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Reporting on novel complex intervention development for adults with social
communication impairments after acquired brain injury

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ABSTRACT

Purpose: Interventions are often poorly described in published controlled trials, with relatively little information regarding intervention development, content and fidelity. This makes it difficult to conduct replication studies, interpret and compare findings across studies and for therapists to deliver the intervention in clinical practice. Complete reporting of interventions (including fidelity) is now recommended for treatment studies, and this standardised approach is achieved using the Template for Intervention Description and Replication (TIDieR). The aim of this paper is to describe the multi-phase process of developing a novel intervention for adults with acquired brain injury (ABI), and report on the findings from involving practicing therapists in this process.

Methods: Phase 1 involved a review of relevant literature and specifying the intervention as a prototype intervention manual. Phase 2 comprised a focus group with eight practicing therapists exploring their experiences and perceptions of the intervention, potential active components, and essential elements; it also included review of the prototype manual. Data from the focus group discussion was transcribed and analysed thematically. Phase 3 investigated actual fidelity of the intervention undertaken, achieved by observers viewing videoed sessions and appraising against the fidelity checklist, which was then analysed using Cohen's kappa.

Results: Project-based intervention was defined as having six essential elements: a project or tangible end product focus; group-based intervention; individualised communication-based goals; communication partner involvement; acknowledgement and support of participants' cognitive ability; and consideration and plan to address impaired awareness. Analysis of

focus group data revealed four themes of essential elements; group context; therapeutic skills; and manual core components and informed the development of a fidelity checklist with 13 essential and 6 desirable criteria. Fidelity assessed using percent agreement was acceptable for almost all rater pairs; where significant, Kappa coefficients had values ranging from poor to excellent ($k=0.34 - 1.0$) depending on rater pair and session.

Discussion: The TIDieR framework provided a clear systematic approach for the complete description and reporting of a complex communication intervention for people with ABI. This paper comprehensively described the development and manualisation of an intervention in collaboration with practicing therapists which can be used for future testing. In addition, the process undertaken has the potential to inform rehabilitation researchers in other fields on the development of complex interventions.

INTRODUCTION

Detailed description of the rehabilitation intervention provided is increasingly important in healthcare research and practice. This includes specification of the intervention content and delivery, and there is particular emphasis on active components that theoretically or hypothetically explain how intervention should achieve change for the intended population. A number of recent studies however suggest that reporting of interventions provide inadequate detail. Whilst treatment regime and dose were relatively well reported, van Heugten and colleagues [1] systematic review of 95 randomised trials of cognitive rehabilitation for adults with ABI found very little information reported on intervention content. A smaller review of 14 randomised trials of memory rehabilitation group interventions for neurological conditions [2] found intervention development, duration, group size and composition, and the content and structure were particularly poorly reported. Within speech pathology, a recent review of 162 randomised controlled trials of various interventions found better reporting of intervention regime (largely intervention delivery) and poorer (less) reporting of intervention content [3]. These findings are not specific to ABI or speech pathology, but indeed persistent across fields for example physiotherapy [4] and non-pharmacological interventions [5]. Finally, several studies indicate that published controlled trials to date have insufficiently described the active components of the intervention under investigation [1, 3, 4, 6], with consequences for replication and translation to practice [7, 8].

A further aspect of intervention description not widely examined is that of fidelity, which examines whether an intervention was implemented as intended, and is important for interpretation and rigour of findings [9] specifically being able to make decisions about intervention efficacy and replication. In the review of aphasia interventions by Hinckley and Douglas [10] only 14% (21/149) of studies explicitly reported intervention fidelity. More recently, Ludemann and colleagues [3] found that procedures for monitoring fidelity were

described in 59% of studies, and actual details of how well the intervention was delivered reported in 46% of studies. The authors of both reviews have consistently argued for better reporting of behavioural intervention trials including fidelity practices, and the need for clear guidance to assist in this process. Internationally acknowledged reporting guidelines can facilitate this. Both the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement [11] and Standard Protocol Items (SPIRIT) 2013 statement [12] contain a single item each that recommends authors describe an intervention in as much detail to ensure replication. However, this single item is insufficient for describing many of the interventions that exist in rehabilitation research [13]. Subsequently the Template for Intervention Description and Replication (TIDieR) was developed to provide more comprehensive guidance to researchers and constitutes a checklist of 12 items for minimum information recommended for intervention description [7]. The TIDieR was developed following a literature review, a Delphi survey of an international panel of 125 experts to guide item selection, and a face-to-face panel meeting, and followed the methodological framework for developing reporting guidelines as advised by the EQUATOR Network (<https://www.equator-network.org/>).

