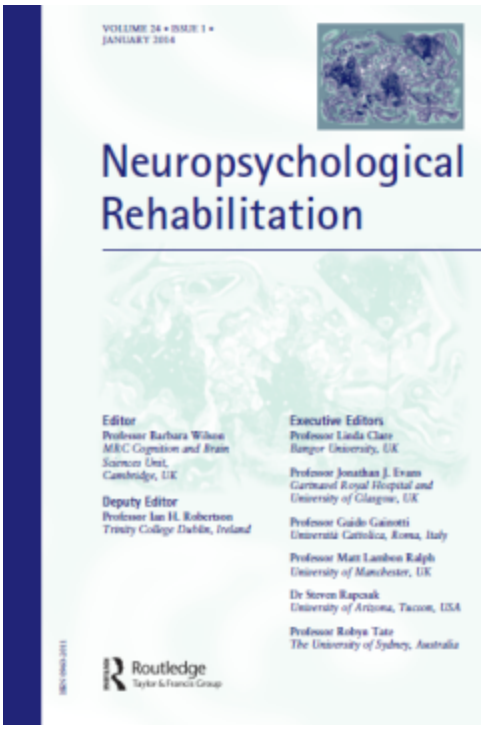

A Single-Case Experimental Evaluation of a New Group-Based Intervention to Enhance Adjustment to Life with Acquired Brain Injury: VaLiANT (Valued Living After Neurological Trauma)

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Complete List of Authors:	Sathananthan, Nick; La Trobe University School of Psychology and Public Health, Department of Psychology and Counselling Dimech-Betancourt, Bleydy; La Trobe University School of Psychology and Public Health, Department of Psychology and Counselling Morris, Eric; La Trobe University School of Psychology and Public Health, Department of Psychology and Counselling Vicendese, Don; La Trobe University, Department of Mathematics and Statistics; The University of Melbourne School of Population and Global Health Knox, Lucy; La Trobe University School of Psychology and Public Health Gillanders, David; The University of Edinburgh School of Health in Social Science dasNair, Roshan; University of Nottingham, Institute of Mental Health; University of Nottingham School of Medicine Wong, Dana; La Trobe University School of Psychology and Public Health, Department of Psychology and Counselling

Keywords:	Acquired Brain Injury, Adjustment, Acceptance and Commitment Therapy, Stroke, Cognitive Rehabilitation, Valued Living

A Single-Case Experimental Evaluation of a New Group-Based Intervention to Enhance Adjustment to Life with Acquired Brain Injury: VaLiANT (Valued Living After Neurological Trauma)

Sathananthan, Nick[1]; Dimech-Betancourt, Bleydy[1]; Morris, Eric[1]; Vicendese, Don[2,3]; Knox, Lucy[1]; Gillanders, David[4]; Das Nair, Roshan[5,6]; and Wong, Dana[1]
[1]School of Psychology and Public Health, La Trobe University, Melbourne, Australia
[2]Department of Mathematics and Statistics, La Trobe University, Melbourne, Australia
[3]Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia.
[4]School of Health in Social Sciences, University of Edinburgh, Edinburgh, UK
[5]Institute of Mental Health, University of Nottingham, Nottingham, UK
[6]School of Medicine, University of Nottingham, Nottingham, UK

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Abstract

Adjustment to life with acquired brain injury (ABI) requires self-identity and behaviour to be updated, incorporating injury-related changes. Identifying and enabling new values-consistent behaviours could facilitate this process. We evaluated the feasibility, acceptability, and preliminary efficacy of VaLiANT, a new group intervention that aims to enhance 'valued living' following ABI. We used a non-concurrent multiple baseline single case experimental design (SCED) with an 8-week follow-up phase and randomisation to multiple baseline lengths (5-7 weeks). Eight participants (50% women, aged 26-65; 4 Stroke, 3 Traumatic Brain Injury, 1 Epilepsy) attended eight group sessions with assessments before, during and after the group. Target behaviour was valued living, assessed weekly by the Valued Living Questionnaire. Secondary outcomes included measures of wellbeing, mood, psychological acceptance, self-efficacy regarding ABI consequences, cognitive complaints, and intervention acceptability. Target behaviour was analysed through visual and statistical analysis while secondary outcome data was analysed via reliable change indices and descriptive statistics. Target behaviour data displayed no convincing patterns of improvement. Reliable improvements were found for most participants on secondary outcomes, particularly subjective wellbeing and anxiety. Intervention delivery was feasible with high acceptability ratings. Further investigation of VaLiANT is warranted, based on the feasibility and acceptability of intervention delivery and signals of efficacy identified across adjustment-related secondary outcomes.

Acquired brain injuries (ABI) are associated with lifelong physical, cognitive, emotional, and psychosocial consequences which can lead to substantial societal and healthcare costs (Access Economics, 2009; Deloitte Access Economics, 2013; Gloede et al., 2014). These consequences result in a set of new limitations for survivors that can reduce participation in meaningful life activities and dramatically alter self-identity (Carroll & Coetzer, 2011). Adjusting to life with an ABI is a multi-factorial process involving both psychological aspects (i.e., becoming aware of and accepting new limitations to form an updated and realistic post-injury self-identity; Gracey et al., 2009), and behavioural aspects (i.e., adjusting behaviour to accommodate new limitations to still allow pursuit of personally meaningful goals and activities; Brands et al., 2012). Better adjustment following ABI is strongly associated with higher subjective wellbeing and lower emotional distress (Carroll & Coetzer, 2011; Doering et al., 2011; Schönberger et al., 2014). Unfortunately, long term adjustment-related outcomes often remain poor, as indicated by lower quality of life and wellbeing (Jacobsson et al., 2010; Ramos-Lima et al., 2018), reduced participation in life roles and meaningful activites (Bergström et al., 2017), and negative evaluations of self-identity (Carroll & Coetzer, 2011; Doering et al., 2011). Facilitating adjustment to ABI-related changes is therefore an important rehabilitation target that may improve quality of life and participation – arguably the ultimate goals of rehabilitation.

Cognitive impairment and mood disturbance are common consequences that affect the majority of individuals with ABI (Anson & Ponsford, 2006; Hackett & Pickles, 2014; Mellon et al., 2015; Rabinowitz & Levin, 2014). These cognitive and emotional sequelae are associated with reduced independence in activities of daily living (ADLs; Gall et al., 2009; Jokinen et al., 2015; Liman et al., 2012), reduced participation in meaningful life activities (Feigin et al., 2010; Mole & Demeyere, 2020; Theadom et al., 2018), and overall poorer quality of life and wellbeing (De Wit et al., 2017; Draper et al., 2007; Gadidi et al., 2011;

Grauwmeijer et al., 2014). These symptoms can also lead to reduced capacity for adaptive behaviour change. For example, cognitive impairment can limit appropriate, flexible goal setting and behaviour, and mood disturbance can impact motivation which may reduce engagement in rehabilitation (Beadle et al., 2018; Kutlubaev & Hackett, 2014; Whyte et al., 2011). As such, cognitive impairment and mood disturbance can act as significant barriers to both the psychological and behavioural aspects of adjustment.

Importantly, cognitive and emotional symptoms are frequently highlighted as areas of long-term unmet needs by people with ABI, indicating that they are not adequately managed by existing services (Andrew et al., 2014; Pickelsimer et al., 2007). This highlights the need for evidence-based interventions that address cognitive and emotional symptoms to facilitate adjustment. However, evidence for the efficacy of rehabilitation programs targeting cognition and mood separately remains mixed (Gertler et al., 2015; Lincoln & Flannaghan, 2003; Ponsford et al., 2016; Rogers et al., 2018). For example, some cognitive rehabilitation interventions can be effective in the short term, however these improvements are not always maintained and do not consistently generalise to non-targeted everyday cognitive functions (das Nair et al., 2016; Elliott & Parente, 2014; Loetscher et al., 2019). Similarly, Cognitive Behavioural Therapy (CBT) for depression and/or anxiety has been shown to improve mood in some studies but not others, with some indication that trial design and dose of therapy may impact outcomes (Gertler et al., 2015; Ponsford et al., 2016; Wang et al., 2018). Importantly, positive outcomes for these interventions have primarily been identified at the level of impairment (World Health Organization, 2001) and these changes do not consistently translate into improved quality of life, wellbeing, activity, or meaningful participation (das Nair et al., 2016; Velikonja et al., 2014; Wang et al., 2018; Withiel et al., 2019). This suggests that existing 'siloed' interventions do not consistently lead to better adjustment related outcomes.

This could be due to a lack of integration between interventions targeting both cognitive *and* emotional changes. Many neural networks that process cognition also process emotion (particularly frontal-limbic networks; Pessoa, 2008) and there is a high frequency (approximately 60%) of comorbid cognitive and emotional difficulties after ABI suggesting that these processes are interrelated (Kimonides et al., 2018; Nijsse et al., 2017; Ponsford et al., 2014). From a functional perspective, an ABI survivor who has memory impairments may develop anxiety about forgetting tasks, and that anxiety may then impact cognitive performance. Targetting only cognitive impairment or mood disturbance in rehabilitation may not sufficiently address all barriers to adjustment and may also increase patient burden and costs.

Recent evidence indicates that valued living, the extent to which we engage in behaviours that are consistent with our personal values (e.g., about our relationships or work), is strongly associated with better adjustment-related outcomes (e.g. participation and quality of life) in both ABI (Pais et al., 2019) and other chronic health condition populations (Graham et al., 2016; Sheppard et al., 2010; Smout et al., 2014). Arguably, valued living may serve as a framework for facilitating adjustment by helping individuals reform their self-identity via awareness of their values, and by building new patterns of behaviour that still allow pursit of meaningful activities.

Acceptance and Commitment Therapy (ACT) is a psychological therapy designed specifically to enhance valued living. It aims to increase engagement in meaningful life activities by helping individuals identify what is important to them (i.e. their values), and by improving acceptance and psychological flexibility towards negative thoughts and emotions that may otherwise prevent valued living (Hayes et al., 2006). ACT has established efficacy in psychiatric and chronic health conditions (Dindo et al., 2017; Gloster et al., 2020). There is preliminary randomised controlled trial (RCT)-level evidence supporting its use to improve

mood, anxiety, and psychological distress in TBI (Sander et al., 2021; Whiting et al., 2020; Whiting et al., 2018), and lower level evidence in stroke (Graham et al., 2015; Large et al., 2020; Majumdar & Morris, 2019) and other neurological conditions (Gillanders & Gillanders, 2014; Hill et al., 2017). However, these studies have not directly addressed cognitive impairment; and there is no clear evidence for ACT improving psychological and behavioural aspects of adjustment following ABI.

Based on this body of evidence, we predict that interventions that concurrently address cognitive and emotional barriers to valued living may result in better adjustment, as reflected by improvements at the levels of impairment (e.g. social anxiety, memory difficulties), activity limitation (e.g. forgetting conversations with others, activities of daily living) and participation (e.g. attending social events), with overall improvements to wellbeing and satisfaction with life. Given that ACT directly targets valued living, which has been shown to relate directly to psychosocial and functional outcomes, combining ACT with cognitive rehabilitation may result in improved adjustment. This study served as a Phase I evaluation of the design and implementation of a new 8-week group intervention called VaLiANT: Valued Living after Neurological Trauma. VaLiANT combines cognitive rehabilitation with ACT principles to improve adjustment in ABI survivors. The study aimed to 1) evaluate the potential efficacy of VaLiANT on the primary outcome of valued living and a range of secondary measures of adjustment (at the level of impairment, activity and participation, as well as wellbeing and satisfaction with life), 2) evaluate the feasibility and acceptability of the intervention, and 3) inform the need for, and design of, a subsequent Phase II randomised controlled trial (including selection of outcome measures).

Methods

This study was approved by the La Trobe University Human Research Ethics Committee (HEC #18423) and written informed consent was obtained from all participants.

Design

We used a non-concurrent multiple baselines design with AB and follow-up phases and replication across 8 participants. The baseline phase (5, 6, or 7 weeks) was immediately followed by an eight-week intervention phase (VaLiANT), before a final eight-week follow-up phase. The reporting of results was in line with the Single-Case Reporting guideline in BEhavioural interventions criteria (SCRIBE; Tate et al., 2016).

Participant Selection

Participants were required to have experienced an ABI at least 3 months before enrolment in the study; be 18 years of age or over; be experiencing cognitive and/or emotional difficulties (identified descriptively by self, close other and/or clinician in initial screening); and be able to attend the group program at La Trobe University Psychology Clinic. Individuals with pre-existing intellectual disability, severe psychiatric disorders, comorbid neurodegenerative conditions, and insufficient cognitive and/or language abilities to complete outcome measures or participate in the intervention were excluded. Participants were recruited via advertisements (including flyers and weblinks) through email listservs (e.g., NPinOz, BRAINSPaN), local health services, practitioner networks, an existing ABI research participant database, and relevant online platforms such as EnableMe (Stroke Foundation).

Materials

Sample Characterisation

Stroke severity was classified using the National Institutes of Health Stroke Scale (NIHSS; Brott et al., 1989). TBI severity was classified by interpreting Glasgow Coma Scale scores (GCS), post-traumatic amnesia length (PTA), and loss of consciousness length (LOC) in line with guidelines from the Centers for Disease Control and Prevention (2015). Several cognitive measures were administered to assist with sample characterisation: 1) the Test of

Premorbid Functioning (TOPF) to measure premorbid intellectual ability (Pearson, 2009); 2) the Rey Auditory Verbal Learning Test (RAVLT) as a measure of verbal learning and memory (Schmidt, 1996); 3) and the Trail Making Test A and B (TMT) as a measure of processing speed and cognitive flexibility (Tombaugh, 2004).

Target Behaviour (Primary Outcome)

The target behaviour was participants' subjective evaluation of their level of valued living over the previous week, assessed by the Valued Living Questionnaire (VLQ) composite score (Wilson et al., 2010). The VLQ is a two-part questionnaire that measures valued living across 10 value domains. Participants 1) rate 10 value domains (e.g., family, work, spirituality, etc) for importance, and 2) rate how consistent their behaviour has been over the last week with each of these values domains. Both parts are rated on a 10-point Likert scale with higher scores meaning higher importance and consistency. The mean of the products of the importance and consistency scores from the different domains forms the composite score. Higher scores represent a person holding a range of values as important and living consistently with these. The VLQ has been used in ABI research (Pais et al., 2019) and the composite score is recommended as the primary indicator of valued living with acceptable internal consistency (.77) and construct validity (Wilson et al., 2010).

Secondary Outcomes

Mental wellbeing and life satisfaction were assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennant et al., 2007) and the 5-item Satisfaction With Life Scale (SWLS; Diener et al., 1985) with higher scores indicating greater wellbeing and quality of life. Anxiety and Depression were assessed with the 14-item Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), while the 13-item Everyday Memory Questionnaire – Revised (EMQ-R) was used as an index of subjective memory failures (Royle & Lincoln, 2008) with higher scores representing greater frequency

of mood symptoms and subjective memory failures respectively. The 9-item Acceptance and Action Questionnaire - Acquired Brain Injury (AAQ-ABI) was used as a measure of psychological adjustment towards ABI-related changes (Whiting et al., 2015) with higher scores indicating greater psychological inflexibility. Participation was assessed with the 15-item Community Integration Questionnaire (CIQ; Willer et al., 1993). The 6-item TBI Self-Efficacy Scale (TBI-SES) measured confidence in managing common difficulties following ABI (Huckans et al., 2010). Higher scores on the two latter scales indicated greater participation and self-efficacy respectively.

