=Hospital Anxiety and Depression Scale; PART-O=Participation Assessment of Recombined Tools-Objective; RSES=Rosenberg Self-Esteem Scale; CSA=Coping Scale for Adults.

8.3 Description of individual level change

As no factors above correlated with treatment outcomes, and there was wide variability in percentage changes (see Table 8.2), change was examined at the individual level to identify those people who did and did not respond to the treatment, with a view to present some illustrative cases at the end of the chapter.

Determining what constitutes clinically meaningful change is the subject of substantial study. Osoba et al. (2005) describes a range of procedures that have been used to determine a minimal clinically important difference MCID, including effect sizes, or the standard error of a measurement tool. An approach that has been endorsed by the National Cancer Institute of Canada Trials Group (Osoba et al., 2005) is to use 10% of the scale breadth (or in general, 0.5 of a standard deviation)(Luckett, King, Butow, Friedlander, & Paris, 2010; Norman, Sloan, & Wyrwich, 2003). This approach has been designated for use by an expert panel of physicians with respect to two questionnaires (Wyrwich et al., 2003), by researchers for individual-level analysis in an RCT (Mayo et al., 2014), and more recently, to determine the MCID in communication outcome measures for people with ABI (Chia, Powell, Kenny, Elbourn, & Togher, 2015). This percentage of scale breadth (i.e. 10%) is considered to be reasonable to use as a cut-off point, and unlikely to include “false positives” than may be identified with a lower cut-off point (e.g. 5%) (Osoba et al., 2005). However, use of this criterion is likely to be dependent on the outcomes having established test-retest reliability, for which this has only been established for the QOL, and not communication outcomes.

The 10% criterion was applied in this study, however the data for the WAITLIST group from first to second baseline (from Time 1 to Time 2) was also reviewed (Figure 8.1) to examine whether there was any movement on communication and QOL outcomes during the period of no treatment. Figure 8.1 shows change for

individuals 1-10 on the communication and QOL outcomes. The colours for each outcome are as follows: Interaction (red), Transaction (blue), QOLIBRI (yellow), and SWLS (green). The Y-axis shows each individual. The X-axis shows percentage change from negative to positive change. Individuals 5, 6 and 7 did not have percentage change scores for Interaction and Transaction as the data for their second baseline is missing. Other individuals with no coloured bars (i.e. 1, 2, 3, 4, 7, 9 and 10) did not show change on that outcome.

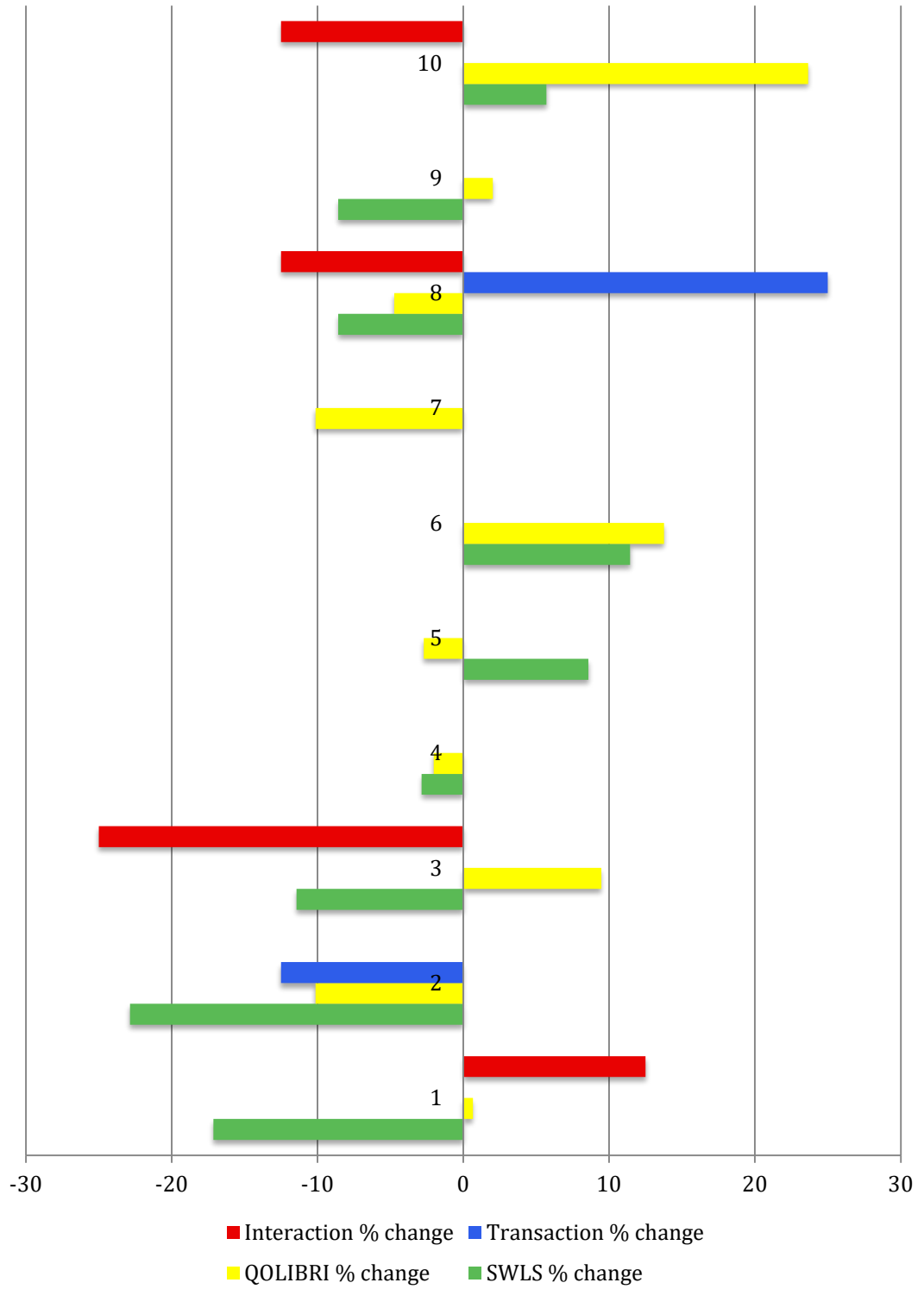


Figure 8.1. Percentage change on outcomes from first to second baseline, for the WAITLIST group (n=10)

The data from the WAITLIST group is concerning, as 7 people were found to have greater than 10% change on at least one outcome. Analysing this further, there were 14 occasions (of a possible 34) where there was greater than 10% change, 6 of these were on the communication outcomes, and 8 on the QOL outcomes. This finding would seem to suggest that a criterion of 10% could still potentially identify ‘false positives’, however it could also reflect a varying nature of outcomes. Thus the following approach was taken. The 10% criterion was applied first, given the previous research evidence, to identify ‘likely responders’ to the treatment. Then, as a precaution, based on the change in the WAITLIST group, a second 20% criterion was then applied to identify ‘clear responders’ to the treatment. A ‘non-responder’ was classified as a person who made less than 10% change.

The following two figures show changes for each individual from pre-treatment to post-treatment, on the communication outcomes (Figure 8.2), and QOL outcomes (Figure 8.3). Raw scores for each individual are shown in Table H1 (in Appendix H). In these figures, the Y-axis shows each individual, and the X-axis shows percentage change from negative to positive (the colours for each outcome are the same as the previous figure). For the communication outcomes, individuals 5, 6, and 7 had missing data so are not included in this analysis, and the individuals with no coloured bars (i.e. 2, 4, 8, 9, 10, 11, 12, 14, 15, 16, 17 and 20), showed no change on one or both of the communication outcomes. For the QOL outcomes, the only individual with no coloured bar (i.e. 14) showed no change on the SWLS.

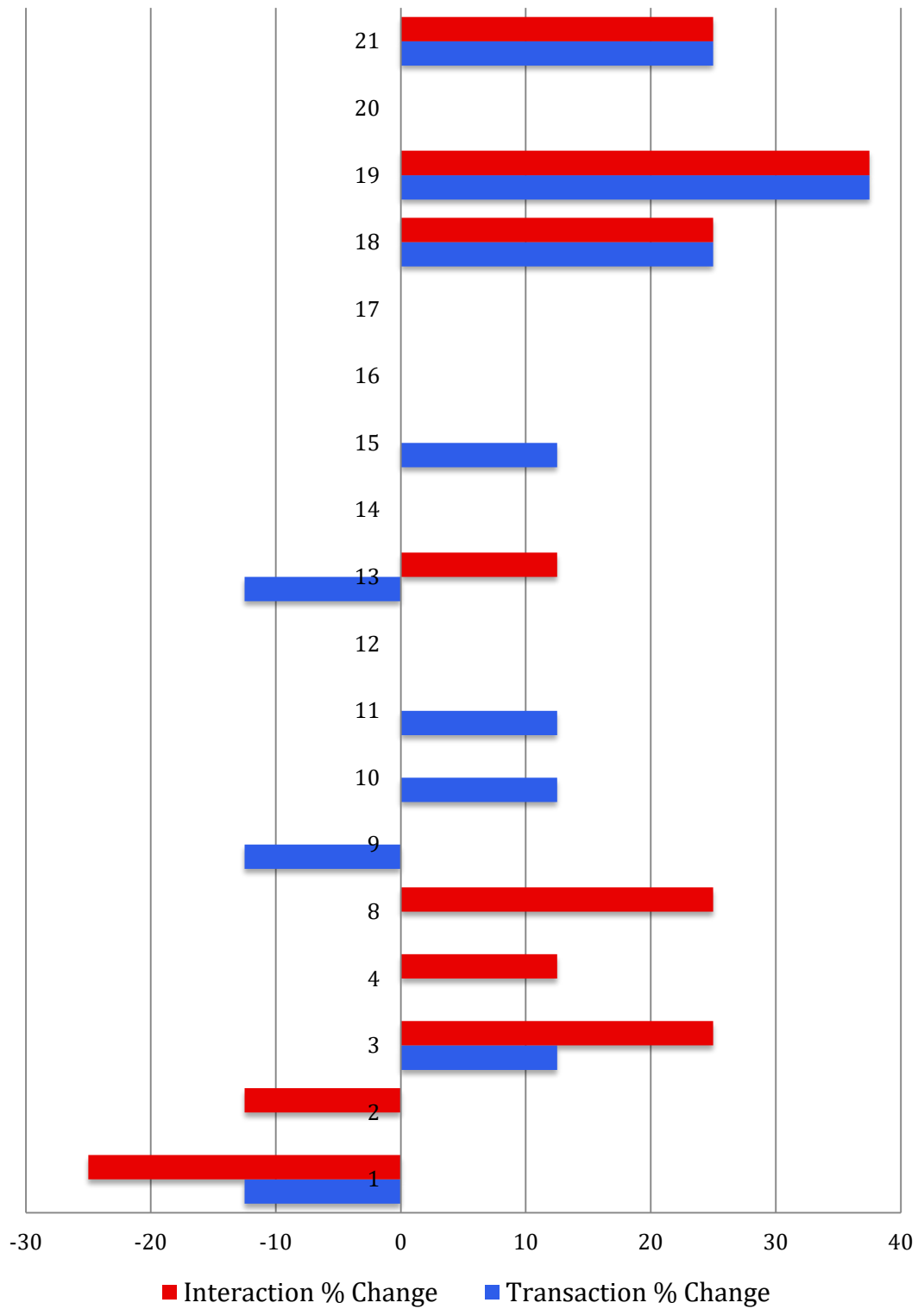


Figure 8.2. Individual response to treatment on communication measures (N=18)

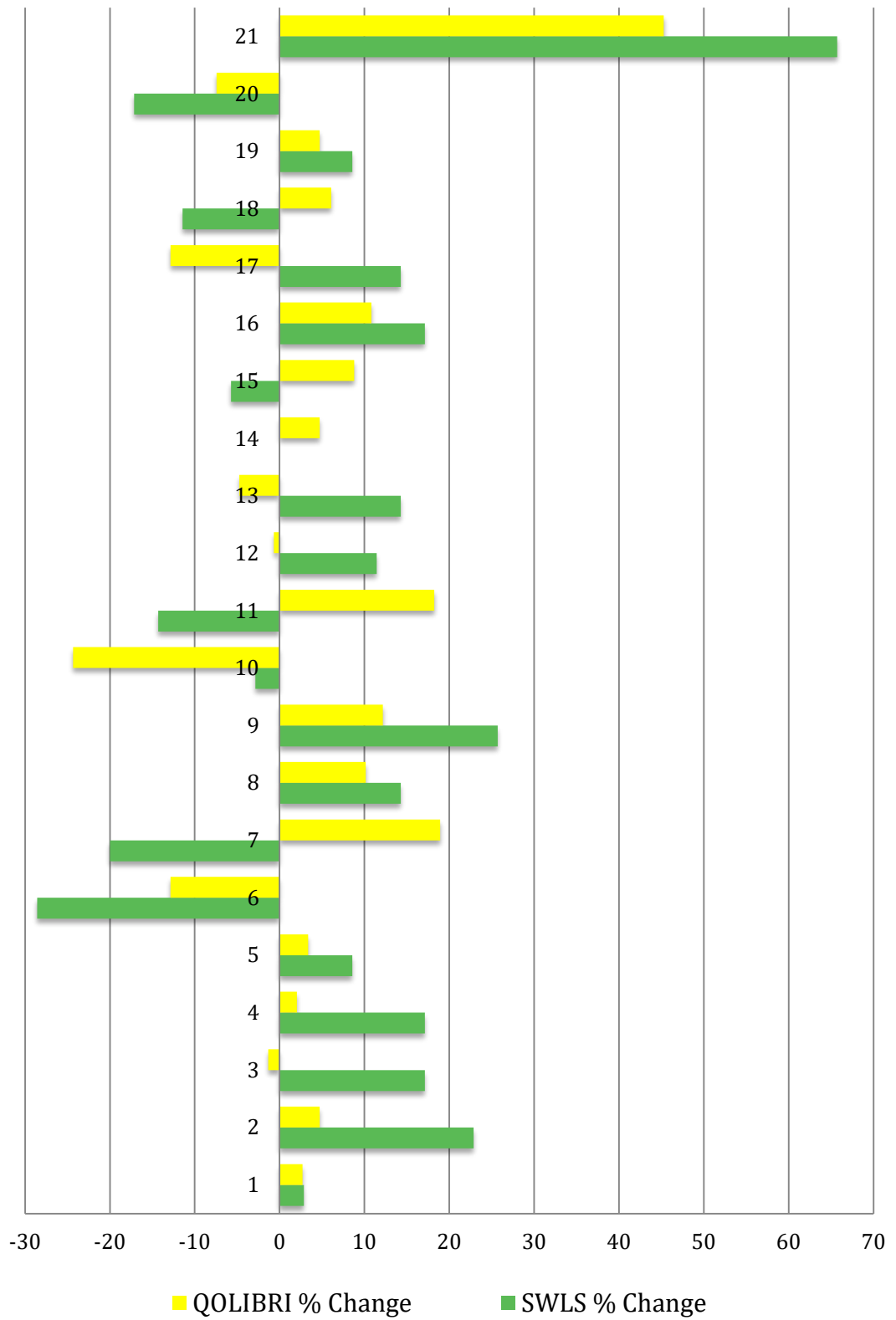


Figure 8.3. Individual response to treatment on QOL measures (N=21)

