Assessing the outcomes of a clinical trial: Primary outcome measures only tell part of the story

Introduction

Identifying outcome measures that are sensitive to change and meaningful to participants is a challenge when designing clinical trials of complex communication interventions. Outcome measures encompassing participants' perceptions of clinically meaningful change and their experience of the treatment process are frequently neglected. This paper presents an overview of the outcome measures used in a 3 arm clinical trial which aimed to investigate (i) social skills training for the person with TBI alone (which we have termed the TBI SOLO condition) and (ii) training communication partners to deal with difficult communication behaviors (the JOINT condition) compared to a delayed waitlist CONTROL condition. The paper asks two research questions:

1. What information did the self-report of perceived communication ability using the La Trobe Communication Questionnaire, and qualitative measures provide in addition to blinded ratings on the Adapted Kagan Scales, the primary outcome measure?
2. How did participants perceive the training experience as measured through post treatment interviews?

Method

44 participants with severe TBI and their everyday communication partners (ECP) participated (Table 1). Inclusion and exclusion criteria are listed under Table 1. Based on ECP availability, participants were allocated to one of three groups: a TBI SOLO group (where only the person with TBI was trained), a JOINT group (both the ECP and the person with TBI were trained together), or a CONTROL delayed treatment condition (Figure 1). The TBI SOLO and JOINT groups received individual and group training in strategies to maximize communicative effectiveness using behavioral approaches including role-plays, cues to assist self-monitoring and positive reinforcement[1]. Treatment included concepts based on sociolinguistic theories of communication[2] and principles of Vygotskian learning theory[3,4] with a focus on everyday discourse. An outline of the treatment program can be found in Table 2.

Each participant in the TBI SOLO and JOINT groups received 3.5 hours of treatment/week for 10 weeks, including a 2.5 hour group session, and a one hour individual session. Group sessions included a review of home-based tasks using tape recorded samples of interactions taken throughout the previous week, introduction of new information and strategies, role plays, practice of strategies and feedback on use of techniques. A protocol was followed for individual sessions, including individualized goal setting, feedback on home-based tasks, problem-solving of issues raised by the participants, practice and troubleshooting. Steps to ensure treatment fidelity included the use of a treatment manual, participation in at least 80% of sessions and data collection on participants' attendance rates and completion of home-based tasks.

Outcome measures were collected at the initial assessment, at one to three weeks after the group intervention was complete and at six months after the intervention. Two discourse samples were collected on each occasion: (1) casual conversation (CC), in which the participants were asked to have a chat about any topic for a few minutes, and (2) purposeful conversation (PC), in which the

participants were asked to generate a list of situations they were expecting to face over the next few weeks in which communication was important to them.

The primary outcome measure, called the Adapted Measure of Participation in Conversation (MPC), evaluated the person with TBI's level of participation in conversation in terms of his/her ability to interact or socially connect with a partner (Interaction scale) and to respond to and/or initiate specific content (Transaction scale) before and after therapy[5,6]. Two trained raters who were blind to group allocation scored a 5-minute videotape of social interactions between the person with TBI and their significant other on a 9-point Likert scale, presented as a range of 0 to 4 with 0.5 levels for ease of scoring. The scale ranges from 0 (no participation) through 2 (adequate participation) to 4 (full participation in conversation). Results were analyzed using repeated measures ANOVAs to examine the effect of group on the degree of change in MPC Interaction and Transaction scores pre and post treatment in purposeful and casual conversation conditions. Intention to treat analysis was used. These data were reported previously at CAC, but have been included in this submission to provide the foundation for answering our mixed methods questions.

Participants and their ECPs also completed the La Trobe Communication Questionnaire (LCQ)[7] at pre and post assessments. The LCQ evaluates the person's perception of their own/significant other's communication skills and comprises 30 items that cover six statistically derived components: Conversational Tone, Effectiveness, Flow, Engagement, Partner Sensitivity and Attention/Focus. Responses to each item are made on a 4-point scale in terms of frequency: 1=never or rarely, 2=sometimes, 3=often, 4=usually or always. The total score ranges from 30 to 120, with higher scores indicating greater perceived frequency of communication difficulties. Two scores were obtained: LCQ Difference score (pre-intervention minus post-intervention) by both the participant with TBI and their ECP, and the number of items on the LCQ that the ECP rated as changed post training.

Social validation interview data were collected from 40 participants who had completed either the JOINT or TBI SOLO training. Semi-structured videotaped interviews with each participant occurred in the final individual session. TBI SOLO participants completed interviews alone (as their communication partner had not participated in the group). JOINT participants completed interviews together but were given the opportunity to speak individually if they wished. The interview included probe topics aimed to elicit information about participants' experiences of the program, potential strengths and changes to the program and changes that may have occurred in different areas of participants' lives as a result of the training (Appendix 1). Interviews were 5 to 30 minutes duration and conducted in a treatment room within the brain injury unit. Using a 6-step generic analysis procedure[8], with use of a constant comparative analysis technique[9], interview data were categorised into topics and then subtopics to identify conceptually discrete units. Two researchers conducted the analysis, with peer triangulation of the data used at key points to determine whether the two researchers drew similar observations from the body of data. Discrepancies were resolved through discussion and further review of the body of data to locate additional support for observations.