Feasibility and Acceptability of the Intervention

In line with previous related studies (Thomas et al., 2019; Toni D. Withiel et al., 2020; Wong et al., 2021), feasibility of the intervention was assessed against the following criteria:

1) recruitment of the minimum number of participants required to run two groups within a six-month timeframe (minimum of 3 per group);
2) acceptable participant drop-out rates (≤20%);
3) sufficient group attendance (≥80% overall participant attendance to the 64 sessions (8 participants * 8 group sessions));
4) sufficient homework completion rates (≥50% completion rate for each session from participants present in the session);
5) sufficient completion rates for major outcome assessments (≥80% completion);
6) treatment fidelity measured by adherence of clinicians to more than 80% of both session objectives and content areas listed in the treatment manual.

To measure adherence, sessions three and six from group one and session one and seven from group two (25% of the total sessions) were randomly selected (via randomizer.org) and evaluated by an independent senior neuropsychologist. They evaluated

whether clinicians were able to meet the session objectives and cover the prescribed content listed in the manual for each session using a checklist based on the manual's objectives and content for each session.

Acceptability of the intervention was measured by asking each participant to rate if they would recommend the intervention to others on a 9-point scale following completion of the intervention (i.e. "How confident are you in recommending the VaLiANT program to a friend who experiences similar problems?", 1 = *Not at all confident*, 9 = *Very confident*). Acceptability was determined by a mean rating of ≥80% (≥7.2/9).

Intervention

The VaLiANT program is a manualised face-to-face group intervention that concurrently targets cognition and emotion by integrating cognitive rehabilitation and ACT techniques. It aims to improve adjustment following ABI by increasing engagement in valued and meaningful activities. The program consists of eight two-hour group sessions run on a weekly basis. Each week focusses on a different value domain (health, work/study, leisure and relationships) and includes exploration of what is important to the participants in this domain using a values card sort. Committed actions (or valued living behaviours) that are consistent with chosen values are then generated by participants, with support from the facilitators. This is followed by various exercises and techniques that encourage engagement in those valued actions by addressing cognitive and emotional barriers to valued living through cognitive compensatory strategies and ACT-based techniques. The group comprises discussion, provision of information and resources through multiple modalities (verbal discussion, PowerPoint slides, and handouts), in-session practice of cognitive and psychological strategies, and weekly homework exercises to encourage implementation of strategies and participation in valued activities in everyday life. In Week 7, there is a concurrent session held with family members and close others of the participants, to assist

them in supporting the participant with their value-consistent activities and strategies. Further details can be found in Appendix A.

The intervention was primarily developed by the authors, drawing on their clinical and research expertise, however evidence-based ACT and cognitive rehabilitation techniques and materials were adapted from existing manualised treatments to supplement the new content (Brassington et al., 2016; O'Donoghue et al., 2018; Radford et al., 2010; Whiting et al., 2020; T. D. Withiel et al., 2020). Group sessions were facilitated by a senior clinical neuropsychologist with assistance from two provisional psychologists, and all sessions were video recorded. Two separate groups were run from February to April and April to June 2019. The VaLiANT program and all assessments were conducted face-to-face at the La Trobe University Psychology Clinic. Group sessions were held in a meeting room with all participants seated around a large table with slides projected onto a large screen. Participation in the intervention was free of charge and participants were not financially compensated. The treatment manual will be published following completion of subsequent clinical trial(s).

Procedure

Two separate recruitment intakes were completed to accommodate the running of two separate VaLiANT groups. Participants were provided with a verbal explanation of the study procedures before completing screening over the phone to ensure they met eligibility criteria. To determine the length of the baseline phase a randomisation window was set between 5 and 7 weeks. Eligible participants were randomly allocated to baseline length by an independent researcher based on a randomisation schedule generated by a random online sequence generator (www.sealedenvelope.com) before data collection commenced. Baseline phases started in a non-concurrent staggered fashion so that all participants within each intake commenced the intervention phase simultaneously, due to the group-based intervention (see Figure 1). The intervention phase (i.e., the eight-week VaLiANT program) was introduced

immediately after the baseline phase was completed. Intervention phase start dates were predetermined based on the running dates of each group. An eight-week follow-up phase commenced immediately following the intervention phase.

Target behaviour (valued living) was assessed weekly across all study phases. Participants completed the VLQ independently via online platform Qualtrics or via telephone with a researcher. This researcher was not blinded to study phase due to knowing the start date of the VaLiANT group.

Three comprehensive assessments were completed in addition to the weekly target behaviour assessments. A pre-intervention assessment (T1) was conducted just prior to the intervention phase commencing, and involved collecting demographic and sample characterisation information and all secondary outcome measures. A post-intervention (T2) and follow-up assessment (T3) were conducted within two weeks of the intervention phase and follow-up phase ending respectively, and they involved completion of secondary outcome measures only. T1 assessments were conducted by one of the group facilitators. T2 and T3 assessments were conducted by a researcher independent of the intervention and all these assessments were conducted face-to-face and took approximately 90-minutes.

Data Analysis

GraphPad Prism (Version 8) was used to graph primary outcome data which was analysed through a mixture of visual and statistical analysis. Missing primary outcome data was handled in line with recommendations by using a multiple imputation approach (Peng & Chen, 2018). The Amelia II R package was selected due to the statistical validity of its approach in handling time-series data (Honaker & King, 2010; Honaker et al., 2011). For phases where there were missing data, the imputation model used the observed data from that phase to create five plausible complete datasets. A final dataset was generated by using the average of the five imputed values for each missing point; further information about this

process is detailed by Honaker and King (2010); and Honaker et al. (2011). The imputed datasets for the VLQ were used in all visual and statistical analyses; however, analyses were not conducted on phases where there were four or more imputed values (out of the 5 – 8 per phase).

Visual analysis followed established guidelines (Lane & Gast, 2014; Ledford et al., 2018) and focussed on 1) the level; the mean value of data within each phase, 2) trend; the slope of the best fitting line within each phase, 3) variability; the range and fluctuation of data within each phase, and 4) overlap; the amount of overlapping data across phases (Kratochwill et al., 2013). The SCDA plugin for R was used to assist evaluation of trend by fitting linear trend lines to data using the split middle method (Bulté & Onghena, 2013). In cases where the baseline data were stable and suggested a clear trend for improvement prior to the introduction of the intervention, R code was used to project the baseline trend into the following phases (Manolov, 2014) to assist with trend evaluation. In line with recommendations for visual analysis of rehabilitation intervention data (Krasny-Pacini & Evans, 2018), the immediacy of effect and consistency of data patterns across similar phases were not considered due to the hypothesised data patterns (i.e. slow intervention effect onset, variability between participants' phases).

Statistical analysis was conducted using the percentage of data exceeding median trend (PEM-T), also known as the extended celeration line, to provide a quantification of change in data between phases (White & Haring, 1980; Wolery et al., 2010). PEM-T is a non-parametric index of data non-overlap between phases and it typically displays moderate-high levels of agreement with visual analysis (Yucesoy-Ozkan et al., 2020). PEM-T was selected over other overlap indices that also control for trend (i.e Tau-*U*) due to limitations of these methods in controlling trend with few data points and their reduced accuracy with significant within-case variability (Fingerhut et al., 2021). PEM-T comparisons were

conducted between baseline and intervention, and intervention and follow-up. In each comparison, the median split middle trend line of the earlier phase was extended into the subsequent phase using R code: https://www.dropbox.com/s/rlk3nwfoya7rm3h/PEM-T.R?dl=0 (Wolery et al., 2010). For interpretation, the magnitude and direction of values was considered with an improvement in behaviour indicated by PEM-T values >0.5 (i.e. more than 50% of data falling above trend line) while deterioration was indicated by values <0.5 (range 0-1; Yucesoy-Ozkan et al., 2020).

Methods used to assess secondary outcome data depended on the characteristics of the measure. Reliable Change Indices (RCI; Jacobson & Truax, 1991) were calculated to determine the proportion of participants achieving statistically reliable change on the WEMWBS, HADS subscales, Acceptance and Action Questionnaire - Acquired Brain Injury, SWLS, and EMQ-R, with comparisons conducted between T1 vs. T2, and T1 vs. T3. Instrument reliability information was drawn from ABI samples on all measures (Bogner et al., 2017; Majumdar & Morris, 2019; Royle & Lincoln, 2008; Whelan-Goodinson et al., 2009; Whiting et al., 2015). When available, test-retest reliability coefficients were chosen over Cronbach's alpha due to lower false positive rates (Ferrer & Pardo, 2014). Clinically Significant Change (CSC; Jacobson & Truax, 1991) was analysed based on the best method available for each measure. The HADS subscales were analysed using externally valid clinical categories, with a change in category representing clinical improvement. On each subscale scores below 8 equated to clinical recovery (Bjelland et al., 2002) and participants who remained within this 'normal' range throughout the study were excluded from RCI/CSC analysis for that subscale. The WEMWBS and SWLS were analysed by determining a clinical cut-off using criteria C from Jacobson and Truax (1991) which utilised psychometric information from a healthy comparison sample (SWLS; Diener et al., 1985; WEMWBS; Tennant et al., 2007). The EMQ-R and Acceptance and Action Questionnaire - Acquired

Brain Injury were not analysed for CSC as the criteria required achievement of impossible values on each measure (i.e. below 0). The CIQ and TBI-SES were assessed descriptively to indicate any changes of importance.

Results

Methodological Quality Ratings

The methodological quality of the study was critically evaluated using the Risk of Bias in N-of-1 Trials Scale (RoBiNT; Tate et al., 2013). The study met external validity criteria but performed less strongly on internal validity criteria, with points lost due to the inability to blind participants, clinicians, and assessors to participant phase, and the nature of the group-based intervention meaning that participant baselines could end but not commence simultaneously (total score = 20/30; see Appendix B).

Case Description

Eight community-dwelling adults with a diagnosis of ABI were recruited into the study. Participants varied in age (26 – 65 years) and time since injury (8 months – 34 years), and the majority of participants displayed impairment on at least one measure of cognition (see Table 1). All participants spoke English and none identified as Aboriginal and/or Torres Strait Islander. Two consecutive groups were run with participant AA to participant FF comprising the first group. Participants GG and HH were within a second group that also included an additional 3 individuals with ABI who received the intervention but were not offered participation in the study. These individuals were excluded due to the a-priori threshold of eight study participants having been met, but were included in the group to optimise the group size. An additional three participants were screened for eligibility but did not commence the study or join the groups due to work/study schedules which conflicted with the group time and dates. Only participant DD reported receiving regular psychological services outside of the study. No adverse events were identified for any participant.

Target behaviour

An overview of each participant's target behaviour (valued living, with improvements reflected by higher scores) is presented in text and in Figure 1. Participant AA was randomly allocated to the 7-week baseline length, participants BB, CC, and GG to the 6-week baseline, and participants DD, EE, FF, and HH to the 5-week baseline. All participants had missing target behaviour data (ranging from 2-6 data points) with the highest proportion missing in the follow-up phase. Missing data were mainly due to participant illness or difficulty contacting participants to complete the measures.

Participant AA

Participant AA had a mild stroke with subsequent difficulty meeting the demands of her job due to fatigue, anxiety, and a decline in her working memory. She also had reduced engagement in valued social/leisure activities which contributed to low mood. Participant AA attended the first four sessions of the group, however she missed sessions 5 and 8 due to work demands, and sessions 6 and 7 due to overseas travel.

Visual analysis indicated variable behaviour during baseline which stabilised in subsequent phases (see Figure 1). Level decreased from baseline (M = 39.87) to intervention and follow-up (M = 33.19; 32.97). Baseline and intervention phase data followed a gradual decreasing trend that switched to an increasing trend in follow-up. While visual inspection of overlap indicated a high degree of overlapping data across all phases, statistical analysis indicated an improvement in intervention phase data above the decreasing baseline trend (PEM-T = 0.88) and further improvement in follow-up phase data which fell above the decreasing intervention trend (PEM-T = 1.00).

Participant BB

Participant BB experienced a severe TBI. He lacked engagement in meaningful activities, was unemployed, socially isolated, and required support with most activities due to

hemiparesis, significant cognitive impairment, and sleep and fatigue difficulties. Participant BB attended all group sessions.

Visual analysis indicated variable data within each phase with minimal change in level of behaviour from baseline (M = 46.04) to intervention and follow-up (M = 45.43; 46.55). Trend was increasing in baseline and follow-up and decreasing during intervention. Visually there was a high degree of overlapping data across all phases, however statistical analysis indicated that intervention phase data deteriorated and fell below the increasing baseline trend (PEM-T = 0.00) while follow-up phase data improved and was above the decreasing intervention trend (PEM=T = 1.00).

Participant CC

Participant CC experienced a series of mild strokes. She was retired, lived alone, and experienced reduced participation in valued family relationships after becoming estranged from her adult children following her strokes and associated cognitive and psychological changes, with associated feelings of grief and mood disturbance. Participant CC attended all sessions of the group.

Visual analysis indicated stable behaviour during baseline with greater variability during subsequent phases. Level decreased from baseline (M = 66.9) to intervention and follow-up (M= 54.73; 56.78). Trend was increasing during baseline and decreasing during intervention and follow-up. Visual inspection suggested a high degree of data overlap across all phases while statistical analysis indicated that intervention phase data deteriorated and was below the increasing baseline trend (PEM-T = 0.13) while follow up phase data improved above the decreasing intervention trend (PEM-T = 0.88).

Participant DD

Participant DD had complex refractory epilepsy following a childhood injury. He lacked engagement in meaningful activities, experienced significant mood disturbance and

suicidal ideation after being widowed four years prior, and he required support from his parents with most activities of daily living due to cognitive impairment and fatigue. He missed session 5 (for unknown reasons) and session 7 (due to illness).

Data were stable within all phases and level increased from baseline (M = 45.06) to intervention (M = 51.89) before decreasing at follow-up (M = 46.16). Baseline trend was increasing while intervention and follow-up trends were decreasing. Intervention phase data fell within the projected trend envelope while follow-up data fell below, suggesting no impact of intervention on trend. There was moderate visual data overlap across phases and statistical analysis indicated that intervention phase data deteriorated and was below the increasing baseline trend line (PEM-T = 0.25) and follow-up phase data also deteriorated and was below the decreasing intervention trend (PEM-T = 0.25).

Participant EE

Participant EE experienced a severe stroke and subsequently was unemployed and had limited engagement in meaningful activities due to hemiparesis, fatigue, cognitive impairment, and significant mood disturbance with suicidal ideation. He lived with his pregnant wife and expressed concern about becoming a parent with an ABI. Participant EE did not attend session 2 due to illness and session 5 and 7 for unknown reasons. He withdrew from the study following completion of the intervention phase.

Visual analysis indicated stable data within both phases. There was an increase in level between baseline (M = 34.74) and intervention (M = 50.99). Baseline data followed an increasing trend while intervention data was slightly decreasing, however intervention data fell above the projected trend envelope suggesting an improvement in behaviour above that explained by the baseline trend. Visually there was no overlap of data, and statistical analysis indicated an improvement in intervention phase data (PEM-T = 0.63).