Communication impairments are common following ABI and can have a significant effect on life participation particularly in areas of social functioning, social integration into the community and return to work [14, 15] with subsequent impact on quality of life (QOL)[16]. Remediation of these impairments is complex as people with ABI can present as a heterogeneous group with the pattern of deficits varying amongst individuals [17]. As a result, interventions are considered complex and difficult to define as they are multifaceted, containing several potentially ‘active ingredients’ or components. 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”, p.2) [18].

Complex interventions are also hard to define because they are frequently tailored to the specific problems and goals of the individual or group [19], particularly for adults with ABI where interventions need to be individualised and contextualised [20].

This paper reports on the process of developing a novel complex intervention for adults with ABI. Current evidence for social communication interventions is stronger for context-sensitive approaches compared to impairment-based interventions [21]. Context-sensitive approaches take a broader, more holistic view of communication, and use a range of impairment-based approaches within real-life contexts [22]. Project-based intervention is a group-based context-sensitive approach, for which some evidence exists in other populations including education [23], ageing [24] and ABI [25, 26]. Participants engage in groups, and as a group, chose a tangible *project* to complete, designed to help others [25, 26]. The project provides participants opportunities to address the range of communication, cognitive, behavioural and emotional changes that can occur following ABI [17]. While early work on project-based intervention for adults with ABI provided an operational definition [25, 26] replication is difficult, as the intervention was minimally described as 10 guiding principles [25, 26]. For example, features include “focuses on a personally meaningful goal, ideally a goal that includes a concrete product” and “requires deep processing and thorough analysis/investigation of many dimensions of a problem or activity” [26, p286]; and principles include “contextual supports are critical to success” [25, p72].

Our intervention has been tested in a study, comparing the group-based intervention to usual care using a waitlist-controlled design in 21 adults with ABI, where participants engaged in small groups of 2-3 participants [27]. Findings indicate the intervention was feasible and led to some positive changes in communication skills and QOL. However, each delivery of the intervention was different according to the individuals in the group, and the project chosen. This flexibility poses a challenge for intervention description. Thus, the

overall aim of this current paper is to report on the development process, intervention description and fidelity findings of a novel complex intervention. The paper is structured around three phases: the first phase aims to manualise project-based intervention using the TIDieR checklist, and reports on the literature review and manualisation of the intervention arriving at a prototype for discussion; the second phase aims to validate the proposed intervention and develop materials for testing fidelity, with involvement of practising therapists; and the third phase aims to report the actual fidelity achieved of project-based intervention via observers rating videoed session delivery using a bespoke fidelity checklist.

Methods

Phase 1: Manualisation of intervention using TIDieR

Studies on project-based intervention were first identified through a manual hand search of existing literature in ABI [25, 26]. Seminal studies in education [23, 28] were identified through general literature searching, and further searches revealed additional studies in ageing [24, 29, 30, 31]. Literature on remediation of communication impairments after ABI was then identified from within the PsycBITE database, a repository of external quality-rated research studies drawn from seven databases. A search performed in November 2014 using the terms: all study types (method), TBI/Head Injury (neurological group), language/communication/speech (target area), adults 18+ and English found 30 articles which reported on social communication interventions for people with ABI. Thirdly, literature syntheses (systematic and non-systematic reviews [32, 33] and best practice recommendations derived from an international panel of expert researchers and clinicians in cognitive rehabilitation (known as INCOG) [34] were reviewed. From the reviewed literature, essential elements, strategies and exercises were identified and extracted that may be suited to the current design of the intervention.