Results

Primary outcome measures: At baseline there were no statistically significant differences between the three groups on the prognostic variables of age, sex and education, severity of injury and on MPC ratings (Table 1). Mean scores for the three groups at pre- and post-test on the primary outcome variable are detailed in Table 3. Treatment effects were defined as a significant group (*JOINT* vs. *TBI SOLO* vs. *CONTROL*) x time (pre vs. post) interaction for repeated measures

ANOVAs on the MPC (2 subscales). There was a significant treatment effect for conversational skill as measured by the MPC Interaction scale in both the casual conversation ($F(2, 38) = 3.78$, $p = 0.03$, $\eta_p^2 = 0.17$) and purposeful conversation ($F(2, 38) = 4.01$, $p = 0.03$, $\eta_p^2 = 0.17$) conditions, i.e. the *JOINT* group improved relative to the other two (Table 3, Figures 2 and 3). A significant treatment effect was also found on the MPC Transaction Scale in both the casual conversation ($F(2, 38) = 5.64$, $p = 0.007$, $\eta_p^2 = 0.23$) and the purposeful conversation ($F(2, 38) = 5.44$, $p = 0.008$, $\eta_p^2 = 0.22$) conditions (Table 3, Figures 2 and 3).

Self report social communication measure

Difference scores. Both the TBI SOLO and JOINT groups showed significantly greater LCQ difference scores from pre to post training when compared with the CONTROL group. Highly significant LCQ Difference scores were obtained in the JOINT group for both the communication partners and the participants with TBI (ECP, p=0.009; person with TBI, p=0.02) (Figure 4).

Number of LCQ items which changed (out of 30 items). ECPs from the JOINT group reported an average of 17/30 items had improved (range= 0–27), with 12/13 ECPs indicating positive changes, and 10 of these 13 indicating that over 10 items had improved. In the TBI SOLO group ECPs reported an average of 8 items had improved (range = 3–18) while in the CONTROL group there was an average of 1 item improved (range= 0 – 4). The TBI JOINT group had significantly more changed communication behaviours compared to the CONTROL group ($p<0.01$) and the TBI SOLO group ($p<0.0001$). The TBI SOLO had significantly more changed behaviours than CONTROL group ($p<0.0001$).

Social validation interviews

The data resulted in six themes (Table 4). Participants described different features as being helpful to their learning, including taping of conversations, written notes of the course content, role plays, practical demonstrations, feedback, home practice, modeling of communication skills by peers and support from peers. Most participants reported that the combination of both individual and group sessions was helpful. Participants also provided examples of how their everyday communication, relationships and confidence had improved and how these changes were attributed to the training program.

Discussion

Training communication partners was more efficacious in improving the everyday interactions of people with TBI than training the person with TBI alone as measured by the primary outcome measure, the blinded Adapted Kagan scales. While these measures supported the statistical efficacy of the program, investigating the participants' perceptions of communication change and the training program considerably enhanced this significant finding.

Trained ECPs reported a significant change on the LCQ following the training while TBI participants noted fewer changes. Most ECPs were wives and mothers, who had changed their communication styles following their husband's or son's injury, and which, in some cases, were detrimental to successful everyday interactions. Sensitively targeting the behaviors of the ECP such as their use of test questions and speaking on behalf of the person with TBI led to a significant change in everyday interactions. The changes on the LCQ may indicate the ECPs' increased awareness of their contributions to conversations with their relative with TBI.

The qualitative feedback regarding the effectiveness of the program from the perspective of participants complemented the quantitative result and provided social validation of intervention

efficacy. Insights were obtained from the participants and their ECPs regarding the changes that had occurred in their lives following the training. In many cases, these reported changes were directly attributed to the communication-training program. The qualitative data helped us to understand how and why the training was perceived to be effective in a way that could not be directly explained by the primary outcome measures alone[10].

Limitations included the small sample size and possible bias during the interviews due to the possibility of socially desirable responding. Nonetheless, this study represents an important step forward in investigating interventions for social communication impairment following TBI. It is the first three arm trial to examine the treatment efficacy of training familiar communication partners of people with a TBI compared to traditional treatment and, importantly, to a control group. The combination of quantitative and qualitative data extends the conclusions that can be drawn beyond those which could be determined using quantitative data alone. The inclusion of these measures provided an increased understanding of the communication changes perceived by participants, the impact of those changes and the potent 'ingredients' of the training program. The qualitative data enabled an evaluation of the acceptability of the treatment to the JOINT group participants, which was particularly important given the non-traditional nature of focusing on communication partners. We conclude that a combination of outcome measures is needed to adequately reflect the complexity of communication when designing large clinical trials, and that such a combination should be used to evaluate treatment outcomes during clinical practice.

Format preference: Platform Presentation

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Table 1. Demographic characteristics, severity levels, and primary outcome measures at baseline for all participants (mean, ± SD (range)).

