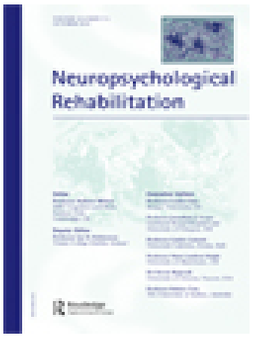

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Can acceptance and commitment therapy facilitate psychological adjustment after a severe traumatic brain injury? A pilot randomized controlled trial

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ABSTRACT

This study investigated if an Acceptance and Commitment Therapy (ACT) intervention (ACT-Adjust) can facilitate psychological adjustment and reduce psychological distress following severe traumatic brain injury (TBI). The study design comprised a single centre, two-armed, Phase II pilot randomized controlled trial. Nineteen individuals with severe TBI (PTA ≥7 days) who met a clinical threshold for psychological distress (Depression Anxiety Stress Scales-21; DASS > 9) were randomly allocated to either ACT-Adjust (n = 10) or an active control, Befriending Therapy (n = 9), in conjunction with a holistic rehabilitation programme. Primary (psychological flexibility, rehabilitation participation) and secondary (depression, anxiety & stress) outcomes were measured at three-time points (pre, post and follow up). Significant decreases were found for DASS-depression (group by time interaction, $F_{1,17} = 5.35$, $p = .03$) and DASS-stress (group by time interaction, $F_{1,17} = 5.69$, $p = .03$) in comparison to the Befriending group, but not for the primary outcome measures. The reduction in stress post-treatment was classed as clinically significant, however interaction differences for stress and depression were not maintained at one month follow up. Preliminary investigations indicate potential for ACT in decreasing psychological distress for individuals with a severe TBI with further sessions required to maintain treatment gains. The pilot results suggest further investigation is warranted in a larger scale clinical trial.

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Acceptance and commitment therapy; Randomized controlled trial; Depression; Anxiety; Stress; Traumatic brain injury; Psychological flexibility.

The rehabilitation journey after severe traumatic brain injury (TBI) involves a complex adjustment process as the individual copes with multiple changes.

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These changes include motor-sensory, cognitive and emotional/behavioural impairments coupled with changes in life circumstances (such as employment and relationship status), often accompanied by strong experiences of loss and grief (Roundhill, Williams, & Hughes, 2007). Post-injury adjustment involves cognitive, behavioural and emotional adaptation as well as a search for meaning (Freeman, Adams, & Ashworth, 2015). This process commonly occurs within the context of significant psychological distress (Bombardier et al., 2010; Gould, Ponsford, Johnston, & Schönberger, 2011).

Clinicians have limited evidence-informed treatment options to draw upon in responding to the psychological challenges associated with adjustment to TBI. Existing psychological treatments, predominantly CBT-based, have largely focused on reducing symptoms of psychological distress. Previous trials have suggested efficacy in reducing a range of psychological symptoms after TBI including depression (Fann et al., 2015), hopelessness (Brenner et al., 2018; Simpson, Tate, Whiting, & Cotter, 2011), anxiety (Hsieh et al., 2012) and anger (Medd & Tate, 2000). However, a Cochrane review found the evidence-base for the efficacy of traditional CBT with the TBI population is still slim (Gertler, Tate, & Cameron, 2015). Furthermore, CBT interventions applied in a research environment typically target single psychological conditions, although interventions targeting mixed psychological presentations including both anxiety and depression are emerging (Ponsford et al., 2016).

Transdiagnostic approaches, including Acceptance and Commitment Therapy (ACT), may constitute an alternative therapeutic modality to facilitate psychological adjustment after TBI (Gracey, Longworth, & Psaila, 2016; Shields, Ownsworth, O'Donovan, & Fleming, 2016). ACT draws upon the same treatment principles as CBT without tailoring the protocol for a specific diagnosis (McHugh, 2011). Treatment aims to either increase or decrease behaviours (internal or external) that allow a person to move toward valued goals rather than focussing on symptom reduction. The therapeutic goal of ACT is to promote psychological flexibility by working through and achieving skills in six core processes including acceptance, cognitive defusion, being in the present moment, the self–as-context, values and committed action (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Increased psychological flexibility, allows the individual to engage in values consistent behaviour despite the presence of distressing thoughts and feelings (Hayes, Strosahl, & Wilson, 2003). The reduced emphasis on eliminating symptoms means ACT may be a good therapeutic "fit" for TBI, where the aim is learning how to live effectively despite the presence of symptoms.

Empirical support for the theoretical foundations of ACT include trials showing that enhanced psychological flexibility facilitated adjustment to various chronic health conditions (Graham, Gouick, Krahé, & Gillanders, 2016). Reviews have suggested the utility of using ACT after a TBI (Kangas & McDonald, 2011; Soo, Tate, & Lane-Brown, 2011; Whiting, Deane, Simpson, McLeod, & Ciarrochi, 2017) but the evidence base is limited to case studies (Sylvester, 2011;

Whiting, Deane, Simpson, Ciarrochi, & Mcleod, 2018) and military samples (Blevins, Roca, & Spencer, 2011; Lang et al., 2017). The largest published study to date of an ACT intervention was with US military veterans who presented with a range of psychiatric conditions ($n = 160$). The study sample included a subset of individuals (65%) with an identified mild/moderate TBI in addition to their psychiatric condition. Participants were randomized, regardless of TBI status, to either a generic ACT treatment (Lang et al., 2017) or Present Centred Therapy (PCT). PCT is a manualised control therapy designed to account for specific aspects of psychotherapy and focusses on current life concerns, symptoms and client-directed problem solving (Lang et al., 2017). In this study, no differences were found between the ACT intervention and PCT although a moderate treatment effect for reduced general distress and improved psychological flexibility was found for both groups. A secondary analysis (Bomyea, Lang, & Schnurr, 2017) revealed the same treatment response among the individuals with a mild/moderate TBI as was reported for the whole sample. Although these studies indicate ACT may be useful for people with TBI, there are a number of methodological issues which have constrained the impact of the findings.

