Feasibility and initial efficacy of project-based treatment for people with ABI

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ABSTRACT

Background: Communication impairments are common and pervasive for people a long-time following acquired brain injury (ABI). These impairments have a significant impact on a person's quality of life (QOL) post-injury. Project-based treatment is a treatment approach that could have an impact on communication skills and QOL for people with ABI a long-term post-injury. 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 tangible end product.

Aims: To evaluate the feasibility and initial efficacy of project-based treatment on improving the communication skills and QOL for people with ABI.

Methods and Procedures: An exploratory controlled trial with alternate allocation of groups, and follow-up at 6-8 weeks was completed. Twenty-one people with chronic ABI were recruited in groups of 2-3 from community settings, allocated to either a TREATMENT (n=11) or WAITLIST group (n=10). Participants attended a 20-hour group-based treatment over six weeks where they worked towards achieving a project that helped others. To determine feasibility, four criteria were used: demand, implementation, practicality and acceptability. A range of communication and QOL outcomes was used to determine a fifth feasibility criterion, initial efficacy. Some of these criteria were additionally used to evaluate the feasibility of the outcomes.

Outcomes and Results: All participants received the treatment as allocated with high attendance and no dropouts. The treatment was feasible to deliver as intended and was highly acceptable to participants. Medium and large effect sizes were found from pre to post-treatment, and from pre-treatment to follow-up for measures of conversation, perceived communicative ability, and QOL.

Conclusions and Implications: Project-based treatment is feasible with indications of initial efficacy for both communication skills and QOL. The treatment provides a promising new approach for improving communication skills and QOL in people with chronic acquired brain injuries in the community setting.

Keywords: treatment, rehabilitation, communication, cognitive-communication, quality of life, project, controlled trial, brain injury

What this paper adds

What is already known on the subject?

Communication impairments are common after ABI and can have a significant impact on a person's QOL post-injury. Approaches for improving communication skills should be goal-driven, account for existing cognitive and emotional impairments, and view communication skills within a broader context.

What this paper adds to existing knowledge?

This study provides preliminary evidence to show that project-based treatment is a feasible context-sensitive treatment approach to improving communication skills and QOL in people with ABI. Taking part in a group project designed to *help others* was meaningful to participants as was setting individualised collaborative communication goals. The study also provides valuable insight into the feasibility of treatment outcomes used to show change in conversation.

What are the potential or actual clinical implications of this work?

The implications of this study add further evidence for the improvement of communication skills for people with ABI a long-time post-injury. Being involved in a group-based, goal-driven, context-sensitive meaningful treatment can have some positive impact on people with ABI. The approach of completing projects during treatment merits further investigation.

INTRODUCTION

Social communication problems following ABI can lead to difficulties with social appropriateness, topic management, turn taking, and initiating, maintaining and extending a conversation (Coelho et al., 1991, Mentis and Prutting, 1991, Snow et al., 1997). These problems arise primarily from cognitive impairments, including impaired attention, memory and executive function, rather than in aphasia from stroke where the impairments are primarily linguistic (McDonald et al., 2014). Such cognitive-communication disorders (CCD) (Togher et al., 2014) can be difficult to diagnose (Frith et al., 2014) and typically persist for many years post-injury (Bond and Godfrey, 1997).

CCDs are complex and highly heterogeneous (Snow et al., 1997) with a substantial impact on the lives of people with ABI. The presence of these impairments negatively affects the QOL of people with ABI (Dahlberg et al., 2006), particularly in the areas of social functioning, social integration into the community, and return to work (Meulenbroek and Turkstra, 2016). These changes may also underpin problems developing social networks, forming new friendships and relationships, and increased feelings of loneliness and social isolation (Hoofien et al., 2001, Zencius and Wesolowski, 1999).

Context-sensitive treatment approaches for the improvement of CCDs take a broader, more holistic view of communication that incorporates a person's activities and participation (World Health Organisation, 2001), and use a range of impairment-based interventions embedded within functional and real-life contexts (Ylvisaker, 2003). Evidence for these approaches is stronger than for impairment-based interventions and includes being goal-driven, group-based with or without individual sessions, and provides opportunities for communication skills practice and feedback (Finch et al., 2016). These components also form part of recent guidelines that highlighted the importance of individualised communication goals, group-based treatment, and education, training and support to the communication

partner of the person with ABI as key recommendations for the improvement of CCDs (Togher et al., 2014).

Project-based treatment is a group-based context-sensitive approach (Ylvisaker et al., 2007, Feeney and Capo, 2010). It has the potential to have a positive, broader impact on both communication skills and QOL for people with ABI. The 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 to others and/or the wider community (e.g. creating an educational video). The project can produce 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 can result in products useful for others, and offer opportunities for social engagement and communication with others (Feeney and Capo, 2010).

Project-based learning is commonly used as an approach in classroom teaching designed to engage students in exploring problems (Blumenfeld et al., 1991). The approach requires a meaningful driving question, generated by students, that organises the activities of a group and these activities result in a final product that addresses the driving question (Blumenfeld et al., 1991). The notion of projects where there is an end-product designed by the activities of a group have broadly been used in rehabilitation to improve QOL for people with ABI (Vandiver and Christofero-Snider, 2000, Thomas, 2004), and older people in residential care settings (Knight et al., 2010, Southcott, 2009). However, the current evidence base is limited, methodological rigour is lacking, and the treatment is not explicitly framed within the project-based treatment literature, making it difficult to replicate the treatment principles (Feeney and Capo, 2010, Ylvisaker et al., 2007). More specifically, there are no studies that have evaluated the principles of project-based treatment in a systematic way to determine if projects can improve *both* communication skills and QOL in people with ABI.