To further explore the effect of the treatment, the achievement of individual communication goals was compared with percentage change on the outcomes. As correlations involving GAS were considered problematic due to the nature of this scale, a descriptive comparison was considered to be of greater use. Achievement of goals can be construed as an effect of treatment, according to the individuals taking part. Figure 8.4 shows the post-treatment ratings of the GAS goals, as rated by the person with ABI and their communication partner. The Y-axis plots each individual, and the X-axis presents the degree of gain in GAS goals as rated by the person with ABI (orange) and communication partner (aqua). GAS goals are originally rated on a 0-4 scale where 1 is the baseline level (where all individuals start), 0 is “less than expected” level of achievement, 2 is the “expected” level of achievement, 3 is “better than expected”, and 4 is “much better than expected”. Subsequently, the possible change score in GAS goal can range from -1 to +3. No person with ABI was rated, either by himself /herself or by communication partner, to have achieved a change score of -1 (i.e. “much less than expected”). In order for an individual to be considered as ‘responding’ to treatment, *both* the individual and his/her communication partner must have at least +1 change score on GAS; individual perceptions of positive change only, in the absence of agreement from their communication partner, e.g. individuals 11, 12 and 20, were not considered to constitute positive change/response to treatment. As the communication partner did not rate the GAS goal for individuals 4 and 6, these people were not used in subsequent analyses.

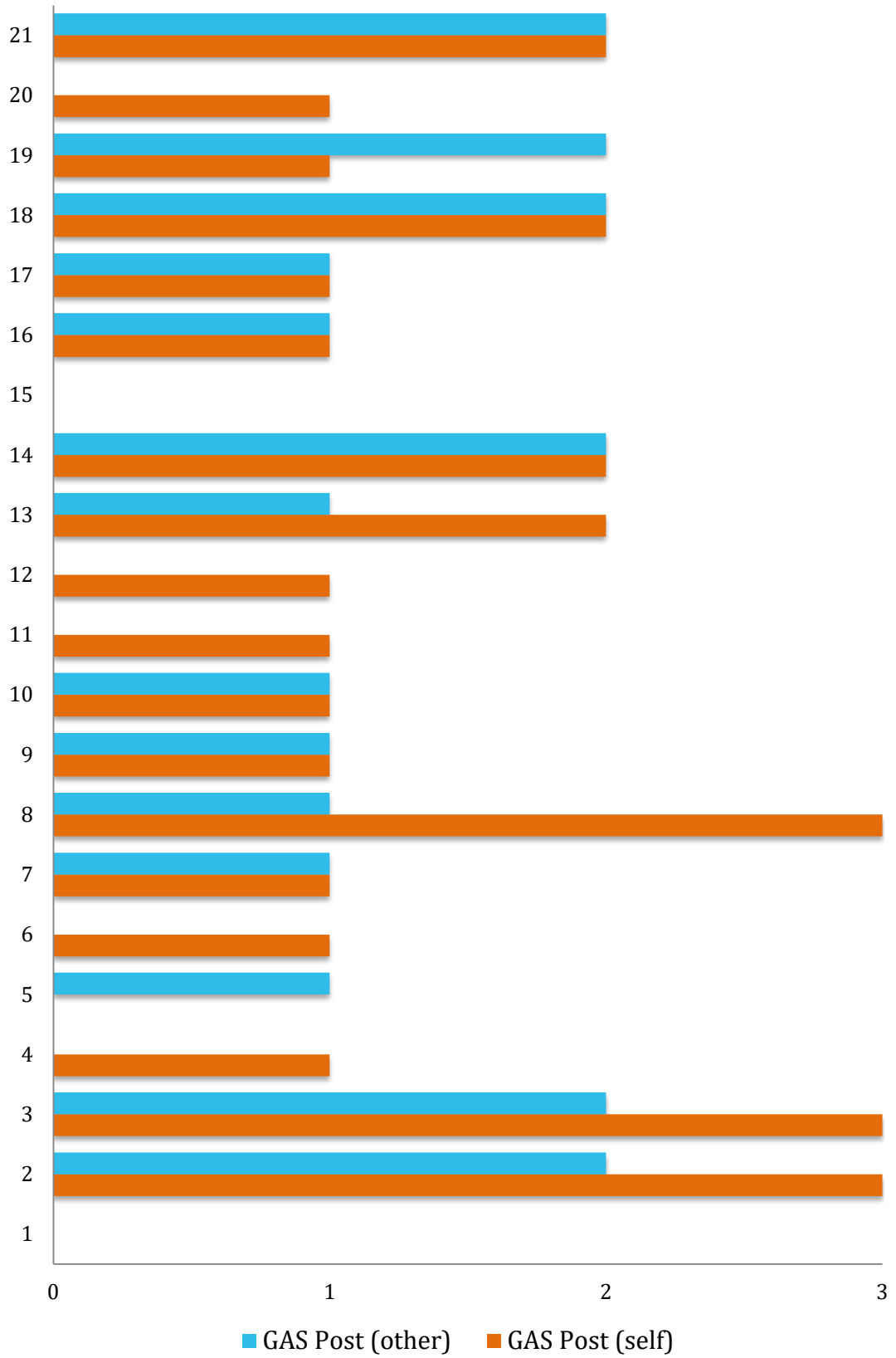


Figure 8.4. Change scores on GAS (N=21)

For both communication outcomes, there were three clear responders (i.e. 18, 19 and 21), one likely responder (i.e. 3), and five non-responders (i.e. 12, 14, 16, 17 and 20), with one person (i.e. 1) getting more than 10% negative change on both outcomes. For both QOL outcomes, there was one clear responder (i.e. 21), three likely responders (i.e. 8, 9 and 16), and five non-responders (i.e. 1, 5, 14, 15 and 19), with one person (i.e. 6) getting more than 10% negative change on both outcomes. The pattern of results for all other individuals was rather mixed, with positive percentage change on one outcome but not the other, and vice versa; or no change on one communication outcome (e.g. Interaction) but change on the other.

At the individual level, GAS goals were rated at the “expected” level of achievement or higher by 86% of people with ABI (18/21), i.e. achieving change score of minimum of +1, and by 74% of communication partners (14/19). Examining each individual person, 62% (13/21) were rated at the “expected” level of achievement or higher by *both* the person with ABI and their communication partner. To compare with the previous results, all four responders (clear and likely responders) on the communication outcomes achieved a positive change score of at least +1, and of the five non-responders, only three achieved the same GAS change score. All four responders on the QOL outcomes achieved a positive change score of at least +1, and of the five non-responders, only two achieved the same GAS change score. For the two people who made more than 10% negative change, one person did not change on GAS, and the other person could not be analysed, as their communication partner did not rate them.

As highlighted, the three figures presented above show a mixed pattern of results, with clear responders and non-responders on the outcomes. With such variability across the outcomes, criteria was devised to identify the clear responders, likely responders, and non-responders to treatment, across all outcomes (Table 8.7).

Table 8.7. Description of criteria to define responders and non-responders to treatment.

Type of responder	Communication outcomes (both)		QOL outcomes (both)		GAS	Individual
Clear total responder	> +20% change	AND	> +20% change	AND	$\geq +1$	21
Clear responder	> +20% change	OR	> + 20% change	AND	$\geq +1$	18, 19
Likely total responder	> +10% change	AND	> +10% change	AND	$\geq +1$	None
Likely responder	> +10% change	OR	> +10% change	AND	$\geq +1$	3, 8, 9, 16
Non-responder	< 10% change	AND	< 10% change	AND	≥ 0	14

From these results, people with ABI who responded or not to the treatment were more easily identified. In the following section, two brief descriptions of contrastive cases will be presented to highlight the characteristics of these people, namely the clear total responder (individual 21) and the non-responder (individual 14).

8.4 Selected case descriptions

The first case to be presented is individual 21, who was a clear total responder. This case was a 39-year-old woman called Cath⁴, who had her injury 3 years previously, as a result of a burst aneurysm. She lived at home with her husband and had a supportive mother and father, who were actively engaged in the treatment process. On profiling assessments, Cath had impaired cognitive ability, reduced social participation, presented with anxiety, depression, and low self-esteem. Her ability to cope was greatly impaired with few productive coping strategies and more non-productive strategies, low optimism, and no sharing strategies. Cath had engaged with her local brain injury organisation pre-treatment and attended counselling sessions but still presented with emotional issues. At the start of treatment, Cath reported that it was difficult to have conversations, that she had low confidence in talking with others, and would become agitated when talking with her mother. Her goal was to ‘try and give more extended responses in conversations’ as her responses tended to be short, using only a few words to answer questions, with the conversation seeming forced and stilted at times. By the end of treatment, Cath improved on both scales of the MPC, taking full and appropriate participation in conversations, and improved on her GAS goal to the ‘better than expected’ level. She also improved from 9 to 32 on the SWLS (maximum score is 35), and increased from 29% to 74% on the QOLIBRI. Cath made comments that highlighted she could recognise changes in her communication skills, could identify how her conversations had improved with her mother and father, and how she felt better within herself. She highlighted how she could talk more, which was related to her goal, and that her mother was impressed with how much more Cath talked to her, which she didn’t do previously. This case highlights that positive improvement can occur despite

⁴ The name used here is a pseudonym

emotional problems existing pre-treatment, and that the treatment had a positive emotional impact, which she was able to recognise, as well as identify specific positive changes to her communication skills. Potentially, her ability to be aware and recognise the changes, most likely led to the improvement.

The whole of me feels more uplifted which is really really good. I just feel so much uplifted.

It's mainly my conversations with people [that have changed] and mainly mum and dad. I can have a longer conversation with mum and dad now which is really really good.

The second case to be presented is individual 14, who was the non-responder. This case was of a 24-year-old woman Simone⁵. She had a severe traumatic injury 7 years earlier as a passenger in a motor vehicle accident. She had early inpatient and post-acute residential rehabilitation, and at the time of present treatment, was living in her own home with carer support. Her cognitive ability was in the extremely low range, she presented as depressed, but was not anxious nor did she present as having low self-esteem, though her coping ability was poor, with little use of productive coping strategies. She had a supportive mother, but Simone was always critical of herself, frequently asking for reassurance if she perceived she had not completed a task or activity correctly. Despite this, Simone was talkative and social. Indeed, she said she was never afraid to speak her mind. Her goal was to 'remember to finish the topic before swapping it, and give less information', as she was tangential when speaking, frequently shifting topics, giving excessive information, and frequently presupposing

⁵ The name used here is a pseudonym

information of her listener. By the end of treatment she made no clinically meaningful changes on the communication or QOL outcomes. However, she was observed to make improvements in respect to her GAS communication goal to the 'better than expected level'. While Simone's comments post-treatment were mainly focused on the achievement of her goal, there were other minor comments that indicated enjoyment of the group, and improved awareness of the different effects of brain injury. It is likely that Sam's degree of cognitive impairment may have affected her ability to generalise information and tasks outside of the treatment environment. Additionally, she was less aware of her impairments, constantly apologising for her actions, and requiring regular reassurance and encouragement to realise what she was capable of doing. Her communication partner indicated that this presentation was evident in all aspects of her life. While further direct input may have assisted this process, the case illustrates that Simone's presentation was complex, and probably unlikely to change considerably in 6 weeks.

I read it every morning [the text]. I didn't just look at it and think, oh god got that yesterday, I would sit there and read it, and if I didn't have time in the morning, what I would do is when I'm in the car I'd read it and then it would help me through the day and then if I did ever make a bit of a burp, I would go back, read it, and be like oh yeah.

It [the treatment] gave me a few bits of knowledge about brain-injured people as well because I'd never realise that all brain-injured people are different and I didn't realise by how much.

I didn't understand why I was doing questionnaires after the project had been done but... I don't know really. Sorry.

The above descriptions intended to provide an illustration of two contrastive cases, where one person was a clear responder and one was not. People with ABI are heterogeneous with complex presentations, and there can be a multitude of factors that can affect response to treatment. However, in both cases, Cath and Simone were able to achieve their individualised goal, highlighting that people with ABI can still make positive gains years post-injury. The discussion in Chapter 10 further examines factors related to the individual and to the treatment itself that may affect a person's response to the treatment.

8.5 Summary

This chapter examined the degree of change made by individuals from pre-treatment to post-treatment. People with ABI are heterogeneous and some responded more favourably to the treatment than others. Understanding who responds most to any given treatment has important implications for clinical practice and for whom a treatment should be recommended. The substantial range in percentage change on each of the outcome measures, illustrates the sample's heterogeneity.