In relation to the heterogeneity of the study samples, some studies included acquired brain injury with a mix of aetiologies (Bradbury et al., 2008; Hodgson, McDonald, Tate, & Gertler, 2005; Medd & Tate, 2000). While reflective of clinical practice, this mix makes it difficult to partial out the specific effect for people with TBI. Severity of TBI (based on post-traumatic amnesia score, PTA) was also highly variable in some studies, spanning mild (PTA < 1 h) to severe injury (PTA > 24 h) (Ashman, Cantor, Tsaousides, Spielman, & Gordon, 2014; Bell et al., 2011; Bombardier et al., 2009; Bomyea et al., 2017; Fann et al., 2015), with the potential consequence of over-inflating the potential benefits of interventions for the participants with the more severe injuries. Also, time since injury varied greatly within some samples (e.g., from very recent < 1 month to >20 years; Powell, Heslin, & Greenwood, 2002). It would be anticipated that factors contributing to psychological distress and impeding the adjustment process may vary, depending on where the person is located on their post injury journey (Antonak, Livneh, & Antonak, 1993). In addition to the challenges with sample heterogeneity, it was not always clear whether participants met a clinical threshold for the disorder being treated (Bombardier et al., 2009). Finally, in some studies, psychological factors were a secondary outcome rather than the focus of treatment (Ownsworth, Fleming, Shum, Kuipers, & Strong, 2008).

To address these issues, the current study investigated psychological treatment efficacy for individuals with a severe TBI (i.e., post traumatic amnesia, PTA > 7days), within five years post-injury. In addition, the intervention was compared to an active control, something that is not commonly used in treatment trials with participants who have had a TBI, rather than the more typically employed usual treatment or wait list control (Bédard et al., 2014; Bell et al.,

2011; Brenner et al., 2012, 2018; Simpson et al., 2011). The use of an active control allows for the control of a number of factors including therapist contact, the expectancy of the client, a therapeutic alliance, and replication of intervention time (Bendall et al., 2006). Only a small number of completed randomized controlled trials have implemented an active control condition or compared different treatment modalities with individuals with a severe TBI (Ashman et al., 2014; Fann et al., 2015; Hsieh et al., 2012; Lang et al., 2012; Vanderploeg et al., 2008).

In deciding on the control treatment to use, one consideration is the manualisation of the control intervention in order to maintain an equivalent level of standardization across the treatment condition and control conditions (Hart, Fann, & Novack, 2008; Schulz, Altman, & Moher, 2010). Befriending therapy (Bendall, Killackey, Jackson, & Gleeson, 2003), as an active control intervention, meets these guidelines for manualisation and standardization. Befriending therapy has been successfully used as a way to provide social support to psychiatrically unwell people (Mead, Lester, Chew-Graham, Gask, & Bower, 2010), as well as a control condition in the treatment of schizophrenia (Bendall et al., 2006; Jackson et al., 2008).

In guiding selection of appropriate primary and secondary measures (Craig et al., 2008), a review of previous ACT studies and this population group (Bomyea et al., 2017; Sylvester, 2011; Whiting et al., 2017) identified three important domains of outcome, namely increased psychological flexibility, increased participation in meaningful activities (committed action) and decreased levels of psychological distress in the context of the issue creating the distress. Psychological flexibility in the context of acquired brain injury can be assessed using the Acceptance and Action Questionnaire for Acquired Brain Injury (AAQ-ABI). The AAQ-ABI was initially developed by Sylvester (2011) and further validation (Whiting, Deane, Ciarrochi, McLeod, & Simpson, 2015) indicated a strong relationship to the broad measure of psychological flexibility, the Acceptance and Action Questionnaire-II (Bond et al., 2011) and sensitivity to changes in psychological flexibility (Whiting et al., 2017).

Another major outcome of ACT is to allow people to engage in a meaningful life despite experiencing ongoing struggles, captured by the committed action component of the ACT model. Within TBI, the concept of committed action appears to be a difficult construct to encapsulate and has been operationalized differently in the published case studies. Sylvester (2011), operationalized committed action by a functional measure of participation, the Participation Objective, Participation Subjective Scale (POPS; Brown, 2004). This is a broad measure of participation with some domains having limited relevance to people for example, domestic activities such as washing dishes for some young men, reducing the appropriateness of the measure to assess committed action in the context of values. The other TBI case study has explored operationalizing committed action in the context of rehabilitation engagement using the

Motivation for Rehabilitation Questionnaire (MOT-Q) (Chervinsky et al., 1998) and social functioning with limited success (Whiting et al., 2017). In this study we have chosen the Motivation for Rehabilitation Questionnaire (MOT-Q) and a tool to measure values success as it appears to be closer to the construct in our study.

ACT-Adjust is a novel, manualised ACT program developed to facilitate psychological adjustment after TBI (Whiting, Simpson, McLeod, Deane, & Ciarrochi, 2012; Whiting et al., 2018). The primary hypothesis was participants receiving ACT-Adjust would show improved levels of psychological flexibility and participation in meaningful activities (primary outcomes) compared to participants in an active control condition. Participants receiving ACT-Adjust were also expected to report significant reductions in psychological distress and increases in quality of life (secondary outcomes) compared to the active controls. Finally, it was hypothesized that participants in ACT-Adjust would maintain treatment gains in primary/secondary outcomes at one-month follow-up post-treatment.

Methods

Design

The three hypotheses were tested through a randomised controlled trial (RCT) using a 2 × 2 (group × time) repeated measures factorial design, with participants randomly allocated to the intervention or active control group on a 1:1 ratio. Both groups also received constrained usual care (Freedland, Mohr, Davidson, & Schwartz, 2011), which included a standard holistic rehabilitation programme (Tate, Strettles, & Osoteo, 2004) with the exception of psychological treatment. The trial is reported according to the CONSORT statement (Schulz et al., 2010) and the protocol (Whiting et al., 2012) registered on the Australian New Zealand Clinical Trials Registry ACTRN12610000851066.

Formal power analysis was not undertaken, but an analysis based on prior studies that had participants with TBI provided a guide for determining the target sample size. Power analysis to estimate sample size was complicated by the small number of outcome studies where participants had severe TBI and by the lack of prior studies with such samples using the primary outcome measures specified in this study. However, previous RCTs using severe TBI groups have found moderate to large effect sizes (ES of 0.5 and 1.0) on the primary outcome measure with 8 to 10 participants in each group (Hsieh et al., 2012; Simpson et al., 2011). In a study using a mixed ABI group, a large effect size on the primary outcome variable was reported even with a small sample size ($n = 16$, ES = .89; Medd & Tate, 2000). Thus, a moderate to large ES was anticipated (0.5 to 1.0) and a sample size of 48 (24 in each group) was thought sufficient to detect effects in this range.