Therefore, the purpose of this study was to evaluate the feasibility of project-based treatment for improving communication skills and QOL in people with ABI, using a controlled trial, wherein groups of participants were alternately allocated to either an immediate TREATMENT group or WAITLIST control group. As this was an exploratory study of a treatment with little current evidence for people with ABI, the first aim was to test feasibility for a definitive phase III trial of the treatment. 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). A range of criteria have been established for assessing feasibility (Bowen et al., 2009), five of which are relevant to the current study, and have previously been described 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. Feasibility was assessed in respect to two areas: (1) the treatment itself; and (2) the measures chosen. A second aim was to collect initial efficacy data on communication and QOL outcome measures.

METHODS

Participants

People with ABI were recruited from charitable inpatient brain injury organisations and local support groups across the UK. Consultant psychologists and/or speech and language therapists (SLTs) identified potential patients who had been discharged from brain injury organisations. Additionally, day-service coordinators of local support groups identified participants currently receiving input. Inclusion criteria for participants were a diagnosis of

ABI; at least 1-year post-injury; discharged from rehabilitation services; presence of CCD as reported by a SLT; able to identify a communication partner to attend assessment sessions; time available to attend assessment and treatment sessions; a mobile phone that was able to receive text messages; able to consent to participate in the study; and sufficient English to participate in the study. For participants who had sustained a traumatic brain injury (TBI), injury severity was determined by the period of post-traumatic amnesia (PTA), Glasgow Coma Scale score at time of injury, or clinical presentation (i.e. the extent of cognitive and physical impairments). Exclusion criteria included: dysarthria that would affect their ability to be understood by others in the group or severe aphasia, as diagnosed by a SLT; receiving therapy from a SLT for the duration of the study; diagnosis of an active mental health disorder; or significant behavioural problems that would disrupt group participation.

As this was a feasibility trial, 24 participants were targeted with 12 in each arm of the trial, in line with published recommendations (Julious, 2005). Across recruitment sources, 100 potential participants were identified, with 21 eligible participants who provided informed consent to participate in the study. Allocation to groups (of 2-3 people with ABI) was based on geographical location and availability to attend treatment sessions. Alternate allocation of groups to either the TREATMENT or WAITLIST group was then completed throughout the course of the study. In other words, the first group was a treatment group, the second group a waitlist group, the third group a treatment group and so forth.

Intention-to-treat analyses were used. Recruitment and allocation to groups is shown in the CONSORT diagram (Figure 1). Ethical approval for the study was granted by City University London School of Health Sciences Ethics Committee, and the Brain Injury Rehabilitation Trust Ethics Committee.

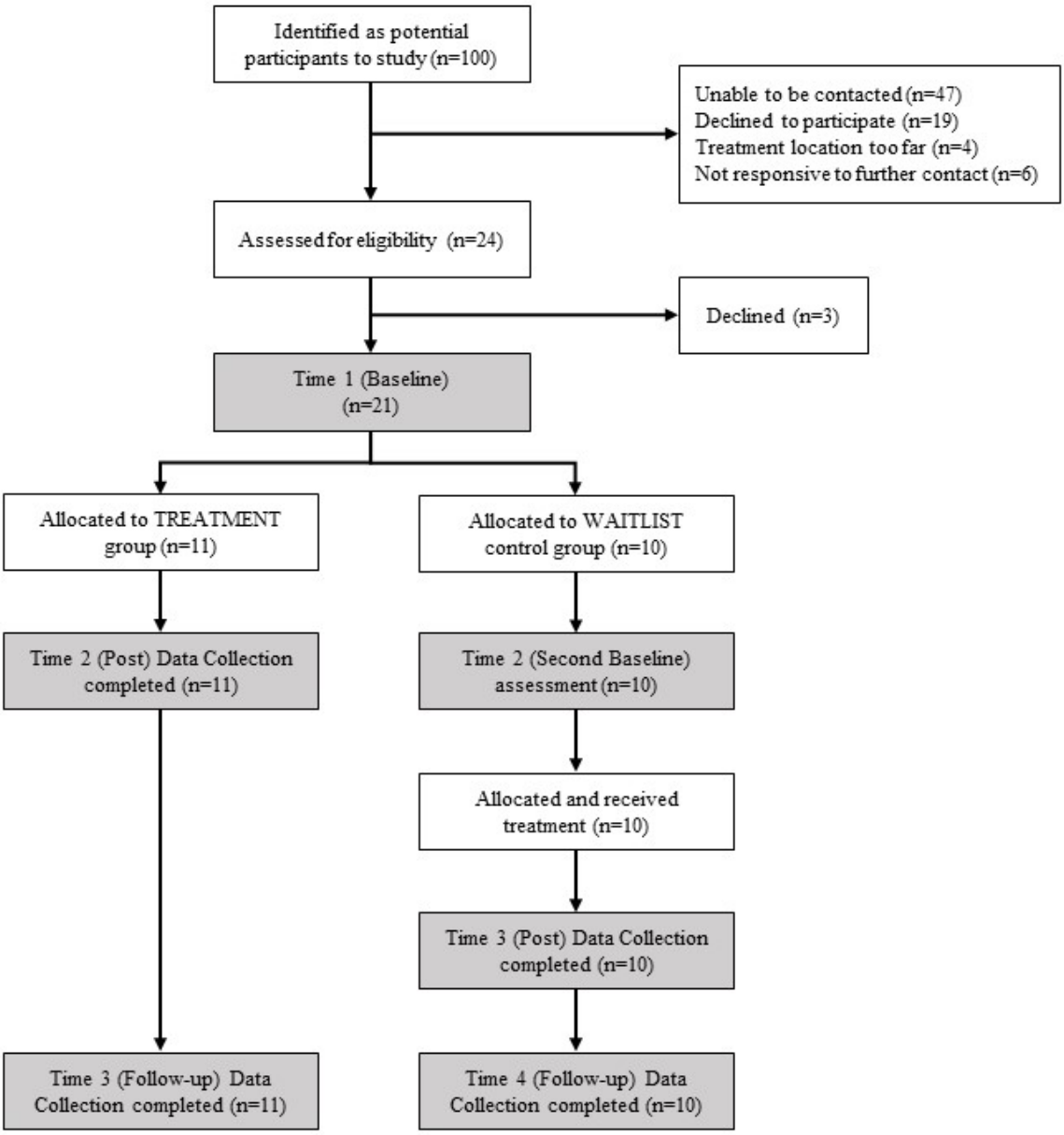

Figure 1. CONSORT diagram

MEASURES

Feasibility of project-based treatment was assessed through five criteria proposed by Bowen et al. (2009). Detail regarding the first four criteria and the way in which they were assessed is comprehensively shown in Table 1. The fifth criterion, initial efficacy was assessed using the following outcomes.