To begin with, this chapter aimed to understand the relationship between percentage change on outcomes, and their internal construct. Moderate and strong correlations were found between scales within each of the communication outcomes, and between the QOL outcomes, which suggests that like constructs correlate with each other. Analyses revealed a strong correlation between the Interaction and Transaction scales of the MPC, between the Acknowledging and Revealing Competence scales of the MSC, among the appropriate, effort, interesting, and rewarding scale, of the Impression scales, and between the SWLS and QOLIBRI. There was also a moderate

correlation between the communication skills of the person with ABI (i.e. Transaction) and their communication partner (i.e. Revealing Competence). These findings are not surprising, as scales such as the Interaction and Transaction scales are both meant to measure the skills of the person with ABI; the four Impression scales are meant to measure the overall impression of the conversation; and the SWLS and QOLIBRI are both meant to measure QOL. Given the strong correlations between scales within the communication outcomes, it may be more satisfactory in future research studies to consider a single indicator for each of these outcomes. That is, choosing one of the scales of the MPC, the MSC, and Impression scales. There was no association between change on the primary communication outcomes, and the QOL outcomes, which suggests that change from the study for people is being driven by different ingredients.

In determining who responds most to the treatment, there was no predictable pattern of change in outcome in relation to the age, time post-injury, gender, type of injury, or measures of cognitive, emotional, and social functioning. Response to treatment was then examined in terms of clinically meaningful change, or MCID. However, determining response to treatment is a real challenge for researchers as there is no clear consensus on what constitutes clinically meaningful change, and how this should be calculated. Part of the problem lies in setting the criterion of clinical significance, which in itself, is problematic as what constitutes clinical significance and a real life difference for one person, may not be for another person (Howard, Best, & Nickels, 2015). Based on current evidence, and comparing the scores of the WAITLIST group from first to second baseline, two criteria were set. The first was considered a likely response to treatment if there was >10% change, and the second was considered a clear response to treatment, which was >20% change. Using this criterion, some individuals were identified as responding to the treatment more than others. This

information was then used to describe two cases, one of a clear responder and another of a non-responder.

The case illustrations demonstrate the complex nature of brain injury, and the myriad of factors that could potentially have an impact on treatment success. Some of the comments made by people with ABI in their interviews were used to understand the response to treatment. To further understand the experience of the treatment, and its perceived benefit to participants, the next chapter presents a qualitative analysis of the results emerging from the post-treatment interviews conducted with all participants.

Chapter 9 Qualitative results

As this study also explored feasibility, it was important to determine the impact of the treatment by exploring the experiences of people with ABI who attended. This chapter describes the themes that emerged from the structured interviews conducted post-treatment with all people with ABI. These results mainly provide information about the acceptability of the treatment to people with ABI, with some added information about its initial efficacy, two criteria important to testing the feasibility of a treatment.

Overall, three major themes emerged from the data: *treatment experience*, *benefit of the treatment*, and *assessment* (see Table 8.8). The first theme, *treatment experience*, is the largest in the data and subsumes general experience, experience that pertains to the group, experience that pertains to the project, and working on goals. These sub-themes contain several categories each. The second theme, *benefit of treatment* has five sub-themes that include communicative benefits, other benefits, emotional effects of the project, meeting others, and having something to do. Finally, people with ABI were explicitly questioned for their view on the *assessment experience*, and this constitutes the third theme, with two sub-themes, perception of change, and length of questionnaires. Table I1 (in Appendix I) provides a comprehensive list of definitions used for coding references into each theme, sub-theme, and category. Each of these themes will be described in detail below with supporting quotations from the people with ABI.

Table 9.1. *List of themes, sub-themes, and categories from qualitative analysis*

Themes	Sub-themes	Categories
TREATMENT EXPERIENCE	General experience	Emotional reaction, satisfaction with treatment, emerging value, other
	Group experience	Group dynamics/fit, emotional reaction, sharing, other
	Project experience	Project motivation, emotional reaction, project end product, sense of achievement, other
	Working on goals	Texting, reminders (memory and goal), goal setting
BENEFIT OF TREATMENT	Communicative benefit (increased awareness and skills)	
	Other benefits (awareness of self and cognition)	
	Emotional effects	
	Meeting others	
	Something to do	
ASSESSMENT EXPERIENCE	Perception of change	
	Length of questionnaires	

9.1 Treatment experience

Treatment experience comprises four sub-themes, and the first refers to the general experience of the treatment, with no specific reference to the group, project, or working on goals, which are discussed separately. Nearly every person commented on the general treatment experience, and the majority of the responses were positive, with people with ABI using strong, affirming language, “great experience” (P9), “brilliant” (P13), “well chuffed” (P20), “really positive” (P3), and “really really good” (P21). A

minority (n=3) had less positive initial comments, which were specifically linked to their views of commencing the treatment:

I actually thought it was a bit childish to start with (P10)

The majority of people with ABI were satisfied with the treatment, including the three individuals above, and reported that it should be repeated in an identical manner. A few people with ABI (n=3) suggested some minor changes including reducing the length of sessions, “bit long” (P12), and the pace, which could be “quicker” (P18).

People’s responses indicated that the value of treatment emerged over time, and evolved from negative to positive, mainly across sessions, and on occasion within sessions. Most people spoke about being initially nervous and worried about what the treatment entailed and whom they would be working with in the group. As the treatment progressed, their perceptions became more positive as they “got into the swing of it” (P4), and they started to see the value of the treatment. Change was also reported within sessions, where people described a “change in mind-set” (P6).

When it was first talked about I thought is it going to be another one of this funny wonders but as the weeks progressed and I could feel that we were making progress and I thought it was all worthwhile (P17)

Because I turned up more or less every time, I felt I was really fed up but by the end of the session, I felt alright. So, that was important for me (P11)

Other categories in this first sub-theme included the size of the group, and session intensity, and structure. Several people with ABI commented upon group size,

separate to speaking about the group experience, and noted that a group of 2-3 people was sufficient. Six people suggested that the treatment could have worked with a slightly larger group, but no more than five people, acknowledging the difficulties that could arise from larger groups: “different opinions might be hard to get the goal done. People with different ideas” (P12). A minority commented on the intensity of sessions (i.e. no more than twice a week), and structure (i.e. same venue, break in the middle) to also be sufficient.

The second sub-theme in *treatment experience* was that of the group experience, and dynamics and fit of group members, which was the strongest of all categories. People reported that to work, a group needs the right motivation, and mix of people:.

The right mixture of people. Without that you haven't got it so if there was one thing, it was the mixture of people, that was the thing that did it (P19)

The group didn't need to be friends, but there needed to be trust, and equal understanding of each other's abilities to work. Groups were perceived to have worked well because people could openly discuss and share ideas, talk to each other, and bring a range of opinions and abilities together:

seeing how my gifts and abilities could be used as well as intermingle them with other people's cause we all have different ones so bring them together (P6)

The role of the therapist was perceived to facilitate group members to work together. However, not all groups worked well as one person reported frustration about another group member being slower, and a second person reported frustration about another group member's lack of computer literacy.

Overall, the majority of people with ABI rated the group experience positively, and two people explicitly reported they preferred the treatment as a group and not one-on-one. One person described meeting other people challenging however, other comments made by this individual indicated he “really enjoyed working with the other group members” (P12).

The group gave many people with ABI an opportunity to share their experiences, ideas, and problems within the group. Through doing this, people would receive feedback from each other or the therapist that was accepted positively thus, contributing to people feeling a sense of belonging. This meant people felt equal to one another, safe, supported, and not judged by others, which enabled people with ABI to use the group context to communicate with each other, and practise, and rehearse the use of their individual communication goals.

our little group we were all sharing and talking and supporting each other (P10)

Because you or [name of person with ABI] didn't make me the odd one out. I felt that the three of us were all equal (P17)

so that I could try out these new things, asking questions and expressing myself which was very very new and taking baby steps to try and do it (P6)

The third sub-theme in *treatment experience* relates specifically to undertaking the project. Motivation behind the project featured here, and each group chose a different project to do, such as a pamphlet, educational video, podcast, and artwork. For each, there was a strong sense of helping others, whether that was to help people who had sustained a similar injury, or to increase awareness of brain injury to the general

public. One person explicitly engaged in the project, and the treatment, for the sole reason of *helping others* in the group.

Over half of the people described feelings from their involvement in the project, which were overwhelmingly positive. People felt it worked well, and that the experience was “good fun” (P15), “interesting” (P18), “great” (P19), and “rewardable ...fantastic” (P1).

One important aspect of the project experience included the creation of an end product, which was commented upon by a third of people with ABI. The project idea and product needed a focus that united group members, and was a tangible outcome.

I think the project start was a big thing. We didn't even know what the project is and suddenly one day I just had a, came up with the idea of 'better future', the other group members agreed with that (P12)

To start with I thought, “ohhhh, I can't do this!” but actually it was really good to have something to get your teeth into and to actually see something at the end of it, the fruits of your work really (P6)

A strong sense of satisfaction and achievement was gained from completing the project and seeing the end product, and was commented upon by third of the group. Most people reported being proud, surprised, happy, and rewarded with what they had accomplished. For one person, his sense of achievement arose from witnessing the reactions of others, not involved in the project:

Once we had them up on the wall and that old lady came in and just, “I had that”, tears flowing and I was just like gobsmacked. Driving home literally I was thinking

we've created a monster. If this goes out there and we get reactions like that from people, it's going to work. Brilliant. Over the moon. If I could have, I would have jumped for joy (P10)

In addition, other categories to emerge related to the project experience included, doing project tasks, and the need for structure. Tasks that needed to be done as part of the project included filming and editing the video, finding and printing pictures, or cutting and pasting pictures from the internet into the pamphlet. Some of these tasks were identified as enjoyable and motivating. Having a structure to the sessions was equally important for a few people. Elements such as the traffic light system to help with problem solving, making a plan at the beginning of each session, creating a list of actions for the following session, and simply keeping a similar structure to each session, helped people with ABI anticipate, and feel comfortable with what would happen within sessions.

The fourth, and final sub-theme of *treatment experience* was working on goals. People's comments about text messaging (of goals) featured strongly, without any specific reference to their purpose, or content. People mainly used positive language (e.g. good, fine, pleased) to describe their experiences of the text-messages, and reported that the messages were "interesting" (P20) and "useful" (P10). While most comments were positive, one person found the daily text messages "annoying" (P7), and this was related to the high frequency of text messages, each day of the treatment. Only two practical suggestions were made, to send the messages on "alternate days" (P17), and to have them "appear at random times" (P16).

The text messages acted as a reminder to people. Almost half of the group described the texts as a memory reminder of something, and that it was useful, helpful, and as one person indicated "a good kick up the arse" (P10). P7 who found the texts

annoying, didn't feel like he needed the constant reminders, as he could remember the text independently. Interestingly, the way people responded to the text was different; some would take the time to read the text on every occasion, while others could recall the text without reading it:

It was very handy the texts that you kept sending me to the point that I was remembering them and I didn't have to go to the text to look and see what I have to do (P10)

Around a third of the group commented on the text, as being a reminder of their individual communication goal. For some, the text had a significant impact on how they perceived and acted towards their own goal. Moreover, a few people commented on how the texts were a useful reminder to their communication partner, who would then prompt the person with ABI about their goal.

having the text reminders has made the idea of being in control of the conversation become more important to me so then I start think about different questions to ask them and stuff to keep the conversations going (P16)

you might have done a good thing there cause even though you sent it to me each day you sent it to [name daughter] and [name second daughter]. I think every time and I think that got to me in a way, they're asking me, "did you get your message? What did it say sort of thing?", it's like reminding me (P2)

A third of the group made positive comments about goal setting, and working on goals, separate to comments relating to text messaging. More specifically, several

people spoke about the role of videotaping to help build communicative awareness, which led to the identification of a communication goal. One person (P6) reported that videotaping should be timed appropriately for the person with ABI, and not done too soon after the injury. Finally, two people talked about goals with reference to predicting their communication performance and evaluating their goal achievement each session.

I thought the setting of the goals was good thing to get some goals set out (P12)

It was very powerful for me because if you'd have sat there and told me, I probably would have thought, well, where's he coming from from this or... but to see it, it really sent it deep into me to know there's no hiding from it, I can see it (P6)

I guess it gave me a goal to aim for during the session I tried to better my score I set at the start (P12)

9.2 Benefit of treatment

Nearly every person with ABI reported some benefit from the treatment, which is described in this theme. Many of the comments related to awareness, and change in skills. A review of the data revealed a clear distinction between awareness and changes in *communication*, and awareness and changes in *other areas* (i.e. self and cognition). In some cases, people with ABI made comments only to communication, and not other areas. For that reason, the findings are presented as these two sub-themes, and data are distributed fairly equally between them.

People with ABI became more aware of how they communicated with others from involvement in the treatment, in particular, of specific changes they could make to improve their own conversations with others. Some people with ABI provided actual

examples where they had made changes to their communication. In all cases, the changes were directly linked to a person's individualised communication goal and led to better conversations with others. On occasion, people reported that their family and friends had observed the positive changes.

it helped me firstly to see where I still had areas of improvement in my conversational skills and expressing myself um... which I knew there were problems but I couldn't pinpoint them and no-ones ever been able to bring them up before um... and I think part of it would be able to see it for myself, that was the big thing (P6)

Like I said with one of my friends when we went for a drive, because I'd said to him I'm supposed to be using natural fillers, I can't actually think of anything to use as a natural filler that I'm happy to use, we had the jokes tip of the tongue and all that but it didn't flow. But natural fillers did flow. So when I came up to the word natural fillers just literally fell in place. I just went natural filler and he said, "ah, ok", sat back, started doing whatever he was doing and left it while I was thinking of the word then we carried on the conversation. It worked really well. And it does with my family as well (P10)

The second sub-theme referred to changes of awareness and skills in areas other than communication including self and cognition. Most changes related to people with ABI being more reflective and learning new skills. Five people with ABI reported an increased awareness of brain injury and that people can present differently following a brain injury. Other changes were more related to cognition and included changes to planning, taking time to do tasks, improved problem solving, and concentration.

Concentration levels a bit better from the start. It's given me more positive outlook which helps me to concentrate. I can sit down and read something and get more out of it (P12)

These positive changes to awareness and skills helped people with ABI to reflect on the emotional impact the treatment had on them. Most people in this sub-theme described positive feelings including “confidence” (P4), “uplifted” (P21), “I felt on a high” (P2), and “stronger” (P9). One person acknowledged that the treatment helped her to “got a lot of stress out of my head” (P20), despite initially feeling emotional from being reminded of, and talking about, the brain injury. A second person (P11) described herself to be “more content” despite the fact that she can “still worry about things. I still get pissed off”.