Participants

Participants were recruited from the outpatient service of Liverpool Brain Injury Rehabilitation Unit (LBIRU), Australia. Selection criteria comprised (i) having sustained a severe TBI (post-traumatic amnesia ≥7 days) after 18 years of age; (ii) being between 18 and 65 years old and less than five years post-injury; (iii) having sufficient cognitive-linguistic capacity to complete self-report measures and participate in the programme; and (iv) reporting a clinically significant level of psychological distress (Depression > 13, Anxiety > 9 and Stress > 18; Depression Anxiety Stress Scales 21-item; DASS) (Lovibond & Lovibond, 1995). Exclusion criteria comprised (i) having a severe psychiatric illness, including psychotic disorder or substance addiction as determined by the medical file, self-report or consultation with the rehabilitation team; and (ii) currently undergoing psychological intervention.

Measures

Nine standardized self-report instruments measuring primary/secondary outcomes were administered. One proxy-report measure was completed by a significant other (family member/close friend). In addition, a study specific protocol (demographic/injury details) and objective neuropsychological screening measure were administered at baseline.

Primary outcome measures

Psychological flexibility (brain injury specific). The Acceptance and Action Questionnaire – Acquired Brain Injury (AAQ-ABI: Whiting et al., 2015) is a nine-item self-report measure scored on a 5-point Likert scale (0 = "not at all true" to 4 = "very true"; range 0–36). Items assess psychological flexibility around the thoughts, feelings and behaviours that may arise after incurring a brain injury (e.g., My worries and fears about my brain injury are true) with higher scores indicating greater psychological inflexibility. The measure has sound psychometric properties ($\alpha = .89$; ICC = .92) (Whiting et al., 2015).

Rehabilitation participation. The Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q: Chervinsky et al., 1998) is a 31-item self-report scale ("strongly disagree" = −2 to "strongly agree" = +2) that measures participant willingness to engage in the rehabilitation process and was used in the present study to assess participants' committed action. Total scores range from to – 62 to 62 with strong internal consistency ($\alpha = 0.9$) (Chervinsky et al., 1998).

Values-consistent living. The Survey of Life Principles Version 2.2–Card sorting task (SLP: Ciarrochi & Bailey, 2008) served a dual role, measuring values

importance and during the intervention for values identification. The SLP has 60 items reflecting life principles across various domains (e.g., "acting with courage", "designing things"). Respondents allocate each principle to one of three categories; (1) not very important; (2) moderate importance; and (3) highest importance. From the highest importance category, respondents select their top 10 and rate them using a 5-point Likert scale (0 = "not very" to 4 = "extremely") on (1) How important was the value (Importance) and (2) How consistently are you acting in accordance with your value (Success). SLP scores of value importance have demonstrated good internal consistency (Cronbach's $\alpha = .79–.97$) (Ciarrochi & Bailey, 2008).

Secondary outcome measures

Self-report measures used in either ACT treatment trials or with a TBI population were utilized to pilot the most effective outcome measure. The AAQ-II (Bond et al., 2011) is a frequently employed outcome measure in ACT trials and assesses general psychological flexibility. General distress was assessed using the DASS, (Lovibond & Lovibond, 1995) a 21 item self-report measure of depression, anxiety and stress. The DASS is commonly used in clinical practice within Australia, includes the broader psychological component of stress and the existing factor structure was found to be replicated in samples with a moderate to severe TBI (Randall, Thomas, Whiting, & McGrath, 2017). The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was also used to assess psychological distress as it is reported to be less vulnerable to the confounding effects of somatic symptoms in the measurement of anxiety and depression after TBI (Schönberger & Ponsford, 2010). This measure has demonstrated sensitivity to change in some TBI outcome studies (Draper, Ponsford, & Schönberger, 2007) but not in others (Simpson et al., 2011), indicating that other measures of distress might be required.

Measures of psychological distress commonly used in ACT interventions were also included in the secondary measures. The Positive and Negative Affect Scales (PANAS: Watson, Clark, & Tellegen, 1988) as it incorporates positive mood and the General Health Questionnaire–12 (GHQ-12: Hardy, Shapiro, Haynes, & Rick, 1999) for distress and minor psychiatric disorders. Quality of Life was assessed using the 12-item Short Form Health Survey (SF-12: Ware, Kosinski, & Keller, 1996), with two subscales, physical and mental health. The proxy rated version of the Sydney Psychosocial Reintegration Scale-2 (SPRS-2: Tate, Simpson, Soo, & Lane-Brown, 2011) was administered to assess social participation. Family members or clinicians rated the 12-item measure with higher scores indicating an increasing level of independence and participation.

Baseline cognitive function

Objective assessment of cognitive function was assessed using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS: Randolph,

1998). The RBANS assesses five neurocognitive domains as well as overall cognitive function and provides a scaled score profile with six index scores.

Procedures

Following ethical approval from the Sydney South West Local Health District Human Research Ethics Committee, the clinical psychology waiting list of LBIRU outpatient service was reviewed for potential participants from September 2011 to October 2014 ($n = 169$). The screening and recruitment process is outlined in Figure 1.

Participants provided informed consent and completed the baseline measures (Time 1; T1) by the therapist administering the ACT intervention (ACT-Adjust). Participants were allocated to either ACT-Adjust or Befriending by block randomization ($n = 4$, two per condition) using computer-generated random numbers. Group size was limited to two in order to ensure effective engagement of both participants and to facilitate some group processes as had been shown in previous interventions with TBI participants (Simpson et al., 2011; Whiting et al., 2018). To conceal allocation prior to assessment, the randomization was conducted independently by a person off-site. All participants remained in the condition to which they were allocated. Three participants withdrew from the trial (see Figure 1).