The first author who has 15 years clinical experience in the field of ABI, and experience of delivering and evaluating manualised intervention in this population [35], drafted the intervention manual prototype. The prototype manual provided a detailed introduction and overview of the proposed intervention, including session by session outlines. The manual was first submitted for expert review. This was conducted by the third author (internationally leading researcher in the field) and a practising Speech and Language Therapist from Australia who had 12 years' experience in working with adults with ABI and in conducting project-based intervention, chosen specifically for expertise in proof reading manuals for publication. The manual was then considered in the Phase 2 focus group. The TIDieR checklist (comprised 12 items) which is considered in the results succinctly describes the essential elements of the intervention, dosage, setting and mode of delivery, materials, procedures and fidelity.

Phase 2: Validation of intervention and development of materials

Practising therapists were recruited from local brain injury professional networks to voluntarily participate in this study as consultants. Inclusion criteria were: (1) practising health professional (e.g. Occupational Therapist, OT; Speech and Language Therapist, SLT); (2) have more than 2 years' experience of treating adults with ABI; and (3) experience of what they would perceive as project-based intervention. Eight therapists expressed interest in participating (C1-C8) and were eligible and thus recruited. Therapists (7 SLTs, 1 OT) had an average 8.63 years' experience working with adults with ABI (3-13 years) and an average 6.75 years' experience (2-13 years) in what they would perceive as project-based intervention. Consultants C1-C6 participated in two focus group sessions, and consultants C1-C4 and C7 and C8 participated in the fidelity testing.

In the first (of two) focus group sessions, consultants were asked a series of questions that probed their thoughts and opinions as to what components were important to project-based intervention for adults with ABI and what materials they would expect to see in an intervention manual. Three key questions were presented: ‘tell me about your experiences of running projects’, ‘what would the role of the therapist be?’ and ‘what would you like to see in a manual?’. Efforts were made by the facilitator (first author) not to influence the opinions of the consultants but rather probe and encourage elaboration and examples of what was being said. The session was audio and videotaped. Qualitative data from the session was transcribed verbatim and analysed to identify meaningful codes of information, which were used to form categories [36]. A constant comparative analysis technique was used to compare codes and categories [37]. As similarities and differences were identified between codes and within categories, data were rearranged and re-categorised into emerging themes.

To validate the accuracy of the findings two steps were undertaken: (1) themes, categories and codes of meaningful data were checked and verified by the last author, and some data were re-coded and re-arranged following this check; and (2) member checking was conducted with the consultants in a second focus group session. No changes were made to the data following this check. Data were used for two purposes: to validate the prototype intervention manual, including specifics pertaining to proposed active components; and for developing a behavioural checklist of intervention fidelity. The second focus group session was used for the consultants to review the manual and checklist in detail before they were finalised.

Phase 3: Fidelity

The fidelity checklist, which was developed from the focus group themes, contained observable behaviours of the trainer and/or participant during intervention sessions. The

checklist was used to rate the presence or absence of behaviours from videoed sessions using a 3-point scoring scale: (1) absent; (2) present to some degree; or (3) present [36] (Table 1). Behaviours were classified as essential or desirable criteria (not required but would enhance the delivery of the intervention if present i.e. group facilitation skills), and categorised into behaviours specific to the project, participant and therapist. The checklist was then checked and agreed with the authors and consultants in the second focus group session. The final checklist comprised 13 essential (items 1-13) and 6 desirable behaviours (items 14-19): 4 project-related behaviours (items 1-4), evident from the behaviour of participants and/or therapist; 10 therapist behaviours (4 essential – items 5-8; 6 desirable – items 14-19); and 5 participant behaviours (items 9-13).

Table 1. *List of essential and desirable criteria on the fidelity checklist*

Essential Criteria – Project-behaviours		Present	Present to some degree	Absent
1.	People make reference to what the end goal is during the session (i.e. it is easy to identify what the project is)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Each of the participant's roles in the project can be clearly identified during the session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Each participant's individual goal(s) can easily be identified in the session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	The rationale for the session can be identified and a plan for how it will be organised is clear throughout	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Essential criteria – Therapist behaviours				
5.	The therapist facilitates and supports identification of problems and a range of options/actions to solve them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	The therapist uses appropriate tools and strategies to support the session (e.g. visual scaffolds)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	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?")	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	The therapist is flexible during the session (i.e. able to listen to different ideas and opinions and able to modify on-line through negotiation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Essential criteria – Participant behaviours				