Group	JOINT (n=14)	TBISOLO (n=15)	CTRL (n=15)	F	df	p
Demographic variables						
Gender (M:F)	11:3	14:1	13:2	1.35*	2	0.49
Age (years)	30.29 ± 13.98 (18-62)	39.67 ± 10.70 (18-55)	38.07 ± 15.06 (19-68)	2.02	2,41	0.15
Education (years)	12.00 ± 2.25 (7-15)	12.80 ± 3.67 (8-20)	12.73 ± 3.17 (8-18)	0.29	2,41	0.75
TPO (years)	8.04 ± 5.10 (1-21)	8.13 ± 8.32 (1-25)	9.71 ± 6.70 (2-23)	0.82	2,41	0.45
PTA (days)	87.77 ± 56.93 (7-180)	96.43 ± 61.23 (20-180)	66.64 ± 65.51 (6-182)	0.87	2,38	0.43
ECP Gender (M:F)	4:10	2:13	3:12	1.08*	2	0.59
ECP Age (years)	50.29 ± 11.26 (24-64)	49.00 ± 15.72 (17-77)	49.67 ±19.42 (21-79)	0.02	2,41	0.78
ECP Education (years)	13.14 ± 3.06 (10-19)	12.93 ± 2.74 (9-18)	12.40 ± 2.29 (10-16)	0.29	2,41	0.75
Cognitive communication severity						
SCATBI	97.00± 14.21(80-129)	103.20±13.21(82-127)	102.67±14.36(85-129)	0.87	2,41	0.43
Primary outcome measures						
MPC Interaction CC	2.18±0.61(1.00-3.5)	2.27±0.65(1.00-3.5)	2.37±0.79(0.5-3.5)	0.27	2,41	0.76
MPC Transaction CC	2.07±0.62(1.00-3.0)	2.30±0.70(1.00-3.5)	2.27±0.59(1.00-3.0)	0.53	2,41	0.59
MPC Interaction PC	1.89±0.53(1.00-2.5)	2.13±0.58(1.00-3.0)	2.17±0.62(1.00-3.0)	0.96	2,41	0.39
MPC Transaction PC	1.96±0.63(1.00-3.0)	2.10±0.63(1.00-3.0)	2.30±0.62(1.00-3.0)	1.05	2,41	0.36

* Chi square statistic used for dichotomous variables

Inclusion criteria were: (1) a moderate-severe TBI at least 9 months previously defined as a score on the Glasgow Coma Scale (GCS) of 9-12 (moderate) 8 or less (severe) and/or a period of Post Traumatic Amnesia (PTA) of 1-24 hours (moderate) more than 24 hours (severe), (2) significant social skills deficits, (3) be of at least average premorbid intelligence and (4) have a regular communication partner with whom they interact on a daily basis. Exclusion criteria included: (a) drug and alcohol addiction or active psychosis, (b) aphasia, (c) a non-English speaking background (d) severe amnesia, and (e) severe dysarthria. Caregivers interacted with the person with TBI on a regular basis, had not sustained a brain injury or had a known psychiatric history.

Table 2. Group training program overview

Session	Session title	Description
1	Introduction	Introductory session where the purpose of training, group guidelines and home practice expectations are established and members introduced to each other and clinicians.
2	Brain Injury and Communication	An educational component on TBI and communication including how cognitive, physical and behavioural symptoms that may impact on communication using video case studies
3	Effective communication 1	Explores the forms and purposes of communication, different contexts and communication structures used in each context, different roles in communication and how communication role affects outcomes of interactions.
4	Effective communication 2	Extends Session 3 and examines general communication facilitation strategies, and explores barriers and facilitators to good communication in everyday life.
5	Collaboration (titled 'Starting and Participating in Conversations' for the TBI SOLO group)	Focuses on techniques that help conversations to be a collaborative, more equal and organized process. For the JOINT group, it also helps communicative partners provide structure and support to the person with TBI for their conversations.
6	Elaboration (titled 'Extending Conversations' for the TBI SOLO group)	Focuses on the concept of keeping conversations going' by exploring techniques that help to organise and link topics, with use of both questions and comments. For the JOINT group, this session assists communication partners to scaffold conversations for the person with TBI without taking over the conversation.
7	Asking Questions	Explores the use of appropriate and helpful questions to start and keep conversations going. For the communication partners in the JOINT group, this session also suggests how to avoid negative, or 'testing' questions and instead focus on a positive questioning style.
8 - 10	Improving Skill and Confidence	Revises the information and practises each technique learnt in previous sessions with actual conversations. Session 10 also celebrates group member's achievements and outcomes with a group lunch.

Each group session contains session handouts, a mix of role plays, information content, conversational practice and each pair is encouraged to play recorded home practice tapes to discuss with the other group members. A morning tea break each week allows people to socialise with and get support from other group members.

Table 3: Scores at pre and post treatment on primary outcome variables for the 3 groups: TBI SOLO Group, JOINT group where everyday communication partners were also trained and the CONTROL delayed treatment group as well as F values for multivariate treatment effects (time by group interactions), degrees of freedom (d.f.), probability level (p) and effect sizes (η_p^2).

CC = Casual conversation; PC = Purposeful conversation

MPC		***Pre- Treatment***			***Post-treatment***			***Treatment effect (Gp x Time)***			
		JOINT	**TBI SOLO**	**Control**	**JOINT**	**TBI SOLO**	**Control**	***F***	**d.f.**	***p***	***Eta²***
Interaction CC	Mean SD	2.18 0.61	2.27 0.65	2.37 0.79	2.77 0.56	2.50 0.48	2.39 0.66	3.78	2, 38	0.032	0.166
Transaction CC	Mean SD	2.07 0.62	2.30 0.70	2.27 0.59	2.65 0.38	2.32 0.54	2.25 0.67	5.64	2, 38	0.007	0.229
Interaction PC	Mean SD	1.89 0.53	2.13 0.58	2.17 0.62	2.58 0.34	2.29 0.80	2.29 0.51	4.01	2, 38	0.026	0.174
Transaction PC	Mean SD	1.96 0.63	2.10 0.63	2.30 0.62	2.58 0.28	2.11 0.74	2.21 0.47	5.44	2, 38	0.008	0.223

