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Improving the communication of people with severe Traumatic Brain Injury (TBI): a clinical trial

Submission date	Recruitment status
01/03/2007	No longer recruiting
Registration date	**Overall study status**
10/05/2007	Completed
Last Edited	**Condition category**
23/05/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
402687

Study information

Scientific Title
Improving the communication of people with severe Traumatic Brain Injury (TBI): a clinical trial

Study objectives
Two approaches have been shown to improve the communication of those with TBI. Training in social skills is helpful, as is training Everyday Communication Partners (ECPs) to deal with difficult communication behaviours. However, to date, no research has concurrently studied these two approaches to rehabilitation. Consequently, it is unknown whether best results are achieved with either method. The present project compares the two approaches for treating communication disorders after TBI.
Specifically:
1. Social communication skills training for people with TBI alone (TBI condition) will improve social communication skills and communication participation. It will have little effect on their communication partners behaviour
2. A combined approach (JOINT condition), training the person's everyday communication partner will improve the ECPs communicative behaviour towards the person with TBI and lead to the most improvement of social skills and communication participation of the person with TBI relative to the single approach (above)
3. Any combination of treatment will be more efficacious than no treatment (delayed treatment CONTROL)
4. The combined treatment approach (JOINT) will lead to earlier gains in communicative behaviour (greater cost-effectiveness) than seen in the TBI training program in isolation

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Sydney South West Area Health Service HEC, approved on 04/04/2006, ref. 2006/004
2. University of Sydney HEC, approved on 16/05/2006, ref. 9225

Study design
Randomised, controlled, single-blind trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions

A social-communication training program for people with TBI will be compared with another program designed for the everyday communication partners of people with TBI.

'The Social Communication Training Program' targets identified social-communication difficulties in people with TBI. The program also includes formal, structured role-plays and informal social conversation situations with the purpose of teaching the person with TBI to differentiate between situations, and communicate accordingly. Their communication partner may help with homework, but does not specifically attend the treatment and is not the target of training.

'The Everyday Communication Partners Training Program' in contrast, involves both the person with TBI and their everyday communication partner in the group and individual sessions. The training is focused upon providing education and training to the everyday communication partner, to improve their ability to interact with the person with TBI successfully.

Each program will consist of weekly three-hour group sessions for 10 weeks with an individual 1 hour session per week to target individual needs and reinforce learning from the group sessions. Administration of the group program will be via a standardised manual with opportunity to address individual needs within this framework.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Measure of Participation in Conversation: The primary measure will evaluate the person with TBI's level of participation in conversation in terms of his/her ability to interact or socially connect with a partner and to respond to and/or initiate specific content. The rater scores a 5-minute videotape of a social interaction 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). Two independent blind raters will score the videotapes. All participants will be assessed on the primary outcome variables pre treatment, two times during treatment, immediately post treatment and 6 months post treatment.

Secondary outcome measures
All participants will be assessed on the following secondary outcome variables pre treatment, immediately post treatment and 6 months post treatment.

1. Discourse measures will provide a detailed analysis of the structure and flow of conversation between the person with TBI and their everyday communication partner. Analysis of the interactional 'exchange structure' between person with TBI and their Everyday Communication Partner during a problem solving task will provide a measure of who has the power in the conversation (by the role the participant takes in information giving). Analysis will also be completed on the 'Generic Structure Potential' of the conversation on the problem solving task. This examines the broader structural elements of a conversation.

2. Social skills measures will examine broader aspects of social skills including:
a. Degree of "rewardingness" in a conversational interaction as judged on a 9 point scale by blind

raters
b. Global ratings of participants' self esteem, measured with the Rosenberg Self-Esteem Scale and the Coopersmith Inventory
c. Social perception ability, measured by the total score on the Awareness of Social Inference Test (TASIT). This test requires the person with TBI to interpret the emotion of speakers engaged in everyday conversations (as depicted on videotape) as well as the meaning and intentions behind their specific comments, some of which are not literally true (i.e. lies or sarcastic comments)
d. Global ratings of the contributions made by the communication partners in conversation will be measured by the score on the Measure of Skill in Supported Conversation
e. Perceived communicative ability from the point of view of both person with TBI and their everyday communication partner, will be measured with the average score on the Latrobe Communication Questionnaire (LCQ)

3. Participants' social activity level will be assessed via structured interview using the Sydney Psychosocial Reintegration Scale (SPRS). This questionnaire measures the effect of brain injury on a person's lifestyle in three categories: occupational activities (work, recreation), interpersonal relationships and independent activities of daily living. Both the person with TBI and their communicative partner will complete the assessment separately.

4. Care-giver burden will be measured by the Care Burden Questionnaire. This will be administered to everyday communication partners to evaluate the consequences of supporting the person with TBI.

5. Cost effectiveness of training conditions will be compared on the primary outcome measure as indicated by the group that makes a 0.5 change on the Measure of Participation in Conversation in the shortest amount of time.

Overall study start date
01/05/2007

Completion date
01/12/2009

Eligibility

Key inclusion criteria
Participants must:
1. Have sustained a moderate to severe TBI for 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) or more than 24 hours (severe). GCS and PTA is routinely assessed at the participating centers and recorded in hospital files
2. Be observed by ward or community staff to have significant social skills deficits
3. Be of at least average pre-morbid intelligence (as assessed on the WAISIII Vocabulary subtest and demographic information)
4. Have a regular communication partner with whom they interact on a daily basis

Family members or care-givers will be familiar to the person with TBI, have not sustained a brain injury or have a psychiatric history, and interact with the person with TBI on a regular basis.

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
108

Total final enrolment
44

Key exclusion criteria
1. Drug and alcohol addiction or active psychosis as defined by their treating doctor
2. Aphasia (language impairment) as assessed by their speech pathologist
3. Non-English speaking background
4. Severe amnesia, as assessed by Wechsler Memory Scale
5. Severe dysarthric (motor speech) impairments which make speech unintelligible

Date of first enrolment
01/05/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Australia

Study participating centre
Speech Pathology
Lidcombe
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Sponsor information

Organisation
University of Sydney (Australia)

Sponsor details

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Sponsor type
Not defined

Website
http://www.usyd.edu.au/su/reschols/welcome.html

ROR
https://ror.org/0384j8v12

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council (NH&MRC) Project Grant (Australia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/09/2009	23/05/2019	Yes	No
Results article	results	01/07/2013	23/05/2019	Yes	No