9.	The project appears meaningful and motivating to participants within the group	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	In order to achieve the project, participants initiate interaction with other group members	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Participants demonstrate an understanding of the plan for the session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Participants contribute to the plans and/or any problems that may arise in the session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	The participant demonstrates an understanding of their goal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Desirable criteria – Therapist behaviours

14.	The therapist communicates respect to participants in a non-patronising and sensitive manner (e.g. by acknowledging difficulties that they may have)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	The therapist can re-direct and focus the group back to the project when the conversation goes off topic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	The therapist seeks and gives information and/or encourages discussion without dominating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	The therapist gives positive feedback (i.e. to reward interaction and suggestions made by participants)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19.	The therapist seeks agreement from all participants when making decisions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Across the study, eight intervention groups were delivered to a total of 21 participants with ABI. Five groups contained three participants and three groups contained two participants. Each group was comprised a single individual session followed by nine group sessions. All intervention sessions were videotaped. Consultants completed fidelity checks of randomly selected intervention sessions using the bespoke behavioural checklist (Table 1) which has been the method used in other brain injury treatment studies [39, 40]. Three consultants (C1, C2 and C7) rated two sessions from the first two intervention groups, and two different consultants (C4 and C8) rated one session from the third intervention group. Most researchers perform fidelity checks on between 10-20% of the data [10]. In this study, 11% of the group-level data (3/27 sessions) from the first three treatment groups was checked. These prospective checks were completed to prevent therapist drift and to ensure that sufficient time was allowed to make any necessary changes to the treatment for any successive groups.

The consultants were instructed on the use of the checklist in order to make appropriate judgements. Percent agreement between consultants was first calculated where >70% was regarded as an acceptable level of agreement [41]. Cohen's kappa was also used [42] where a kappa coefficient of .75-1.00 is excellent, .60-.74 is good, .40-.59 is fair and below .40 is poor [43]. As *three* consultants were used for two intervention groups, agreement was determined between each consultant pair [44].

Results

Phase 1: Manualisation of intervention using TIDieR

A concise overview of the intervention is provided below with further detail according to the TIDieR checklist (Table 2). In applying project-based intervention to adults with ABI, there are six essential elements: a project or tangible end product focus; group-

based intervention; individualised communication-based goals; communication partner involvement; acknowledgement and support of participants' cognitive ability; and consideration and plan to address impaired awareness. An intervention manual was used throughout the study and provides substantial background information for a therapist to deliver it, as well as resources such as goal-setting handouts, and visual scaffolds to assist with goal planning, problem solving and organisational behaviour. Various other materials were used according to the selected projects, such as videotaping equipment and editing software; printing equipment; craft supplies; a camera; on-line digital music and USB drives; and computer and internet access. Session procedures included planning, problem solving, verbal prompting and feedback to complete the project. Memories were aided with memoires (minutes) alongside texted action points to support recall and carry over.

Table 2. Project-based intervention TIDieR Checklist

TIDieR Item	Description
<p>1. Brief Name Provide the name or a phrase that describes the intervention.</p>	<p>Group communication project-based intervention</p>
<p>2. Why Describe any rationale, theory, or goal of the elements essential to the intervention.</p>	<p>This intervention contains six essential elements:</p> <ul style="list-style-type: none"> • Project or tangible end product designed to help others [25, 26], is embedded in meaningful activities that facilitate engagement [26, 45], and can influence QOL [46]. • Group-based interventions have strong evidence for the treatment of social communication impairments [21, 33]. • Individualised communication-based goals are key to success [21, 34], can increase participation in the intervention [47], and lead to more successful outcomes [48]. Methods used are text messaging to facilitate goal recall [49], videotaping to improve awareness [50], and metacognitive skills training to help improve self-monitoring of goal performance [47]. • Communication partner involvement impact conversations [51, 52], and can help to maintain treatment improvements, and support generalisation to real-life contexts [53]. Involvement can occur as an adjunct to an intervention [33] where they can be educated about positive communication strategies [53]; be involved