Table 4. Topics derived from interviews

Topic	*Brief description of topic*	*Example illustrative quotes*
Improved communication skills		
Improvement in skills of participant with TBI	Description of the participant with TBI having improved communication skills or using new skills, reports of others in the individual's life noticing changes in communication skills, feelings about communication in the future	1. ECP-01: He's listening, reacting to the other person, asking questions at the right time and giving input and having his own opinion. Conversations are more successful. 2. TBI JOINT-20: I have become more short and sweet when I talk. 3. ECP-35: Now he's learnt what to say, when not to say it, what to hold back. 4. TBI SOLO-4: And one time after the conversation I wasn't happy and after I thought about what I'd could have done to make it better, so that's one thing I got from this course too, afterwards I'll say 'ah well I could have added that to this or applied that strategy to the conversation, that would have made it go better or more interesting' which I never used to do. 5. TBI JOINT-20: Jane (a friend) has said to me that it (my communication) has improved and David's mum says it has improved… because I left her a message and she rang up and she talked to Mum for a bit and she talked to me and then she told Mum that it has improved and she told me it as well. 6. TBI SOLO-2: I've had doctor's appointments and they have noticed my speech is more clear and my rate is slower. 7. TBI JOINT-35: I know the skills now. All I have to do is apply them.
Improvement in skills of communication partner	Description of the communication partner having improved communication skills or using new skills	1. ECP-15: It's been beneficial for me, now I don't talk as fast or bombard him. Now I slow down and I put things clearly for him. 2. ECP-46: Sometimes just little key cues that I do give him which gets him back on the track of the task... I didn't pick up it was actually more about me than him until a few weeks. Then I thought well this is more about me being the teacher and communicating with him and working as a team and propping him up as we go in conversation... so it's given me the tools. 3. ECP-30: It's been a tool for us to first of all I think just to listen to the other person, sort of ask questions, and at the same time try to make the conversation more easier between us … if we have a problem, we discuss, not just explain or tell what to do, but just make it easier on both of us. 4. ECP-28: Well, I think it's been very beneficial to us both, cos I had a few things to learn too, because you

		get into bad habits over the years. 5. ECP-33: When we are out socially now, I come in as that support because I know what he's saying but other people don't understand what he's saying because you know some of his jokes are so way left field... but now I can come in and say oh you're meaning that, and it saves his face and he doesn't look like an idiot.
Evaluation of goals and progress	Evaluative statements about what has been achieved during the program	1. TBI SOLO-2: I think it's worked really well for me, I seem to have achieved the goals I set for myself when I started. 2. TBI JOINT-32: Sometimes I don't remember them (the communication strategies) or I don't pay attention to it, so my relationship with my friends and my family is up and down. 3. ECP-35: It's a bit like making a cake. You can have all the knowledge, you can have all the ingredients but you've got to be able to cook it and the same thing with that they've got to put it into practice in everyday living and even though we've got the skills now, where do we go? ... So that's our next goal.
Impact of improved communication skills		
Improved relationships	Description of an improvement in relationships or roles with family members, friends or others	1. TBI JOINT-20:(Our relationship) has grown since we have been coming to this lesson and we can talk about anything between us now... I think it is going well with me and Mum but with Dad and me that's another story. 2. ECP-20: It used to go on and on until I sort of got exasperated but now with this new skill... I just have to say "let him off the hook" or "just let it go" and she understands what I'm saying... and stops the heated arguments, and it makes life a lot easier. 3. TBI SOLO-39: I don't get as frustrated with him as easily and walk away so it makes me sort of tolerate him a little bit more. 4. TBI SOLO-37: Two of our friends have been in hospital having operations so it puts me on a different level. So I'm able to offer them comfort and reassurance whereas (before it was) them always having to do it for me. 5. ECP-6: And they actually want to socialize with us whether before they just walked away. Now we'll never get rid of them! They want to sit and have a conversation with him but they used to only talk to me.
Improved confidence	Reports of a feeling of confidence in communication situations	1. ECP-15: I feel number one that he has gained confidence and has made more of a social life because of that confidence and recently he's made a new friend which he hasn't done before. 2. TBI JOINT-15: I've now regained my self, level of self

		confidence. I've regained my level of social standing, I used to be scared to get involved in conversations but now I know how to get into conversations, I know how to get into them properly without being rude. 3. ECP-20: I was at a stage where I didn't know exactly what to do next with (her) conversation... it's given me the confidence to know what I'm doing, it's given me a plan, it's given me some structure and it's given me something that I'm able to fall back on... I can go back to the notes."
Improved social life and independence	Statements of any increase in social activities, social interaction, ability to perform tasks independently, or reduction in need for supports	1. ECP-32: She also mentioned to me yesterday that we have to invite people over – one of our friends which we haven't seen for a long time, so that's something I haven't heard from her for a while. 2. TBI SOLO-34: I find friends are talking more to me now... I think it's what I'm doing because I'm listening and I'm commenting and not saying the wrong things… I'm talking to different people and I tend to go to more places than what I was. 3. ECP-15: We can go shopping and if they ask me a question (now) I say you can ask him! And by talking to him it makes other people less afraid to talk to him, and I think what was I so afraid about? He can carry a conversation. 4. ECP-20: If I feel that she's going to go over and talk to someone I'll say "keep it safe" and that's all I need to say without having a great big long lecture. 5. ECP-33: I feel like, you know, a big rock has lifted off your shoulders... It's just so nice when you're sitting there and you're having a coffee and the waitress comes around who's a cute little uni student and she's just very nice, always has a chat with S and when she's now chatting I just sit there, not feeling that oh God, what's he going to say now, you know? And he does it so beautifully and so relaxed.
Regaining self identity	Statements of feelings about perceptions of self or others' perception of self	1. ECP-6: He cooked a barbecue with A (son), A said he had a great conversation and they both had fun. A said he felt it was, 'like having his old dad back'. 2. TBI SOLO-43: I bumped into a bunch of my old mates... It didn't feel like I was standing out, (I felt) like I was one of them. A lot better. 3. ECP-46: He's starting to learn the concept of being an adult rather than as a child... so he's taken on some adult ways.
Experiences of the program		
Valuable components	Statements regarding the aspects of the	1. TBI JOINT-6: We've learnt a lot. I thought I knew to start with but I didn't. I didn't know anything, but now after the 10 weeks course I do know a lot.