A third of people commented on the opportunity to meet new people, and having something to do, comprising benefits of treatment. People enjoyed meeting the others in the group, which gave them the opportunity to socialise, and have “a little natter” (P13). This is further illustrated that post-treatment, two people referred to other group members as “friend[s]”. Others commented on how the treatment gave them an opportunity to “to get out of here [home]” (P4), which sometimes led to further benefits e.g. “Getting on the bus on my own and going into various shops that I wanted to go in” (P11); and one person commented on projects he could do in the future.

9.3 Assessment

The final theme refers to the assessment process itself, and comments were made in direct response to an interview question specifically asking people whether the treatment outcome questionnaires gave them a sense of what may have changed from

the treatment. There was a strong sense of uncertainty in the data. Many people indicated “I don’t know” (P3) and that they “weren’t sure” (P20). Some people initially indicated that the questions made some sense, but then revealed confusion and uncertainty when probed further.

I didn’t understand why I was doing questionnaires after the project had been done
(P14)

Not all of them, they sort of... bedazzled (P4)

Other people simply reported that they didn’t feel the questionnaires explained what might have changed, with comments such as “no, I don’t think so” (P19), “I don’t think they changed” (P9), and “not particularly” (P11). There were frequent comments that suggested poor recall of the questionnaire items might have influenced their understanding of what may have changed, “I can’t remember any of the actual questions” (P16). A few people recognised the assessments were being used to measure change, which is of course the purpose or intention of the research and researcher.

I’ll expect they’ll be compared to the answers we gave at the start (P12)

A few people reported that the questionnaires were different to others they had completed after their injury with other professionals in other contexts, with some questionnaires (e.g. LCQ, SWLS) making sense, but could not provide any further information when probed further.

Whereas your questions are good questions. These are questions that I really understand and process and think actually, I'm not happy with that at all, I'm happy with this (P10)

Finally, in the second sub-theme, approximately two-thirds of the group commented on the assessment sessions and length of questionnaires conducted at each time point. Most people reported that the number of questionnaires to complete was adequate, and their responses primarily showed consensus and were not especially illuminating.

9.4 Summary

The majority of people with ABI perceived project-based treatment to be a positive experience to have engaged in, and reflected this in a general sense, as well as directly related to the project they collaboratively worked on, and the group members with whom they worked. They perceived the treatment to have value, which for many emerged over time. This most likely occurred as people experienced changes and progress in the experience, and developed a deeper understanding of the project and the essence of what was being attempted, driven by motivation and a sense of achievement. There is a prevailing sense in the data that whilst the importance of group dynamics was raised, members achieved a sense of fit, sharing with each other, and a sense of belonging which created a safe supportive practice environment to work on their individualised communication goals. Generating and pursuing individualised communication goals was important to people with ABI, and text messaging was deemed acceptable by people with ABI as a means of reminding and learning goals, as well as prompting pursuit of goals outside the treatment context. People perceived

positive outcomes from the treatment in terms of increased awareness of one's communication, improved communication ability, increased awareness of self, and improved cognitive skills. Similarly, people with ABI acknowledged the social interaction opportunities afforded through the treatment. Finally, although it was a secondary aim of the interviews to explore people with ABI's experiences of the assessment, their comments are nonetheless insightful for the lack of specificity and considerable uncertainty reflected in their responses. There was generally poor recall of what had been evaluated, and no certainty that the formal measures reflected the value or perception of change from people with ABI's point of view. It is possible that due to poor recall that people with ABI requested no changes to the assessment and were generally agreeable it was without concern. Overall, these findings suggest that the treatment was feasible in terms of its acceptability, as people were satisfied post-treatment, and there was evidence to underscore some of the quantitative data in terms of the initial efficacy of the treatment.

Chapter 10 Discussion

The primary aim of this research was to evaluate the efficacy of project-based treatment, a novel treatment designed to address and remediate communication skills and QOL. The previous four chapters present the quantitative and qualitative findings from the study. This chapter will summarise and interpret those findings in three main sections that examine: (1) feasibility of project-based treatment; (2) whether the treatment made a difference, with reference to both the quantitative and qualitative results; and (3) factors that affect change, both with respect to the individual involved in the treatment, and treatment factors. These sections will be followed by an exploration of the clinical implications of the research, limitations, and considerations for future research in the field.

10.1 Fidelity and feasibility of project-based treatment

As project-based treatment was considered complex, it first needed to be adequately defined. Practising clinicians (*or consultants*) in speech and language therapy and occupational therapy with experience of implementing project-based treatment with people with ABI were involved in defining the treatment. While a draft of the treatment manual had been created, clinicians discussed the critical features of the treatment, identified practical issues with implementation of the treatment, provided practical feedback about the treatment manual, and reviewed a behavioural checklist that would later be used to check fidelity of the treatment. Involvement of practising clinicians helped to increase the likelihood of acceptability, and integration of the treatment into clinical practice if effective. Cross-discipline implementation of the

treatment is also made more likely with inclusion of clinicians from different disciplines.

This was an exploratory study, so it was important to demonstrate that there was evidence of treatment fidelity, and that the treatment was feasible. Fidelity checks were completed to ensure that the treatment was implemented as intended. These processes are often overlooked, yet are important in making decisions about treatment efficacy and replication. The treatment must also be feasible for the therapist and the participants to deliver and attend, and furthermore, those receiving the treatment must deem the treatment acceptable in the format it was delivered, to consider further trials of the treatment. Both fidelity, and feasibility of the treatment are discussed here.

Fidelity checks established that the treatment was implemented as intended. Fidelity may be attributed to a well-specified treatment manual developed for the research, and a transparent well-defined behavioural checklist developed to conduct prospective fidelity checks, with written strategies for monitoring fidelity during a treatment trial. Early fidelity checks established the presence of all behaviours considered essential and desirable to the implementation of project-based treatment, however, determining the *relative* presence of behaviours was problematic, with disagreement as to whether behaviours were ‘present’ or ‘present to some degree’. Hart et al. (2013) reported similar problematic findings with three response categories (i.e. present, present to some degree, absent), and a two-response category (i.e. present, absent) is suggested instead. Despite this issue, no behaviours were considered absent, providing evidence that the treatment was implemented as intended.

Feasibility in this research was considered using five criteria; demand, implementation, practicality, acceptability, and initial efficacy (Aboulafia-Brakha et al., 2013); the first four of these criteria are discussed in turn, and efficacy is considered in

its own right (section 10.2). Concerning demand, recruitment rate was considered. Twenty-one people with ABI were recruited over a period of 16 months, at a rate of 1.3 recruits per month. This figure is similar to studies that reported recruitment rates of 1.2-1.4 recruits per month for people following stroke (Palmer et al., 2012; Woolf et al., 2015), but less than a study that reported 3 recruits per month for people with TBI (Dahlberg et al., 2007) (although in the last study, the researchers started with a pool of 882 potential people with ABI). In the current study, 100 people were identified, and 53 could be contacted, with the remaining people not responding to contact, or their contact details being incorrect. Of the people contacted, 24 agreed to participate in the treatment (recruitment rate: 24% of total participants, or 45% of those who could be contacted). Reasons for not participating were people did not want to be involved in a treatment that reminded them of their brain injury, people did not feel the treatment was suited to them, and the geographical location of the treatment. Three people dropped out after the eligibility assessment due to personal reasons including moving home, relationship problems, and a lack of interest in the study. This recruitment rate is similar to other studies that report rates of between 15% (Dahlberg et al., 2007) and 27% (McDonald et al., 2013) for people with ABI. For the participants recruited, there was a high retention rate, from pre-treatment to follow-up, with all participants attending the pre-treatment, post-treatment, and follow-up assessments. Alternate allocation to the TREATMENT and WAITLIST group could be completed, and all participants remained in the group to which they were allocated.

The sample of people with ABI used in this research was representative, and not dissimilar to other studies involving chronic, long-term cases of people with ABI (Arundine et al., 2012; Bradbury et al., 2008; Goverover et al., 2007; McDonald et al., 2013; Ownsworth et al., 2008). In this study, the mean age of participants was 45.8

years, 11.95 years post-injury, approximately equal distribution of men to women (12:11), more traumatic than non-traumatic injuries (13:8), and poor cognitive functioning based on the RBANS Total Score (mean score = 70.85). Each person with ABI presented to the treatment with evidence of a CCD. All people with ABI needed to be able to consent to participate, which is often a prerequisite of treatment studies involving people with ABI (Brenner et al., 2012; Dahlberg et al., 2007; McDonald et al., 2013).

For implementation of treatment, eight groups were conducted. Of these, five contained three participants, and three contained two participants. The main difficulty arose in recruiting a group of participants from a similar geographical location in which the treatment could be conducted. As a result, three groups were smaller however, groups of 2-3 people are considered adequate (Brenner et al., 2012; McDonald et al., 2013; Simpson et al., 2011). There was no difficulty with choosing a location for the groups, and there were few problems with transportation to the treatment location. The format of nine 2 hour sessions over 6 weeks was adhered to in general, but rescheduling was allowed to accommodate unplanned events, which happened on 7/72 occasions. Of the 21 participants, 13 attended 100% of group sessions, and 8 attended 90% of group sessions, and participants notified of absences in advance. This was better than other studies that have reported 75-83% attendance (Aboulafia-Brakha et al., 2013; Dahlberg et al., 2007; Togher et al., 2013). The session length was adequate, allowing time to discuss a participants individual goals, plan out the tasks of the session, complete them, and have regular breaks for those that fatigued easily.

Regarding practicality, identification of a project that was suited to the needs and abilities of the group was important. One of the main indicators that the treatment was practical was the completion of eight projects, within the 6 weeks, and within

session time. Not all participants in each group had knowledge of computers, but had a keen interest to try, as facilitated by the therapist. A range of approaches could be used flexibly to facilitate the group, although some people with ABI, due to changes in awareness, may have benefited from additional individual sessions, which has been adopted in other communication-based studies (McDonald et al., 2008). A novel, practical, and important addition to the treatment was the use of text messaging to send goals, and actions from individual sessions, which were perceived by people with ABI to be useful. The use of text messaging has previously been used to improve goal recall (Culley & Evans, 2010) but not incorporated as part of a treatment.

Judgements regarding acceptability of treatment were made based on the overall qualitative reports from people with ABI. Reports suggested that people with ABI were satisfied with the treatment, and did not identify any of the treatment components as unacceptable. They reported initial nervousness and worry about what the treatment entailed, and with whom they would be working. However, once the group got underway, the value of the treatment emerged. The language used by participants to describe their experiences of the treatment, the group, and completing the project, was overwhelmingly positive. People with ABI described aspects such as group dynamics, and the opportunity to share ideas and opinions, as important to the group experience; and being motivated to help others, and working on a tangible end product, as important to the project experience. People with ABI also reported working on goals and the use of text messaging as particularly useful during the treatment. The experiences of people completing assessments were also explored. This revealed that people with ABI were uncertain about what may have changed from the questionnaires, with poor recall of items. However, there was fairly good agreement that the length of questionnaires was

acceptable. The findings from the qualitative analysis suggest that the treatment, and assessment process could be considered feasible for people with ABI.

This research demonstrated that project-based treatment could be implemented as intended to a representative range of participants who were relatively easily recruited, was feasible to conduct in the community setting with this client group, and the treatment was well-received by people with ABI who participated. The following section will address initial efficacy, which is the final feasibility criterion.

10.2 Did the treatment make a difference?

Chapters 7 to 9 showed that project-based treatment could make some modest improvements to communication skills and QOL. These improvements were shown for people with ABI in the TREATMENT group compared to the WAITLIST group, and in the follow-up analyses, which examined change over time for all people with ABI. However, these results should be interpreted cautiously, as will be explained in the following sections.

10.2.1 Change between TREATMENT and WAITLIST group

This study suggested that project-based treatment could make circumscribed significant improvements in communication skills, from pre-treatment to post-treatment, for both the person with ABI and their communication partner compared to a WAITLIST control group. For the primary outcome measures, people with ABI in the TREATMENT group were perceived to have higher interaction scores compared to the WAITLIST control group, however there was no significant change on the SWLS. For the secondary outcome measures, communication partners had higher revealing competence scores, and the quality of the conversation improved with less effort

perceived by blind raters, in the TREATMENT group compared to the WAITLIST group. However, there were no significant changes for the secondary outcome measure of QOL, the QOLIBRI. While the significant changes are encouraging, there is reason for caution, as the results are not highly significant, and would be considered non-significant under an adjusted Type I error rate.

Better interaction suggests that people with ABI in the TREATMENT group were perceived to share and engage in the conversation more, had better active listening skills, and use of turn taking, and may be attributed to context or individualised goals. That is, the group treatment provided a context in which people could interact and participate in the conversation with others and some people (who were over-talkative and verbose) specifically set interaction communication goals, and were more aware of their interaction post-treatment.

Communication partners were perceived to reveal the competence of people with ABI more, which means that they allowed the people with ABI to respond, organised information in conversations, and invited responses to questions appropriate to a person's ability. Showing change in partner skills from a low level of input to communication partners is encouraging. That is, communication partners attended one session where they watched a videotaped conversation between themselves and the person with ABI and assisted in generating the person's communication goal which was texted to the partner regularly thereafter; and had one telephone conversation to review progress with the therapist mid-way through the treatment. The text messages and telephone conversation may have acted as a reminder to communication partners to prompt people with ABI to have better conversations. This shows benefit even with this relatively loose dose of input and suggests involvement of communication partners in a similar manner for future research and practice.

Changes to skill in both the person with ABI *and* communication partner resulted in an overall conversation that was perceived as less effortful, more spontaneous, and flowing. Conversations are often perceived as effortful, as communication partners need to do the work to ask questions, make comments, and prompt the person with ABI to respond (Bond & Godfrey, 1997). It is proposed that the above positive findings for both speakers resulted in this dyadic improvement. That is, the improved interaction scores for the person with ABI is likely to have contributed to the perception of less effort, as they were able to engage and participate in the conversation more; and the increased awareness of the person with ABI's needs on the part of the communication partner is likely to have facilitated flow in conversation.