Table 1. *Feasibility criteria and outcomes*

Feasibility criteria	**Outcomes of interest**	**Result**	**Conclusion (Yes/No/Partial)**
Demand *"to what extent was it used?"*	Recruitment rate of participants	21/100 (21%) over 16 months	No
	Retention rate of participants	21/21 (100%)	Yes
	Recruitment rate of communication partners	21/21 (100%)	Yes
	Retention rate of same communication partner at all time points	19/21 (90%)	Yes
	Alternate allocation of groups to each trial arm	All groups alternately allocated to either TREATMENT or WAITLIST group.	Yes
	Retention in trial arm	All participants remained in group to which they were allocated	Yes
Implementation *"was it delivered as planned"*	Grouping of participants	Eight groups completed (five contained 3 participants; three contained 2 participants)	Yes
	Number of sessions	Adherence to format of 1 individual and 9 group sessions over 6 weeks	Yes
	Length of sessions	All sessions 2-hours, allowing time to discuss goals, complete session tasks and rest breaks	Yes
	Participant attendance	13 participants attended 100% of sessions; 8 participants attended 90%	Yes
Practicality *"could it be administered to the intended population"*	Delivery of treatment	All projects completed on-time (https://goo.gl/LhzOCz) All groups could identify a project, tasks and resources required Some projects identified in first group session, others after several sessions	Yes
	Text messaging	All individual goals and actions from group sessions successfully sent to all participants	Yes
	Homework "action plan" tasks completed (as determined by treating therapist)	Completed 73% of the time overall (range = 0-100%)	Partial
Acceptability	Experiences and satisfaction of the treatment	Participant experience of the treatment, group, and project	Yes

"was it satisfying for the intended participants"	overwhelmingly positive with no components deemed unacceptable. Working on goals and use of text messaging reported as useful.

Baseline measures

Injury and demographic characteristics were obtained from each participant including, age, time post-injury, type of injury, and severity (for TBI). Further assessments were administered to assess the range of functioning of participants. To establish a baseline of cognitive functioning, a standardised assessment of cognitive abilities, Repeatable Battery of the Assessment of Neuropsychological Status (RBANS) (Randolph, 1998); and an assessment of executive function, Wisconsin Card Sorting Test (WCST) (Heaton et al., 1993) were administered by an assessor. All remaining measures were self-administered by the participant only. To assess social functioning, a measure of social participation, the Participation Assessment with Recombined Tools – Objective (PART-O) (Whiteneck et al., 2011); and a measure of social support, the Interpersonal Support Evaluation List (ISEL-SF) (Cohen et al., 1985), were completed. For emotional functioning, a measure of psychological distress, the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983); and self-esteem, the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965), were completed. Finally, The Coping Scale for Adults – Short Form (CSA-SF) (Frydenberg and Lewis, 1996) was administered to measure a person's ability to cope post-injury.

Primary outcomes

The *Adapted Measure of Participation in Conversation* (MPC) (Togher et al., 2010) is a measure of communication that contains two scales (Interaction and Transaction) that are each blindly scored by raters to determine the level of participation of the person with ABI

from a videotaped conversation. Interaction refers to how the person with ABI socially connects with the other person, engages and shares the conversation. Transaction refers to how the person with ABI exchanges information, expresses feelings and opinions, and understands the content of the conversation. Both scales use a 9-point Likert scale ranging from 0 (no participation) to 4 (full participation) with 0.5 intervals. The original version of the MPC have well-established inter-rater reliability and construct validity (Kagan et al., 2004), the adapted measures have excellent inter-rater and strong intra-rater reliability (Togher et al., 2010), and have shown sensitivity to change (Behn et al., 2012, Togher et al., 2013).

The primary QOL outcome was *The Satisfaction With Life Scale* (SWLS) which is a valid and reliable global measure of life satisfaction (Diener et al., 1985). The SWLS has five items that are rated on a 7-point scale ranging from 1 (strongly disagree) to 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. The SWLS has been widely adopted to assess a person's life satisfaction following ABI (Corrigan et al., 2001), and has shown sensitivity to change in treatment studies for people with CCDs following ABI (Braden et al., 2010, Dahlberg et al., 2007).

Secondary outcomes

The *Adapted Measure of Support in Conversation* (MSC) (Togher et al., 2010) contains two scales (Acknowledge and Reveal Competence) that rate the conversation skills of the communication partner and the support they provide to the person with ABI on a 9-point Likert scale. As the skills of communication partners can both promote and hinder the skills of people with ABI (Togher et al., 1997a, Togher et al., 1997b) there was some involvement of partners in this study. The adapted MSC was included to detect if the partners

learnt any skills to improve their conversations with participants and/or if any improvements made by participants had an impact on the skills of their communication partner. The Acknowledging Competence (AC) scale 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. The 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 adapted MSC is presented above with the primary outcome measure (adapted MPC). The *Impression Scales* (Bond and Godfrey, 1997) were used to rate the overall impression of the conversation taking into account the skills of both the person with ABI and their communication partner. There are four scales (appropriate, effortful, interesting and rewarding) which are scored on a 9-point Likert scale. Both the adapted MSC and Impression Scales were blindly scored by raters from the same videotaped conversation as used for the adapted MPC.