	course participants thought were valuable or important	2. ECP-20: It's what I was wanting to do but I didn't know how to do it. I was getting there but I wouldn't have completely got there by myself. I feel that the course has been on the plane where I was wanting to go. 3. TBI JOINT-32: I was more confident actually coming to here cos I was sharing my experience with other people that are similar to my situation, so they understand where I'm coming from. 4. TBI SOLO-9: The individual sessions have been great when learning to talk and then when I go in the group, and play the tape and ask the other guys their opinion, they tell me and I take their opinions and they helped a lot. Hearing it from others was good. 5. ECP-20: I think the notes have been very good because sometimes I can go back to those notes... you don't always take in 100% of the information you've given but the notes are there. 6. ECP-20: When things were getting tough at home and we were running short of time... and I started thinking about coming to the group I remembered commitment and I think we've got to be committed to this because we agreed on that. And that was helpful as well. 7. ECP-33: I think the best thing was the way you did the role playing, it was a perfect way of explaining... of making each one look at ourselves and see. 8. ECP-33: You've shown us how to do that without just telling us how to do it, you've actually shown us. 9. ECP-35: It's also been good because you've been able to, as the third person, say now have you thought to look at it this way and put a different perspective on the way he's thought on a situation. 10. ECP-33: It was a brilliant idea with the taping because playing back was just an incredible eye opener for S.
Challenges and need for improvements	Identification of aspects of the course which participants found challenging and suggestions about aspects that could be changed	1. ECP-35: I think maybe if people, if you just said to them you may find it daunting, it's not school but we're here to learn, not to criticise, then I probably would have thought oh okay, that's how I was supposed to feel but everyone seems sort of fairly relaxed and I thought, oh, am I the only one who's feeling so terrified? 2. TBI SOLO-34: The practice conversations I thought were a bit strange. 3. TBI SOLO-37: If I didn't agree with what someone said, I found that challenging. 4. TBI SOLO-37: It was fatiguing, mentally fatiguing because it was for two hours. 5. TBI SOLO-39: A little bit the homework, only because I don't really have someone that I talk to regularly. 6. ECP-6: I'd like more of one on one, because I feel we open up more with (the clinician) than the group, we

		are quieter in a group, it does him so much justice…. he's so good when he opens up. 7. ECP-20: I feel it would be nice to have, later on, some sort of follow up to see how we're going and to keep us informed... It could also be for a bit of encouragement because sometimes it's hard work for the carer and also for the person with the brain injury. It's really hard work learning new skills and follow up would just be a bit of encouragement... It could be six months down the track or something like that... it would give us another push along. 8. ECP-25: It could have been a little bit shorter maybe because there was a few weeks where I felt like we were just repeating things. 9. ECP-20: Having something for the rest of the family to understand the program... if they might have come to one or two sessions to understand what we were trying. 10. ECP-46: Got a bit boring sometimes when we had to come down every week.
Benefit of communication partner attendance	Comparative statements about attending the course with or without a communication partner	1. ECP-35: Because we've learnt the same things we can put it into practice... his speech pathologist has been teaching him these things... and she's great, but it just didn't click and because I wasn't in on the sessions, I could read it but I just didn't get it. 2. ECP-33: I believe that (without a communication partner attending), I don't think we'd get as good a result because you know S with his memory and no matter how many handouts you gave us, it would not be the same. 3. ECP-25: There'd be like little parts where it's like okay he needs a boost or a push in the right direction and without that like there wouldn't be any moving forward. 4. ECP-35: It's been probably a bit, was a bit daunting for myself. I thought it was, when I first came in, honestly I could have left... it was just too confronting and the way that I felt in myself I just, because you don't know what, you're doing the best you can and now you're coming and people are going to tell you what you've done may not have been right... I just don't know whether I was ready for criticism but that's not how it was at all but that's how I thought... I actually had a panic attack for the first two things (sessions)... I thought I hope I can make it through the whole session because I just, and I think when it brings it back to you when you see the other families... I wasn't sure what was expected of me. 5. ECP-46: It's not as hard on us as it is on the patient type of thing so yeah I was happy to go through

		whatever." “I didn’t pick up it was actually more about me than him until a few weeks (ago). 6. TBI JOINT-35: I don't think I would have got out of what I got with Mum if I did it by myself because Mum is there as also a reminder or if you like stuff up or if you ask her a question … if I came in by myself, she wouldn't have a clue. She'd only teach me on what she knows as a person, not from what this has taught both of us to do.

ECP= Everyday communication partners from the JOINT group; TBI JOINT = TBI participants from the JOINT Group where they were trained with their everyday communication partner; TBI SOLO = TBI participants who underwent training on their own without their partners being present.