ACT-Adjust was delivered by an ACT trained clinical psychologist with ten years' experience in TBI. Befriending Therapy was delivered by three therapists (an ACT trained clinical psychologist with more than seven years' experience in TBI; a registered psychologist with more than 10 years' experience working in mental health and disabilities and one clinical psychology postgraduate student). Post-intervention (Time 2; T2, after session 6) and follow up measures (Time 3, T3; after session 7) were administered by an independent assessor (research officer with postgraduate psychology qualifications) blinded to the treatment condition. The blinded assessor completed a protocol to monitor blinding effectiveness. There was 100% non-disclosure of treatment group allocation by participants and the blinded assessor guessed correct treatment group allocation at both T2 ($n = 16$) and T3 ($n = 16$) in 58.1% of cases, suggesting blinding was largely effective.

Treatment protocol

ACT-Adjust

ACT-Adjust involved seven weekly, 1.5-hour group sessions with each session focussing on a component of the ACT model (Table 1). The programme was manualised and content included mindfulness exercises, psycho-education, discussion and experiential exercises relevant to that session's focus. Building on previous research, strategies were implemented to accommodate for cognitive

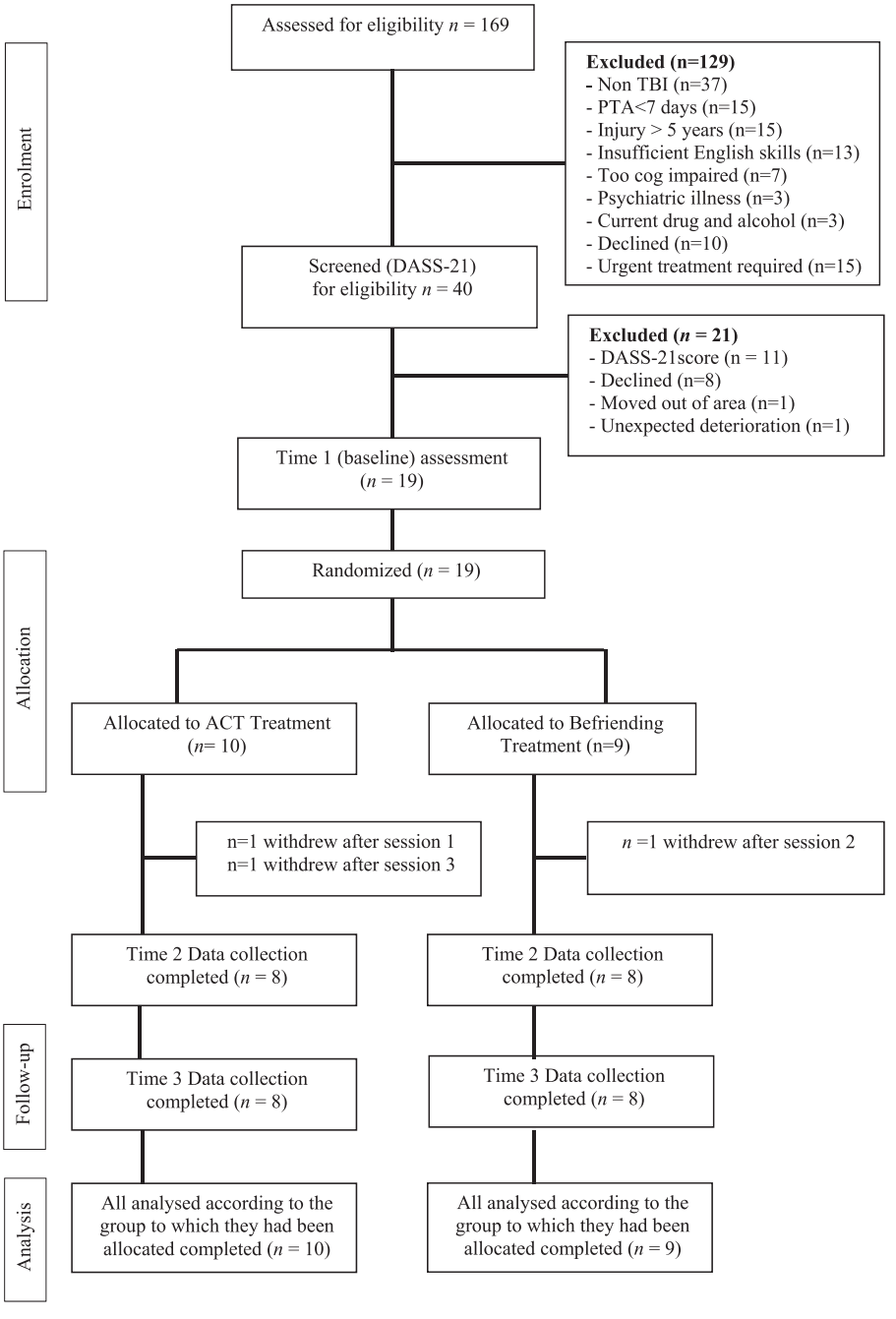

Figure 1. Study flow diagram.

impairments (Gallagher, McLeod, & McMillan, 2019; Kangas & McDonald, 2011; Soo et al., 2011; Whiting et al., 2017) including repeating programme content, presenting information in multiple formats (i.e., verbally & visually), and using experiential exercises. The programme was reviewed to promote consolidation

Table 1. Summary of ACT treatment programme.

N	Session title	Session goals/ principles	Experiential exercises	Homework activity
1	Introduction/ confronting the agenda	Getting to know each other Establishing framework of the group Introduce workability of current coping strategies	Mindful breathing Confronting the agenda Mindfulness of the breath Discussion about homework	Monitor mood & coping used over the week
2	Control is the problem	Understanding about control and the normalcy of human suffering Introduce values	Mindful breathing Review homework Walking while telling yourself you can't walk to the back of room Chocolate cake – avoid thinking about a chocolate cake while therapist describes it in detail Let suffering get close[a] Passengers on the bus – metaphor representing all the difficult thoughts, feelings and memories you carry with you	Noticing control behaviours – identifying a valued activity being avoided & noting what occurs (thoughts/ feelings/behaviours) when they try to engage in the activity
3	Acceptance and defusion	Understanding impact of language, learning defusion techniques	Breathing meditation Milk, milk, milk – repeating the word milk repeatedly to reduce meaning of the word Physicalise the thought – defusion exercise to make a distressing thought more concrete Don't get eaten machine[b]	Defusion – practicing physicalizing the thought
4	Self-as-context and contact with present moment	Separating self from thoughts/feelings/ actions Education about mindfulness	Mindfulness of breath Separation of self[c] Observer exercise[d] Chessboard metaphor Eating a sultana mindfully	Practice everyday mindfulness Practice mindfulness meditation (recording)
5	Values	Difference between goals (committed action) and values	Noticing thoughts mindfulness exercise Lighthouse metaphor Travelling west metaphor Survey of Life Principles 2.2[b] Funeral metaphor	Principles and action exercise[b]
6	Values and committed action	Engaging in committed action in conjunction with values Recap and review of each session	Body scan meditation Committed action identification Recall experiential exercises & rationale for exercise	Daily diary exercise involving principles & action[b]
7	Relapse prevention (one month after session 6)	Review progress & consolidate learning	Body scan meditation Discuss progress & homework Recall experiential exercises & rationale for exercise	NA