Perceived communicative ability was assessed with *The La Trobe Communication Questionnaire* (LCQ), which is a reliable and valid 30-item questionnaire (Douglas et al., 2007, Douglas et al., 2000). The questionnaire was self-administered by the participant (LCQ-Self) and their communication partner (LCQ-Other). 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 greater perceived communicative ability.

Communication goals were set with each participant and evaluated using *Goal*

Attainment Scaling (GAS) (Turner-Stokes, 2009) which has been utilised in other communication treatment studies for people with ABI (Braden et al., 2010, Dahlberg et al., 2007). Goals are scored on a 5-point outcome scale ranging from 0 to 4 (Malec, 1999), where 1 was the baseline level. The participant and their communication partner rated the goals separately. The *Quality of Life in Brain Injury* (QOLIBRI) is a 37-item questionnaire completed by the participant to assess disease-specific health-related QOL (HRQOL) (von Steinbüchel et al., 2010a, von Steinbuchel et al., 2010b). 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. While this measure has not been extensively used in treatment studies, part of the feasibility of this trial included piloting emerging outcomes. The QOLIBRI has been tested extensively on people with ABI in the UK and Europe, and has been shown to have good validity, good internal consistency, good test-retest reliability (von Steinbüchel et al., 2010, von Steinbuchel et al., 2010)

Rater training and reliability

Four SLTs were recruited to score videotaped conversations on the adapted MPC, MSC and Impression Scales. Raters were trained to use the scales, which involved familiarising themselves with the scales, scoring videotaped conversational interactions, comparing and discussing any discrepancies. Conversations were randomly assigned to raters, who were blind to the time point of the conversation and the participants group assignment. Raters were not blind to the purpose of the study. To calculate inter-rater reliability, the four raters independenty evaluated twenty-three conversations (32%) of the total data.

Feasibility of measures

The feasibility of the conversational measures used (adapted MPC; adapted MSC; Impression Scales) and the process for participants completing the questionnaires was evaluated in terms of three criteria: implementation; practicality; and acceptability. For implementation, completion of primary and secondary outcomes by participants, and length of time for raters to score videotaped conversational samples using the conversational measures was considered. For practicality, rater training, and reliability of conversational measures was evaluated. Acceptability was judged based on participants' comments from post-treatment interviews completed with each participant.

PROCEDURE

All participants completed a baseline assessment to collect injury and demographic characteristics and to complete assessments that defined cognitive, social, and emotional functioning. Outcome data were collected at three-time intervals: (1) one to two weeks prior to the commencement of the treatment; (2) one to two weeks post treatment; and (3) six-to-eight weeks post treatment (follow-up). Participants in the WAITLIST group had outcome data collected at four time points as they underwent assessment twice prior to the treatment, each separated by a 6-week gap when they received no treatment.

At each time point, participants attended 1 or 2 sessions to complete outcome measures. The participant completed the SWLS, LCQ-Self, QOLIBRI, and their communication partner the LCQ-Other. In addition, the participant and their communication partner participated in a videotaped conversation where they were instructed to 'speak about a topic of interest for 10 minutes' while the researcher left the room (Behn et al., 2012). Conversation has often been used as an outcome of treatment for people that present with communication impairments (Behn et al., 2012, Togher et al., 2013, Kagan et al., 2001).

Where possible, the same communication partner was used for each time point. All sessions to complete the video conversation and outcome measures were taped using a Flip Video Camera HD mounted on a tripod. Video conversations were reviewed and edited to delete inadvertent references to training or times of the year that would have revealed the time of videotaping. The first author then randomised the conversations using a list randomiser (Haahr, 1998).

Additionally the participant and their communication partner rated communication-based GAS goals separately at three time points only (i.e. immediately pre-treatment, post-treatment, follow-up). Semi-structured interviews were conducted with each participant post-treatment to gather qualitative data. A topic guide explored participants experiences of being involved in the treatment, the perceived benefits, and feelings and impressions of particular components that may have contributed to perceived effectiveness. All of the data was analysed by the first author using content analysis (Spencer et al., 2004) where the content and context of the interview transcripts were analysed and themes identified. The first author, who was not blind to treatment condition, completed baseline and outcome measures.

Treatment

Treatment commenced within one week of the last baseline assessment and was completed in ten 2-hour sessions over 6 weeks (see Table 2). Each session had one 10-15 minute scheduled break. Project-based treatment was manualised to standardise the goal setting process and methods to introduce group members to each other and to introduce the idea of a project. The manual gave structure and clarity (contributing to fidelity), but also provided flexible and individualised guidance to the treating therapist (first author) to accommodate the different group projects and individualised communication goals of each person with ABI. The manual was developed in consultation with experts, SLTs and an

occupational therapist with experience in project-based treatment. Session 1 was an individual session that involved the person with ABI, their communication partner, and the researcher who was a qualified SLT (first author). The objective of session 1 was to identify GAS communication goals to be targeted during the treatment (e.g. try and give more extended responses in conversations). Sessions 2-10 were group sessions attended by 2-3 participants and the researcher and conducted in quiet rooms at a geographically central location to each group. Communication partners did not attend these sessions. The group context provided a facilitative and supportive environment where people with ABI could interact and cooperate with others, express their ideas and opinions, and gain and give peer feedback, in order to achieve individualised GAS communication-based goals, and complete a project. To help participants achieve their GAS goals three main strategies were used. First, communication goals were texted to the participant on a daily basis using an online text messaging service (www.textanywhere.net)(Culley and Evans, 2010). Second, communication goals were texted to communication partners on a weekly basis so that they could remind the participant of their goal and help facilitate generalisation of goals outside of the group treatment environment. Third, at the beginning of each group session the participant was invited to verbalise their own goal, self-rate their expected performance for the treatment session (on a scale of 1-10), and rate their performance at the end of the session, with a discussion of any discrepancies or changes they could make for successive sessions.