Participant FF

Participant FF experienced a severe TBI at 15-years of age. The referring neuropsychologist described poor social cognition, rigid thinking, and slowed processing which resulted in unwanted social isolation and workplace conflict. Participant FF lived alone, experienced fatigue, and had limited social support due to recently moving interstate. Participant FF attended all group sessions.

Due to the high amount of imputed data, visual analysis was not conducted on follow-up phase data, and the intervention vs. follow-up PEM-T comparison was not interpreted. Visual analysis indicated stable data within both phases with a decrease in level from baseline (M = 48.6) to intervention (M = 44.22). Trend was decreasing at baseline and increasing during intervention. While there was almost total overlap of data visually, statistical analysis indicated improvement in behaviour during intervention above the decreasing baseline trend (PEM-T = 0.75).

Participant GG

Participant GG had a mild stroke. She was unemployed, lived alone, and had limited participation in valued family and social activities which led to loneliness, low mood, and anxiety. Her difficulties with fatigue, concentration, and slow processing also impacted her ability to engage socially. Participant GG attended all sessions of the group.

Visual analysis indicated stable data within all phases. Data level decreased from baseline (M = 47.92) to intervention (M = 46.42) before an increase at follow-up (M = 55.01). Trend was increasing across all phases; however, intervention and follow-up data fell below the projected baseline trend envelope. While there was almost total overlap of data across all phases visually, statistical analysis indicated deterioration in behaviour during intervention and follow-up with data falling below the increasing baseline and intervention trends respectively (PEM-T = 0; and = 0.25).

Participant HH

Participant HH had experienced a severe TBI. He experienced memory and emotion regulation difficulties which prevented him from participating in valued activities including work. He lived with his wife and adolescent son who had a neurodevelopmental disorder. He reported difficulty regulating anger which related to being perceived differently due to his TBI. Participant HH attended all sessions of the group.

Visual analysis indicated stable data within all phases. Data level decreased from baseline (M = 42.3) to intervention and follow-up (M = 37.6; 28.87). Trend was decreasing at baseline and follow-up and slightly increasing during intervention. Visual analysis indicated complete visual overlap between baseline and intervention, and no overlap with follow-up. Statistical analysis indicated improvement in intervention data above the decreasing baseline trend (PEM-T = 1.00) and deterioration in follow-up data below the increasing intervention trend (PEM-T = 0.00).

Secondary Measures:

Evaluation of secondary measures was not possible for participant EE due to completing only his T1 assessment. All other participants (except participant HH) displayed reliable and clinically significant improvement on at least one out of six secondary outcome measures analysed through RCI (see Table 2). Participants AA, DD, and FF achieved reliable improvements on four measures, participants BB and CC on three measures, and participant GG on one measure out of the possible six at either their T2 or T3 assessment. Similarly, all six measures had at least two out of seven participants achieve reliable improvement during the study, with the HADS-A and WEMWBS improving in the highest number of participants (see Table 3). Participant HH did not achieve reliable improvement on any measure at any timepoint and displayed deterioration on the HADS-A at T2, although this improved back to baseline levels by T3. Participant CC also displayed reliable deterioration on the SWLS at T2 which persisted at T3.

Descriptive analyses of the CIQ and TBI-SES revealed variable results. On the CIQ, participant BB and FF displayed increases in social integration only while participant DD and GG displayed increases in social integration and daily productivity. Participants AA, CC, and HH displayed reductions in home and social integration. On the TBI-SES, participant BB, CC, FF, GG, and HH showed increased confidence in managing aspects of their daily life (e.g. work, leisure, personal affairs, injury consequences) while participant DD was less confident. Participant BB, CC, DD felt more confident in managing negative emotions while participant HH felt less confident. Participants CC displayed less confidence in managing her interpersonal relationships. Participant AA did not display any major changes on the TBI-SES.

Feasibility and Acceptability

Recruitment rates exceeded the minimum number required to run two groups within the allocated six-month timeframe and participant drop-out was low with one participant withdrawing during the follow-up phase of the first group (total drop-out = 12.5%). Session attendance across all sessions was 55/64 (86%) while the major outcome assessment completion rate was 22/24 (92%). For each session, at least 50% of participants in attendance had completed the homework (range = 60% - 87.5%). Treatment adherence ratings suggested that all objectives and main content areas from session one, three and six were deemed to have been covered. Evaluation of session seven indicated that a discussion around social barriers and an ACT defusion exercise were not covered due to time constraints, however all session objectives were still met. From all four sessions, 16/16 (100%) session objectives were met, and 34/36 (94%) prescribed content areas were delivered. Participant acceptability ratings of the intervention ranged from 6 to 9 with 5/7 participants rating the intervention >8 for confidence in recommending the VaLiANT program to friends with similar problems. The overall mean acceptability rating across participants was 8/9 (89%).

Discussion

This study served as a Phase I evaluation of the preliminary efficacy, feasibility, and acceptability of VaLiANT, a new 8-week face-to-face group intervention that aimed to improve valued living and adjustment following ABI. While the primary target behaviour data were variable, signals of efficacy were identified across a range of secondary outcome measures. The feasibility and acceptability of the intervention were also supported and these findings support the need for and viability of a larger clinical trial.

Target behaviour data was highly variable and visual and statistical analysis provided limited evidence to support VaLiANT in improving valued living. Previous studies have indicated that valued living can improve following ACT in non-ABI populations (Michelson et al., 2011; Wersebe et al., 2017). However, it has been recognised that clients often show an initial decrease in valued living when completing ACT as they recognise the discrepancy between their values and current behaviour, before a delayed improvement (Wilson et al., 2010). There are many additional barriers following ABI that may have limited or slowed behaviour change, including decreased self-awareness, independence, and functional capacity. Individuals with ABI may therefore require more time to develop their personal resources to support valued living, and improvements might emerge more slowly over time. Thus, the lack of change in valued living may reflect the development of increasing insight as participants became acculturated to the concepts of values and valued living, and could also reflect the additional barriers associated with ABI and their impact on consistently living in accordance with one's values.

However, a number of issues were identified with the use of the VLQ during data collection. Participants were noted to have difficulty answering the items due to the abstract nature and cognitive demands of the questionnaire, such as having to remember their behaviour over the past week, identify which behaviours were in line with a particular value,

and then make an overall evaluation of how consistent these behaviours were with their importance rating for that domain. Members of our research team recently conducted a cognitive interviewing study which confirmed that a number of comprehension errors are regularly made by people with ABI when completing the VLQ (Miller, Lawson, Power, das Nair, Sathananthan, & Wong, under review). As such, the VLQ may not have accurately measured valued living within this population. An adapted version of the VLQ has subsequently been developed in an attempt to improve its validity in ABI cohorts with cognitive and communication difficulties, and this adapted version will be used in the Phase II trial of VaLiANT.

Despite the lack of improvement in valued living, positive outcomes were identified across a range of secondary outcome measures. The highest frequency of improvement was seen in mental wellbeing and anxiety symptoms, with over half of our participants showing reliable and clinically significant improvements on these measures. Higher subjective wellbeing and emotional distress have been strongly associated with better adjustment following ABI (Carroll & Coetzer, 2011; Doering et al., 2011; Schönberger et al., 2014). Improvements to wellbeing and mood have been found following ACT in healthy (Fledderus et al., 2010) and subclinical depressive samples (Bohlmeijer et al., 2011), however these improvements have not been consistently demonstrated following ACT or cognitive rehabilitation in ABI cohorts (Cicerone et al., 2019; das Nair et al., 2016; Majumdar & Morris, 2019). These promising preliminary findings could reflect the unique combination of cognitive rehabilitation with ACT techniques used in VaLiANT which may have the potential to improve adjustment following ABI.

Interestingly, participants displayed different patterns of improvement across the various secondary measures and stable deterioration was evident on the Satisfaction with Life Scale for one participant. This variability in response to VaLiANT was not unexpected given

the complex nature of the intervention which incorporated both cognitive and emotional elements, as well as the fact that eligibility criteria was open to encompass anyone with cognitive or emotional difficulties that impacted valued living. However, certain factors may have moderated this variability in response. For example, participant GG and HH displayed the least positive change following the intervention and were the only participants from the second group included in the study. The dynamic of a group has been identified as a core ingredient that can impact outcomes in group interventions (Borek et al., 2019) and it is possible that the second group may have had a less cohesive or effective dynamic. Identifying possible sources of variability and key predictors of the various outcomes of VaLiANT will be an important focus for future research. Overall, these findings support the inclusion of a range of outcome measures for VaLiANT, and suggest that mental wellbeing may be a more appropriate primary outcome measure in future evaluations. In addition, these findings support the progression to a Phase II RCT as weekly measurement of multiple outcome measures is unlikely to be feasible in another SCED, due to the burden on participants.

All a priori feasibility and acceptability criteria were met. The recruitment rate was sufficient and allowed two groups to be run within a six-month time frame with only one participant dropping out during the follow-up period. As such, the current recruitment strategy would allow running of quarterly groups, with low attrition, which would be necessary for a sufficient sample size in a Phase II clinical trial. The majority of participants attended all intervention sessions, although three participants missed multiple weeks due to various reasons. This was unavoidable given the predetermined dates and time of the group intervention, however attendance may be an important moderator of intervention success in future trials. The majority of participants also completed the weekly homework, however this varied per session and homework completion was not able to be assessed in participants who were absent. Homework completion may also be an important moderator of intervention

success and more detailed homework monitoring will be necessary for future trials. Intervention delivery was feasible with all session objectives and the majority of content areas being covered within the evaluated sessions. Some content areas were missed due to time constraints within particular weeks suggesting that restructuring of some sessions is necessary. While the collection of weekly target behaviour data was inconsistent, all major secondary outcome data assessments were completed within their allocated timeframes (excluding participant EE's assessments following withdrawal from the study). This suggests that the current outcome assessment structure can be feasibly implemented in subsequent trials, in which weekly measurement would not be required. Finally, acceptability ratings of the intervention were high with the majority of participants indicating that they perceived VaLiANT as being useful.

These findings should be considered in the context of some methodological limitations. Ratings of the study's methodological quality with the RoBINT scale indicated weakness with internal validity. While this may have impacted the robustness of target behaviour data, the randomisation to multiple baseline lengths can be considered a design strength, increasing the study's internal validity by reducing systematic bias. As noted previously, the validity of target behaviour (VLQ) scores for participants in our study was questionable due to several issues identified with its administration. While the moderate amount of missing VLQ data could have further limited the robustness of these target behaviour data, missing data was handled with a multiple imputational approach to input possible valid values which can be considered a strength of the study. While secondary outcome data was more promising, these findings were limited by the pre-post measurement design, as these measures were not given weekly across phases. Furthermore, all outcome measures included in this study relied on self-report and required participants to be able to accurately reflect on their recent thoughts, feelings, and behaviour. Cognitive impairment

may have limited some participants' ability to accurately answer questionnaires. However, subjective outcome measures are more strongly associated with participation outcomes following ABI than objective measures, and therefore may be more relevant as outcome measures for interventions aiming to increase meaningful outcomes like participation and quality of life (de Graaf et al., 2020).

In summary, VaLiANT is a feasible and acceptable intervention that shows promise in improving adjustment-related outcomes following ABI. While VaLiANT was not effective in increasing levels of valued living, improvements to wellbeing and mood symptoms were evident for the majority of our participants and likely reflect the true impact of the intervention. These findings suggest that cognitive rehabilitation combined with psychological therapy may have the potential to result in better adjustment-related outcomes than either approach alone. Further investigation in a larger Phase II randomised controlled trial is warranted with a focus on the impact of VaLiANT on wellbeing.

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A Single-Case Experimental Evaluation of a New Group-Based Intervention to Enhance Adjustment to Life with Acquired Brain Injury: VaLiANT (Valued Living After Neurological Trauma)

Sathananthan, Nick[1]; Dimech-Betancourt, Bleydy[1]; Morris, Eric[1]; Vicendese, Don[2,3]; Knox, Lucy[1]; Gillanders, David[4]; Das Nair, Roshan[5,6]; and Wong, Dana[1]
[1]School of Psychology and Public Health, La Trobe University, Melbourne, Australia
[2]Department of Mathematics and Statistics, La Trobe University, Melbourne, Australia
[3]Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia.
[4]School of Health in Social Sciences, University of Edinburgh, Edinburgh, UK
[5]Institute of Mental Health, University of Nottingham, Nottingham, UK
[6]School of Medicine, University of Nottingham, Nottingham, UK

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Abstract

Adjustment to life with acquired brain injury (ABI) requires self-identity and behaviour to be updated, incorporating injury-related changes. Identifying and enabling new values-consistent behaviours could facilitate this process. We evaluated the feasibility, acceptability, and preliminary efficacy of VaLiANT, a new group intervention that aims to enhance 'valued living' following ABI. We used a non-concurrent multiple baseline single case experimental design (SCED) with an 8-week follow-up phase and randomisation to multiple baseline lengths (5-7 weeks). Eight participants (50% women, aged 26-65; 4 Stroke, 3 Traumatic Brain Injury, 1 Epilepsy) attended eight group sessions with assessments before, during and after the group. Target behaviour was valued living, assessed weekly by the Valued Living Questionnaire. Secondary outcomes included measures of wellbeing, mood, psychological acceptance, self-efficacy regarding ABI consequences, cognitive complaints, and intervention acceptability. Target behaviour was analysed through visual and statistical analysis while secondary outcome data was analysed via reliable change indices and descriptive statistics. Target behaviour data displayed no convincing patterns of improvement. Reliable improvements were found for most participants on secondary outcomes, particularly subjective wellbeing and anxiety. Intervention delivery was feasible with high acceptability ratings. Further investigation of VaLiANT is warranted, based on the feasibility and acceptability of intervention delivery and signals of efficacy identified across adjustment-related secondary outcomes.

Acquired brain injuries (ABI) are associated with lifelong physical, cognitive, emotional, and psychosocial consequences which can lead to substantial societal and healthcare costs (Access Economics, 2009; Deloitte Access Economics, 2013; Gloede et al., 2014). These consequences result in a set of new limitations for survivors that can reduce participation in meaningful life activities and dramatically alter self-identity (Carroll & Coetzer, 2011). Adjusting to life with an ABI is a multi-factorial process involving both psychological aspects (i.e., becoming aware of and accepting new limitations to form an updated and realistic post-injury self-identity; Gracey et al., 2009), and behavioural aspects (i.e., adjusting behaviour to accommodate new limitations to still allow pursuit of personally meaningful goals and activities; Brands et al., 2012). Better adjustment following ABI is strongly associated with higher subjective wellbeing and lower emotional distress (Carroll & Coetzer, 2011; Doering et al., 2011; Schönberger et al., 2014). Unfortunately, long term adjustment-related outcomes often remain poor, as indicated by lower quality of life and wellbeing (Jacobsson et al., 2010; Ramos-Lima et al., 2018), reduced participation in life roles and meaningful activites (Bergström et al., 2017), and negative evaluations of self-identity (Carroll & Coetzer, 2011; Doering et al., 2011). Facilitating adjustment to ABI-related changes is therefore an important rehabilitation target that may improve quality of life and participation – arguably the ultimate goals of rehabilitation.