[a]Wilson and DuFrene (2009).
[b]Ciarrochi and Bailey (2008).
[c]Eifert, Forsyth, and McKay (2006).
[d]Hayes et al. (2003).

of content in session six and again in session seven after a one month break as a relapse prevention measure.

Befriending therapy ("befriending")

The active control utilized was Befriending therapy (Bendall et al., 2003) which was developed as a control intervention for psychotherapy clinical trials. Befriending controls for several factors including time spend in therapy, client expectancy, therapeutic alliance and therapist factors (Bendall et al., 2003). The focus of therapy is on neutral topics which are of interest to participants but are unlikely to elicit a negative emotional response. The relationship with participants is friendly and engaging rather than empathic, with the therapist providing positive statements rather than reframing or problem solving (Bendall et al., 2003). The Befriending group was delivered to mirror the ACT-Adjust group, meeting weekly for six sessions for approximately 1.5 h with a follow up session undertaken one month later. This provided a total of seven sessions. The therapist used the Befriending manual (Bendall et al., 2003) and participants were issued handouts at session one detailing group rules, activity for the first session and the structure for the following sessions (see Table 2).

Assessment of treatment fidelity

Treatment fidelity was undertaken by a Registered Psychologist trained in ACT, who was both independent and located off site. Sessions were audio recorded and reviewed for adherence to the treatment protocol using two purpose-

Table 2. Summary of the befriending therapy programme.

Session	Content
1	Introduction of each group member Discussion around group rules and aims Education about Befriending Therapy Identification of weekly topics by brain storming using the whiteboard For Example: • Going for a coffee • Talking about a previous holiday • Educating others in the group about a hobby or sport • Watch a movie over the week and discuss next session Set the agenda for the sessions 2–6
2–6 • Each participant, including the therapist, to speak on the designated • topic with equal time allowance • Time for questions and general discussion	Session content set according to timetable established in Session 1
7	Discussion and review of progress over previous month Referral for ongoing services discussed and facilitated

designed fidelity measures (see Appendix I). The 14 item ACT adherence measure used a 5-point Likert scale (1 = "not at all" to 5 = "extensively"; range 14–70), higher scores indicated greater adherence. Befriending (Bendall et al., 2003) has six factors differentiating it from active therapy which were rated on a 5-point Likert scale (0 = "none of the time" to 5 = "all of the time"; range 6–30). Higher scores indicated greater adherence.

Data analysis

Data were entered into PASW Statistics Version 19.0 (IBM Corp, 2013). Data screening to test for normality was undertaken using Shapiro Wilks tests for all outcome measures across each treatment group. For Hypotheses 1 and 2, repeated measures analysis of variance was conducted for all primary and secondary variables (group by time) using intention to treat analysis with last value carried forward to account for missing data. This was done for two cases in the ACT group and one case in the Befriending group. Both 95% confidence intervals (CI) and effect size (ES, partial eta squared) were calculated.

Hypothesis 3, to evaluate the retention of any treatment gains after one month a 2 (group: ACT vs Befriending) by 2 (time: T1 vs T3) repeated-measures ANOVA was conducted. The p value for the group by time (T1, T3) ANOVA was set at $p < .05$. No Bonferroni adjustment was undertaken due to the exploratory nature of the research which sought to trial a number of outcome measures relevant to both TBI and ACT intervention studies and a smaller than planned sample size ($n = 8$ completers in each group). With studies using smaller samples, treatment effects may be overlooked if the focus is on stringent tests of significance (Feise, 2002; Perneger, 1998). Confidence intervals, effect sizes, statistically significant results and clinically significant results will be reported as is recommended by Cumming (2013).

Results

There were no significant differences between the participants who were randomized versus those who met criteria but declined treatment on the DASS subscales, age, gender, and PTA score. There was a significant difference for time since injury, with those who declined treatment sustaining more recent injuries (Median = 6.5 months, IQR = 9) than those who agreed to participate (Median = 26.6 months, IQR = 32) (Mann–Whitney $U = 24.5$, $p < .01$). Demographic and injury variables for the trial participants are displayed in Table 3.

Primary and secondary outcome variables showed normal distributions on all baseline measures (T1). Variables with non-normal distributions ($n = 2$, PANAS-Negative affect and HADS-Depression, both at T2) were transformed (Log10) for all time periods (T1, T2 and T3) for statistical testing. The transformed variables were normally distributed. At initial screening, all participants ($n = 19$)

Table 3. Demographic characteristics by group assignment.