There were no significant changes found for either the primary or secondary outcome measure for QOL, from pre-treatment to post-treatment for the TREATMENT group, compared to the WAITLIST control group. These results are consistent with the RCT of Dahlberg et al., (2007), where no significant change was observed between groups from pre-treatment to post-treatment on the SWLS. Some potential reasons to explain these QOL findings, which will be considered in subsequent sections (see 10.2.2 and 10.3), relate to the timing of treatment for people who have sustained chronic injuries, the short length of treatment, and methodological challenges including small sample size and variability in the data.

Examining the measures of conversation (i.e. MPC, MSC, and Impression scales), other studies have reported greater improvements from treatment, compared to a control group, on the same measures. In one study, the person with ABI was trained with their communication partner and improvements were found post-treatment on both scales of the MPC, MSC, and three of the Impression scales, compared to a control group (Togher, McDonald, et al., 2010; Togher et al., 2013). In a second study where

paid carers were trained alone, improvements were found post-treatment on both scales of the MSC, and three of the Impression scales, but not the MPC, compared to a control group (Behn et al., 2012). In both these studies the people with ABI were younger (average 30-40 years), were fewer years post-injury (average 7-9 years) than people in the current study, and employed different treatments. Specifically, both studies' treatments focused on the communication partner, who attended all treatment sessions. Whilst the current study involved the communication partners, and some improvements were found, greater involvement of the communication partner in the treatment sessions may have been needed to show greater change on the measures of conversation. Furthermore, both studies described above focused primarily on communication through training of positive, and facilitative strategies to improve the interactions people with ABI. In the current study, there was some attention given to training communication strategies, but the primary focus of the treatment sessions was on achieving the project, which suggests that further input on communication may have led to greater change on the communication measures.

10.2.2 Change across all individuals

With TREATMENT and WAITLIST groups combined, this study demonstrated modest significant findings, across the three time points of pre-treatment, post-treatment, and follow-up. For the primary outcome measures, there was no change for the communication outcomes (i.e. MPC), but a trend towards significance for the primary QOL outcome, the SWLS. For the secondary outcome measures, there was a significant change over time on both MSC scales, and communication partners perceived more communicative ability for people with ABI as rated on the LCQ. There was also a significant improvement for the secondary QOL outcome, the QOLIBRI.

However, similar to the between group analyses, the results should be interpreted cautiously, as the results are not highly significant, and would be non-significant under an adjusted Type I error rate. Also, there is the issue of consistency of effects that is problematic, as both Interaction scores and Effort scores failed to reach significance with data from all people with ABI.

Change in communication outcome measures varied according to time point (i.e. post-treatment versus follow-up). Communication partners were perceived to be significantly better on both scales of the MSC (i.e. Acknowledging and Revealing Competence) from pre-treatment to post-treatment. However, there was a significant decrease in scores for both MSC scales, from post-treatment to follow-up, suggesting any improvement resulting from the treatment was lost when the treatment was withdrawn. Post-treatment, communication partners did not receive any contact with the therapist (via text or telephone), which may have contributed to this finding. However, other studies have shown that any improvements made by the communication partners post-treatment, are maintained at follow-up 6 months later, despite no contact between these time points (Behn et al., 2012; Togher et al., 2013). This would suggest that the communication partners in this study may have required additional time and support to help maintain the skills post-treatment, especially in the context of the low dose of involvement in the first instance.

On the LCQ, communication partners perceived no significant change from pre-treatment to post-treatment, but did report significant improvement from post-treatment to follow-up, almost 8 weeks later, and are a unique finding as there is little relevant literature for comparison. A study by Braden et al. (2010), did show significant improvements on the LCQ both post-treatment, and at follow-up by communication partners, who were not involved in a social skills treatment for people with ABI,

however in that study the treatment was entirely focused on the improvement of social communication skills, whereas the current study was not. In this study, the extra time post-treatment may have allowed communication partners the opportunity to reflect and understand the type of communicative difficulty the person with ABI was having, and thus leading to perception of an improvement at follow-up. As highlighted earlier, further attention to communication skills during the treatment may have yielded more significant results post-treatment.

There was no significant change for the primary communication outcome (i.e. MPC), which is problematic. While an effect was found comparing the TREATMENT group with the WAITLIST group, the effect was lost with inclusion of the follow-up scores, and a larger sample size, which suggests that people in the WAITLIST group did not improve to the same extent as the TREATMENT group on this measure, and there were no further improvements from post-treatment to follow-up. As highlighted earlier, further input on communication skills, with strategies to help people with ABI continue improving and maintain existing skills, and greater involvement of the communication partner may have led to significant changes.

Improvement in QOL on the QOLIBRI occurred over time (i.e. at follow-up) rather than from just pre-treatment to post-treatment. That is, people were more satisfied, and less bothered with various aspects of their lives (e.g. social, physical, cognitive, and emotional health) at follow-up. The QOLIBRI was chosen as an emerging HRQOL, disease-specific measure for people with ABI (Wilde et al., 2010), however responsiveness to change on this measure had not been definitively established to date. A previous treatment study did not show change on the QOLIBRI over a 3 month period (Spikman et al., 2010), however the treatment was specifically focused on the training of executive strategies, not improving QOL. One study has shown change

on the QOLIBRI, over a 1 year period but this was following up 132 people between two time points, and not used to measure the effects of a specific treatment (Lin et al., 2014). The QOL review in section 3.2.2 identified that multi-dimensional HRQOL measures rarely show change (i.e. in 34% of studies). Given that there was a significant change over time in this study, it suggests that the treatment did have an effect on HRQOL. A person's perception of their cognitive, social, and emotional health was improved, which is confirmed by some of the qualitative reports of people with ABI. However, given that the finding was not highly significant, caution should be exercised, until the results can be confirmed with further studies, and the responsiveness of change for the measure is better established.

There was also a trend towards significance on the SWLS, which could have been positively influenced by working on a project to completion in a group environment, even though there was no explicit emphasis on coping, perceived self-efficacy, and self-identity by way of the outlined treatment. This finding is not that dissimilar to Dahlberg et al. (2007) who found no significant difference between pre-treatment and post-treatment scores on the SWLS, but a significant difference between pre-treatment and follow-up scores following a 12 week treatment. Other studies have reported significant improvements on the SWLS from pre-treatment to post-treatment (Braden et al., 2010; Huckans et al., 2010), however SWLS scores at baseline were lower in these studies than in the current study, the significant change was not strong (i.e. >0.001), and the people included had comorbid conditions and difficulties for which they were receiving other services, meaning effects cannot be solely attributed to the treatment. Change has consistently been shown in treatment studies that have used the SWLS in periods over 6 months, either as a follow-up measure following a 12-13 week treatment (Braden et al., 2010; Dahlberg et al., 2007), or following 6 months of a

case management service (Heinemann, Corrigan, & Moore, 2004). In the three studies, the SWLS was used as a secondary outcome to detect the wider effects of a targeted treatment. While what led to the trend for positive improvement on the SWLS is not clear, the findings suggest that treatments may need to be longer to achieve significant effects, or that the SWLS may be more sensitive over longer periods of time.

10.2.3 Discussion of outcomes

The treatment, for both the between and within group analyses, showed a range of modest improvements resulting from the treatment. However as identified earlier, there is reason to caution these significant results, as they were not highly significant, and would not be considered significant under an adjusted Type I error rate. While some of these findings could be explained by factors relating to the person with ABI and the treatment, as will be discussed in subsequent sections, the measures used may also explain these results. This section will discuss some of the problems with the measures used to determine treatment outcome, some of which were briefly discussed in the previous section for the QOL outcomes.

In the first instance, the outcome measures may have been insensitive to change from project-based treatment. With the exception of the QOLIBRI, all treatment outcomes were chosen as they showed responsiveness to change following a behavioural treatment for people with ABI. That is, the communication outcomes (i.e. MPC, MSC, Impression Scales, LCQ) showed change in studies where the primary focus of the treatment was improving communication skills (Behn et al., 2012; Braden et al., 2010; McDonald et al., 2008; Togher, McDonald, et al., 2010; Togher et al., 2013); and the SWLS had shown change in 4/6 studies (see Table 3.1 in QOL review), with two of these six studies also focused on improving communication skills (Braden

et al., 2010; Dahlberg et al., 2007). However, despite the emphasis on communication in the current treatment, it is possible that the nature of the gains in communication and QOL generated by project-based treatment were not detected by the outcome measures, as they were not sensitive to this complex, integrated intervention. On-going scrutiny of outcome measures' sensitivity or responsiveness to different treatments is warranted in future research.

The reliability of the measures and in particular, the communication measures, may also explain the lack of significant findings, and includes test-retest reliability, inter-rater reliability, and a broader issue of reliability in conversation sampling, all of which can affect the degree to which change could confidently be identified on these measures. Firstly, although these measures are the measures of choice, they do not have established test-retest reliability. Secondly, inter-rater reliability was not comparable with earlier studies using the MPC and MSC that reported *excellent* levels of inter-rater reliability (Togher et al., 2013; Togher, Power, et al., 2010). In a further study that trained raters for 35 hours, inter-rater reliability was mainly excellent for the MSC and most Impression scales, with fair-to-good reliability for the MPC and the rewarding Impression scale (Behn et al., 2012). More recently, a study reported excellent reliability for the MPC, but fair-to-excellent reliability on the MSC (Rietdijk, Togher, Brunner, & Power, 2015). The inter-rater reliability in the current study, following 18 hours of training, was mainly good, with only one scale (i.e. MSC-Revealing Competence) in the excellent range. However, there was a large range in the confidence intervals of ICCs, from fair to excellent, 0.40 to 0.95, suggesting that reliability was more variable than the statistics would imply. This could be the result of less training in the use of the measures. Thirdly, the findings raise a query as to how stable people with ABI are in conversation. That is, although there was no significant difference between

baselines for the WAITLIST groups, there was evident variability between ratings over the two time points. The only other study to examine people with ABI over two time points, found no significant difference on the MPC and MSC for a group of people with TBI (n=17) between 3 and 6 months post-injury, despite some individual variability in ratings for a selection of 4 people (Chia et al., 2015). Given that few studies have previously explored differences at the individual level, it suggests that more research is needed to consistently examine the stability of conversation, and change, at both the individual and group level.

The lack of change on the communication and QOL questionnaires may have also been due to the lack of alignment between the content of the measures, and the treatment. Many people were uncertain that the questionnaires reflected their sense of change from the treatment, or explained what had changed from the treatment. The few people who identified that the LCQ and SWLS made the most sense to them, were unable to provide any additional information when probed further. These qualitative reports suggest that people with ABI were unable to see the purpose or relevance of the questionnaires being given at each time point, in relation to the treatment. The treatment may have generated a range of benefits for people that were not detected on the current primary and secondary outcome measures of communication and QOL, and other constructs may indeed reveal more change from project-based treatment.

10.2.4 Change on individualised, communication goals

As a supplement to the outcome measures used to capture change, participants' perception of achievement of their individual communication goals constitutes a further mechanism for identifying change. This section explores the positive changes made on the GAS goals by people with ABI, how the goals were closely aligned with the

treatment process and evaluation method, and the agreement in goal ratings between the person with ABI and their communication partner. Finally this section explores reasons for the lack of change on the primary outcome measures despite changes on GAS.

This study found significant improvement on individualised GAS goals set at the beginning of treatment for all participants over time, from pre-treatment to follow-up. The greatest degree of positive change occurred between pre-treatment and post-treatment, with maintenance between post-treatment and follow-up. Post-treatment, 86% (18/21) of people with ABI reported achievement of their goals on GAS, and 74% (14/19) of communication partners reported achievement. Not all people with ABI achieved their communication goal however, this may be more related to other factors that include, impaired awareness, motivation, how meaningful the goal was to the person, and level of involvement of the communication partner. Where achievement of goals was found, this may have occurred as people rated the goal in a socially desirable way. However, at both time points, post-treatment, and follow-up, people with ABI and their communication partners, rated the goals independently of one another, and were blind to how they rated the goals at the previous time point. Moreover, the GAS scale, and the corresponding levels of achievement, was not shown to either person, so as to not influence their ratings. This positive finding then suggests a perception of real improvement in communication performance that is observable to others. These findings are in line with other studies that have reported achievement of communication goals post-treatment using GAS (Braden et al., 2010; Dahlberg et al., 2007), and suggests that GAS is an effective way of quantifying progress, and level of achievement towards communication based goals for people with ABI. Furthermore, it reinforces that individualised goals can be set for people with ABI, and achieved within a group context.

One reason for why these goals could be achieved is related to the close alignment between the communication goal, the method of evaluation (i.e. GAS), and the treatment process. The setting of individualised, communication goals was a key part of the treatment, with a range of strategies to help attain achievement. Goal setting was integrated into the early treatment sessions, where they were set collaboratively with the person with ABI, and their communication partner, using a videotaped conversation. The GAS continuum was used to quantify progress towards achievement of the goal. Goals were then texted regularly to both the person with ABI, and their communication partner, and incorporated into each group treatment session, where people with ABI would predict and evaluate their goal performance at the beginning and end of each session. The treatment sessions provided a context where people with ABI could reflect on their communication skills with others, practise and rehearse their skills, and give and receive feedback from other group members and the therapist. The qualitative findings support that people were more aware of their communication skills, felt they had changed and improved their skills in their goal areas, and associated their goals with the text messaging, which has previously been shown to improve goal recall (Culley & Evans, 2010). In this study, people with ABI were explicitly aware of their goals during the treatment period, which is likely to have contributed to change.