Table 2. *Description of project-based treatment*

Session	Purpose	Tasks completed
1	• Identify individualised GAS communication-based goals. • Identify strategies to facilitate the dyad's conversational interactions.	• Watched pre-treatment videotaped conversation. • Discussed communication strengths and weaknesses. • Set individual goals formally using GAS, in simple and accessible terms for the participant to understand. • Discussed facilitative strategies and techniques to improve conversations (e.g. positive question style).
2	• For the group members to meet each other. • Share and self-rate communication goals • Introduce the concept of a project to the group.	• Established group rules • Shared individual communication goals and self-rate predicted performance • Discussed each group member's personality, strengths, weaknesses, hobbies and interests. • Defined what a project is, looked at some examples and started to brainstorm possible ideas for a project • Rated performance on individual communication goal and discuss discrepancies in rating.
3	• Introduce a framework for goal planning. • Share and self-rate communication goals • Start developing a project idea. • Allocate specific job roles for each of the group members to undertake as part of the project.	• Shared individual communication goals and self-rated predicted performance • Introduced goal planning framework based on the goal-obstacle-plan-do-review (Ylvisaker et al., 1998), represented using a traffic light system. • Introduced visual scaffolds to help with setting a session-by-session, week-by-week plan of what needed to be achieved.

		• Allocated roles for group members to undertake during the completion of the project (e.g. script writer, computer technician, copy editor). • Rated performance on individual communication goal and discussed discrepancies in rating.
4-10	• Share and self-rate communication goals • Work towards completion of the project.	• Shared individual communication goals and self-rated predicted performance. • Tasks chosen reflected the complexity of the project being undertaken and included tasks such as: videotaping, writing scripts, taking photographs and recording voice-overs. • Group members facilitated to reflect on what had been done, what was yet to be done, time left to complete the project, project changes to be made, and problems and potential solutions. • The final session involved some form of celebration to signify achievement of the project. • Rated performance on individual communication goal and discuss discrepancies in rating.

Data analysis

To determine the *initial efficacy* of the treatment, three main sets of analyses were conducted. First, preliminary analyses assessed the: (1) inter-rater reliability of the outcome measures using the intra-class correlation (ICC)(3,1) procedure (Shrout and Fleiss, 1979) using two-way mixed ICCs with consistency. The single measure ICC is mainly 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; (2) comparability of the groups at baseline was conducted on the demographic characteristics, baseline assessments, primary and secondary outcome measures using independent *t* tests; and (3) the difference between scores at Time 1 (baseline) to Time 2 (second baseline) for the WAITLIST group using paired samples *t* tests to ensure stability of treatment outcomes over time.

The second set of analyses were conducted to determine the effect of treatment on the TREATMENT compared to WAITLIST group. Mixed ANOVAs were used to determine the effect of treatment on the two groups (i.e. TREATMENT vs. WAITLIST) using data from time points 1 and 2. These analyses, therefore, compared participants who had and who had not received treatment. The third set of analyses was conducted to determine change over time for all participants involved in the treatment, and whether any gains were maintained at follow-up. Repeated measures ANOVA were used to determine change over time for all participants involved in the treatment, and whether any gains were maintained at follow-up using data from the TREATMENT (time 1, 2, 3) and WAITLIST group (time 2, 3, 4). Treatment gains were 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. The GAS scores were analysed separately with a Friedman's test as 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. All analyses were computed using SPSS, Version 22.0.

As this is a feasibility study, a stringent criteria based on effect sizes rather than p values was applied, with the exception of the GAS scores. The primary focus of a study should be to determine whether or not the effect of an intervention is clinically rather than statistically important (Perdices, 2017). Effect sizes are independent of sample size and given the sample in this study is small, the effect sizes are more meaningful in the reporting of initial efficacy. To determine effect size we used partial eta squared and classified the size of the effect using the guidelines set by Perdices (2017): small effect (η_p^2=0.01), medium effect (η_p^2=0.13) and large effect (η_p^2=0.26). While we considered both medium and large effect sizes across all analyses, the most meaningful outcomes were those where a large effect was found for *both* the mixed and repeated measures ANOVA's. In addition to offering preliminary evidence of efficacy, large effect sizes would also suggest that the measure would be sensitive to change in a larger, follow-up study. For the GAS scores, a treatment effect was found where a p-value <0.05 was found.

RESULTS

Feasibility of treatment

Table 1 summarises the results of the first four feasibility criteria assessed in detail. Eight projects (from eight groups) were completed within six weeks, and within session time, and participants reported high satisfaction and described positive experiences of the treatment. Most criteria and outcomes were considered feasible however, one outcome was not feasible (demand) and one outcome was partially feasible to complete (homework). Concerning demand, the recruitment rate of participants was not feasible with 21 participants recruited from a pool of 100

(21%) over a 16-month period. Concerning practicality, completion of homework "action plan" tasks was variable with 0-100% of tasks completed by participants (average = 73%) and not entirely feasible. Initial efficacy results are presented below.

Initial efficacy. No significant differences were found between the TREATMENT and WAITLIST groups on the injury and demographic characteristics and initial assessments of cognitive, social and emotional functioning, and coping ability (Table 3). No significant differences were found between TREATMENT and WAITLIST groups for any outcome measures at baseline except the LCQ (other) scores, $t(18) = 0.54$, p=0.03. No significant differences were found between the first and second baseline for participants in the WAITLIST control group. The first set of interaction effects evaluated group (TREATMENT vs. WAITLIST) by time (Time 1 vs. Time 2) (Table 4). Videotaped conversation data for three participants in the WAITLIST group at Time 2 (second baseline) were lost so the sample size for that group is slightly lower (n=7). A large effect size was found for one measure that rated the skills of the communication partner (MSC-RC)($F_{1,16}$=6.64, p=0.02, η_p^2=0.29); and medium effect sizes for a measure that rated the conversational skills of the person with ABI (MPC-Interaction) ($F_{1,16}$=5.11, p=0.04, η_p^2=0.24), and a measure that rated the overall impression of the conversation (Effort)($F_{1,16}$=5.43, p=0.03, η_p^2=0.25). All other outcomes had small effect sizes.