	<p>in goal-setting; give feedback about goals and homework tasks; and practice skills at home and in the community [54].</p> <ul style="list-style-type: none"> • Acknowledgement and support of participants’s cognitive ability which can impact intervention delivery, uptake or development of target skills [32]. Text reminders prompt the individual to remember and think about their goals and engage in goal-directed behaviour [55]. Step-by-step procedures, with metacognitive skills training, can help to deal with impaired executive function [32, 56] and improve everyday problem solving [56], and could be supported by visual scaffolds, such as the goal-obstacles-plan-do-review framework [57], or the traffic light system [58]. This training can help build self-awareness, increase strategy use, and generalise skills to real-life contexts [32, 47, 56]. • Consideration and plan to address impaired awareness, can affect response to intervention reducing motivation to engaged [32, 47, 59]. Approaches specifically useful are: safe and supportive intervention environment, video-taping, feedback and involvement of communication partners [60].
<p>3. What <u>Materials</u>: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention</p>	<p>An intervention manual describes the procedures involved in designing and creating the project (contact the first author for further details and access). It provides background information and communication recommendations, and session content. Materials include: (1) information for communication partners on positive communication strategies; (2) hand-outs and worksheets for: setting communication-based goals; introducing the group to each other and explaining project work; goal planning and problem solving; and identifying and agreeing a group project; and (3) organisational visual scaffolds. Participants require a mobile phone to receive text message reminders.</p>

<p>providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).</p>	
<p>4. What <u>Procedures</u>: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.</p>	<p>Sessions focused on planning (e.g. using storyboards), problem solving, and undertaking the agreed project (including frequent prioritisation of tasks), with verbal prompting and feedback from the therapist. Procedures also included videotaping to assist with goal identification, text messaging for goals to participants, and metacognitive skills training (sessional goal recall, reflection on performance over past week, anticipated performance during session, and evaluating performance at session end). Summary records of achievements and action points (for home practice) were written at the end of each session, with action points texted to participants and their communication partners between sessions. The intervention manual provides detailed information about the procedures employed.</p>
<p>5. Who provided For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.</p>	<p>Intervention in this study was provided by a single speech and language therapist (first author, 15 years' experience in ABI and 8 years' experience in project-based intervention), however for future application, the detailed intervention manual and self-evaluation version of the fidelity checklist would form the basis for other rehabilitation professionals to provide the intervention.</p>

<p>6. How Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.</p>	<p>Intervention involved primarily face-to-face sessions. The first session involved the participant, their communication partner and the therapist only to generate goals. The next nine sessions were group-based attended by two to three people with ABI and the treating therapist. The communication partners did not attend these group sessions. There was daily text messaging of goals and weekly text messaging of action points, and an interim phone call between the therapist and the communication partner several weeks into the intervention.</p>
<p>7. Where Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.</p>	<p>Intervention was delivered in central locations accessible to participants (residential rehabilitation centre, University campus, private charitable organisation, a local library), with the first session in participant's own homes.</p>
<p>8. When and how much Describe the number of times the intervention was delivered and over what period of time including the</p>	<p>Intervention consisted of 10 sessions (each 2 hours) delivered over a 6-week period. Factors that affected a participant's ability to receive the full dose of intervention included participant illness, prior appointments and transportation problems to the intervention location.</p>

<p>number of sessions, their schedule, and their duration, intensity or dose.</p>	
<p>9. Tailoring If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.</p>	<p>There was no prescribed tailoring however inherent in the nature of group-based intervention and project orientation, each group was different and tasks completed were tailored to accommodate the range and complexity of projects chosen as well as participants' cognitive abilities. In other words, some projects were considered less complex, and required different activities to complete. To allow for individualization of each groups project, the details of the intervention for each group were regularly reviewed to ensure adherence to the essential elements and fidelity checklist.</p>
<p>10. Modifications If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).</p>	<p>No modifications were made to the intervention during the course of this study.</p>
<p>11. How well <u>Planned</u>: If intervention adherence or fidelity was assessed, describe how and by whom, and if any</p>	<p>Planned fidelity procedures included manualising the intervention, recording all aspects of the intervention (session attendance, home practice, text messages, phone calls), a single therapist delivering the intervention, and planned use of a fidelity checklist by observers watching a randomly selected sample of videotaped sessions and sessional self-evaluation by the treating therapist [9, 19].</p>

<p>strategies were used to maintain or improve fidelity, describe them.</p>	
<p>12. How well <u>Actual</u>: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.</p>	<p>All procedures were implemented during the treatment study.</p>