Cognitive impairment and mood disturbance are common consequences that affect the majority of individuals with ABI (Anson & Ponsford, 2006; Hackett & Pickles, 2014; Mellon et al., 2015; Rabinowitz & Levin, 2014). These cognitive and emotional sequelae are associated with reduced independence in activities of daily living (ADLs; Gall et al., 2009; Jokinen et al., 2015; Liman et al., 2012), reduced participation in meaningful life activities (Feigin et al., 2010; Mole & Demeyere, 2020; Theadom et al., 2018), and overall poorer quality of life and wellbeing (De Wit et al., 2017; Draper et al., 2007; Gadidi et al., 2011;

Grauwmeijer et al., 2014). These symptoms can also lead to reduced capacity for adaptive behaviour change. For example, cognitive impairment can limit appropriate, flexible goal setting and behaviour, and mood disturbance can impact motivation which may reduce engagement in rehabilitation (Beadle et al., 2018; Kutlubaev & Hackett, 2014; Whyte et al., 2011). As such, cognitive impairment and mood disturbance can act as significant barriers to both the psychological and behavioural aspects of adjustment.

Importantly, cognitive and emotional symptoms are frequently highlighted as areas of long-term unmet needs by people with ABI, indicating that they are not adequately managed by existing services (Andrew et al., 2014; Pickelsimer et al., 2007). This highlights the need for evidence-based interventions that address cognitive and emotional symptoms to facilitate adjustment. However, evidence for the efficacy of rehabilitation programs targeting cognition and mood separately remains mixed (Gertler et al., 2015; Lincoln & Flannaghan, 2003; Ponsford et al., 2016; Rogers et al., 2018). For example, some cognitive rehabilitation interventions can be effective in the short term, however these improvements are not always maintained and do not consistently generalise to non-targeted everyday cognitive functions (das Nair et al., 2016; Elliott & Parente, 2014; Loetscher et al., 2019). Similarly, Cognitive Behavioural Therapy (CBT) for depression and/or anxiety has been shown to improve mood in some studies but not others, with some indication that trial design and dose of therapy may impact outcomes (Gertler et al., 2015; Ponsford et al., 2016; Wang et al., 2018). Importantly, positive outcomes for these interventions have primarily been identified at the level of impairment (World Health Organization, 2001) and these changes do not consistently translate into improved quality of life, wellbeing, activity, or meaningful participation (das Nair et al., 2016; Velikonja et al., 2014; Wang et al., 2018; Withiel et al., 2019). This suggests that existing 'siloed' interventions do not consistently lead to better adjustment related outcomes.

This could be due to a lack of integration between interventions targeting both cognitive *and* emotional changes. Many neural networks that process cognition also process emotion (particularly frontal-limbic networks; Pessoa, 2008) and there is a high frequency (approximately 60%) of comorbid cognitive and emotional difficulties after ABI suggesting that these processes are interrelated (Kimonides et al., 2018; Nijsse et al., 2017; Ponsford et al., 2014). From a functional perspective, an ABI survivor who has memory impairments may develop anxiety about forgetting tasks, and that anxiety may then impact cognitive performance. Targetting only cognitive impairment or mood disturbance in rehabilitation may not sufficiently address all barriers to adjustment and may also increase patient burden and costs.

Recent evidence indicates that valued living, the extent to which we engage in behaviours that are consistent with our personal values (e.g., about our relationships or work), is strongly associated with better adjustment-related outcomes (e.g. participation and quality of life) in both ABI (Pais et al., 2019) and other chronic health condition populations (Graham et al., 2016; Sheppard et al., 2010; Smout et al., 2014). Arguably, valued living may serve as a framework for facilitating adjustment by helping individuals reform their self-identity via awareness of their values, and by building new patterns of behaviour that still allow pursit of meaningful activities.

Acceptance and Commitment Therapy (ACT) is a psychological therapy designed specifically to enhance valued living. It aims to increase engagement in meaningful life activities by helping individuals identify what is important to them (i.e. their values), and by improving acceptance and psychological flexibility towards negative thoughts and emotions that may otherwise prevent valued living (Hayes et al., 2006). ACT has established efficacy in psychiatric and chronic health conditions (Dindo et al., 2017; Gloster et al., 2020). There is preliminary randomised controlled trial (RCT)-level evidence supporting its use to improve

mood, anxiety, and psychological distress in TBI (Sander et al., 2021; Whiting et al., 2020; Whiting et al., 2018), and lower level evidence in stroke (Graham et al., 2015; Large et al., 2020; Majumdar & Morris, 2019) and other neurological conditions (Gillanders & Gillanders, 2014; Hill et al., 2017). However, these studies have not directly addressed cognitive impairment; and there is no clear evidence for ACT improving psychological and behavioural aspects of adjustment following ABI.

Based on this body of evidence, we predict that interventions that concurrently address cognitive and emotional barriers to valued living may result in better adjustment, as reflected by improvements at the levels of impairment (e.g. social anxiety, memory difficulties), activity limitation (e.g. forgetting conversations with others, activities of daily living) and participation (e.g. attending social events), with overall improvements to wellbeing and satisfaction with life. Given that ACT directly targets valued living, which has been shown to relate directly to psychosocial and functional outcomes, combining ACT with cognitive rehabilitation may result in improved adjustment. This study served as a Phase I evaluation of the design and implementation of a new 8-week group intervention called VaLiANT: Valued Living after Neurological Trauma. VaLiANT combines cognitive rehabilitation with ACT principles to improve adjustment in ABI survivors. The study aimed to 1) evaluate the potential efficacy of VaLiANT on the primary outcome of valued living and a range of secondary measures of adjustment (at the level of impairment, activity and participation, as well as wellbeing and satisfaction with life), 2) evaluate the feasibility and acceptability of the intervention, and 3) inform the need for, and design of, a subsequent Phase II randomised controlled trial (including selection of outcome measures).

Methods

This study was approved by the La Trobe University Human Research Ethics Committee (HEC #18423) and written informed consent was obtained from all participants.

Design

We used a non-concurrent multiple baselines design with AB and follow-up phases and replication across 8 participants. The baseline phase (5, 6, or 7 weeks) was immediately followed by an eight-week intervention phase (VaLiANT), before a final eight-week follow-up phase. The reporting of results was in line with the Single-Case Reporting guideline in BEhavioural interventions criteria (SCRIBE; Tate et al., 2016).

Participant Selection

Participants were required to have experienced an ABI at least 3 months before enrolment in the study; be 18 years of age or over; be experiencing cognitive and/or emotional difficulties (identified descriptively by self, close other and/or clinician in initial screening); and be able to attend the group program at La Trobe University Psychology Clinic. Individuals with pre-existing intellectual disability, severe psychiatric disorders, comorbid neurodegenerative conditions, and insufficient cognitive and/or language abilities to complete outcome measures or participate in the intervention were excluded. Participants were recruited via advertisements (including flyers and weblinks) through email listservs (e.g., NPinOz, BRAINSPaN), local health services, practitioner networks, an existing ABI research participant database, and relevant online platforms such as EnableMe (Stroke Foundation).

Materials

Sample Characterisation

Stroke severity was classified using the National Institutes of Health Stroke Scale (NIHSS; Brott et al., 1989). TBI severity was classified by interpreting Glasgow Coma Scale scores (GCS), post-traumatic amnesia length (PTA), and loss of consciousness length (LOC) in line with guidelines from the Centers for Disease Control and Prevention (2015). Several cognitive measures were administered to assist with sample characterisation: 1) the Test of

Premorbid Functioning (TOPF) to measure premorbid intellectual ability (Pearson, 2009); 2) the Rey Auditory Verbal Learning Test (RAVLT) as a measure of verbal learning and memory (Schmidt, 1996); 3) and the Trail Making Test A and B (TMT) as a measure of processing speed and cognitive flexibility (Tombaugh, 2004).

Target Behaviour (Primary Outcome)

The target behaviour was participants' subjective evaluation of their level of valued living over the previous week, assessed by the Valued Living Questionnaire (VLQ) composite score (Wilson et al., 2010). The VLQ is a two-part questionnaire that measures valued living across 10 value domains. Participants 1) rate 10 value domains (e.g., family, work, spirituality, etc) for importance, and 2) rate how consistent their behaviour has been over the last week with each of these values domains. Both parts are rated on a 10-point Likert scale with higher scores meaning higher importance and consistency. The mean of the products of the importance and consistency scores from the different domains forms the composite score. Higher scores represent a person holding a range of values as important and living consistently with these. The VLQ has been used in ABI research (Pais et al., 2019) and the composite score is recommended as the primary indicator of valued living with acceptable internal consistency (.77) and construct validity (Wilson et al., 2010).

Secondary Outcomes

Mental wellbeing and life satisfaction were assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS; Tennant et al., 2007) and the 5-item Satisfaction With Life Scale (SWLS; Diener et al., 1985) with higher scores indicating greater wellbeing and quality of life. Anxiety and Depression were assessed with the 14-item Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), while the 13-item Everyday Memory Questionnaire – Revised (EMQ-R) was used as an index of subjective memory failures (Royle & Lincoln, 2008) with higher scores representing greater frequency

of mood symptoms and subjective memory failures respectively. The 9-item Acceptance and Action Questionnaire - Acquired Brain Injury (AAQ-ABI) was used as a measure of psychological adjustment towards ABI-related changes (Whiting et al., 2015) with higher scores indicating greater psychological inflexibility. Participation was assessed with the 15-item Community Integration Questionnaire (CIQ; Willer et al., 1993). The 6-item TBI Self-Efficacy Scale (TBI-SES) measured confidence in managing common difficulties following ABI (Huckans et al., 2010). Higher scores on the two latter scales indicated greater participation and self-efficacy respectively.

Feasibility and Acceptability of the Intervention

In line with previous related studies (Thomas et al., 2019; Toni D. Withiel et al., 2020; Wong et al., 2021), feasibility of the intervention was assessed against the following criteria:

1) recruitment of the minimum number of participants required to run two groups within a six-month timeframe (minimum of 3 per group);
2) acceptable participant drop-out rates (≤20%);
3) sufficient group attendance (≥80% overall participant attendance to the 64 sessions (8 participants * 8 group sessions));
4) sufficient homework completion rates (≥50% completion rate for each session from participants present in the session);
5) sufficient completion rates for major outcome assessments (≥80% completion);
6) treatment fidelity measured by adherence of clinicians to more than 80% of both session objectives and content areas listed in the treatment manual.

To measure adherence, sessions three and six from group one and session one and seven from group two (25% of the total sessions) were randomly selected (via randomizer.org) and evaluated by an independent senior neuropsychologist. They evaluated

whether clinicians were able to meet the session objectives and cover the prescribed content listed in the manual for each session using a checklist based on the manual's objectives and content for each session.

Acceptability of the intervention was measured by asking each participant to rate if they would recommend the intervention to others on a 9-point scale following completion of the intervention (i.e. "How confident are you in recommending the VaLiANT program to a friend who experiences similar problems?", 1 = *Not at all confident*, 9 = *Very confident*). Acceptability was determined by a mean rating of ≥80% (≥7.2/9).

Intervention

The VaLiANT program is a manualised face-to-face group intervention that concurrently targets cognition and emotion by integrating cognitive rehabilitation and ACT techniques. It aims to improve adjustment following ABI by increasing engagement in valued and meaningful activities. The program consists of eight two-hour group sessions run on a weekly basis. Each week focusses on a different value domain (health, work/study, leisure and relationships) and includes exploration of what is important to the participants in this domain using a values card sort. Committed actions (or valued living behaviours) that are consistent with chosen values are then generated by participants, with support from the facilitators. This is followed by various exercises and techniques that encourage engagement in those valued actions by addressing cognitive and emotional barriers to valued living through cognitive compensatory strategies and ACT-based techniques. The group comprises discussion, provision of information and resources through multiple modalities (verbal discussion, PowerPoint slides, and handouts), in-session practice of cognitive and psychological strategies, and weekly homework exercises to encourage implementation of strategies and participation in valued activities in everyday life. In Week 7, there is a concurrent session held with family members and close others of the participants, to assist

them in supporting the participant with their value-consistent activities and strategies. Further details can be found in Appendix A.

The intervention was primarily developed by the authors, drawing on their clinical and research expertise, however evidence-based ACT and cognitive rehabilitation techniques and materials were adapted from existing manualised treatments to supplement the new content (Brassington et al., 2016; O'Donoghue et al., 2018; Radford et al., 2010; Whiting et al., 2020; T. D. Withiel et al., 2020). Group sessions were facilitated by a senior clinical neuropsychologist with assistance from two provisional psychologists, and all sessions were video recorded. Two separate groups were run from February to April and April to June 2019. The VaLiANT program and all assessments were conducted face-to-face at the La Trobe University Psychology Clinic. Group sessions were held in a meeting room with all participants seated around a large table with slides projected onto a large screen. Participation in the intervention was free of charge and participants were not financially compensated. The treatment manual will be published following completion of subsequent clinical trial(s).

Procedure

Two separate recruitment intakes were completed to accommodate the running of two separate VaLiANT groups. Participants were provided with a verbal explanation of the study procedures before completing screening over the phone to ensure they met eligibility criteria. To determine the length of the baseline phase a randomisation window was set between 5 and 7 weeks. Eligible participants were randomly allocated to baseline length ~~(5, 6, or 7 weeks)~~ by an independent researcher based on a randomisation schedule generated by a random online sequence generator (www.sealedenvelope.com) before data collection commenced. Baseline phases started in a non-concurrent staggered fashion so that all participants within each intake commenced the intervention phase simultaneously, due to the group-based intervention (see Figure 1). The intervention phase (i.e., the eight-week VaLiANT program)

was introduced immediately after the baseline phase was completed. Intervention phase start dates were predetermined based on the running dates of each group. An eight-week follow-up phase commenced immediately following the intervention phase.

Target behaviour (valued living) was assessed weekly across all study phases. Participants completed the VLQ independently via online platform Qualtrics or via telephone with a researcher. This researcher was not blinded to study phase due to knowing the start date of the VaLiANT group.

Three comprehensive assessments were completed in addition to the weekly target behaviour assessments. A pre-intervention assessment (T1) was conducted just prior to the intervention phase commencing, and involved collecting demographic and sample characterisation information and all secondary outcome measures. A post-intervention (T2) and follow-up assessment (T3) were conducted within two weeks of the intervention phase and follow-up phase ending respectively, and they involved completion of secondary outcome measures only. T1 assessments were conducted by one of the group facilitators. T2 and T3 assessments were conducted by a researcher independent of the intervention and all these assessments were conducted face-to-face and took approximately 90-minutes.

Data Analysis

GraphPad Prism (Version 8) was used to graph primary outcome data which was analysed through a mixture of visual and statistical analysis. Missing primary outcome data was handled in line with recommendations by using a multiple imputation approach (Peng & Chen, 2018). The Amelia II R package was selected due to the statistical validity of its approach in handling time-series~~, cross-sectional~~ data (Honaker & King, 2010; Honaker et al., 2011). For phases where there were missing data, the imputation model used the observed data from that phase to create five plausible complete datasets. A final dataset was generated by using the average of the five imputed values for each missing point; further information

about this process is detailed by Honaker and King (2010); and Honaker et al. (2011). The imputed datasets for the VLQ were used in all visual and statistical analyses; however, analyses were not conducted on phases where there were four or more imputed values (out of the 5 – 8 per phase).