Table 3. *Demographic characteristics*

				TREATMENT vs. WAITLIST		
	ALL people with ABI (n=21)	TREATMENT (n=11)	WAITLIST (n=10)	F	*df*	*p*
Age	45.80 ± 14.47	43.55 ± 14.39	48.30 ± 14.91	-	-	0.47
Gender						1.0[a]
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[a]
Trauma	13 (62%)	8 (73%)	5 (50%)	-	-	
Non-trauma	8 (38%)	3 (27%)	5 (50%)	-	-	
Injury severity (n=13)						1.0[a]
Severe	12 (93%)	7 (88%)	5 (100%)	-	-	
Moderate	1 (7%)	1 (12%)	0 (0%)	-	-	
RBANS						
Total Score	70.85 ± 15.27	70.63 ± 15.80	71.10 ± 15.51	0.06	1,19	0.95
WCST						
Categories	3.62 ± 1.78	3.45 ± 1.70	3.80 ± 1.93	0.043	1,19	0.67
Per. Errors	25.24 ± 15.47	29.18 ± 18.65	20.90 ± 10.25	2.38	1,19	0.23
PART-O	37.52 ± 9.22	36.91 ± 5.70	38.20 ± 12.32	5.34	1,19	0.77[b]

ISEL	20.71 ± 2.76	20.64 ± 3.56	20.80 ± 1.69	2.49	1,19	0.90
HADS						
Anxiety	6.52 ± 4.72	7.27 ± 4.29	5.70 ± 5.25	1.24	1,19	0.46
Depression	6.71 ± 3.59	7.00 ± 3.58	6.40 ± 3.78	0.003	1,19	0.71
RSES	17.24 ± 5.37	16.45 ± 5.68	18.10 ± 5.15	0.14	1,19	0.50
CSA						
Productive	59.43 ± 17.79	55.36 ± 19.60	58.80 ± 14.98	2.09	1,19	0.66
Non-productive	50.29 ± 19.85	53.45 ± 19.39	51.30 ± 22.60	0.55	1,19	0.81
Optimism	56.90 ± 19.40	56.82 ± 19.40	59.50 ± 18.77	0.14	1,19	0.75
Sharing	52.38 ± 29.98	53.64 ± 35.85	47.00 ± 23.12	2.39	1,19	0.62

[a]Fisher-exact statistic. *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.
[b]Levene's test of equality of variances significant so "equal variances not assumed" p value reported

Table.4. *Mean scores, standard deviations, and interaction effects, on treatment outcomes for the two groups.*

Outcome	TREATMENT group			WAITLIST group			Interaction effects			
	N	Pre-treatment	Post-treatment	N	First baseline	Second baseline	F	*df*	*p*	ES[a]
MPC										
Interaction	11	2.72 ± 0.47	3.09 ± 0.63	7	3.07 ± 0.45	2.86 ± 0.48	5.11	1,16	0.04	0.24
Transaction	11	2.77 ± 0.41	3.14 ± 0.50	7	2.86 ± 0.63	2.93 ± 0.19	1.23	1,16	0.28	0.07
SWLS	11	19.09 ± 7.44	21.73 ± 5.55	10	19.30 ± 7.93	17.70 ± 7.48	2.281	1,19	0.147	0.11
MSC										
AC	11	2.55 ± 0.82	2.95 ± 0.88	7	2.79 ± 0.57	2.93 ± 0.35	0.77	1,16	0.39	0.05
RC	11	2.32 ± 0.78	3.00 ± 0.66	7	2.69 ± 0.61	2.64 ± 0.46	6.64	1,16	0.02	0.29
Impression Scales										
Appropriate	11	2.91 ± 0.74	3.32 ± 0.40	7	3.21 ± 0.27	3.21 ± 0.64	2.12	1,16	0.17	0.12
Effortful[b]	11	2.73 ± 0.75	3.23 ± 0.52	7	2.50 ± 0.58	2.29 ± 0.57	5.43	1,16	0.03	0.25
Interesting	11	2.91 ± 0.86	3.14 ± 0.55	7	2.79 ± 0.49	2.93 ± 0.45	0.06	1,16	0.81	0.004
Rewarding	11	2.69 ± 0.98	3.09 ± 0.49	7	2.36 ± 0.56	2.71 ± 0.49	0.02	1,16	0.89	0.001
LCQ										
Self	11	63.45 ± 15.60	64.64 ± 17.81	10	60.10 ± 20.54	57.30 ± 18.73	1.64	1,19	0.22	0.08
Other	11	71.09 ± 16.36	68.09 ± 15.42	9	55.56 ± 12.32	54.00 ± 10.36	0.11	1,18	0.74	0.01
QOLIBRI	11	53.50 ± 22.22	60.13 ± 20.00	10	62.97 ± 20.56	64.93 ± 14.24	0.629	1,19	0.438	0.03

Note. Values are mean ± SD. [a]ES=effect size (η_p^2). [b]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 Questionnaire. SWLS = Satisfaction With Life Scale; QOLIBRI = Quality of Life in Brain Injury.

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 (Table 5). A large effect size was found for one measure which rated the skills of the communication partner (MSC-RC)($F_{2,34}$=7.4, p=0.002, η_p^2=0.30). Medium effect sizes for found for four measures which rated the skills of the communication partner (MSC-AC)($F_{2,34}$=3.78, p=0.03, η_p^2=0.18), perceived communicative ability as rated by the communication partner (LCQ-Other) ($F_{2,40}$=3.48, p=0.04, η_p^2=0.15), and both quality of life measures, the SWLS ($F_{2,40}$=2.972, p=0.06, η_p^2=0.13) and QOLIBRI ($F_{1.46,29.15}$=3.622, p=0.05, η_p^2=0.15). All other measures had small effect sizes.
The treatment found a significant increase over time in GAS scores as rated by the participant, $X^2(2)$=28.71, p<0.001, and their communication partner, $X^2(2)$=25.48, p<0.001 (Table 6). In other words, both respondents perceived achievement of individualised communication goals over time.