Intervention in this study was provided by a single speech and language therapist (first author), however for future application, the detailed intervention manual and self-evaluation version of the fidelity checklist would form the basis for training providers. Intervention was primarily provided in group-based face-to-face sessions, with daily text messaging of goals and weekly text messaging of action points. The communication partner was involved in the initial session and participated in an interim phone call. Intervention was delivered in central locations accessible to participants (residential rehabilitation centre, University campus, private charitable organisation, a local library), with the first session in participant's own homes. Intervention consisted of 10 sessions (each 2 hours) delivered over a 6-week period. Table 3 shows the content of each session. Factors that affected a participant's ability to receive the full dose of intervention included participant illness, prior appointments and transportation problems to the intervention location.

There was no prescribed tailoring however inherent in the nature of group-based intervention and project orientation, each group was different and tasks completed were tailored to accommodate the range and complexity of projects chosen as well as participants' cognitive abilities. In other words, some projects were considered less complex, and required different activities to complete. Planned fidelity procedures included manualising the intervention, recording all aspects of the intervention (session attendance, home practice, text messages, phone calls), a single therapist delivering the intervention, and planned use of a fidelity checklist by observers watching a randomly selected sample of videotaped sessions and sessional self-evaluation by the treating therapist [9, 19]. All procedures were implemented during the treatment study and observed fidelity findings reported in Phase 3.

Table 3. *Session-by-session outline of project-based intervention*

Session	Purpose	Tasks completed
1	<ul style="list-style-type: none"> • Identify individualised social communication goals. • Identify strategies to facilitate the successful conversations 	<ul style="list-style-type: none"> • Watched pre-treatment videotaped conversation. • Discussed communication strengths and weaknesses. • Set individual goals, in simple and accessible terms for the participant to understand. • Discussed facilitative strategies and techniques to improve conversations (e.g. positive question style).
2	<ul style="list-style-type: none"> • For the group members to meet each other. • Share and self-rate communication goals • Introduce the concept of a project to the group. 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Shared individual communication goals and self-rated predicted performance • Introduced goal planning framework based on the goal-obstacle-plan-do-review, 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	<ul style="list-style-type: none"> • Share and self-rate communication goals • Work towards completion of the project. 	<ul style="list-style-type: none"> • 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.
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Phase 2: Validation of intervention and development of materials

The analysis of the focus group revealed four themes and 18 categories, as outlined in Table 4. The themes were: (1) Essential elements; (2) Group context; (3) Therapeutic skills; and (4) Manual core components. All participants validated the positive role of project-based intervention in working with adults with ABI from the perspective of two different disciplines (i.e. Speech and Language Therapy, Occupational Therapy). The first theme validated much of what was already known from the literature about essential elements (e.g. choose a meaningful project) [21, 25, 26, 34] but also extended this with finer details specifically roles and home practice elements. The second two themes provided additional information concerning the skills of the trainer and delivery methods [34]. The final theme confirmed the existing content of the prototype intervention manual while highlighting additional content such as troubleshooting potential problems that may arise and affect successful implementation of the intervention if not addressed (e.g. what to do if the group

could not generate a project idea). Participants were shown the manual and fidelity checklist during the second focus group session where feedback informed some minor adaptations to each.

Table 4. *Themes and categories from focus group*

Theme	Category	Description
ESSENTIAL ELEMENTS	Meaningful project	Participants need to agree a project they are all interested in
	Cognitive skills	The project must involve a range of planning and organisational skills, flexibility and problem- solving skills.
	Roles	The project should involve the allocation of different roles (e.g. minute-taker)
	Positive outcomes	Involvement in the project should be positive and enjoyable
	Completion of homework	Homework needs to be done but can often be a challenge
GROUP CONTEXT	Peer support and motivation	Group participants are able to give each other support and feedback within and outside the group
	Goal-setting	Focus on setting individual and group goals
	Group membership	The group should be voluntary with pre-group discussions about the content of the group
	Address barriers	Barriers may be individual (e.g. fatigue) or group-related (e.g. tension between participants)
	Group composition and session duration	Small group size with sessions of no more than 2 hours.
THERAPEUTIC SKILLS	Motivating participants	The therapist needs to be energetic, enthusiastic and motivating
	Facilitate group interaction	The therapist needs to be facilitative and not directive when encouraging interaction between group participants