Visual analysis followed established guidelines (Lane & Gast, 2014; Ledford et al., 2018) and focussed on 1) the level; the mean value of data within each phase, 2) trend; the slope of the best fitting line within each phase, 3) variability; the range and fluctuation of data within each phase, and 4) overlap; the amount of overlapping data across phases (Kratochwill et al., 2013). The SCDA plugin for R was used to assist evaluation of trend by fitting linear trend lines to data using the split middle method (Bulté & Onghena, 2013). In cases where the baseline data were stable and suggested a clear trend for improvement prior to the introduction of the intervention, R code was used to project the baseline trend into the following phases (Manolov, 2014) to assist with trend evaluation. In line with recommendations for visual analysis of rehabilitation intervention data (Krasny-Pacini & Evans, 2018), the immediacy of effect and consistency of data patterns across similar phases were not considered due to the hypothesised data patterns (i.e. slow intervention effect onset, variability between participants' phases).

Statistical analysis was conducted using the percentage of data exceeding median trend (PEM-T), also known as the extended celeration line, to provide a quantification of change in data between phases (White & Haring, 1980; Wolery et al., 2010). PEM-T is a non-parametric index of data non-overlap between phases and it typically displays moderate-high levels of agreement with visual analysis (Yucesoy-Ozkan et al., 2020). PEM-T was selected over other overlap indices that also control for trend (i.e Tau-*U*) due to limitations of these methods in controlling trend with few data points and their reduced accuracy with significant within-case variability (Fingerhut et al., 2021). PEM-T comparisons were

conducted between baseline and intervention, and intervention and follow-up. In each comparison, the median split middle trend line of the earlier phase was extended into the subsequent phase using R code: https://www.dropbox.com/s/rlk3nwfoya7rm3h/PEM-T.R?dl=0 (Wolery et al., 2010). For interpretation, the magnitude and direction of values was considered with an improvement in behaviour indicated by PEM-T values >0.5 (i.e. more than 50% of data falling above trend line) while deterioration was indicated by values <0.5 (range 0-1; Yucesoy-Ozkan et al., 2020).

~~Statistical analysis was also conducted on target behaviour data using the non-overlap index~~

~~Baseline Corrected Tau (Tarlow, 2017). Baseline Corrected Tau was selected as it complements visual analysis, can control baseline trends, estimates the magnitude of an effect, and displays improvements over the widely used Tau-*U* statistic (Tarlow, 2017). Comparisons were conducted on adjacent phases using an online calculator: http://www.http://ktarlow.com/stats/tau/ (Tarlow, 2016). For effect size interpretation, the magnitude and direction (range -1 to +1) of Tau values were considered, with Tau scores greater than 0 indicating a positive impact of phase change on target behaviour, and scores lower than 0 indicating a negative impact.~~

Methods used to assess secondary outcome data depended on the characteristics of the measure. Reliable Change Indices (RCI; Jacobson & Truax, 1991) were calculated to determine the proportion of participants achieving statistically reliable change on the WEMWBS, HADS subscales, Acceptance and Action Questionnaire - Acquired Brain Injury, SWLS, and EMQ-R, with comparisons conducted between T1 vs. T2, and T1 vs. T3. Instrument reliability information was drawn from ABI samples on all measures (Bogner et al., 2017; Majumdar & Morris, 2019; Royle & Lincoln, 2008; Whelan-Goodinson et al.,

2009; Whiting et al., 2015). When available, test-retest reliability coefficients were chosen over Cronbach's alpha due to lower false positive rates (Ferrer & Pardo, 2014). Clinically Significant Change (CSC; Jacobson & Truax, 1991) was analysed based on the best method available for each measure. The HADS subscales were analysed using externally valid clinical categories, with a change in category representing clinical improvement. On each subscale scores below 8 equated to clinical recovery (Bjelland et al., 2002) and participants who remained within this 'normal' range throughout the study were excluded from RCI/CSC analysis for that subscale. The WEMWBS and SWLS were analysed by determining a clinical cut-off using criteria C from Jacobson and Truax (1991) which utilised psychometric information from a healthy comparison sample (SWLS; Diener et al., 1985; WEMWBS; Tennant et al., 2007). The EMQ-R and Acceptance and Action Questionnaire - Acquired Brain Injury were not analysed for CSC as the criteria required achievement of impossible values on each measure (i.e. below 0). The CIQ and TBI-SES were assessed descriptively to indicate any changes of importance.

Results

Methodological Quality Ratings

The methodological quality of the study was critically evaluated using the Risk of Bias in N-of-1 Trials Scale (RoBiNT; Tate et al., 2013). The study met external validity criteria but performed less strongly on internal validity criteria, with points lost due to the inability to blind participants, clinicians, and assessors to participant phase, and the nature of the group-based intervention meaning that participant baselines could end but not commence simultaneously (total score = 20/30; see Appendix B).

Case Description

Eight community-dwelling adults with a diagnosis of ABI were recruited into the study. Participants varied in age (26 – 65 years) and time since injury (8 months – 34 years),

and the majority of participants displayed impairment on at least one measure of cognition (see Table 1). All participants spoke English and none identified as Aboriginal and/or Torres Strait Islander. Two consecutive groups were run with participant AA to participant FF comprising the first group. Participants GG and HH were within a second group that also included an additional 3 individuals with ABI who received the intervention but were not offered participation in the study. These individuals were excluded due to the a-priori threshold of eight study participants having been met, but were included in the group to optimise the group size. An additional three participants were screened for eligibility but did not commence the study or join the groups due to work/study schedules which conflicted with the group time and dates. Only participant DD reported receiving regular psychological services outside of the study. No adverse events were identified for any participant.

Target behaviour

An overview of each participant's target behaviour (valued living, with improvements reflected by higher scores) is presented in text and in Figure 1. Participant AA was randomly allocated to the 7-week baseline length, participants BB, CC, and GG to the 6-week baseline, and participants DD, EE, FF, and HH to the 5-week baseline. All participants had missing target behaviour data (ranging from 2-6 data points) with the highest proportion missing in the follow-up phase. Missing data were mainly due to participant illness or difficulty contacting participants to complete the measures.

Participant AA

Participant AA had a mild stroke with subsequent difficulty meeting the demands of her job due to fatigue, anxiety, and a decline in her working memory. She also had reduced engagement in valued social/leisure activities which contributed to low mood. Participant AA attended the first four sessions of the group, however she missed sessions 5 and 8 due to work demands, and sessions 6 and 7 due to overseas travel.

Visual analysis indicated variable behaviour during baseline which stabilised in subsequent phases (see Figure 1). Level decreased from baseline (M = 39.87) to intervention and follow-up (M = 33.19; 32.97). ~~and there was almost total overlap of data across all phases.~~ Baseline and intervention phase data followed a gradual decreasing trend that switched to an increasing trend in follow-up. While visual inspection of overlap indicated a high degree of overlapping data across all phases, statistical analysis indicated an improvement in intervention phase data above the decreasing baseline trend (PEM-T = 0.88) and further improvement in follow-up phase data which fell above the decreasing intervention trend (PEM-T = 1.00).

~~Statistical analysis indicated deterioration in behaviour during intervention and with further deterioration during follow-up, however both changes were not statistically significant.~~

Participant BB

Participant BB experienced a severe TBI. He lacked engagement in meaningful activities, was unemployed, socially isolated, and required support with most activities due to hemiparesis, significant cognitive impairment, and sleep and fatigue difficulties. Participant BB attended all group sessions.

Visual analysis indicated variable data within each phase with minimal change in level of behaviour from baseline (M = 46.04) to intervention and follow-up (M = 45.43; 46.55)~~). Data were variable within each phase with a high degree of overlap across all phases.~~. Trend was increasing in baseline and follow-up and decreasing during intervention. Visually there was a high degree of overlapping data across all phases, however s~~S~~tatistical analysis indicated that intervention phase data deteriorated and fell below the increasing baseline trend (PEM-T = 0.00) while follow-up phase data improved and was above the decreasing intervention trend (PEM=T = 1.00). ~~no change in behaviour during intervention,~~

~~with slight deterioration from baseline levels at follow-up however this was not statistically significant.~~

Participant CC

Participant CC experienced a series of mild strokes. She was retired, lived alone, and experienced reduced participation in valued family relationships after becoming estranged from her adult children following her strokes and associated cognitive and psychological changes, with associated feelings of grief and mood disturbance. Participant CC attended all sessions of the group.

Visual analysis indicated stable behaviour during baseline with greater variability during subsequent phases. Level decreased from baseline (M = 66.9) to intervention and follow-up (M= 54.73; 56.78). ~~. Trends were decreasing and there was a high degree of data overlap across all phases.~~ Trend was increasing during baseline and decreasing during intervention and follow-up. Visual inspection suggested a high degree of data overlap across all phases while s~~S~~tatistical analysis indicated ~~deterioration~~ that intervention phase data deteriorated and was below the increasing baseline trend (PEM-T = 0.13) while follow up phase data improved above the decreasing intervention trend (PEM-T = 0.88).

~~in behaviour during intervention before a slight improvement towards baseline levels during follow-up, however both changes were not statistically significant.~~

Participant DD

Participant DD had complex refractory epilepsy following a childhood injury. He lacked engagement in meaningful activities, experienced significant mood disturbance and suicidal ideation after being widowed four years prior, and he required support from his parents with most activities of daily living due to cognitive impairment and fatigue. He missed session 5 (for unknown reasons) and session 7 (due to illness).

Data were stable within all phases and ~~.~~ ~~L~~level increased from baseline (M = 45.06) to intervention (M = 51.89) before decreasing at follow-up (M = 46.16) ~~with moderate data overlap across phases~~. Baseline trend was increasing while intervention and follow-up trends were decreasing. Intervention phase data fell within the projected trend envelope while follow-up data fell below, suggesting no impact of intervention on trend. There was moderate visual data overlap across phases and s~~S~~tatistical analysis indicated that intervention phase data deteriorated and was below the increasing baseline trend line (PEM-T = 0.25) and follow-up phase data also deteriorated and was below the decreasing intervention trend (PEM-T = 0.25).

~~a statistically significant improvement in behaviour during intervention before a statistically significant deterioration back to baseline levels during follow-up.~~

Participant EE

Participant EE experienced a severe stroke and subsequently was unemployed and had limited engagement in meaningful activities due to hemiparesis, fatigue, cognitive impairment, and significant mood disturbance with suicidal ideation. He lived with his pregnant wife and expressed concern about becoming a parent with an ABI. Participant EE did not attend session 2 due to illness and session 5 and 7 for unknown reasons. He withdrew from the study following completion of the intervention phase.

Visual analysis indicated stable data within both phases. There was an increase in level between baseline (M = 34.74) and intervention (M = 50.99). ~~with no overlapping data.~~ Baseline data followed an increasing trend while intervention data was slightly decreasing, however intervention data fell above the projected trend envelope suggesting an improvement in behaviour above that explained by the baseline trend. Visually there was no overlap of data, and s~~S~~tatistical analysis indicated an ~~statistically significant~~ improvement in intervention phase data (PEM-T = 0.63) ~~behaviour during intervention.~~.

Participant FF

Participant FF experienced a severe TBI at 15-years of age. The referring neuropsychologist described poor social cognition, rigid thinking, and slowed processing which resulted in unwanted social isolation and workplace conflict. Participant FF lived alone, experienced fatigue, and had limited social support due to recently moving interstate. Participant FF attended all group sessions.

Due to the high amount of imputed data, visual analysis was not conducted on follow-up phase data, and the intervention vs. follow-up ~~Tau~~ PEM-T comparison was not interpreted. Visual analysis indicated stable data within both phases with a decrease in level from baseline (M = 48.6) to intervention (M = 44.22). ~~with almost total overlap of data.~~ Trend was decreasing at baseline and increasing during intervention. While there was almost total overlap of data visually, s~~S~~tatistical analysis indicated ~~deterioration~~ improvement in behaviour during intervention ~~that was not statistically significant.~~ above the decreasing baseline trend (PEM-T = 0.75).

Participant GG

Participant GG had a mild stroke. She was unemployed, lived alone, and had limited participation in valued family and social activities which led to loneliness, low mood, and anxiety. Her difficulties with fatigue, concentration, and slow processing also impacted her ability to engage socially. Participant GG attended all sessions of the group.

Visual analysis indicated stable data within all phases. Data level decreased from baseline (M = 47.92) to intervention (M = 46.42) before an increase at follow-up (M = 55.01). Trend was increasing across all phases; however, intervention and follow-up data fell below the projected baseline trend envelope. ~~and there was almost complete overlap of data across all phases.~~ While there was almost total overlap of data across all phases visually, s~~S~~tatistical analysis indicated ~~non-significant slight~~ deterioration in behaviour during intervention and

follow-up with data falling below the increasing baseline and intervention trends respectively (PEM-T = 0; and = 0.25). ~~before a statistically significant improvement from baseline levels during follow-up.~~

Participant HH

Participant HH had experienced a severe TBI. He experienced memory and emotion regulation difficulties which prevented him from participating in valued activities including work. He lived with his wife and adolescent son who had a neurodevelopmental disorder. He reported difficulty regulating anger which related to being perceived differently due to his TBI. Participant HH attended all sessions of the group.

Visual analysis indicated stable data within all phases. Data level decreased from baseline (M = 42.3) to intervention and follow-up (M = 37.6; 28.87). Trend was decreasing at baseline and follow-up and slightly increasing during intervention. ~~Baseline and intervention data overlapped completely while follow-up data shared no overlap with other phases.~~ Visual analysis indicated complete visual overlap between baseline and intervention, and no overlap with follow-up. Statistical analysis indicated ~~deterioration~~ improvement in intervention data above the decreasing baseline trend (PEM-T = 1.00) ~~in~~ and deterioration in follow-up data below the increasing intervention trend (PEM-T = 0.00). ~~behaviour during intervention which was not significant, before further statistically significant deterioration in behaviour during follow-up.~~

Secondary Measures:

Evaluation of secondary measures was not possible for participant EE due to completing only his T1 assessment. All other participants (except participant HH) displayed reliable and clinically significant improvement on at least one out of six secondary outcome measures analysed through RCI (see Table 2~~3~~). Participants AA, DD, and FF achieved reliable improvements on four measures, participants BB and CC on three measures, and

participant GG on one measure out of the possible six at either their T2 or T3 assessment. Similarly, all six measures had at least two out of seven participants achieve reliable improvement during the study, with the HADS-A and WEMWBS improving in the highest number of participants (see Table 3). Participant HH did not achieve reliable improvement on any measure at any timepoint and displayed deterioration on the HADS-A at T2, although this improved back to baseline levels by T3. Participant CC also displayed reliable deterioration on the SWLS at T2 which persisted at T3.

Descriptive analyses of the CIQ and TBI-SES revealed variable results. On the CIQ, participant BB and FF displayed increases in social integration only while participant DD and GG displayed increases in social integration and daily productivity. Participants AA, CC, and HH displayed reductions in home and social integration. On the TBI-SES, participant BB, CC, FF, GG, and HH showed increased confidence in managing aspects of their daily life (e.g. work, leisure, personal affairs, injury consequences) while participant DD was less confident. Participant BB, CC, DD felt more confident in managing negative emotions while participant HH felt less confident. Participants CC displayed less confidence in managing her interpersonal relationships. Participant AA did not display any major changes on the TBI-SES.