Table 5. *Change over time comparisons for all people with ABI (N=21)*

	N	Pre-treatment	Post-treatment	Follow-up	F	*df*	*p*	ES[a]
MPC								
Interaction	18	2.78 ± 0.46	3.06 ± 0.57	2.97 ± 0.63	1.75	2,34	0.19	0.09
Transaction	18	2.83 ± 0.34	3.06 ± 0.48	2.89 ± 0.53	1.81	2,34	0.18	0.10
SWLS	21	18.43 ± 7.30	20.76 ± 7.20	21.48 ± 6.88	2.972	2,40	0.06	0.13
MSC								
AC	18	2.69 ± 0.69	3.06 ± 0.76	2.72 ± 0.71	3.78	2,34	0.03	0.18
RC	18	2.45 ± 0.68	2.98 ± 0.63	2.60 ± 0.64	7.40	2,34	0.002	0.30
Impression Scales								
Appropriate	18	3.03 ± 0.70	3.19 ± 0.57	2.86 ± 0.61	2.37	2,34	0.11	0.12
Effortful	18	2.56 ± 0.70	2.94 ± 0.82	2.72 ± 0.71	1.78	2,34	0.19	0.10
Interesting	18	2.92 ± 0.71	3.03 ± 0.70	2.92 ± 0.60	0.27	2,34	0.77	0.02
Rewarding	18	2.69 ± 0.81	2.89 ± 0.65	2.67 ± 0.61	1.00	2,34	0.38	0.06
LCQ								
Self	21	60.52 ± 17.01	61.95 ± 17.11	58.81 ± 15.62	1.67	2,40	0.20	0.08
Other	21	62.95 ± 16.08	63.14 ± 16.10	57.19 ± 14.92	3.48	2,40	0.04	0.15
QOLIBRI	21	58.94 ± 19.29	63.16 ± 19.25	65.89 ± 18.24	3.622[b]	1.46, 29.15	0.05	0.15

Note. [a]ES=effect size (η_p^2). [b]Greenhouse-Geisser reported here as Mauchly's test of sphericity was significant at <0.05. 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.

Table 6. *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

Feasibility of measures

Concerning implementation, completion of all questionnaires (SWLS, LCQ, QOLIBRI), videotaped conversations and GAS goals was feasible as they were completed at all time points for all participants. The length of time to rate conversations on the measures (adapted MPC, MSC, Impression Scales) was not entirely feasible. Raters spent approximately 30-40 minutes to score each conversation which involved watching the conversation twice with additional time to reflect on scoring for each of the measures. For practicality, rater training took 18 hours (across five sessions) to achieve acceptable levels of reliability for them to continue rating on the videotaped conversations from the study. Reliability of the conversational measures (based on 32% of the data which was randomly and blindly assigned to raters) was varied with the majority of scales with *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 excellent. Table 7 below shows the ICCs and confidence intervals for the conversational measures.

Table 7. *Intra-class correlations and 95% confidence intervals for conversational measures*

Outcome	ICC	95% CI
MPC		
Interaction	0.73	[0.56, 0.86]
Transaction	0.66	[0.48, 0.82]
MSC		
AC	0.71	[0.54, 0.85]
RC	0.90	[0.80, 0.95]
Impression Scales		
Appropriate	0.63	[0.44, 0.80]
Effortful[a]	0.60	[0.40, 0.78]
Interesting	0.63	[0.44, 0.80]

Rewarding	0.71	[0.54, 0.85]

Note. [a]Note 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

The acceptability of the outcomes was determined by the participants comments on their completion. Participants expressed uncertainty over what might have changed, with poor recall of items of the questionnaires. The number and length of questionnaires (i.e. three questionnaires with 72 items in total) was considered acceptable by participants.

DISCUSSION

This study provides preliminary feasibility and efficacy data of project-based treatment for improving communication skills and QOL in people with chronic ABI. Positive feasibility results were found for the implementation, practicality and acceptability of the treatment. There was 95% overall attendance for all sessions (one-individual and nine-group treatment sessions), higher than the 75-83% reported in other treatment studies involving people with ABI (Aboulafia-Brakha et al., 2013, Dahlberg et al., 2007, Togher et al., 2013). All eight projects were completed within six weeks, and within 2-hourly sessions, and participants reported high satisfaction and described positive experiences of the treatment.

While recruitment rate was low (21%), it was comparable to other ABI studies (between 15-27%) who have recruited from rehabilitation centres and community-based programs (Dahlberg et al., 2007, McDonald et al., 2008) and highlights a challenge in recruiting participants from this population. Many participants (47%) could not be contacted as many had

been discharged from services months or years earlier and may have moved home and changed their contact details. This is a problem for a group of people who are often isolated, lose touch with services, and lack initiation to respond. Participants who declined or withdrew after eligibility reported they did not want to be reminded of their ABI and felt that the treatment was not suited to them, which may be related to poor awareness and/or adjustment that can affect one's ability to engage with a treatment (Ownsworth, 2014). Four people could not be involved due to a lack of other local participants to form a group, which is an issue with group-based treatments. Recruitment was comparably easier from local support groups as people were engaged with those services. These findings would suggest that future trials need to recruit from a larger pool of participants and from a range of services (e.g. local hospitals, comprehensive brain injury rehabilitation programs, local support groups). This study did recruit people with more chronic injuries than would otherwise have been identified if recruitment was completed soon after discharge to ensure contact details are accurate, or with people already engaged in services could be considered. Despite the low recruitment rate, retention was excellent at 100% for participants and very high at 90% for communication partners. Waitlist participants remained engaged during the six-week wait and two baselines. The highly individualised nature of the treatment, of both goals and projects chosen by each group, is likely to have contributed to high retention.