	Support organisational skills	Suggestions for supporting organisation (e.g. session plans)
	Flexible thinking	The therapist must not be rigid rather s/he should be flexible and allow group members to generate ideas
	Communicate reasons clearly	Be clear about the aims and rationale of each session
MANUAL CORE COMPONENTS	Resources and materials	Needs some background literature, case studies and session plans
	Running a group	Needs some information on how to run a good group (e.g. group rules, troubleshooting suggestions)
	Goal-setting and outcomes	The manual should contain information about how to write goals and how to identify outcome measures for measuring progress

The second focus group session was used for the consultants to review the manual and checklist in detail before they were finalised.

Phase 3: Fidelity

Overall across all sessions, consultants rated all behaviours to be ‘present’ or ‘present to some degree’ with no behaviours rated as ‘absent’ throughout. Fidelity assessed using percent agreement was *acceptable* for all rater pairs (with the exception of C1 + C2 on group 1, see Table 5). However, fidelity assessed using Kappa coefficients varied and ranged from *poor* to *excellent* depending on pair. For the first session, agreement for one pair was *poor* ($\kappa = 0.34$) with raters discrepant on ‘present’ or ‘present to some degree’. Prior to the second session, the three consultants reached consensus on what constituted each of these response categories (i.e. present vs. present to some degree). Agreement then increased to *fair* ($\kappa =$

0.44) through good ($\kappa = 0.64$) for two consultant pairs. The level of agreement was *excellent* for the third intervention session ($\kappa = 1.0$).

Table 5. *Fidelity checks for intervention sessions*

Intervention 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%	0.31	[-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

Discussion

The developmental process of novel complex interventions is rarely reported in the literature, and yet important for understanding the motivation and purpose of a new intervention and influences future replication and clinical uptake. This study aimed to report on this process including the description and fidelity testing of an intervention for adults with ABI. Project-based intervention could be manualised and described using six essential elements. It was validated by practicing therapists and specified using the TIDieR checklist. Fidelity materials could also be developed and tested on three treatment groups as part of a broader feasibility trial [27].

To manualise the intervention, review of the literature and involvement of practicing therapists led to the developing of project-based intervention for adults with ABI that has six essential elements. Two of these – a tangible project output and group-based intervention - are arguably relevant to the project-based intervention with any population, but four are unique to clinical application in brain injury. Individualised communication goals, consideration of the individual's cognitive ability and awareness, and communication partner involvement are now core to this intervention and should be included in any further replication study. They are essential as they influence the individual's likelihood of engaging, learning, practising, improving, and maintaining new skills and abilities.

There are similarities between our novel intervention and original work of Ylvisaker and colleagues [26]. Both recognise the importance of cognition and awareness, a context for language and communication skills practice, and meaningful goals. Our intervention however specifies the need for individualised *communication* goals, and uniquely involves the communication partner as a means of bridging goals into everyday life and providing support in the home environment. Other group-based intervention for people with ABI similarly suggests that group context is crucial [61, 62, 63] and the pursuit of goals is integral to

success [61]. Helpfully, the positive feasibility results from our main study [27] confirm these essential elements can be implemented. Participants could identify and complete projects during the intervention period, participants attended the groups and reported positive experiences of working with others, participants achieved communication goals, strategies for addressing impairments in cognition and awareness were implemented (e.g. videotaping, text messaging) and the majority of communication partners was involved throughout. These positive indications combined with the intervention specification using the TIDieR framework (Table 2) and manual (available from first author) which contains resources and detailed procedures to implement the intervention, offers a unique contribution to the field and opportunity for further testing by other researchers.

To validate the prototype intervention manual and help inform the creation of the fidelity checklist, a unique aspect to this study was the involvement of practicing therapists. A challenge with creating an intervention manual of this type was that it needed to be sufficiently flexible to allow individualisation between groups and the projects chosen, but not too flexible that there was insufficient guidance for therapists. The advantage of using practising therapists ensured that the manual satisfied these two criteria. Moreover, practising therapists were able to identify practical challenges that may not have been otherwise identified, which may have affected successful implementation of project-based intervention if not addressed. For example, tension between group participants and what to do if the group could not generate a project idea were identified. Potential solutions were subsequently incorporated into the manual to address these challenges. Therapists also contributed to the fidelity checklist. Other studies with therapist behaviours within the checklist have tended to be created by the research team and not involve practicing therapists [39, 40]. The items of the checklist in this study were originally written by the research team, as informed by the focus group of practicing therapists, and then checked and agreed by them in a second

session with added detail to make items clearer. Future implementation of the intervention into clinical practice could be done by therapists across disciplines using the checklist.