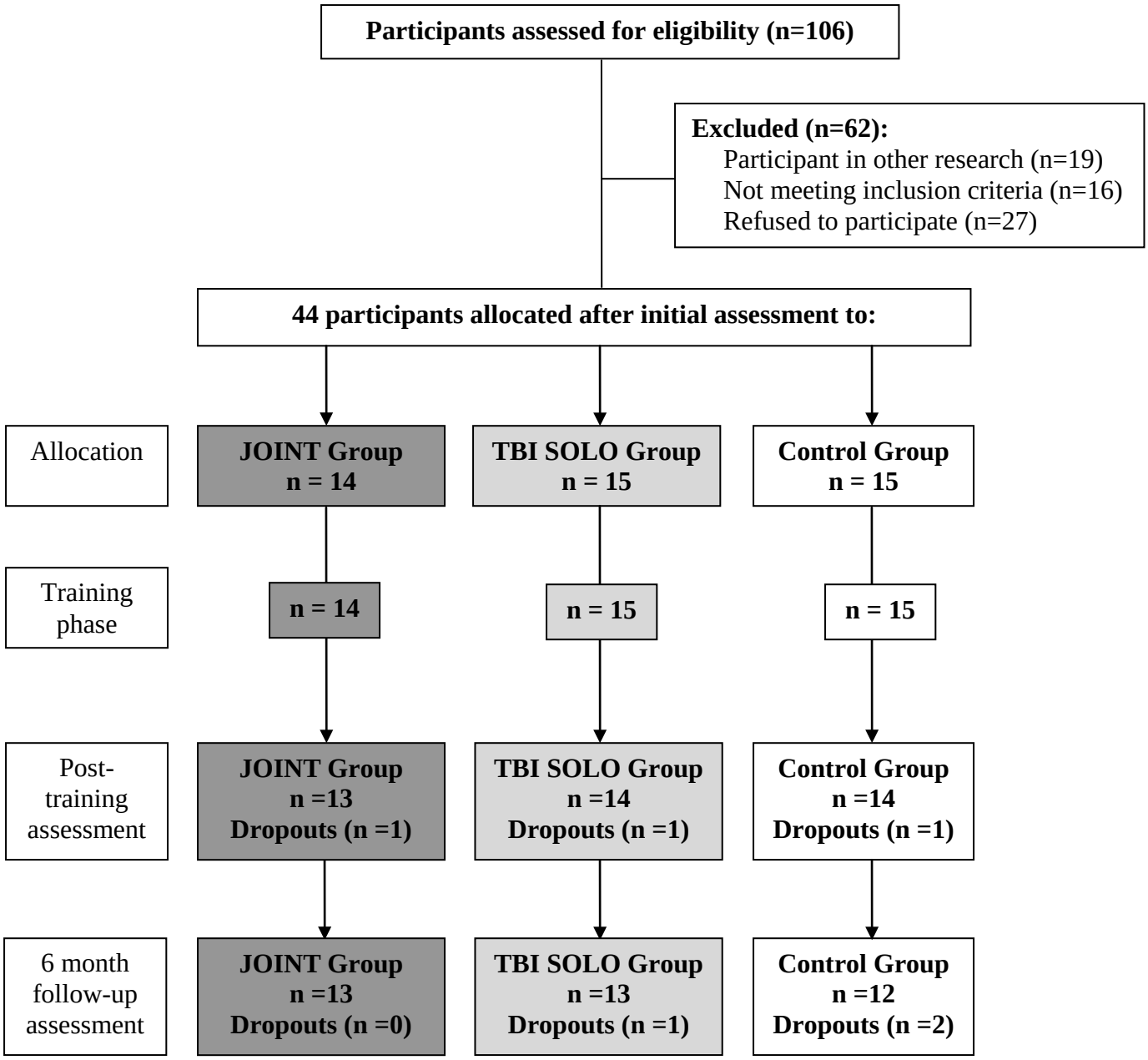


Figure 1. Allocation and flow diagram for the three groups

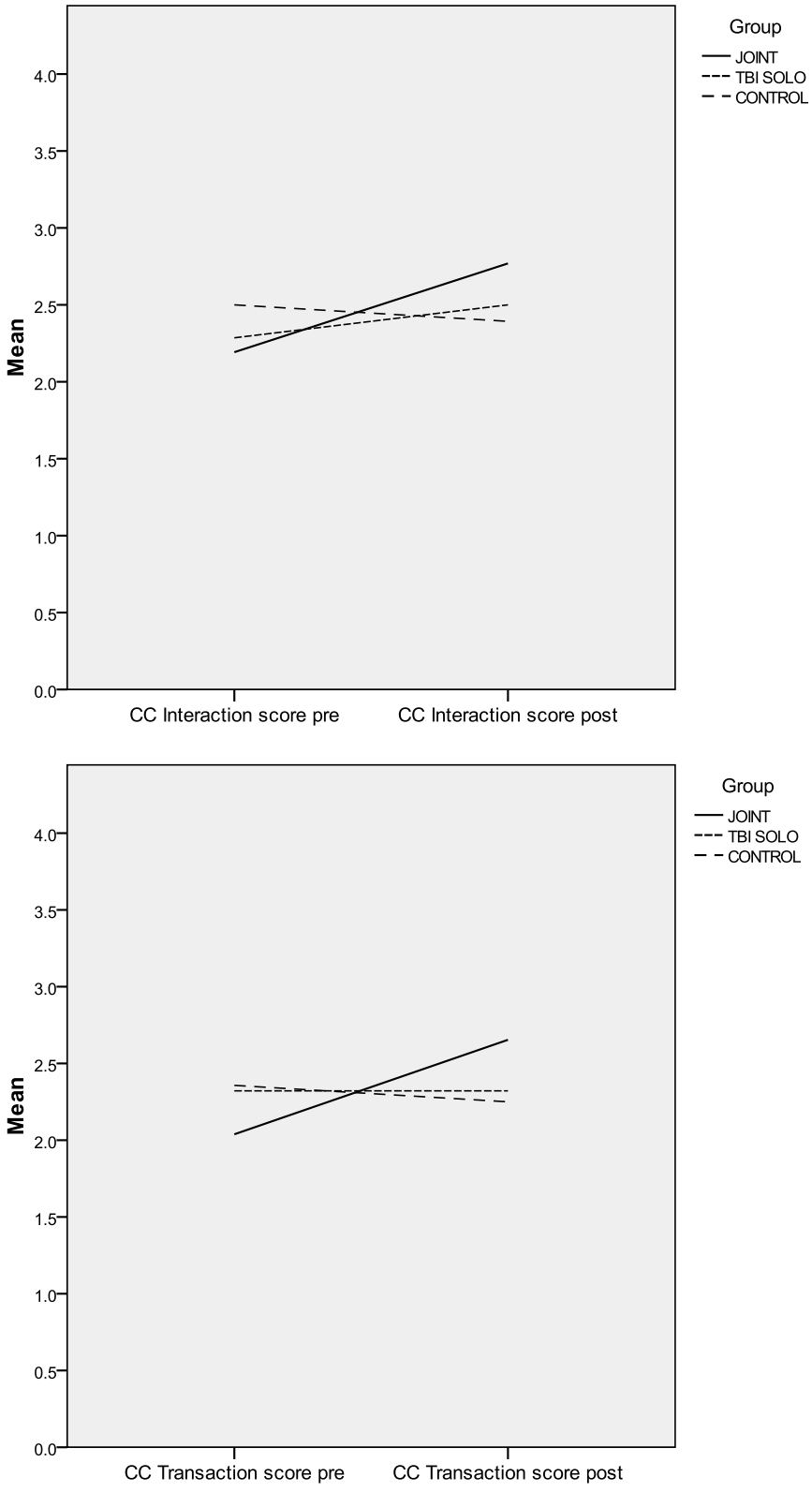


Figure 2. MPC Interaction and Transaction scores pre and post treatment in the Casual Conversation (CC) condition