Feasibility and Acceptability

Recruitment rates exceeded the minimum number required to run two groups within the allocated six-month timeframe and participant drop-out was low with one participant withdrawing during the follow-up phase of the first group (total drop-out = 12.5%). Session attendance across all sessions was 55/64 (86%) while the major outcome assessment completion rate was 22/24 (92%). For each session, at least 50% of participants in attendance had completed the homework (range = 60% - 87.5%). Treatment adherence ratings suggested that all objectives and main content areas from session one, three and six were deemed to

have been covered. Evaluation of session seven indicated that a discussion around social barriers and an ACT defusion exercise were not covered due to time constraints, however all session objectives were still met. From all four sessions, 16/16 (100%) session objectives were met, and 34/36 (94%) prescribed content areas were delivered. Participant acceptability ratings of the intervention ranged from 6 to 9 with 5/7 participants rating the intervention >8 for confidence in recommending the VaLiANT program to friends with similar problems. The overall mean acceptability rating across participants was 8/9 (89%).

Discussion

This study served as a Phase I evaluation of the preliminary efficacy, feasibility, and acceptability of VaLiANT, a new 8-week face-to-face group intervention that aimed to improve valued living and adjustment following ABI. While the primary target behaviour data were variable, signals of efficacy were identified across a range of secondary outcome measures. The feasibility and acceptability of the intervention were also supported and these findings support the need for and viability of a larger clinical trial.

Target behaviour data was highly variable and visual and statistical analysis provided limited evidence to support VaLiANT in improving valued living. Previous studies have indicated that valued living can improve following ACT in non-ABI populations (Michelson et al., 2011; Wersebe et al., 2017). However, it has been recognised that clients often show an initial decrease in valued living when completing ACT as they recognise the discrepancy between their values and current behaviour, before a delayed improvement (Wilson et al., 2010). There are many additional barriers following ABI that may have limited or slowed behaviour change, including decreased self-awareness, independence, and functional capacity. Individuals with ABI may therefore require more time to develop their personal resources to support valued living, and improvements might emerge more slowly over time. Thus, the lack of change in valued living may reflect the development of increasing insight as

participants became acculturated to the concepts of values and valued living, and could also reflect the additional barriers associated with ABI and their impact on consistently living in accordance with one's values.

However, a number of issues were identified with the use of the VLQ during data collection. Participants were noted to have difficulty answering the items due to the abstract nature and cognitive demands of the questionnaire, such as having to remember their behaviour over the past week, identify which behaviours were in line with a particular value, and then make an overall evaluation of how consistent these behaviours were with their importance rating for that domain. Members of our research team recently conducted a cognitive interviewing study which confirmed that a number of comprehension errors are regularly made by people with ABI when completing the VLQ (Miller, Lawson, Power, das Nair, Sathananthan, & Wong, under review). As such, the VLQ may not have accurately measured valued living within this population. An adapted version of the VLQ has subsequently been developed in an attempt to improve its validity in ABI cohorts with cognitive and communication difficulties, and this adapted version will be used in the Phase II trial of VaLiANT.

Despite the lack of improvement in valued living, positive outcomes were identified across a range of secondary outcome measures. The highest frequency of improvement was seen in mental wellbeing and anxiety symptoms, with over half of our participants showing reliable and clinically significant improvements on these measures. Higher subjective wellbeing and emotional distress have been strongly associated with better adjustment following ABI (Carroll & Coetzer, 2011; Doering et al., 2011; Schönberger et al., 2014). Improvements to wellbeing and mood have been found following ACT in healthy (Fledderus et al., 2010) and subclinical depressive samples (Bohlmeijer et al., 2011), however these improvements have not been consistently demonstrated following ACT or cognitive

rehabilitation in ABI cohorts (Cicerone et al., 2019; das Nair et al., 2016; Majumdar & Morris, 2019). These promising preliminary findings could reflect the unique combination of cognitive rehabilitation with ACT techniques used in VaLiANT which may have the potential to improve adjustment following ABI.

Interestingly, participants displayed different patterns of improvement across the various secondary measures and stable deterioration was evident on the Satisfaction with Life Scale for one participant. This variability in response to VaLiANT was not unexpected given the complex nature of the intervention which incorporated both cognitive and emotional elements, as well as the fact that eligibility criteria was open to encompass anyone with cognitive or emotional difficulties that impacted valued living. However, certain factors may have moderated this variability in response. For example, participant GG and HH displayed the least positive change following the intervention and were the only participants from the second group included in the study. The dynamic of a group has been identified as a core ingredient that can impact outcomes in group interventions (Borek et al., 2019) and it is possible that the second group may have had a less cohesive or effective dynamic. Identifying possible sources of variability and key predictors of the various outcomes of VaLiANT will be an important focus for future research. Overall, these findings support the inclusion of a range of outcome measures for VaLiANT, and suggest that mental wellbeing may be a more appropriate primary outcome measure in future evaluations. In addition, these findings support the progression to a Phase II RCT as weekly measurement of multiple outcome measures is unlikely to be feasible in another SCED, due to the burden on participants.

All a priori feasibility and acceptability criteria were met. The recruitment rate was sufficient and allowed two groups to be run within a six-month time frame with only one participant dropping out during the follow-up period. As such, the current recruitment strategy would allow running of quarterly groups, with low attrition, which would be

necessary for a sufficient sample size in a Phase II clinical trial. The majority of participants attended all intervention sessions, although three participants missed multiple weeks due to various reasons. This was unavoidable given the predetermined dates and time of the group intervention, however attendance may be an important moderator of intervention success in future trials. The majority of participants also completed the weekly homework, however this varied per session and homework completion was not able to be assessed in participants who were absent. Homework completion may also be an important moderator of intervention success and more detailed homework monitoring will be necessary for future trials. Intervention delivery was feasible with all session objectives and the majority of content areas being covered within the evaluated sessions. Some content areas were missed due to time constraints within particular weeks suggesting that restructuring of some sessions is necessary. While the collection of weekly target behaviour data was inconsistent, all major secondary outcome data assessments were completed within their allocated timeframes (excluding participant EE's assessments following withdrawal from the study). This suggests that the current outcome assessment structure can be feasibly implemented in subsequent trials, in which weekly measurement would not be required. Finally, acceptability ratings of the intervention were high with the majority of participants indicating that they perceived VaLiANT as being useful.

These findings should be considered in the context of some methodological limitations. Ratings of the study's methodological quality with the RoBINT scale indicated weakness with internal validity. While this may have impacted the robustness of target behaviour data, the randomisation to multiple baseline lengths can be considered a design strength, increasing the study's internal validity by reducing systematic bias. As noted previously, the validity of target behaviour (VLQ) scores for participants in our study was questionable due to several issues identified with its administration. While the moderate

amount of missing VLQ data could have further limited the robustness of these target behaviour data, missing data was handled with a multiple imputational approach to input possible valid values which can be considered a strength of the study. While secondary outcome data was more promising, these findings were limited by the pre-post measurement design, as these measures were not given weekly across phases. Furthermore, all outcome measures included in this study relied on self-report and required participants to be able to accurately reflect on their recent thoughts, feelings, and behaviour. Cognitive impairment may have limited some participants' ability to accurately answer questionnaires. However, subjective outcome measures are more strongly associated with participation outcomes following ABI than objective measures, and therefore may be more relevant as outcome measures for interventions aiming to increase meaningful outcomes like participation and quality of life (de Graaf et al., 2020).

In summary, VaLiANT is a feasible and acceptable intervention that shows promise in improving adjustment-related outcomes following ABI. While VaLiANT was not effective in increasing levels of valued living, improvements to wellbeing and mood symptoms were evident for the majority of our participants and likely reflect the true impact of the intervention. These findings suggest that cognitive rehabilitation combined with psychological therapy may have the potential to result in better adjustment-related outcomes than either approach alone. Further investigation in a larger Phase II randomised controlled trial is warranted with a focus on the impact of VaLiANT on wellbeing.

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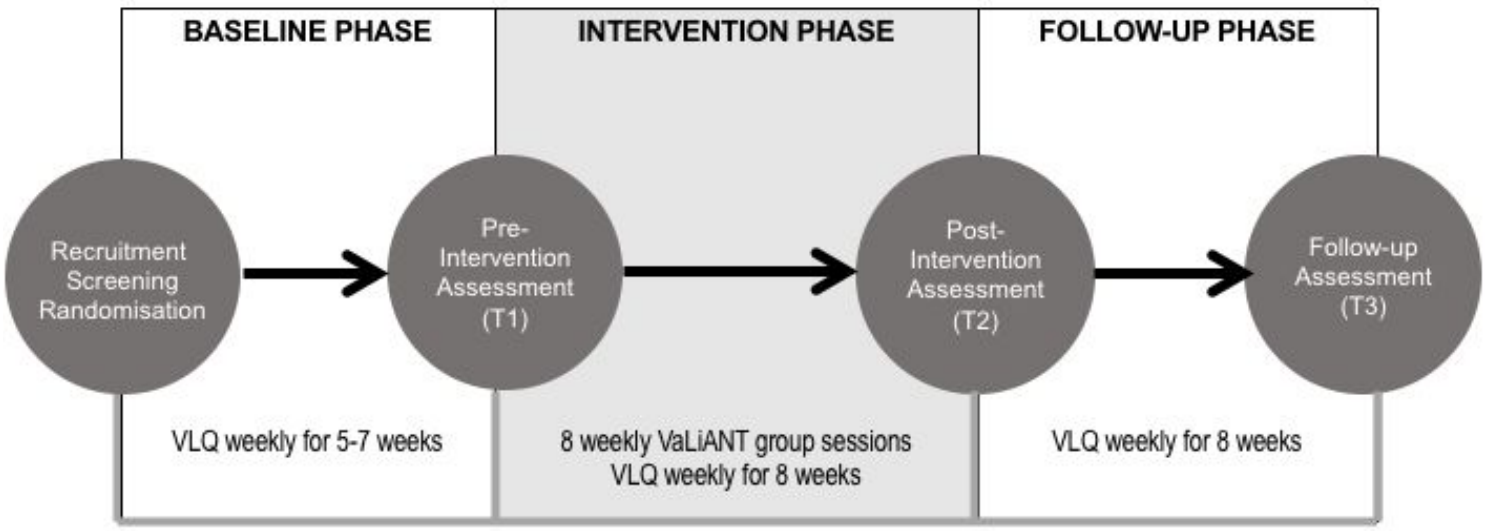

Figure 1. Flowchart of study phases and assessment timepoints. VLQ = The Valued Living Questionnaire

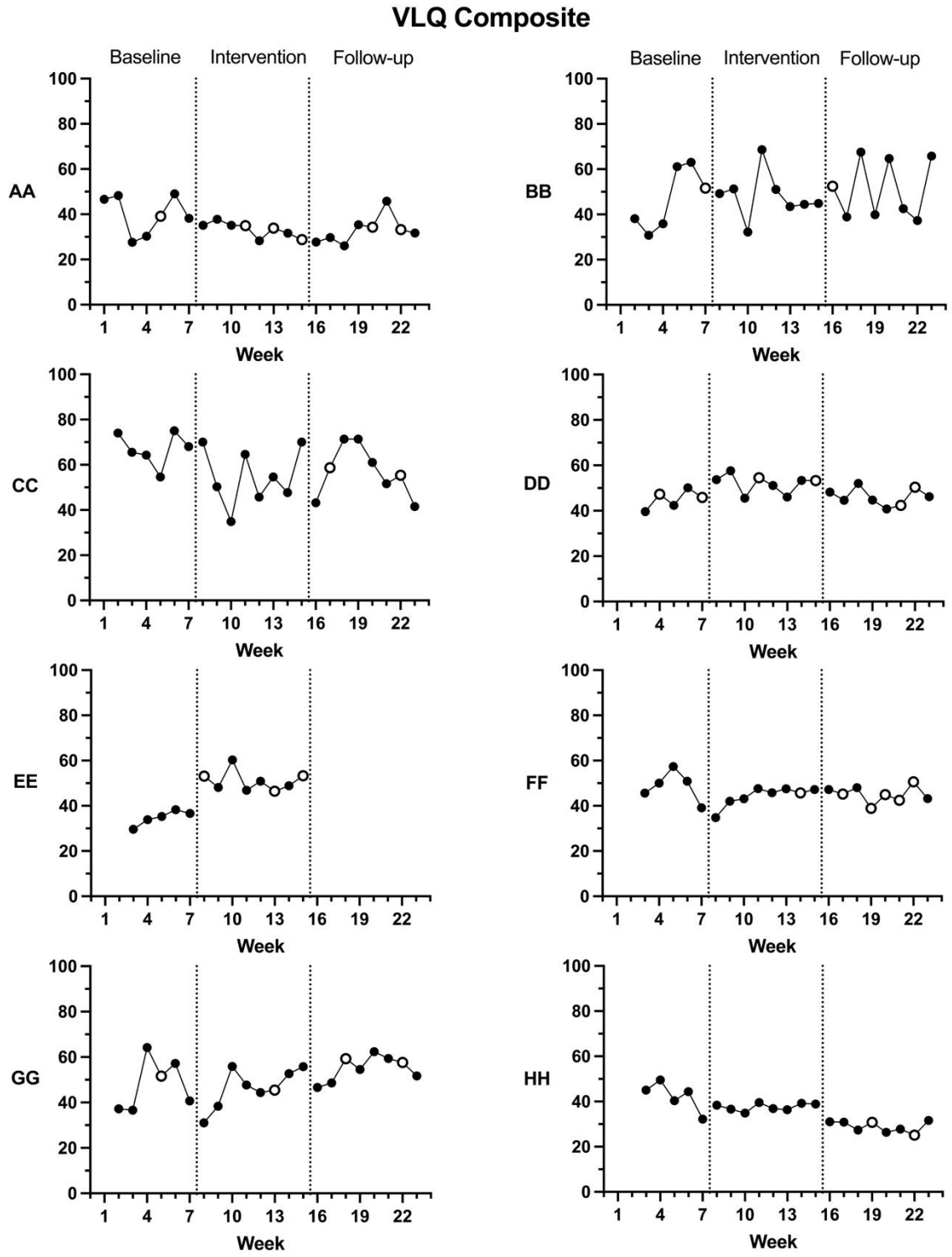

Figure 2. Participants' Valued Living Questionnaire (VLQ) composite scale scores. Baseline lengths varied between 5-7 weeks and unfilled circles represented imputed data.