An important contribution of this paper is the treatment fidelity checklist and acceptable fidelity findings. As highlighted in the introduction, speech and language therapy randomised controlled trials literature have shown reasonable attempts at monitoring fidelity: 59% planned and 46% actual fidelity reported but with no further detail about the types of fidelity processes [3]. Conversely Hinckley and Douglas [10] sampled broader study design literature in the field of aphasiology, and report on various procedures used. Similar to Hinckley and Douglas [10], we adopted the most popular method for conducting fidelity checks which was adherence to a treatment protocol or manual using one or more raters reviewing videotapes from a sample of sessions. Supervision and role-play which are additional fidelity practices were not employed in our study.

Similar to other studies, the fidelity checklist included therapist behaviours which were framed more in line with Hart and colleagues [40] (e.g. *Therapist prompts or facilitates patient's generating, weighing and/or selecting future course(s) of action in the context of discussion of a problem of goal area*) than Bornhofen and colleagues [39] (e.g. *Did the therapist convey a warm and encouraging attitude?*). Our checklist also included project-related behaviours, akin to the intervention-specific behaviours outlined in Bornhofen and colleagues [39]. Problematic in the process of checking fidelity in the current study was the use of a three-point scale for demonstration of behaviour: present, present to some degree, and absent. Other research undertaken by Hart and colleagues [40] albeit using a different intervention (telephone counselling intervention) also identified difficulties with three point rating scales of therapist behaviour. They noted inadequate reliability and subsequently reviewed their scale to present or absent. Such an approach would have proved more streamlined here. Importantly though, no behaviours were reported as absent for the three

intervention sessions which suggests that all behaviours were observed to some degree and help to establish that the intervention was implemented as intended.

Interestingly in the fidelity findings, there is a possible training/ instruction implication. Between sessions 1 and 2, two of the three rater pairs (*not* C2 + C7, see Table 5) improve substantially in their agreement ratings suggesting that they benefitted from the opportunity to discuss checklist behaviours more beyond the initial training. It is possible that the initial training for these raters was inadequate and increased instruction at outset might have mitigated this situation. However, of further interest, is the perfect agreement noted for the third session and the unique rater pairing (C4 + C8) where further discussion did not occur. In summary, it would appear that monitoring fidelity through observation of videoed sessions and bespoke tools specific for the intervention is possible, however further research is warranted to explore reasons for discrepancies between raters in order to increase reliability for future testing.

Limitations

Several limitations must be taken into account when interpreting the process described here. The first refers to the use of a single group of therapists to identify the essential elements. Further focus groups involving a wider range of disciplines, therapists from a range of rehabilitation settings, and people with ABI and their family would have been of greater benefit to confirm themes and categories, and the active ingredients of project-based intervention. Second, the facilitator of the focus group and person responsible for the analysis was not independent. Inclusion of an independent person responsible for the analysis may help to prevent any bias that may have arisen.

Conclusion

The focus of this paper was to describe a process for developing a novel complex intervention intended to improve communication skills and QOL in adults with ABI. As interventions for people with ABI become ever more complex containing components that are increasingly tailored to the impairments and goals of the individual, the challenge for rehabilitation researchers is to identify the essential elements at the outset. This paper sought to identify the elements of project-based intervention through a literature review and in collaboration with practising therapists. The process was feasible and enabled a comprehensive description of the intervention using the TIDieR checklist that included the creation of a well-specified manual and bespoke behavioural checklist to check fidelity. This process provides a potential template to help inform rehabilitation researchers in brain injury and other related fields on the process for developing complex interventions. The methods employed help with the monitoring of the intervention trial, help researchers clearly identify the elements that may make the most change to behaviour, and ensure that other researchers and practicing therapists can replicate the intervention into future trials and/or clinical practice.

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