	All randomized participants		Participants who declined treatment
	ACT ($n = 10$)	Befriending ($n = 9$)	($n = 8$)
Age (years), Mean (SD)	36.4 (13.5)	37.2 (12.5)	33.6 (16.9)
Time since injury (months), Mean (SD)	20.7 (17.5)	33.3 (21.5)	7.1 (5.0)
Gender, *n* (%)			
Male	8 (80%)	7 (77.8%)	7 (87.5%)
Female	2 (20%)	2 (22.2%)	1 (12.5%)
PTA (days), Mean (SD)	19.4 (13.7)	36.3 (21.2)	33.5 (23.7)
Years of Education, Mean (SD)	11.2 (2.0)	11.4 (1.0)	
RBANS Index Score, Mean (SD)			
Immediate Memory	84.2 (18.3)	79.4 (15.9)	
Visuospatial	93.3 (20.6)	95.9 (16.0)	
Language	85.0 (16.3)	84.3 (18.1)	
Attention	72.0 (13.8)	80.8 (17.2)	
Delayed Memory	84.6 (18.8)	86.1 (16.9)	
Total Score	79.4 (15.6)	80.8 (15.2)	

Note: PTA: Post-traumatic amnesia, RBANS: Repeatable battery for the assessment of neuropsychological status.

met the clinical threshold and most ($n = 15$) scored above the moderate range on more than one subscale of the DASS. There were no between-group differences across baseline demographic (age, gender, time since injury), cognitive (RBANS and AQ) and outcome measures. Befriending had significantly longer PTA scores (36.3 ± 21.2 days) compared to ACT-Adjust (19.4 ± 13.7) ($t_{(17)} = 2.1$, $p = .05$) but no other significant group differences were identified. Despite the difference in initial injury severity, no significant between-groups difference was demonstrated in mean total cognitive ability scores (R-BANS, t-test, ns). Both groups scored more than one standard deviation below the mean, indicating the presence of cognitive impairment.

Treatment fidelity rating

A total of 21% ($n = 14$) of sessions were rated for treatment fidelity. To allow comparisons between the interventions, the scores were reduced to the item mean. Overall, adherence to the ACT treatment manual and the Befriending manuals were high (ACT; $M = 4.64$, SD = .47 & Befriending; $M = 4.17$, SD = .36 respectively).

Hypothesis 1: Primary outcome measures (T1 vs T2)

Although changes in psychological flexibility (AAQ-ABI) were in the hypothesized direction, repeated measures analysis of variance indicated the treatment group by time interaction for the primary outcome measures of psychological flexibility was not significant ($F_{1,17} = 3.34$, $p = .08$). A visual inspection of confidence intervals showed there was no difference in psychological flexibility between the two groups. There were no significant main effects for group and time.

The time by group interaction on the motivation to participate in rehabilitation (MOT-Q) was not significant, but instead trended in the opposite direction to that hypothesized ($F_{1,17} = 4.11$, $p = .06$). MOT-Q scores reduced slightly in the ACT-Adjust group while MOT-Q scores in the Befriending group increased slightly from baseline to post-intervention. Changes on the Survey of Life Principles (SLP) were in the expected direction but there was no significant interaction effect ($F_{1,17} = .33$, $p = .57$). There were also no main effects for both variables (see descriptive statistics for the three primary outcome measures, Table 4).

Hypothesis 2: Secondary outcome measures (T1 vs T2)

Repeated-measures ANOVA was carried out on the nine secondary outcome measures (descriptive statistics available in Table 4 and Supplementary Table 1). A significant group by time interaction was found on the DASS-depression subscale (time x group: $F_{1,17} = 5.35$, $p = .03$), where DASS-depression scores in the ACT-Adjust had larger decreases over the course of treatment compared to scores in Befriending. This resulted in a medium to large effect size partial $\eta^2 = .24$. There was a main treatment effect for time (baseline to post-intervention) on DASS-depression ($F_{1,17} = 5.35$, $p = .03$) (see Figure 2).

Visual inspection of the group DASS-depression means with standard error, shows the ACT-Adjust group moved from the moderate/severe range at baseline to the mild/moderate range post-intervention. The Befriending group showed no change remaining in the moderate/severe range.

A repeated measures ANOVA revealed a significant group by time interaction for DASS stress ($F_{1,17} = 5.69$, $p = .03$), with the ACT-Adjust group demonstrating a greater reduction in DASS stress scores from baseline to post-intervention compared to the Befriending group. This difference indicated large effect size partial $\eta^2 = .25$. There were no significant main effects for the DASS stress scores (see Figure 3).

Visual inspection of the standard error of the DASS-stress mean scores at each time point indicated the ACT-Adjust group moved from the mild/severe range at baseline to the mild/ moderate range post-intervention (Figure 3). Befriending means on DASS stress increased moving from the mild/moderate range to the moderate to severe range pre to post intervention and were maintained at follow up. None of the other secondary outcome measures demonstrated significant interaction effects or main effects for group and time from baseline to post-intervention (Supplementary Table 1).

Hypothesis 3: Maintenance of gains at 1-month follow-up (T1 vs T3)

A second set of repeated measures ANOVAs was undertaken on those outcomes which had significant group by time interaction effects. No significant differences

Table 4. Comparison of group means, 95% confidence intervals (CI) and effect size across time for primary and secondary outcome measures.

Measure	Time 1				Time 2				T1vsT2[a]	Time 3				T1vsT3[a]
	ACT *M* (SD)	(*n* = 10) 95%CI	Befriend *M* (SD)	(*n* = 9) 95%CI	ACT *M* (SD)	(*n* = 10) 95%CI	Befriend *M* (SD)	(*n* = 9) 95%CI	Effect size Partial η^2	ACT *M* (SD)	(*n* = 10) 95%CI	Befriend *M* (SD)	(*n* = 9) 95%CI	Effect size Partial η^2
AAQ-ABI	19.0(7.1)	13.5,24.5	17.0(7.4)	11.3,22.7	15.7(8.5)	9.6,21.8	17.7(8.0)	11.5,23.8	.17	16.9(8.9)	10.5,23.3	17.7(7.2)	13.6,21.7	.10
MOT-Q	37.6(12.3)	28.8,46.4	27.8(12.1)	18.5,37.1	32.7(14.2)	22.5,42.9	28.9(14.8)	18.5,41.3	.20	26.8(16.1)	15.3,38.3	24.6(17.0)	11.5,37.6	.07
SLP	2.7(.9)	2.1,3.3	2.4(.8)	1.8,3.0	2.9(.7)	2.3,3.4	2.4(.7)	1.9,2.9	.02	3.0(1.0)	2.2,3.7	2.8(.6)	2.3,3.2	.01
AAQ-II	30.6(12.8)	21.4,39.8	33.7(11.3)	25.0, 42.3	27.6(13.9)	17.7,37.5	29.1(10.5)	21.0,37.2	.01	28.1(13.3)	18.6,37.6	29.8(10.9)	21.4,38.1	.01
DASS-D	23.4(11.0)	15.5,31.3	19.6(10.3)	11.6,27.5	16.4(12.3)	7.6,25.2	19.6(10.9)	11.2,27.9	.24*	16.0(13.7)	6.2,25.8	18.4(12.3)	9.0,27.9	.13
DASS-A	17.2(10.6)	9.6, 24.8	13.8(6.7)	8.7,18.9	13.4(11.0)	5.6,21.2	11.8(12.1)	2.4,21.1	.01	10.6(11.7)	2.2,19.0	8.89(11.7)	-.1,17.9	.01
DASS-S	23.6(8.7)	17.4,29.8	23.0(10.2)	15.1,30.7	18.0(12.6)	9.0,27.0	24.4(9.9)	16.8,32.1	.25*	18.0(12.6)	9.0,27.0	23.6(8.6)	17.0,30.2	.12
HADS-D	9.6(3.5)	7.1,12.1	9.9(4.3)	6.6,13.2	9.3(4.3)	6.2,12.4	8.8(4.3)	5.5,12.1	.00	8.9(4.7)	5.6,12.2	10.2(4.7)	6.5,14.0	.03
HADS-A	12.7(4.2)	9.7,15.7	9.7(3.6)	6.9,12.4	10.3(5.7)	6.2,14.4	9.6(4.5)	6.1,13.0	.10	10.3(5.5)	6.3,14.3	10.4(3.7)	7.6,13.3	.18