Of further interest regarding individualised communication goals was the agreement between reports, that is, there was no significant difference between how the person with ABI, and their communication partner, rated the GAS goal, either at post-treatment, or follow-up. This means that the person with ABI was as reliable as their communication partner in making a judgement about the degree of goal achievement using GAS. This is an encouraging finding as no studies that used GAS compared the ratings of the person with ABI with their communication partner (Braden et al., 2010;

Dahlberg et al., 2007). This pattern of results is in contrast to other studies that have highlighted people with ABI have impaired communicative awareness, as they rate their ability as better than how significant other rates them (Dahlberg et al., 2006; Douglas et al., 2007b). In this study, the treatment strategies and context enabled people with ABI to increase their awareness particularly, in relation to their goal as shown in the qualitative findings. This suggests that achievement of goals, targeted in a similar manner, can and should be judged by the person with ABI.

As evidenced in the findings of the study, there is a discrepancy between and among the outcome measures and data derived. The intention of setting an individualised goal with people with ABI was to have an impact on their conversations with others. However, changes on goals were not perceived by blind raters to have a significant impact on all aspects of the videotaped conversations. There are several possible reasons for this finding: (1) the changes to communication were too subtle to be perceived by a blind rater; (2) the changes to communication were not reflected in the constructs being observed by the blind raters; (3) other communicative behaviours hindered the conversation more, meaning positive changes were overshadowed; (4) the communication partners skills (*or lack of*) had a greater impact on the success or failure of the conversation than the improved communication of the person with ABI; and (5) the person with ABI was not thinking about their communication goal when they participated in the videotaped conversation. In order to demonstrate treatment effects in conversations that are scored by blind raters, it may be necessary to set a goal that helps the person with ABI to transfer their newly learnt skills from the treatment context into conversations outside of that context, and provide further support to communication partners.

10.2.5 Perceived benefit of treatment by participants

People with ABI described a range of positive benefits in the post-treatment interviews. Most people reported improvements in their communicative ability, both in terms of awareness of how they communicated, and use of their new skills. Similar communication benefits have been reported in studies evaluating communication treatment for people with ABI, albeit of a different type of treatment (Togher et al., 2012). In this study, comments reflected individualised communication goals, showing that specific communication skills can be successfully targeted within a group treatment. The changes to awareness suggest that people with ABI were able to recognise and accept the implications of their difficulties, and be motivated to engage in a treatment. Some comments highlighted that videotaping at the start of the treatment was a useful strategy for helping to build awareness, a finding that has been reported elsewhere (Schmidt et al., 2013).

Changes to self and cognition were a second benefit of the treatment. People with ABI were more reflective, developing their awareness of brain injury, and the different presentations people can have. The interviews do not reveal the mechanism that facilitated these changes, however people with ABI have previously identified that being able to compare their new and old self, and compare their recovery to others with a similar impairment, is important (O'Callaghan et al., 2012). Potentially, the treatment facilitated this process, and contributed to a more positive sense of self, as people with ABI were emotionally influenced by the treatment and could observe improvements in their skills. Changes to cognition most likely reflect the treatment strategies used to compensate for a person's cognitive impairments. These included, creating a things-to-do list at the beginning of each session, use of the traffic light system to solve problems, doing short structured tasks, and taking regular breaks. The comments do not indicate

that the person with ABI learnt a range of strategies to help them into the future; rather, the strategies seem to have created an environment where the person with ABI was able to complete tasks and the project, as independently as possible, and this has most likely led to the perception of change.

The treatment had a positive emotional impact on many people with ABI, and had the benefit of giving them the opportunity to meet others, and have something to do. During this time frame, some people felt more positive, despite the continued presence of negative feelings. These findings highlight the potential impact of the treatment on emotional state, and are likely to be connected to completing the treatment, and the sense of satisfaction, and achievement from completing the project. People with ABI were able to perceive the social benefit of being involved in the treatment, and were able to be part of a group, interact with other people in similar circumstances to their own, and be involved in a series of activities, that led to the creation of a project. The benefit of meeting others, and having something to do, is inextricably linked to the desire to socialise with others, and participate in meaningful activities, and is frequently identified as important by people with ABI in qualitative research studies (Hägström & Lund, 2008; McColl et al., 1998; Schipper et al., 2011; Shorland & Douglas, 2010).

10.3 Factors that affect change

It is particularly important to consider factors that can affect a person's response to treatment in cases of ABI, given the heterogeneous nature of people's impairments post-injury. There was variability in response to treatment on the primary communication outcomes (i.e. Transaction and Interaction) and QOL outcomes (i.e. SWLS and QOLIBRI), which may reflect the heterogeneous nature of the group. Importantly, variability was noted in the outcomes without treatment (i.e. participants in

the WAITLIST group from first to second baseline), and this must be considered in the broader treatment effects calculations.

In an attempt to identify people who may benefit most from treatment, correlational analyses were done. These were between change pre-treatment to post-treatment, in the primary communication outcomes (i.e. Transaction and Interaction), and QOL outcomes (i.e. SWLS and QOLIBRI), with the demographic and profiling assessments. No correlations were found for change on Interaction, SWLS and QOLIBRI. However, there was a strong negative association between change in Transaction scores, and (1) social functioning (i.e. social support); and (2) coping (i.e. optimism and sharing). In other words, people with little support, less optimism, and little opportunity to share pre-treatment, had greater degrees of improvement in Transaction. The group format of the treatment may help to explain this, as people with ABI may be lonely and isolated, lacking contact with other people, and the group gave them a social opportunity to ask questions, share information, and experiences with others, then being realised in their Transaction with their communication partner. However, these findings should be interpreted cautiously as they were not significant under an adjusted Type I error rate.

The lack of significant findings could be due to several factors. Correlational analyses are likely to be unstable with such a small sample size, and the large number of correlations may have resulted in Type II errors (Anson & Ponsford, 2006b). There was a wide range in percentage change from pre-treatment to post-treatment, and this variability amongst people with ABI paired with variability on the profiling assessments, may have contributed to the lack of significant findings. This would most likely have been corrected with a larger sample size. In addition, a greater degree of change post-treatment may have also been needed to find more significant correlations.

A further obvious reason is that there are factors beyond the scope of this study, which will be described in the following section, that were more associated with change post-treatment than the measures of cognitive, social, and emotional functioning used here.

In summary, analysis of change at a group and individual level revealed that there was a mixed pattern of results, and that the effectiveness of the treatment was unclear. The wide variability in percentage change demonstrates that people with ABI are clearly heterogeneous in their response to treatment. The measures, and lack of reliability, and possible sensitivity, may further contribute to the non-significant findings, and there may be other factors that could affect a person's response to treatment. These factors relate to the person with ABI, and the treatment. Each of these factors will be explored separately in the following sections.

10.3.1 Participant factors

Participant factors including, a person's level of awareness and emotional state could have influenced how an individual responded to the treatment process, and furthermore, how meaningful participants perceived the treatment to be, and how involved their communication partners were, could have additionally contributed to response to treatment. Each of these will be discussed below.

Impaired awareness may have had an impact on treatment success. Some individuals seemed to have good awareness of their difficulties pre-treatment, while others developed awareness of their difficulties during the course of the treatment. Impaired awareness, or acceptance of difficulties, can cause problems with motivation to engage (Fleming et al., 1998; O'Callaghan et al., 2012; Trahan et al., 2006), and those who have some awareness of their difficulties prior to treatment have been shown to respond more positively, in terms of achieving better outcomes (Anson & Ponsford,

2006b; Ownsworth & Clare, 2006; Schrijnemaekers, Smeets, Ponds, van Heugten, & Rasquin, 2014). For those with poor awareness, it remains unclear whether awareness difficulties can be improved a long time post-injury (Schrijnemaekers et al., 2014). The current treatment aimed to improve awareness in several ways, through video and verbal feedback (Schmidt et al., 2013), and by providing a context that facilitated a positive view of self with opportunities for social comparison (Ownsworth, 2014; Stets & Burke, 2000). One problem with increased awareness is that it can increase emotional distress (Richardson, McKay, & Ponsford, 2015), and adversely affect how people with ABI rate their QOL (Goverover & Chiaravalloti, 2014; Sasse et al., 2013), however treatment studies have shown that awareness can be improved without affecting emotional state (Ownsworth et al., 2006; Schmidt et al., 2013). These studies suggest that a supportive, non-confrontational, therapeutic context could potentially buffer some of the emotional effects of increased awareness. In this study, people with ABI reported changes post-treatment to their awareness of communication, self, and cognition, but this was stronger for some people than others. Depending on the basis of unawareness (Fleming & Ownsworth, 2006; Togliola & Kirk, 2000), other strategies may have been needed to develop greater awareness for some people.

A second factor that may have affected treatment outcome was a person's emotional state. Whilst a person's emotional state prior to the commencement of treatment was not associated with outcome, their emotional state following treatment, which was not assessed, may have been. Changes are not thought to occur from increased awareness as previously discussed, but rather from the experience of emotionally unsettling, and stressful, concurrent life events (Bornhofen & McDonald, 2008b; Grant, Ponsford, & Bennett, 2012; Walker et al., 2005). In the current study, some participants encountered life events during the treatment including family tension,

relationship breakdown, problems with house renovations, and a friend being hospitalised. These events may have negatively affected a person's emotional state particularly, for those people with poor coping ability, adversely affecting treatment outcome.

The degree of meaningfulness derived from the treatment by an individual may have also affected response to treatment. Meaningfulness is associated with engagement (Kahn, 1990; May, Gilson, & Harter, 2004; Saks, 2006), and all people with ABI were engaged with the treatment, as indicated by high attendance, participation in group sessions, and satisfaction with the treatment. The treatment was designed to involve people with ABI in activities and tasks, with other group members, in a project to help others that could add meaning, purpose, and structure to their own lives. However, some individuals may have found less meaning in the treatment than others. While meaning and QOL have been shown to be associated (Roepke et al., 2014; Steger et al., 2011), this relationship is mediated by the search for meaning (Steger et al., 2011). In other words, the presence of meaning in a person's life is more strongly associated with QOL for people who are actively searching for meaning in their lives. As evidenced in the literature, people with ABI have a desire for meaning in their lives, whether that is meaningful participation, activity, or engagement (Douglas, 2010a; Häggström & Lund, 2008; Schipper et al., 2011). So potentially, a person's response to treatment may have been affected by whether they were actively searching for meaning in their lives at the time.

Another factor of the treatment that may have had an effect was the degree of involvement of communication partners. While all participants reported high levels of social support (i.e. on the ISEL), some communication partners were more actively involved than others, in improving their own skills, and providing opportunities to

practise and rehearse conversations. This was identified anecdotally by the researcher via participants' comments made during treatment sessions, and noted for some communication partners who would actively seek out the therapist to share their thoughts and experiences following treatment sessions. Improving the skills of the communication partner was important for creating better conversations with people with ABI, and helping them to maintain and generalise skills to other people and settings (Willer & Corrigan, 1994; Ylvisaker et al., 2003). While communication partners did make some positive changes, and report more communicative ability for people with ABI, the relative engagement of the communication partner may have contributed to a person's response to treatment, an aspect that should be assessed more comprehensively in the future. This factor and others will be discussed in the following section, as a lack of positive results may also be related to the design and content of the treatment.

10.3.2 Treatment factors

Other factors that could affect whether a person responds or not, are related to the design of the treatment, and changes that may need to be made to the approach, and delivery of project-based treatment. These include the content, involvement of communication partners, setting goals, the environment, and length of the treatment. Each of these will be discussed below.

The design of the treatment may have been too broad to adequately target communication skills. While many people could achieve their communication goal, more attention directed at communication and improving conversations may be required. Studies that have shown substantial changes to communication skills for people with ABI have put the main focus of group sessions on improving conversations (Braden et al., 2010; Dahlberg et al., 2007; McDonald et al., 2008; Togher et al., 2013).

More attention focused on training strategies that improve conversations may be needed, beyond those used to focus on an individual's communication goals. In addition, the person with ABI needs support to transfer newly learnt skills within treatment sessions to conversations away from the treatment setting.

Greater changes may have occurred if additional input was provided to communication partners. This study was able to show that communication partners could make some positive changes to their skills following an initial training and goal setting session, a mid-treatment telephone conversation, and regular text messages. However, greater improvements may have resulted from further targeted input. For example, other studies have shown that frequent training sessions provided to communication partners alone (Behn et al., 2012; Togher et al., 2004), or together with people with ABI (Togher et al., 2013), can lead to significant changes in communication partner skills, which led to better conversations. Furthermore, individualised goals were only set for people with ABI, and inclusion of a communication goal for the partner to work towards may have also led to further improvements. As communication partners can play an important role in facilitating communication for people with ABI, determining the optimal amount of training and support they require is crucial to ensuring that the gains from treatment are maintained and generalised to other contexts.

Inclusion of additional real-life settings to the treatment may have helped to generalise skills to other contexts. All sessions for each individual group were conducted in the same setting whether that was a room in a residential rehabilitation centre, University campus, private charitable organisation, or a local library. Ylvisaker and Feeney (2000) suggests that a treatment in more real world settings is more likely to be successful particularly in the transfer of communication skills to other contexts.

Dahlberg et al. (2007) incorporated a group session in the community to help with the transfer of skills in a treatment for people with ABI who were on average 9 years post-injury although there was no indication as to the importance of that session. The evidence to support the inclusion of real world contexts is limited, but they show promise for future treatments that intend to help a person with ABI transfer skills.

Setting a participation goal may have helped direct a person's attention to how they could use newly learnt skills to other people and settings. The majority of individual goals focused on discrete communicative behaviours (e.g. give more extended responses, talk a little less). Inclusion of a second, "generalisation" goal, may help with transfer. This goal should reflect participation in the home and/or community (Salter et al., 2011) and be meaningful and motivating to the person with ABI, reflecting what they hope to achieve from the treatment (Grant et al., 2012). For example, join in the conversation at dinner or speak to the shop assistant when doing the groceries. These goals would provide a real meaningful context to practise communication, and an opportunity to build confidence. Inclusion of communication partners would ensure realistic goals are set, and help support the person with ABI. Part of the treatment session could also be used to discuss, and reflect what the person is doing to work towards the achievement of the goal. While this may detract from working on a project, the goal could also be linked to project activities after several treatment sessions.