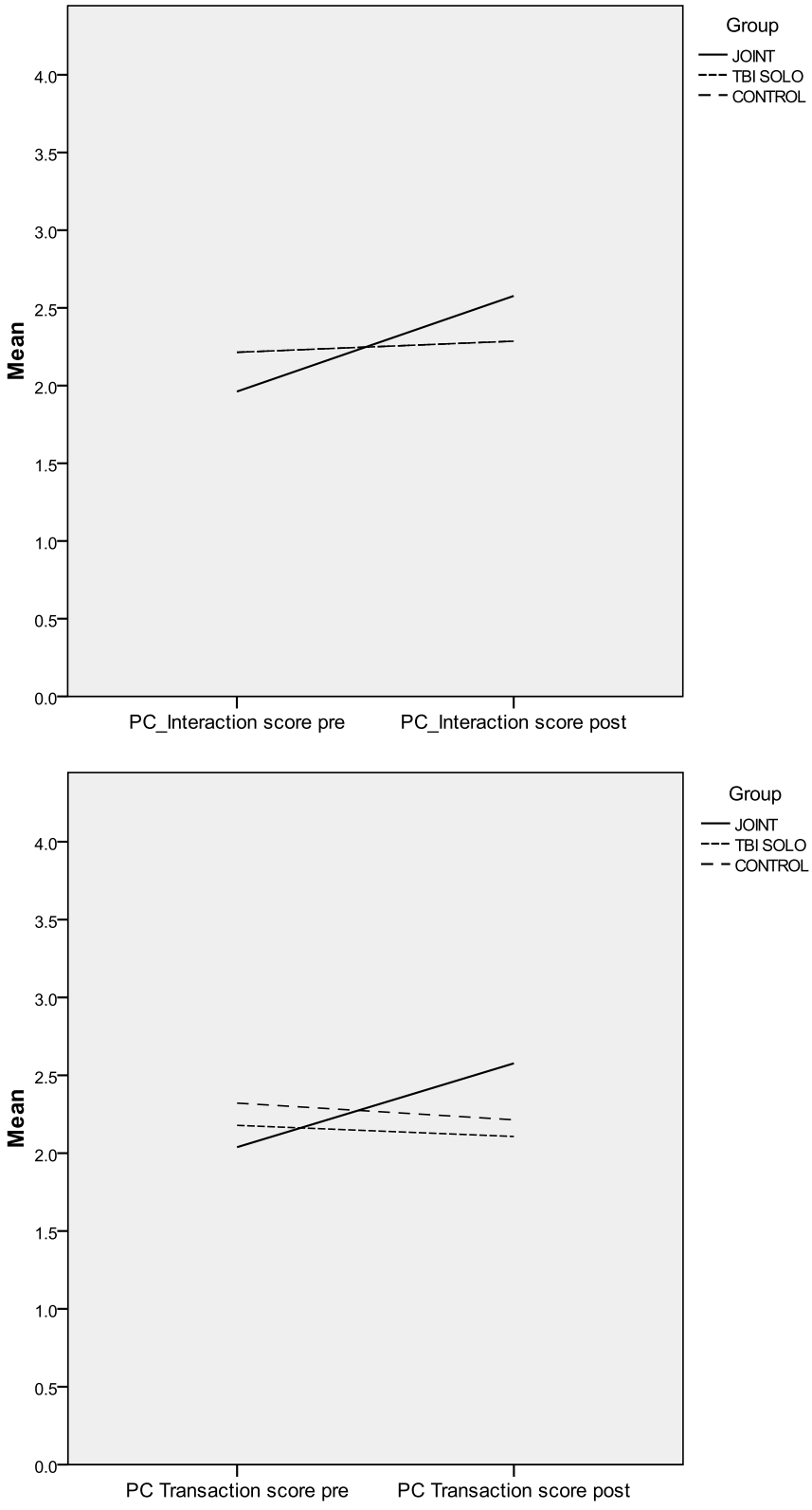
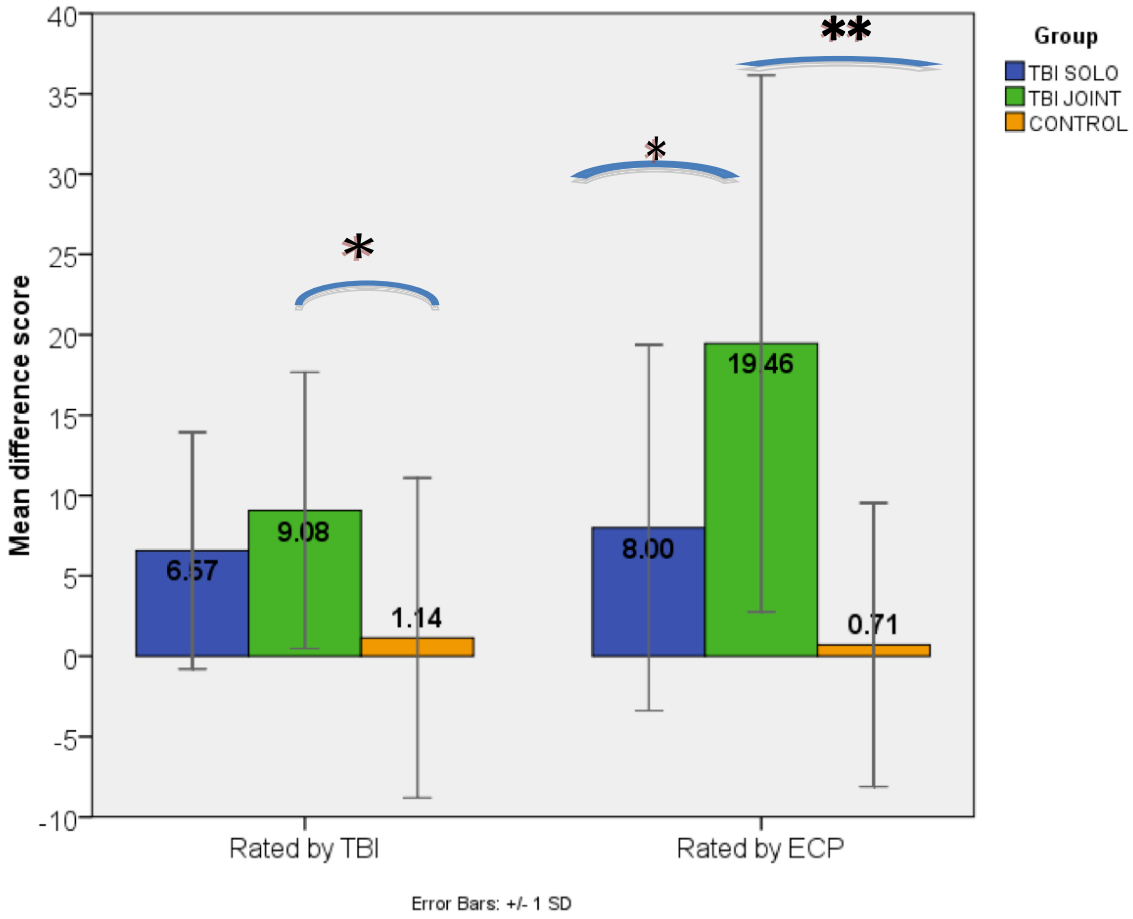


Figure 3. MPC Interaction and Transaction scores pre and post treatment in the Purposeful Conversation (PC) condition



*p <0.05, **p<0.01

Figure 4. Mean difference scores Pre minus Post on the La Trobe Communication Questionnaire.

Appendix 1. Interview probe statements

The interview contained a general opening statement requesting information about the participants' experience of being involved in the program, i.e. "Tell me about your experiences with the social skills communication program" to obtain participants' preliminary reflections. The following probe questions were then used throughout the interview as necessary to ensure all topics of interest were addressed.

Probe topics included "Tell me about …"

1. Your communication (family/friends/strangers)
2. The communication partner's communication skills (JOINT only)
3. Relationship between person with TBI and the communication partner
4. Relationship with family
5. Relationship with friends
6. Social life
7. Confidence with communication/social skills
8. Your communication goals at the end of the program
9. Elements of the program that should be kept
10. Changes that could be made
11. Experience of attending the program with a communication partner (JOINT only).
12. What it would have been like to attend the program with a communication partner (TBI SOLO only)

Member checking was used during interviews to confirm that participants' responses had been understood accurately.