This study provided valuable information about the feasibility of the outcomes. All outcomes were completed at all time points for each participant with no reports of participants being burdened by the number of outcome measures or the length of time to complete them. Other feasibility aspects of the outcomes require attention. The time taken to train raters and for raters to score each videotaped conversation using the chosen conversational scales is not

entirely feasible with larger amounts of data. Reductions to the training time and length of conversations to a 5-minute sample (Togher et al., 2013) may help to improve the implementation and practicality of the outcomes. The inter-rater reliability of the scales was more varied than reported in earlier studies (Togher et al., 2013, Togher et al., 2010, Behn et al., 2012), with four newly graduated practising SLTs as raters. Inclusion of fewer, more experienced therapists may improve reliability however, further work to streamline the number of scales may also need to be considered in the future. Some preliminary information was gained to show stability of the conversational measures (adapted MPC and MSC, Impression Scales) over a no-treatment period for participants in the waitlist group. Some indications of sensitivity of some of the measures was also obtained. No significant changes were found for several self-reported questionnaires, which may have been due to their lack of sensitivity to detect change from the treatment. However, participants expressed uncertainty as to what questionnaires had changed post-treatment with poor item recall, suggesting a lack of alignment between the chosen outcomes and the treatment although the nature of a participants cognitive impairments may also be a related factor. As a result, careful consideration should be taken regarding the use of similar outcomes for any future trials of the treatment. The use of GAS to set and rate goals was feasible; with achievement of goals and high participant satisfaction including the use of text messaging to improve goal recall (Culley and Evans, 2010).

There was some evidence of initial efficacy, albeit weak. It is of concern that the conversational measures were burdensome to score and not entirely indicative of change. Only one measure that rated the skills of the communication partner (adapted MSC-RC) showed large effects across all analyses completed. For all other measures, only medium effects were found in the between group analyses (adapted MPC-Interaction; Effort), or analyses that combined scores

from both groups over time from pre-treatment to follow-up (adapted MSC-AC; LCQ-Other; SWLS; QOLIBRI). Goal Attainment Scaling showed that participants and their partners detected change post-treatment against their individualised communication goals, and this change was maintained at follow up. Scores of the adapted MSC-RC scale suggested that partners became more adept post therapy at revealing the communication ability of the person with ABI, although these skills did not seem to maintain at follow up. Inclusion of individualised goals in this treatment was important to high rates of goal achievement. These changes may extend to the behaviours of communication partners despite their relatively minimal involvement in the therapy. While these results appear positive they should be interpreted cautiously given the low power of the study. A more highly powered study of project-based treatment would need to be completed before making firm conclusions of the efficacy of the treatment, and the measures used to detect change.

This study provides valuable insights into future changes that could be made to the content and delivery of the treatment. More or longer sessions may be needed to demonstrate broader changes to conversation and QOL. Evidence for treatment studies using a context-sensitive approach suggest a minimum of 10 weeks (Finch et al., 2016), but this can often be challenging for clinicians. Preliminary data from this study show that for some people a long time post-injury, a single targeted communication goal can be achieved within six weeks however, more time may be needed to effect further change. This finding reflects the extent of impairments a person has following an ABI and the time and effort needed to ensure gains are maintained and generalised beyond the clinic environment. Some participants, due to changes in awareness, may have benefited from additional individual sessions, which have been adopted in other communication-based studies (McDonald et al., 2008, Togher et al., 2013). For greater

change in communication skills the treatment may benefit from an additional focus on training conversational skills and strategies (Togher et al., 2013, Dahlberg et al., 2007, McDonald et al., 2008), increased involvement of the communication partners (Togher et al., 2013), and setting a real-life participation goal to help with generalisation (Grant et al., 2012). In addition, integrating further strategies to help a person develop a more positive sense of self and increase perceived self-efficacy might have also led to greater changes in QOL as both these concepts are strongly associated (Cicerone and Azulay, 2007). With any changes to the treatment, steps would need to be taken to ensure that the on-going implementation, practicality and acceptability of the treatment remain intact for participants.

LIMITATIONS

The study is limited by a small sample size, which made it difficult to detect differences between groups and participants over time. The design of the study had an alternate allocation of groups to either the treatment or waitlist arm of the trial, owing to the difficulty in recruiting groups of participants from a similar geographical area. As a result, the lack of true randomisation limits the validity and generalisability of the results. Participants had also sustained chronic injuries which limits the extent with which results can be translated to less chronic, more acute injuries. Three participants in the WAITLIST group had missing videotaped data, which also reduced statistical power. There was no independent assessor of the questionnaires although the inclusion of blind assessors for the videotaped conversations partially mitigated this. In addition, having a single therapist who was not blind to treatment groups and timing could limit the extent to which the treatment can be transferred to other therapists.

CONCLUSIONS

Project-based treatment shows promise, as a broad context-sensitive treatment to improve communication skills and QOL in people with ABI who have sustained chronic injuries. In a field where treatments to remediate communication skills after ABI is rapidly expanding (Togher et al., 2014), the challenge is often designing treatments that are effective, evidence-based, and feasible in clinical practice for SLTs and other rehabilitation professionals. The results of the trial revealed that the treatment is feasible with some preliminary efficacy data suggestive of improvement with a larger sample size. Future research should explore factors to help identify the type of person and CCD who would benefit most from this treatment, and make changes to the treatment content to ensure the most gains in communication skills and QOL are made. Moreover, existing and new treatment outcomes that align with the treatment and show responsiveness to change should also be considered. The impact of communication problems following an ABI are significant on a person's QOL, and research into the effectiveness of project-based treatment on both these areas is warranted in any future investigations.

Acknowledgements

We would like to acknowledge the contribution of study participants; the assistance of staff with recruitment; and the students who helped to rate the conversational interactions of participants in this study.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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