Potentially, the single project focus may have been too narrow to improve QOL. Working on several projects, and/or incorporating a greater self-fulfilling end goal may have contributed to better QOL. Working on several projects at once or in succession, may have given people further opportunities to practise skills, and genuinely perceive positive changes within themselves, which may have led to greater improvements in QOL. Furthermore, the end goal for three of the groups in the current study included a

presentation to others (e.g. people with ABI, carers, and/or researchers). Some of the people in these groups commented that this experience was extremely positive for them, particularly in seeing the reaction of others, and may have also affected how they rated their QOL.

Equally, integrating further strategies to help a person develop a more positive sense of self and increase perceived self-efficacy, might have led to greater changes in QOL, as both these concepts have strong links with QOL (Cicerone & Azulay, 2007; Rutterford & Wood, 2006; Vickery, Gontkovsky, & Caroselli, 2005). Providing opportunities for social comparison where people with ABI could focus on self-attributes that are more or less favourable to others is considered important to developing a positive sense of self (Ownsworth, 2014; Stets & Burke, 2000). Useful strategies are ones that improve self-knowledge and skills development including, discussing one's current view of self, the impact of changes following the ABI, learning to appreciate positive self-attributes, and supporting people to maintain pre-injury activities or develop new ones (Ownsworth, 2014; Vickery, Gontkovsky, Wallace, & Caroselli, 2006). These strategies were not explicitly applied in this study. In addition, improving a person's perceived self-efficacy, could also contribute to improving their QOL (Cicerone & Azulay, 2007). By facilitating a person's understanding of their abilities, and how to use them to complete different tasks in different settings, and provide feedback, with opportunities for self-monitoring, could improve perceived self-efficacy.

The length of treatment may be difficult to achieve significant changes in QOL, and communication skills, from a relatively short treatment period. While people with ABI reported that the length of time for the treatment was adequate, it is possible they were reflecting on the time frame needed for project completion, and indeed further

time may have been needed to make greater improvements in skills and life quality. People with ABI have long-term, chronic problems that affect their communication skills, cognitive ability, and emotional health. Expecting a relatively short focused treatment to make major changes may have been unrealistic (Anson & Ponsford, 2006a). While determining the optimal length of treatment is unclear (see QOL review Table 3.7), additional time to integrate some of the strategies described above, with the potential inclusion of a second project, may be of benefit to people with ABI who are a long-term post-injury.

10.4 Clinical implications

The effectiveness of project-based treatment remains unclear with significant findings that should be interpreted cautiously. However, there are aspects of this study that may have clinical implications for rehabilitation professionals working with people with ABI particularly Speech and Language Therapists. This study has shown that for some people, positive changes can be made to communication skills, and QOL, many years post-injury. Implications include how we engage people with ABI in treatment, the importance of group treatment as a delivery method, and how to set goals collaboratively, using videotaping and texting, and the use of GAS as an outcome measure.

One of the successes of this study was the high attendance of participants with no dropouts. People with ABI were engaged with completing the project and found the end product meaningful, describing strong positive experiences, and satisfaction of being involved. While any conclusions about the treatment are tentative, there was a strong sense of helping others being a core motivation for people being involved. That included projects that help other people with ABI, projects to increase awareness of

brain injury to the general public, or taking part in order to help other people in the group complete the project. This finding suggests that meaningful contexts that involve doing an activity with others, for the purpose of helping others, as described by Levasseur et al. (2010), are incredibly meaningful for people with ABI and can contribute to higher levels of engagement. The notion of doing an altruistic act (*or project*), helps fill the desire people with ABI have to give something back, interact with others, and be involved in an activity that is meaningful (Douglas, 2010a; Häggström & Lund, 2008). This finding has implications for how rehabilitation professionals present a treatment, as it could have an impact on how engaged and motivated to participate, people with ABI are.

Another aspect of the treatment for rehabilitation professionals to consider is the use of groups as a delivery method. The evidence for rehabilitation of people with ABI is strongest for group-based treatments (Cicerone et al., 2011) particularly for people with communication impairments (Togher et al., 2014). Group size was adequate at 2-3 people and enabled sufficient opportunities for feedback and discussion, though people with ABI felt a slightly larger group might have also worked. People with ABI were overwhelmingly positive about involvement in a group to complete the project and highlighted that a good group is one where there is the right mix of people. They described this as involving trust, equal understanding of each other's ability, where people can feel safe, supported, and not judged, and to express their ideas and opinions. These comments attest to the importance of a group that is cohesive, where people value the acceptance and support received from a group, and where the experience and cohesion of the group may be curative in itself for some people, and necessary for other therapeutic factors to function (Yalom & Leszcz, 2005). Moreover, having a good therapist-patient relationship is an essential component to the effect of non-

pharmacological treatments (Prigatano, 2003), can help to improve group cohesiveness (Yalom & Leszcz, 2005), and create a supportive and facilitative environment through which to improve self-awareness (Fleming & Ownsworth, 2006).

This study also highlighted that individualised goals can be set and achieved with the person with ABI and their communication partner within a group context. Communication goals could be set collaboratively with a communication partner, using videotaping as a tool to help develop awareness in people with ABI (Schmidt et al., 2013). A range of strategies were effectively used to help the majority of people (16/21) achieve their goal including, text messaging, metacognitive skills training, and involvement of communication partners. People reported increased awareness and change of communication skills specifically linked to their individual goal, which highlights that goals can be set and achieved, as part of a group treatment. Although it was the combination of these strategies that led to change, many people identified text messaging as a particularly useful strategy to remind them of their goal. In addition, GAS was able to be successfully used to rate achievement of the goal, and the person with ABI was as reliable as their communication partner in rating that achievement. Rehabilitation professionals involved in setting goals should consider the clear goal continuum of GAS (Grant & Ponsford, 2014) as a mechanism of identifying, setting, monitoring and evaluating goals, using video-taping, text messaging, metacognitive skills training, and communication partners, as key factors for working with people with ABI.

10.5 Study limitations

While this was an exploratory trial with feasibility testing, there were several limitations. These are related to the treatment design, which affects the methodological

strength of the study, the collection, and subsequent analysis of the qualitative data, which are discussed below. Despite these limitations, the study would be rated as 6/10 on the PEDro scale, which indicates a study of ‘good’ quality.

The methodological strength of the study is reduced owing to a number of factors. Despite being described as a quasi-randomised controlled trial with alternate allocation of groups, the lack of true randomisation limits the validity and generalisability of the results. As this was a PhD study, there was a lack of an independent assessor of the questionnaires although having blind assessors of the videotaped conversations partially mitigated this. Whilst the therapist (NB) was not blind to treatment groups and timing, having a single therapist improved fidelity even though it limits the extent to which the treatment can be transferred to other therapists, which could be the subject of further research. In relation to fidelity, checks were conducted on 16% of the videotaped treatment sessions, with sessions taken only from the first three treatment groups. Not conducting fidelity checks on more treatment sessions or on the remaining five treatment groups may also be considered a limitation, although other operational strategies were put in place to mitigate against therapist drift.

One of the main limitations of this study would be the small sample size, which was partly due to specific inclusion criteria that the person had to have the time available to attend all sessions, be in the geographical area in which the treatment was being conducted, and be able to consent to participate. People with ABI were chronic and long-term post-injury, with the majority of people living independently either alone or with others (e.g. family, spouse, carer) and not receiving additional rehabilitation services. This profile limits the generalisability of the results to people with less chronic injury or to those who are more dependent on support and services. There was also a limit to the number of people who could be included in a PhD study with a sole

therapist. In addition, there were three videotaped conversations lost for three people in the WAITLIST group, at the second time point. As a result, the power of the statistical analyses comparing the TREATMENT and WAITLIST groups, and change over time for all individuals from pre-treatment to follow-up, is reduced. Overall, the study found modest significant findings, which should be interpreted cautiously. Several outcome measures were used, only some of which revealed significant gains; and adjusting the significance level to take account of potential type 1 errors would further reduce the number of significant findings. Results were also inconsistent. For example, the immediately treated group improved significantly on the MPC (Interaction) scale, when compared to the waitlist controls. However, the repeated measures analysis across all participants, i.e. after the waitlist controls had been treated, no longer showed a significant gain on this outcome. In part these inconsistent findings may reflect the small sample size, underscoring the need for a larger investigation. More optimistically, changes on seven of the outcomes that showed significant change revealed medium or large effect sizes.

For the qualitative analysis, a limitation was the interviewer also being the assessor, and therapist. There are certain advantages to this, as the interviewer had the ability to probe comments more easily. However, assumptions were made by the interviewer, which meant opportunities were missed to probe for additional information, which would have added to the treatment's effectiveness. Non-independent analysis of the interviews is a second limitation. To reduce bias, several interviews were coded separately by two people (NB & MC) and then discussed, as was the final formation of themes and sub-themes. Finally, the data for the qualitative analysis came solely from the post-treatment interviews, which supported the feasibility of the treatment and provided preliminary information of its effectiveness. More detailed information of the

treatment's effectiveness could have been gained through multiple data sources, including observation notes and feedback from communication partners.

10.6 Future research

This study points to the need for further areas of research, both with respect to the treatment content and the outcomes used. A number of these areas have been highlighted throughout this chapter, but some of the key points will be discussed below.

Changes could be made to future trials of project-based treatment that might promote more positive outcomes. Project-based treatment aimed to make changes to both communication skills and QOL. As already discussed, there are potential changes that could be made to the treatment in the future. To help with improving communication skills, factors to consider in future research studies include greater attention to communication, more input to the communication partners, inclusion of real-life settings, setting a participation goal, and more individualised support to the person with ABI. For improving QOL, completing more than one project, and integrating more strategies to help the person with ABI develop a positive sense of self, and increased perceived self-efficacy should be considered. Recent developments in the field of positive psychology (Seligman, 2011), which explores factors that improve well-being and make a life worth living, may also contain specific strategies relevant to working with people with ABI (Evans, 2011), and people with communication impairments (Sharp, 2012). For example, strategies may include the identification of character strengths, use of the blessings (record three good things) journal, and a forgiveness letter, to address emotions post-injury. The length of the treatment should also be considered. The optimal length of treatment to create change in behaviour for people that are a long-term post-injury is unclear and further research should explore

this, to ensure gains are made, maintained, and generalised. Finally, future trials should take the research design into account. Any changes that are made to the treatment could first be trialled using a single-case experimental design, before designing a larger trial.

Further examination specifically of the active ingredients of the treatment should be considered. The focus of this study was a behavioural treatment, which was individualised and contextualised to have some effect on a person's behaviour (Ylvisaker et al., 2002). The treatment contained several active ingredients, which were not specified at outset but may be identified in future through examining behavioural change techniques (Michie et al., 2011). A range of 40 techniques (e.g. provide feedback on performance, prompt review of outcome goals, teach to use prompts/cues) have been described to help researchers identify which techniques contribute to the effectiveness of a treatment, and to help describe treatments for implementation and replication in future research and clinical practice (Michie et al., 2011). As many behavioural treatments in brain injury are complex, the investigation of behavioural change techniques to define the active ingredients, and determine the techniques more or less related to positive outcomes would be warranted. Moreover, there is a body of research concerned with the factors that lead to change within group treatments (Lese & MacNair-Semands, 2000; Macnair-Semands, Ogrodniczuk, & Joyce, 2010; Tasca et al., 2014), describing a range of therapeutic factors (e.g. instillation of hope, secure emotional expression, awareness of relational impact, and social learning) that have been shown to grow over time from the point a group is formed (Joyce, MacNair-Semands, Tasca, & Ogrodniczuk, 2011). To examine these factors, inclusion of a measure such as the Therapeutic Factors Inventory-19 (Joyce et al., 2011), could be used to help identify the factors that are more or less important to the perceptions of group members.

Choosing the right measure to determine the effect of a treatment is both a difficult and complex decision to make. Increasingly, scales and questionnaires in brain injury have been defined and described according to the World Health Organisation's International Classification of Functioning, Disability and Health (WHO- ICF)(Geyh, Cieza, Kollerits, Grimby, & Stucki, 2007; Koskinen et al., 2011; Lexell, Malec, & Jacobsson, 2012; Noonan et al., 2009; Perenboom & Chorus, 2003; Salter et al., 2011; Tate, 2010). To guide this process, there are systematic procedures for linking questionnaire items to the framework (Cieza et al., 2002; Cieza et al., 2005). Recently, a group of international researchers have developed WHO-ICF core sets for people with brain injury (Laxe et al., 2013), which contains a list of domains of functioning to help set a standard of what should be measured for this population. Subsequently, these have been compared against existing measures of participation for people with ABI (Chung, Yun, & Khan, 2014). Use of this framework, and core sets, may prove useful in the future for researchers to choose measures that most closely align to the intended aims of the treatment, as can be reflected by the ICF framework.

Further examination of the existing communication and QOL outcomes used in this study would be of interest. Further studies would need to consider a multiple baseline design to ensure that there is stability with the outcomes. While there was no significant difference between the two baseline assessments for the *WAITLIST group*, there was variability at an individual level. Such variability has been noted previously in communication treatment research in TBI (Chia et al., 2015), with similar non-significant findings.

This study also revealed issues with the reliability of conversation ratings (i.e. MPC, MSC, and Impression scales), which have been reported elsewhere (Eriksson et al., 2014; Rietdijk et al., 2015). As correlational analyses revealed strong associations

between scales within the MPC, MSC, and Impression Scales, further research could consider investigating a single scale from each of these outcomes. A second avenue to investigate would be a different measure of conversation. Recently, a Swedish group of researchers have adapted the Kagan scales so that rather than give an overall rating of the conversation, raters are required to give a score for every minute of the conversation (Eriksson et al., 2014; Saldert, Backman, & Hartelius, 2013). This approach may be worth pursuing in the future.

The QOL outcomes show some promise, and inclusion of the QOLIBRI and SWLS, should be considered in future studies investigating the long-term effect of behavioural treatments on QOL. However, for shorter treatments, outcomes that measure other constructs closely linked to QOL should be considered, including perceived self-efficacy (e.g. TBI Self-Efficacy Questionnaire), self-concept (e.g. Tennessee Self-Concept Scale-2), and coping (e.g. Coping Inventory for Stressful Situations). Moreover, two questionnaires that link communication skills with both the construct of perceived self-efficacy (i.e. Communication Confidence Rating Scale for Aphasia) and coping (i.e. Communication-specific Coping Scale) could also be considered in studies examining both communication skills and QOL. Finally, given that self-awareness may influence response to treatment, inclusion of such a measure (e.g. Patient Competency Rating Scale or Awareness Questionnaire) would be recommended in future studies (Anson & Ponsford, 2006b; Winkens, Van Heugten, Visser-Meily, & Boosman, 2014).