*$p < .05$.

[a]Effect size of group by time interaction.

Note: Primary Outcome Measures – AAQ-ABI: Acceptance and Action Questionnaire – Acquired Brain Injury, MOT-Q: Motivation for Traumatic Brain Injury Rehabilitation Questionnaire, SLP: The Survey of Life Principles Version 2.2 – Card sorting task. Secondary Outcome Measures – AAQ-II: Acceptance and Action Questionnaire-II, DASS: Depression Anxiety Stress Scale-21, HADS: Hospital Anxiety and Depression Scale.

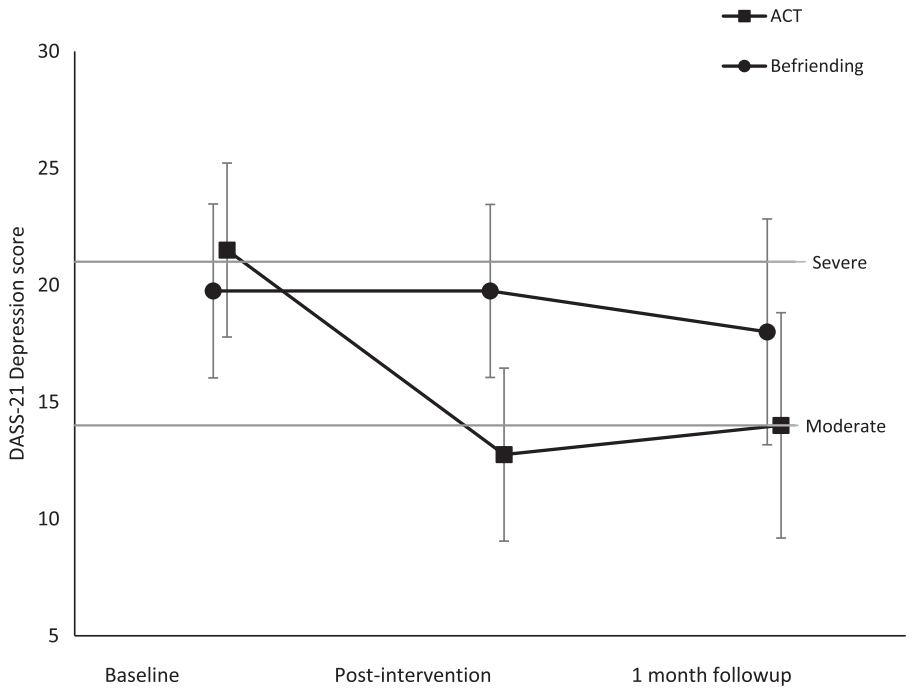

Figure 2. DASS depression mean scores for ACT and befriending across three time points with standard errors.

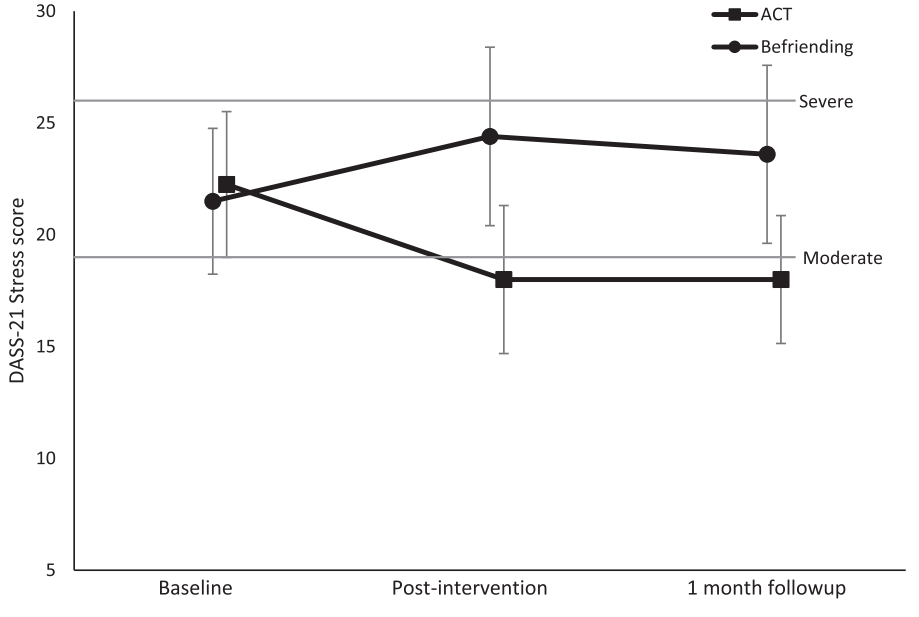

Figure 3. DASS stress mean scores for ACT and befriending across three time points with standard error.

were found for DASS depression ($F_{1,17} = 2.55$, $p = .13$) and DASS stress ($F_{1,17} = 2.37$, $p = .12$) between pre-intervention (T1) and one month follow up (T3), indicating the interaction effect found at post intervention were not maintained at one month after the intervention was completed. The main treatment effect for time (baseline to post-intervention) on DASS-depression was maintained ($F_{1,17} = 5.35$, $p = .03$).