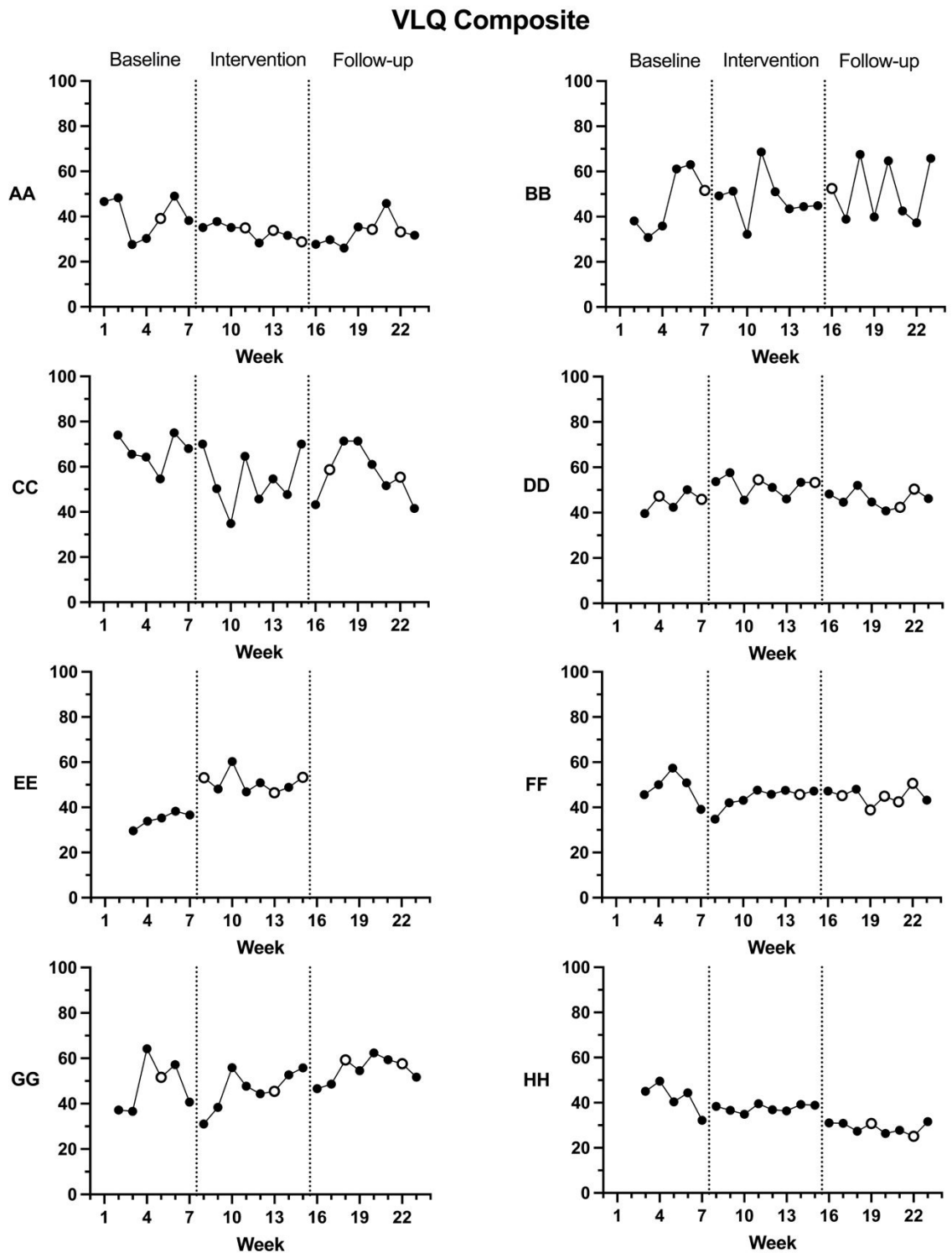

Figure 2. Participants' Valued Living Questionnaire (VLQ) composite scale scores.

Baseline lengths varied between 5-7 weeks and ~~U~~unfilled circles represented imputed data.

Table 1.

Participant Demographic, ABI, and Baseline Variables.

Participant/ age (years)	Sex	TOPF	TMTA[a]	TMTB[a]	RAVLT[b]	Education (years)	Time since ABI	Hemisphere	ABI description/severity
AA (49)	F	109	18	40	50	18	8 months	Right	Stroke; PICA/PCA infarct, GCS = 15
BB (43)	M	90	92*	600*	33*	11	14 years	Bilateral	TBI; MVA, GCS = 3, PTA = >6 months
CC (65)	F	110	43	148*	56	17	4 years	Bilateral	4 strokes ACA infarct with haemorrhagic transformation, cerebellar infarct, frontal infarct, infarct near right lateral ventricle, NIHSS = 3
DD (41)	M	90	62*	171*	35*	13	34 years	Bilateral	Complex refractory Epilepsy
EE (30)	M	95	38*	93*	39*	13.5	15 months	Left	Stroke; Basal Ganglia intracerebral haemorrhage, GCS = 3
FF (26)	F	113	23	46	58	16	11 years	Bilateral	TBI; MVA/subdural and subarachnoid haemorrhage, PTA = 19 days
GG (49)	F	94	31	57	41*	14	21 years	Right	Stroke; Pontine haemorrhage, GCS = 14
HH (51)	M	102	70*	107*	30	11.5	6 years	-	TBI; Subdural haematoma, LOC = >1 month

Note: Blank cells represent missing information. TOPF, Test of Premorbid Functioning; TMT A, Trail Making Test A; TMT B, Trail Making Test B; RAVLT, Rey Auditory Verbal Learning Test; PICA, Posterior Inferior Cerebral Artery; PCA, Posterior Cerebral Artery; GCS, Glasgow Coma Scale score; MVA, Motor Vehicle Accident; PTA, Post-traumatic amnesia length; ACA, Anterior Cerebral Artery, NIHSS, National Institutes of Health Stroke Scale score, LOC = Loss of consciousness length

[a]Scores are presented in seconds. *denotes score which fell 1.5SD below normative mean (Tombaugh, 2004).

[b]Score represents total recall across learning trials on RAVLT. *denotes score which fell 1.5SD below normative mean (Schmidt, 1996)

Table 23.

Reliable Change Analysis for Secondary Measures.

	Scales																	
	WEMWBS			HADS-A			HADS-D			SWLS			AAQ-ABI			EMQ-R		
Participant	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
AA	38	**52***	41*	12	**7***	9	3	1	3	18	25	17*	17	10	6^	47	11*	23*^
BB	50	**66***	**66^**	9	6	**1*^**	0	0	3	27	30	28	6	4	4	14	7*	7^
CC	43	40	40	14	**9***	12	5	7	7	16	6*	6^	11	3*	12*	15	6*	6^
DD	48	**58***	50*	14	**7***	**6^**	9	**6***	**3*^**	16	**25***	22	16	20	11*	17	21	17
EE[a]	37	-	-	10	-	-	9	-	-	17	-	-	22	-	-	33	-	-
FF	46	**57***	**61^**	10	**6***	**3^**	5	1	1	20	27	**32^**	14	13	5*^	9	7	4
GG	45	49	44	3	2	2	8	6	**5^**	11	16	15	8	6	9	20	26	25
HH	40	41	41	9	13*	9*	11	12	11	9	14	14	17	14	23*	40	37	37

Note: Data represents participants' raw scores for each measure. *denotes reliable change between a timepoint compared to the previous timepoint. ^denotes reliable change at the T3 timepoint compared with the T1 timepoint. Bold type represents Clinically Significant Change compared with T1 for available measures (WEMWBS, HADS-A, HADS-D, SWLS). RCI scores were 7.88 (WEMWBS), 3.80 (HADS-A), 2.89 (HADS-D), 7.22 (SWLS), 7.31 (AAQ-ABI), and 6.74 (EMQ-R). WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.

[a]Blank cells represent missing data due to participant withdrawal

Table 2.

Reliable Change Analysis for Secondary Measures.

	Scales																	
	WEMWBS			HADS-A			HADS-D			SWLS			AAQ-ABI			EMQ-R		
Participant	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
AA	38	**52***	41*	12	**7***	9	3	1	3	18	25	17*	17	10	6^	47	11*	23*^
BB	50	**66***	**66^**	9	6	**1*^**	0	0	3	27	30	28	6	4	4	14	7*	7^
CC	43	40	40	14	**9***	12	5	7	7	16	6*	6^	11	3*	12*	15	6*	6^
DD	48	**58***	50*	14	**7***	**6^**	9	**6***	**3*^**	16	**25***	22	16	20	11*	17	21	17
EE[a]	37	-	-	10	-	-	9	-	-	17	-	-	22	-	-	33	-	-
FF	46	**57***	**61^**	10	**6***	**3^**	5	1	1	20	27	**32^**	14	13	5*^	9	7	4
GG	45	49	44	3	2	2	8	6	**5^**	11	16	15	8	6	9	20	26	25
HH	40	41	41	9	13*	9*	11	12	11	9	14	14	17	14	23*	40	37	37

Note: Data represents participants' raw scores for each measure. *denotes reliable change between a timepoint compared to the previous timepoint. ^denotes reliable change at the T3 timepoint compared with the T1 timepoint. Bold type represents Clinically Significant Change compared with T1 for available measures (WEMWBS, HADS-A, HADS-D, SWLS). RCI scores were 7.88 (WEMWBS), 3.80 (HADS-A), 2.89 (HADS-D), 7.22 (SWLS), 7.31 (AAQ-ABI), and 6.74 (EMQ-R). WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.

[a]Blank cells represent missing data due to participant withdrawal

Table 34.

Percentage of Participants Achieving Reliable Improvement (RC) and Deterioration Across Secondary Measures.

Scales	% RC (T1 vs. T2)	% RC (T1 vs. T3)	% RC (T1 vs. T2/T3)	% Deterioration (T1 vs. T3)
WEMWBS	57% (4/7)	28% (2/7)	57% (4/7)	0%
HADS-A[a]	67% (4/6)	50% (3/6)	83% (5/6)	0%
HADS-D[a]	33% (1/3)	66% (2/3)	66% (2/3)	0%
SWLS	14% (1/7)	14% (1/7)	29% (2/7)	14% (1/7)
AAQ-ABI	14% (1/7)	29% (2/7)	43% (3/7)	0%
EMQ-R	43% (3/7)	43% (3/7)	43% (3/7)	0%
Any Measure	71% (5/7)	86% (6/7)	86% (6/7)	14% (1/7)

Note: Only participants with complete data were included (n = 7). WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.
[a]Participants below clinical cut-off score excluded from analysis.

Table 3.

Percentage of Participants Achieving Reliable Improvement (RC) and Deterioration Across Secondary Measures.

Scales	% RC (T1 vs. T2)	% RC (T1 vs. T3)	% RC (T1 vs. T2/T3)	% Deterioration (T1 vs. T3)
WEMWBS	57% (4/7)	28% (2/7)	57% (4/7)	0%
HADS-A[a]	67% (4/6)	50% (3/6)	83% (5/6)	0%
HADS-D[a]	33% (1/3)	66% (2/3)	66% (2/3)	0%
SWLS	14% (1/7)	14% (1/7)	29% (2/7)	14% (1/7)
AAQ-ABI	14% (1/7)	29% (2/7)	43% (3/7)	0%
EMQ-R	43% (3/7)	43% (3/7)	43% (3/7)	0%
Any Measure	71% (5/7)	86% (6/7)	86% (6/7)	14% (1/7)

Note: Only participants with complete data were included (n = 7). WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.
[a]Participants below clinical cut-off score excluded from analysis.

Table 4~~5~~.

Means, Standard Deviations (SD), and Range of Secondary Measures Across Assessment Timepoints.

	T1 (n = 8)		T2 (n = 7)		T3 (n = 7)	
Scales	Mean	SD (range)	Mean	SD (range)	Mean	SD (range)
WEMWBS	43.38	4.72 (37 – 50)	51.86	9.41 (40 – 66)	49.00	10.55 (40 – 66)
HADS-A	10.13	3.52 (3 – 14)	7.14	3.34 (2 – 13)	6	4.16 (1 – 12)
HADS-D	6.25	3.65 (0 – 11)	4.71	4.31 (0 – 12)	4.71	3.35 (1 – 11)
SWLS	16.75	5.50 (9 – 27)	20.43	8.62 (6 – 30)	19.14	8.88 (6 – 32)
AAQ-ABI	12.13	6.27 (2 – 22)	9.14	6.49 (0 – 18)	7.71	6.87 (0 – 21)
EMQ-R	24.38	13.81 (9 – 47)	16.43	11.91 (6 – 37)	17.00	12.18 (4 – 37)
CIQ	19.28	4.81 (11.2 – 25)	18.4	4.27 (11 – 24)	19.74	4.85 (14 – 27)
TBI-SES	37.50	11.65 (19 – 47)	44.86	9.15 (25 – 51)	44.86	11.16 (23 – 54)

Note: WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; CIQ, The Community Integration Questionnaire; TBI-SES, The TBI Self-Efficacy Scale; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.

Table 4.

Means, Standard Deviations (SD), and Range of Secondary Measures Across Assessment Timepoints.

	T1 (n = 8)		T2 (n = 7)		T3 (n = 7)	
Scales	Mean	SD (range)	Mean	SD (range)	Mean	SD (range)
WEMWBS	43.38	4.72 (37 – 50)	51.86	9.41 (40 – 66)	49.00	10.55 (40 – 66)
HADS-A	10.13	3.52 (3 – 14)	7.14	3.34 (2 – 13)	6	4.16 (1 – 12)
HADS-D	6.25	3.65 (0 – 11)	4.71	4.31 (0 – 12)	4.71	3.35 (1 – 11)
SWLS	16.75	5.50 (9 – 27)	20.43	8.62 (6 – 30)	19.14	8.88 (6 – 32)
AAQ-ABI	12.13	6.27 (2 – 22)	9.14	6.49 (0 – 18)	7.71	6.87 (0 – 21)
EMQ-R	24.38	13.81 (9 – 47)	16.43	11.91 (6 – 37)	17.00	12.18 (4 – 37)
CIQ	19.28	4.81 (11.2 – 25)	18.4	4.27 (11 – 24)	19.74	4.85 (14 – 27)
TBI-SES	37.50	11.65 (19 – 47)	44.86	9.15 (25 – 51)	44.86	11.16 (23 – 54)

Note: WEMWBS, The Warwick-Edinburgh Mental Well-being Scale; HADS-A, anxiety subscale from Hospital Anxiety and Depression Scale; HADS-D, depression subscale from Hospital Anxiety and Depression Scale; SWLS, The Satisfaction with Life Scale; AAQ-ABI, The Acceptance and Action Questionnaire after brain injury; EMQ-R, Everyday Memory Questionnaire – Revised; CIQ, The Community Integration Questionnaire; TBI-SES, The TBI Self-Efficacy Scale; T1, baseline assessment; T2, post-intervention assessment; T3, 8-week follow-up assessment.