10.7 Conclusions

This thesis described the first exploratory study to evaluate the effect of project-based treatment, designed as a broad treatment to improve communication skills and

QOL in people with ABI long-term post-injury. The results of the controlled trial revealed that the treatment is feasible, with a high retention rate, and no dropouts. People with ABI were satisfied and positive with their inclusion in the study. Hypotheses that people with ABI who participated in project-based treatment would have improved communication skills and QOL were only partially supported with several significant findings that should be interpreted cautiously. There were modest, circumscribed improvements for both comparing the TREATMENT group with the WAITLIST group, and change over time for all participants from pre-treatment to follow-up.

There are few treatments examining both communication skills and QOL for people with moderate-to-severe ABI a long time post-injury. Project-based treatment is a potential alternative to other treatments that aim to improve communication skills and QOL, in a field where treatments to remediate communication skills after ABI is rapidly expanding (Togher et al., 2014). Whilst the results from this trial are tentative, further information has been gained about the treatment of people with ABI with communication impairments. These include, how to engage people in treatment, the benefit of groups as a delivery method, and how to set and achieve individualised goals within a group context. Directions for future research should involve exploring changes that can be made to the treatment and what active ingredients may lead to change, as well as choosing treatment outcomes that reflect current thinking particularly with use of the WHO-ICF framework, and further examination of communication outcomes.

The impact of communication problems following an ABI is significant and the results highlight the wider importance of including measures of QOL in treatment studies. Treatments for people with ABI should aim to improve QOL, one of the best indicators of the value of treatments (Gill & Feinstein, 1994), which can have an impact

both on the health and social care needs of a person with ABI. Remediation of communication problems that commonly occur post-injury is important, to ensure that people with ABI are able to maintain social networks, form new friendships, return to work, and re-integrate into the community as successfully as possible after sustaining such a major brain injury.

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Appendices

APPENDIX A

PEDro Scale



PEDro-P Scale

Rating Scale for Randomised and Non-Randomised Controlled Trials

	Rater 1:		Rater 2:		Consensus	
	yes	no	yes	no	yes	no
1. Eligibility criteria were specified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

of variability for at least one key outcome	res	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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APPENDIX B

SCED Scale



SCED Scale

Rating Scale for Single Participant Designs

	Rater 1:		Rater 2:		Consensus	
	yes	no	yes	no	yes	no
1. Clinical history was specified. <i>Must include Age, Sex, Aetiology and Severity.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SP1

	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subjects, therapists or settings						
11. Evidence for generalisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX C

First focus group with consultants: Topic guide

Opening probe question	<i>“Tell me about your experiences of running projects”.</i>	
	Prompt questions	Clarifying/checking questions
	<p>“Do you find a difference between running individual versus group projects?”</p> <p>“Tell me about your experiences of running group projects”</p> <p>“What factors affect success?”</p>	<p><i>“Can you explain what you mean by that?”</i></p> <p><i>“Could you provide an example of that?”</i></p>
Features of projects	<i>“What is important for running a successful project?”</i>	
	Prompt questions	Clarifying/checking questions
	<p>“What skills are important for a therapist to have when running a project?”</p> <p>“What would the role of the therapist be?”</p> <p>“What would you consider important for a therapist to be aware of when running individual sessions, to ensure good sessions?”</p>	<p><i>“So do you mean...?” and “are you saying...” and “it sounds like...”</i></p> <p><i>(Probe points like access, commitment, resources, environmental constraints/changes, working with other staff etc)</i></p>
Manual development	<i>“Tell me what would be important for a manual to contain so other therapists could conduct project treatments”</i>	
	Prompt questions	Clarifying/checking questions
	<p>“What would you like to see in a manual?”</p> <p>“Describe the amount of detail you would want in a manual”</p>	<p><i>“So would you say X is important?”</i></p> <p><i>“Could you give an example of that?”</i></p>
Finalise discussion	<i>“Is there anything else you want to raise?”</i>	

APPENDIX D

Project treatment coding sheet

Essential Treatment Criteria

d understanding of their goal.



Desirable Treatment Criteria

cisions.

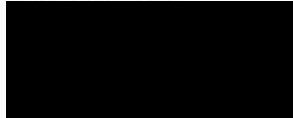


APPENDIX E

BIRT Ethic's approval



Mr Nicholas Behn



21st May 2013

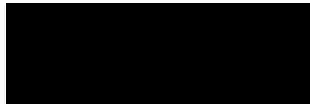
Dear Mr Behn,

Research Proposal: Effectiveness of project-based treatment for people with acquired brain injury (ABI)

Thank you for providing detail of the above proposal for scrutiny by a panel of our Ethics Committee.

I am pleased to confirm that the panel supports your proposal, subject to the condition that participation is limited to those who have mental capacity to consent to do so.

Yours sincerely,



Company Secretary

Direct Tel:
E-mail:



cc



Patrons: Her Grace The Duchess of Northumberland | Vice Patrons: The Rt Hon Lord Robertson of Port Ellen KT GCMG honFRSE PC, Gabby Logan
Life President: Stephen E. Love MA | Life Vice-Presidents: Barbara Besant-Hutchins, Graham Anderson



Founded in 1979, a company limited by guarantee incorporated in England and Wales under registration number 2334589 and registered as a charity in England and Wales under registration number 800797 and in Scotland under registration number SC338972. Incorporating The Brain Injury Rehabilitation Trust, Hamilton Lodge Trust. Registered office: 32 Market Place, Burgess Hill, West Sussex BN15 9HP

APPENDIX F

Post-treatment interviews: Topic guide

Casual conversational task		
Opening probe question	<i>“Your experiences with the treatment are important to us. We’d like to know more about your opinion on how it has been to participate in the treatment. We’ll start with a very general question.... Tell me about your experiences with”</i>	
Other topics probes if not covered...	To pull out change...	Clarifying/checking questions...
<i>“What were your impressions of...”</i> <i>“ How do you feel about ...”</i> <i>“You’ve talked about X, tell me about...”</i>	<i>“Can you compare that to before the treatment/now?”</i> <i>“Can you provide some examples?”</i>	<i>“So do you mean.....?”</i> <i>“Are you saying....”</i> <i>“It sounds like...”</i> Only use Y?N questions here.
Improvements to programme	<i>“If we revised the programme, what would you like to keep?”</i> <i>“And what would you like to change?”</i>	
Assessment Process	<i>“Which ones seemed to make most sense to you when you did them?”</i>	<i>“Did it help explain what changed from the treatment?”</i> <i>“What was still a problem?”</i>
Finalise discussion	<i>“Is there anything else you want to raise?”</i>	
CHECK BACK....	<i>“So overall what you’re saying is...am I understanding that correctly?”</i>	

APPENDIX G

Individual GAS goals

Table G1. Individual GAS goals as texted to participants on a daily basis.

Individual	GAS goal
1	Think about "straight (surname)" and turning OFF the jokes, dominant speaking and tangents. Make conversations 50/50.
2	Think about talking a little less with people and listening to feedback from Ashley and Hayley.
3	Make sure the topic you are talking about is interesting to the other person and makes sense.
4	Not like Barbara, not too much but not too little. Keep it 50/50.
5	Show emotion, and tell us what you're thinking.
6	It's ok to get feedback about my feelings from Helen and Nick and to ask questions (e.g. how you feel about? what do you think about? what's your view on? what have you been up to?).
7	Conversations, eye contact and questions.
8	To make the conversation more interesting and better and not a waste of time by talking about interesting topics.
9	Ask more questions to start or keep the conversation going and to make it more interesting.
10	Use more natural fillers, say less jokes to cover up when I don't know and ask more questions to get the conversation 50/50.
11	Look at the situation, think "how do I deal with it?" and then act. Try new natter outlets (e.g. meditation, church).
12	Remember your tone of voice, gesture and to ask questions.
13	Slow down your speech and remember to not go off on a tangent. We may say to you "that's a tangent".
14	Remember to finish the topic before swapping it, and give less information.
15	"Let's think about that - do I need to say it?".
16	To find a topic of interest to take control of the conversation.

Individual	GAS goal
17	Drop your hand and emphasise key words when speaking. Open the door and let people into the conversation
18	Stand face to face, focus on the other person, and say it back. Keep it 50/50.
19	Show more interest and less boredom by thinking about body language and not a monotone voice.
20	Say "stop, let me talk" and "can I get a word in" to make the conversation more 50/50.
21	Try and give more extended responses in conversations.

APPENDIX H

Raw scores for communication and QOL outcomes

Table H1. Pre-treatment, and post-treatment raw scores for two communication outcomes (N=18), and two QOL outcomes (N=21).

Individual	Interaction		Transaction		SWLS		QOLIBRI	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
1	3.0	2.0	3.0	2.5	21.00	22.00	87.16	89.86
2	3.5	3.0	3.0	3.0	24.00	32.00	80.41	85.14
3	2.5	3.5	3.0	3.5	10.00	16.00	52.70	51.35
4	3.0	3.5	3.0	3.0	27.00	33.00	70.27	72.30
5	-	-	-	-	25.00	28.00	68.24	71.62
6	-	-	-	-	23.00	13.00	75.00	62.16
7	-	-	-	-	18.00	11.00	62.84	81.76
8	2.0	3.0	2.5	2.5	5.00	10.00	60.81	70.95
9	3.0	3.0	3.0	2.5	12.00	21.00	40.54	52.70
10	3.0	3.0	3.0	3.5	12.00	11.00	51.35	27.02
11	3.0	3.0	2.5	3.0	20.00	15.00	21.62	39.86
12	2.0	2.0	2.5	2.5	16.00	20.00	73.65	72.97
13	3.5	4.0	3.5	3.0	15.00	20.00	81.76	77.02
14	3.0	3.0	3.0	3.0	21.00	21.00	43.24	47.97
15	3.0	3.0	3.0	3.5	24.00	22.00	68.24	77.03
16	2.5	2.5	3.0	3.0	21.00	27.00	68.92	79.73
17	2.5	2.5	2.5	2.5	13.00	18.00	55.41	42.56

Individual	Interaction		Transaction		SWLS		QOLIBRI	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
18	2.5	3.5	2.0	3.0	28.00	24.00	72.30	78.38
19	2.0	3.5	2.5	4.0	10.00	13.00	18.92	23.65
20	3.0	3.0	3.0	3.0	33.00	27.00	55.41	47.97
21	3.0	4.0	3.0	4.0	9.00	32.00	29.05	74.32

APPENDIX I

Qualitative analysis themes, sub-themes and categories

Table II. Definition of themes, sub-themes, and categories from qualitative analysis.

Theme	Sub-theme	Category	Definition
TREATMENT EXPERIENCE	General experience	Emotional reactions	Feelings of the entire treatment. Comments specifically about the project are coded separately (despite a link between the two). While the majority of comments are largely positive, some people spoke about early apprehension and reservation.
		Satisfaction of treatment	People provided comments about their satisfaction with the treatment, and any changes they would make. Most comments were positive, with a few practical suggestions (see also “texting” theme).
		Emerging value	The value of the treatment emerged as the treatment progressed.
		Other	These subsume group size, length and intensity of sessions, and appreciation for taking part in the treatment.
	Group experience	Group dynamics/fit	Refer to the fit and dynamics of the group, and the people in the group.
		Emotional reaction	Specific comments and feelings about the experience of the group, and not the project, or general treatment experience.
		Sharing	Refer to the sharing of experiences, ideas and opinions with one another in the group.
		Other	These subsume the group giving people with ABI the opportunity for feedback, a sense of belonging, context to improve communication skills, and the physical environment of the group.

Theme	Sub-theme	Category	Definition
	Project experience	Project motivation	Refer to wanting to do something that could be helpful to others, making others aware of brain injury, giving others with similar difficulties knowledge about ABI, doing a job and getting their story out.
		Emotional reaction	Specific feelings about the experience of doing a project, which for many was positive.
		Project end product	Need to have a tangible end product, and something to focus on.
		Sense of achievement	Doing the group gave a sense of achievement, accomplishment and satisfaction. There is overlap here with emotional reaction (of project experience).
		Other	This subsumes the tasks, activities, and content of the sessions (specific to the individual project group).
	Working on goals	Texting	Specific mention of texting, without reference to the use of texts as a reminder. Comments are generally positive.
		Reminder (memory and goal) reminder	Comments about texts acting as a helpful reminder or prompt, for both the person with ABI, and their communication partner. Some comments referred to the texts reminding individuals of their specific communication goal.
		Goal setting	These statements referred to particular strategies for setting goals, without reference to texting. These included setting goals, videotaping, timing of setting goals and scoring them within sessions.

Theme	Sub-theme	Category	Definition
BENEFIT OF TREATMENT	Communicative benefits		Refer to awareness of communicative ability, and people reporting changes in their communication, sometimes from a situation they have described. Most comments refer to a person's individual communication goal. Comments largely positive, but uncertainty remains for some people with ABI.
	Other benefits		Refer to comments about changes to awareness and skills, in areas other than communication. These include, changes to how people perceive themselves and others, new skills learnt, and cognitive changes (e.g. planning, concentration).
	Emotional effects		Emotional impact of the treatment which evoked predominantly positive feelings but, some negative feelings also described by people with ABI.
	Meeting others		Positive statements about meeting other people in the group, and having the opportunity to socialise with others (these were not statements made specifically about goals or project-related tasks).
	Something to do		Comments about having the opportunity to do something, or be involved in activities other than the project (e.g. going to the shops).
ASSESSMENT EXPERIENCE	Perception of change		Refers to comments made about the assessments and what people felt had changed from involvement in the treatment.
	Length of questionnaires		Refers to the number, and length of questionnaires that were given during the assessment sessions.