Discussion

To the best of our knowledge, this is the first pilot RCT providing indications of the feasibility of ACT in facilitating psychological adjustment and reducing psychological distress after a severe TBI in a civilian population. The data did not support the main hypothesis that ACT-Adjust would be more effective than Befriending in increasing psychological flexibility and participation, although improvements in psychological flexibility in the ACT-Adjust group (compared to Befriending) trended toward significance. A significant group by time (baseline and post-intervention) interaction effect was found for depression and stress (DASS), with reductions in the intervention group between pre- and post-injury not found in the Befriending group. These reductions in depression and stress were statistically and clinically significant but the differences were not maintained one month later.

The treatment effects were large in the ACT-Adjust group for depression and were moderate-to-large for stress. These effect sizes (ES) are comparable to those achieved using CBT with this population, for example ES = 0.89 (Medd & Tate, 2000), ES > 1.0 (Simpson et al., 2011) and ES = 0.50 (Hsieh et al., 2012). The results suggest ACT-Adjust may reduce self-reported levels of depression and stress in individuals with a severe TBI, but the data do not point to the mechanism of change being an increase in psychological flexibility as found in other ACT studies (Ciarrochi, Bilich, & Godsell, 2010). The lack of significant change in psychological flexibility may be due to several factors in addition to the small sample size. Impairments in cognitive flexibility that commonly occur after a TBI may impact on the individual's ability to achieve improvements in their psychological flexibility (Kashdan & Rottenberg, 2010; Whiting et al., 2017). If this is the case, then other components of the therapy (e.g., behavioural activation) may be making a larger contribution to therapeutic change.

Although significant effects were found for depression as measured by the DASS, depression as measured by the HADS demonstrated no significant differences. This result suggests the DASS maybe more sensitive in a TBI populations as has been indicated by previous research. Dahm, Wong, and Ponsford (2013) found the depression items in the DASS more sensitive than depression items on the HADS, as they captured aspects which seemed to be more relevant to individuals after a TBI including devaluation of life, self-deprecation and hopelessness.

The values success dimension of the SLP was trending in the expected direction supporting indications that behavioural activation may have contributed to effects on depression and stress. The non-significant results among the primary outcomes as a group may also be due to the low sample size and insufficient power. It is conceivable, the SLP and MOT-Q were ineffective in capturing the construct of committed action. For example, the SLP is a newer measure with limited validation data and none available with TBI. Furthermore, participants in the ACT-Adjust were already highly motivated (mean MOT-Q scores were greater than one standard deviation above the population mean), suggesting a possible ceiling effect and the decrease following treatment may be due to regression to the mean. An actual measure of behavioural achievement such as using the Goal Attainment Scale (GAS: Malec, 1999) may identify more idiographic and behavioural outcomes. Further investigations of appropriate measures to assess this outcome are required.

The psychological presentation after a TBI is complex and multifaceted and may require a transdiagnostic approach (Gracey et al., 2016). From a symptom perspective, treatments for depression and anxiety after TBI are well researched but there is limited research on the treatment of stress. As a transdiagnostic approach, ACT has successfully reduced chronic stress in a non TBI population (Brinkborg, Michanek, Hesser, & Berglund, 2011) and appears to be applicable for this adjustment process post-TBI. In classic models, stress responses occur when the individual in unable to adjust to a stressor and homeostasis is threatened (Chrousos & Gold, 1992). Sustaining a TBI creates a stress response (Bay, Sikorskii, & Gao, 2009) and the subsequent adjustment process is stressful for the individual as they attempt to cope and adapt to the many changes secondary to the injury (Karlovits & McColl, 1999). After a mild to moderate TBI, chronic stress has been found to be a predictor for the development of depression (Bay, Hagerty, Williams, Kirsch, & Gillespie, 2002) and results in poorer functional outcomes (Bay et al., 2009). In this study, self-reported stress showed significant reductions after the ACT intervention suggesting that ACT may be a promising transdiagnostic approach for reducing psychological distress in people with TBI.

This RCT is one of the few studies to compare psychological treatment to an active control condition with individuals who have a severe TBI. Befriending has been used as both a standalone therapy to treat depression by facilitating social engagement (Mead et al., 2010) and as a control treatment in schizophrenia research (Bendall et al., 2006). Befriending used as an active control condition in this study which is different to using a wait list control, makes the treatment effects of ACT on depression and stress in this study even more notable.

The study had several limitations including a smaller than anticipated sample size (initial proposal was for 24 in each group). The lower than expected recruitment rates may have been a function of the need to meet eligibility criteria. The study was also underpowered to cope with the number of both primary and secondary outcome measures. Post hoc sample size calculations on the primary

outcome in this study (AAQ-ABI), indicates a total sample size of 58 (ES Partial η^2 = .17, Power = .80), is required to establish a significant interaction effect from pre to post intervention (Faul, Erdfelder, Lang, & Buchner, 2007). Another limitation was the short follow-up period (one month) which indicated the interaction effects were not maintained. Studies using CBT to treat post TBI anxiety (Hsieh et al., 2012) have shown a delayed benefit up to six months post-intervention. Future studies could include additional booster sessions and longer follow up to determine whether any improvements are retained or whether there is a delay in treatment response.

Future research should replicate these stringent criteria, extend the study in a larger sample across multiple sites and explore delivering the intervention on a one to one basis. Further investigation into cognitive flexibility and its impact on improved psychological flexibility is suggested. This may consist of using cognitive flexibility outcome measures such as the Trail Making Test (Reitan, 1958) as a covariate in the data analysis. Additionally, research which investigates mechanisms of change in interventions for TBI populations are required including whether psychological flexibility is a mechanism of change or predictor for engagement in therapy. Despite these limitations, our results suggest ACT-Adjust decreased components of psychological distress and facilitated psychological adjustment when compared to an active control in a group of people with severe TBI. Further studies are warranted replicate this effect and clarify the role of psychological flexibility in recovery from severe TBI.

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No potential conflict of interest was reported by the authors.

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