Appendix A: Outline of the VaLiANT Manual

Session	Components	Description
1. Introduction to VaLiANT	Introduction to group	• An overview of the whole program is provided • Group rules are established. • Group members are introduced to each other.
	Introduction to values	• Introduction to the concept of values • Activity for identifying values in others • Card sort activity for identifying personal values. Examples of cards include 'to have joy in my life' from the leisure domain, and 'to continually learn and grow' from the work/study/volunteering domain.
	Passengers on the bus ACT exercise	• Introduction of central group metaphor 'passengers on the bus'. • Metaphor acted out by group members.
	Introduction to mindfulness	• Mindful breathing exercise completed. • Group discussion
	Introduction to committed actions	• Idea of committed actions and experiential avoidance introduced. • Participants complete a name association task and discuss cognitive strategies. • Concept of strategies to support committed actions introduced.
	Homework	• Practice self-monitoring of emotions • Practice cognitive strategies by learning a new name.
2. Being Healthy - Sleep and Fatigue	Homework reflection	• Discussion of previous week's homework
	Introduction to module	• The domain of health and well-being is introduced (focus of next two weeks). • Group discussion • Psychoeducation around importance of health • Health is tied to 'passengers on the bus' metaphor
	Values	• Card sort activity • 'The way to valued living' worksheet introduced
	Psychoeducation	• Psychoeducation around managing sleep disturbance and fatigue is provided • Experiential avoidance discussion included
	Mindfulness	• Body scan exercise completed • Recording provided for use at home
	Committed actions	• Activity identifying committed actions to manage sleep and fatigue • Completion of barriers worksheet

	Homework	• Use a weekly planner to plan at least one day with scheduled rest breaks • Try a mindfulness exercise during one of these rest breaks.
3. Being Healthy – Diet and Exercise	Homework reflection	• Discussion of previous week's homework
	Values	• Card sort activity
	Psychoeducation	• Benefits of healthy eating • Benefits of physical activity • Australian guidelines
	Barriers	• Activity identifying own barriers to health • Activity identifying barriers to health in a case example
	Passengers on the bus ACT exercise	• 'Passengers on the bus' metaphor tied to health • Metaphor acted out by group members.
	Mindfulness	• Mindful eating exercise completed • Discussion
	Committed actions	• Group brainstorm on committed actions for health
	Strategies	• Activity scheduling introduced as strategy for finding time • A menu of additional strategies to support health and wellbeing are supplied
	Homework	• To eat one meal mindfully that week • Use activity schedule to plan health related activity
4. Having a Purpose – Work, Study, or Community Participation	Homework reflection	• Discussion of previous week's homework
	Introduction to module	• To concept of having a purpose is introduced (focus of next two weeks) • Brainstorm exercise
	Values	• Card sort activity
	Committed actions	• Brain storm for case example • SMART goals • Way to valued living worksheet
	Barriers	• Barriers worksheet
	Mindfulness	• Self-compassion exercise • Discussion
	Strategies	• Prospective memory • Completing complex tasks
	Homework	• Use strategies to remember to make a phone call
5. Having a Purpose –	Homework reflection	• Discussion of previous week's homework

Leisure Activities		
	Introduction to leisure	• Idea of leisure is introduced • Therapy ball activity
	Psychoeducation	• Discussion around the importance of leisure • Benefits of leisure activities • Impact of chronic stress • Downward/upward spiral
	Values	• Card sort activity
	Committed actions	• Menu of leisure activities • Brainstorm of case example • SMART goals
	Mindfulness	• Mindfulness of sense exercise • Discussion
	Strategies	• Leisure activity schedule • Strategies for overcoming barriers to leisure activities
	Homework	• Complete a leisure activity schedule
6. Connecting with Others – Relationships Part 1	Homework reflection	• Discussion of previous week's homework
	Introduction to relationships	• Introduction to relationships module • Brainstorm activity
	Values	• Card sort activity
	Strengths	• Identification of personal relationship strengths
	Committed actions	• Brainstorm • SMART goals
	Barriers	• Relationship barriers worksheet
	Mindfulness	• Mindfulness S.T.O.P exercise completed • Discussion
	Strategies	• Group discussion • Word finding difficulties • Cognitive communication strategies
	Homework	• Plan a conversation that will be difficult. Identify strategies to assist you with this.
7. Connecting with Others – Relationships Part 2 ****participants may bring a family member or friend to this session who complete separate**	Homework reflection	• Discussion of previous week's homework

activities until the mindfulness exercise		
	Values	Both participants and guests: • Card sort activity
	Social barriers	Participants: • Discussion around social barriers • Communicating your abilities, needs, and difficulties Guests: • Communication changes following ABI
	Emotional barriers	Participants: • Addressing emotional barriers • Metaphor acted out by group Guests: • How ABI has affected their relationship
	Mindfulness	• Mindfulness S.T.O.P exercise completed • Discussion
	Strategies	• Strategies for communicating effectively • Open communication • Communicating your preference for support
	Homework	• Completed way to valued living worksheet independently • Have a discussion with a someone where you communicate your needs/difficulties/abilities
8. Review – Tying it all Together	Homework reflection	• Discussion of previous week's homework
	Revision of committed actions	• Participants compile a list of their chosen values, committed actions, and barriers. • Reflection on whether these are still important
	Revision of strategies	• Participants compile a list of all strategies taught that were useful for them
	Mindfulness	• Mindfulness S.T.O.P exercise completed
	Post-traumatic growth	• Discussion around post-traumatic growth
	Conclusion	• Farewells

Appendix B: Risk of Bias in N-of-1 Trials (RoBiNT) Scale

Item	Score	Justification
Internal validity (IV) scale		
1. Design with control	0	The study used a nonconcurrent multiple-baseline design
2. Randomisation	2	Participants were randomly allocated to baseline lengths between 5 – 7 weeks according to a randomisation schedule generated by random online sequence generator.
3. Sampling of behaviour	1	Each phase included at least three non-imputed data points. The minimum number of data points in a phase was five (though this included imputed data for some participants whose data was missing at a certain time point).
4. Blinding of people involved in intervention	0	Neither participants nor clinicians were blinded.
5. Blinding of Assessors	0	It was not possible to blind assessors to phase due to the start date of the group being known to the assessors.
6. Interrater agreement	0	A subjective self-report measure of target behaviour was used.
7. Treatment Adherence	2	Treatment adherence was rated by an assessor independent of the study against checklist outlining goals and content for each session. Adherence was greater than 80%, and 25% of data was sampled (4 sessions).
External validity (EV) scale		
8. Baseline characteristics	2	Participant characteristics are provided in a table and referred to in text with a formulation explaining their impact on participation in valued activities and adjustment.
9. Setting	2	Specific information about the location of the intervention and the locations of assessments is provided.
10. DV (target behaviour)	2	Target behaviours were operationalised as Valued Living Questionnaire scores. Scoring was outlined in the methods section.
11. IV	2	A detailed tabular description of the intervention is provided in an Appendix while procedural details are provided in text.
12. Raw data record	2	Raw data record with data point for every session is graphically presented.
13. Data analysis	2	Visual analysis followed protocol and was supplemented with statistical analysis.
14. Replication	2	There were seven participants who completed all 3 phases, so there were six replications included in this study.
15. Generalisation	1	Multiple generalisation measures were utilised at assessments before and after the intervention.
IV TOTAL	**5/14**	
EV TOTAL	**15/16**	

Appendix A: Risk of Bias in N-of-1 Trials (RoBiNT) Scale

Item	Score	Justification
Internal validity (IV) scale		
1. Design with control	0	The study used a nonconcurrent multiple-baseline design
2. Randomisation	2	Participants were randomly allocated to baseline lengths between 5 – 7 weeks by random online sequence generator.
3. Sampling of behaviour	2	Each phase included at least five data points. The minimum number of data points in a phase was five (though this included imputed data for some participants whose data was missing at a certain time point).
4. Blinding of people involved in intervention	0	Neither participants nor clinicians were blinded.
5. Blinding of Assessors	0	It was not possible to blind assessors to phase due to the start date of the group being known to the assessors.
6. Interrater agreement	0	A subjective self-report measure of target behaviour was used.
7. Treatment Adherence	1	Treatment adherence was rated by an assessor independent of the study against checklist outlining goals and content for each session. Adherence was greater than 80%, however only 18.8% of data was sampled (3 sessions).
External validity (EV) scale		
8. Baseline characteristics	2	Participant characteristics are provided in a table and referred to in text with a formulation explaining their impact on valued living and adjustment.
9. Setting	2	Specific information about the location of the intervention and the locations of assessments is provided.
10. DV (target behaviour)	2	Target behaviours were operationalised as Valued Living Questionnaire scores. Scoring was outlined in the methods section.
11. IV	2	A detailed tabular description of the intervention is provided in an Appendix while procedural details are provided in text.
12. Raw data record	2	Raw data record with data point for every session is graphically presented.
13. Data analysis	2	Visual analysis followed protocol and was supplemented with statistical analysis.
14. Replication	2	There were seven participants who completed all 3 phases, so there were six replications included in this study.
15. Generalisation	2	Multiple generalisation measures were utilised at an assessment distinct to each phase.
IV TOTAL	**5/14**	
EV TOTAL	**16/16**	
TOTAL	**21/30**	

Appendix AB: Outline of the VaLiANT Manual

Session	Components	Description
1. Introduction to VaLiANT	Introduction to group	• An overview of the whole program is provided • Group rules are established. • Group members are introduced to each other.
	Introduction to values	• Introduction to the concept of values • Activity for identifying values in others • Card sort activity for identifying personal values. Examples of cards include 'to have joy in my life' from the leisure domain, and 'to continually learn and grow' from the work/study/volunteering domain.
	Passengers on the bus ACT exercise	• Introduction of central group metaphor 'passengers on the bus'. • Metaphor acted out by group members.
	Introduction to mindfulness	• Mindful breathing exercise completed. • Group discussion
	Introduction to committed actions	• Idea of committed actions and experiential avoidance introduced. • Participants complete a name association task and discuss cognitive strategies. • Concept of strategies to support committed actions introduced.
	Homework	• Practice self-monitoring of emotions • Practice cognitive strategies by learning a new name.
2. Being Healthy - Sleep and Fatigue	Homework reflection	• Discussion of previous week's homework
	Introduction to module	• The domain of health and well-being is introduced (focus of next two weeks). • Group discussion • Psychoeducation around importance of health • Health is tied to 'passengers on the bus' metaphor
	Values	• Card sort activity • 'The way to valued living' worksheet introduced
	Psychoeducation	• Psychoeducation around managing sleep disturbance and fatigue is provided • Experiential avoidance discussion included
	Mindfulness	• Body scan exercise completed • Recording provided for use at home
	Committed actions	• Activity identifying committed actions to manage sleep and fatigue • Completion of barriers worksheet

	Homework	• Use a weekly planner to plan at least one day with scheduled rest breaks • Try a mindfulness exercise during one of these rest breaks.
3. Being Healthy – Diet and Exercise	Homework reflection	• Discussion of previous week's homework
	Values	• Card sort activity
	Psychoeducation	• Benefits of healthy eating • Benefits of physical activity • Australian guidelines
	Barriers	• Activity identifying own barriers to health • Activity identifying barriers to health in a case example
	Passengers on the bus ACT exercise	• 'Passengers on the bus' metaphor tied to health • Metaphor acted out by group members.
	Mindfulness	• Mindful eating exercise completed • Discussion
	Committed actions	• Group brainstorm on committed actions for health
	Strategies	• Activity scheduling introduced as strategy for finding time • A menu of additional strategies to support health and wellbeing are supplied
	Homework	• To eat one meal mindfully that week • Use activity schedule to plan health related activity
4. Having a Purpose – Work, Study, or Community Participation	Homework reflection	• Discussion of previous week's homework
	Introduction to module	• To concept of having a purpose is introduced (focus of next two weeks) • Brainstorm exercise
	Values	• Card sort activity
	Committed actions	• Brain storm for case example • SMART goals • Way to valued living worksheet
	Barriers	• Barriers worksheet
	Mindfulness	• Self-compassion exercise • Discussion
	Strategies	• Prospective memory • Completing complex tasks
	Homework	• Use strategies to remember to make a phone call
5. Having a Purpose –	Homework reflection	• Discussion of previous week's homework

Leisure Activities		
	Introduction to leisure	• Idea of leisure is introduced • Therapy ball activity
	Psychoeducation	• Discussion around the importance of leisure • Benefits of leisure activities • Impact of chronic stress • Downward/upward spiral
	Values	• Card sort activity
	Committed actions	• Menu of leisure activities • Brainstorm of case example • SMART goals
	Mindfulness	• Mindfulness of sense exercise • Discussion
	Strategies	• Leisure activity schedule • Strategies for overcoming barriers to leisure activities
	Homework	• Complete a leisure activity schedule
6. Connecting with Others – Relationships Part 1	Homework reflection	• Discussion of previous week's homework
	Introduction to relationships	• Introduction to relationships module • Brainstorm activity
	Values	• Card sort activity
	Strengths	• Identification of personal relationship strengths
	Committed actions	• Brainstorm • SMART goals
	Barriers	• Relationship barriers worksheet
	Mindfulness	• Mindfulness S.T.O.P exercise completed • Discussion
	Strategies	• Group discussion • Word finding difficulties • Cognitive communication strategies
	Homework	• Plan a conversation that will be difficult. Identify strategies to assist you with this.
7. Connecting with Others – Relationships Part 2 ****participants may bring a family member or friend to this session who complete separate**	Homework reflection	• Discussion of previous week's homework

activities until the mindfulness exercise		
	Values	Both participants and guests: • Card sort activity
	Social barriers	Participants: • Discussion around social barriers • Communicating your abilities, needs, and difficulties Guests: • Communication changes following ABI
	Emotional barriers	Participants: • Addressing emotional barriers • Metaphor acted out by group Guests: • How ABI has affected their relationship
	Mindfulness	• Mindfulness S.T.O.P exercise completed • Discussion
	Strategies	• Strategies for communicating effectively • Open communication • Communicating your preference for support
	Homework	• Completed way to valued living worksheet independently • Have a discussion with a someone where you communicate your needs/difficulties/abilities
8. Review – Tying it all Together	Homework reflection	• Discussion of previous week's homework
	Revision of committed actions	• Participants compile a list of their chosen values, committed actions, and barriers. • Reflection on whether these are still important
	Revision of strategies	• Participants compile a list of all strategies taught that were useful for them
	Mindfulness	• Mindfulness S.T.O.P exercise completed
	Post-traumatic growth	• Discussion around post-traumatic growth
	Conclusion	• Farewells

Appendix B: Risk of Bias in N-of-1 Trials (RoBiNT) Scale

Item	Score	Justification
Internal validity (IV) scale		
1. Design with control	0	The study used a nonconcurrent multiple-baseline design
2. Randomisation	2	Participants were randomly allocated to baseline lengths between 5 – 7 weeks according to a randomisation schedule ~~by~~ generated by random online sequence generator.
3. Sampling of behaviour	12	Each phase included at least three non-imputed data points. The minimum number of data points in a phase was five (though this included imputed data for some participants whose data was missing at a certain time point).
4. Blinding of people involved in intervention	0	Neither participants nor clinicians were blinded.
5. Blinding of Assessors	0	It was not possible to blind assessors to phase due to the start date of the group being known to the assessors.
6. Interrater agreement	0	A subjective self-report measure of target behaviour was used.
7. Treatment Adherence	2	Treatment adherence was rated by an assessor independent of the study against checklist outlining goals and content for each session. Adherence was greater than 80%, and 25% of data was sampled (4 sessions). ~~however only 18.8% of data was sampled (3 sessions).~~
External validity (EV) scale		
8. Baseline characteristics	2	Participant characteristics are provided in a table and referred to in text with a formulation explaining their impact on participation in valued ~~living~~activities and adjustment.
9. Setting	2	Specific information about the location of the intervention and the locations of assessments is provided.
10. DV (target behaviour)	2	Target behaviours were operationalised as Valued Living Questionnaire scores. Scoring was outlined in the methods section.
11. IV	2	A detailed tabular description of the intervention is provided in an Appendix while procedural details are provided in text.
12. Raw data record	2	Raw data record with data point for every session is graphically presented.
13. Data analysis	2	Visual analysis followed protocol and was supplemented with statistical analysis.
14. Replication	2	There were seven participants who completed all 3 phases, so there were six replications included in this study.
15. Generalisation	12	Multiple generalisation measures were utilised at assessments before and after the intervention.
IV TOTAL	**5/14**	
EV TOTAL	**165/16**	

The Single-Case Reporting guideline in BEhavioural interventions (SCRIBE) 2016 Checklist

Item Number	Topic	Item Description + notes
1	Title	*Identify the research as a single-case experimental design in the title* The title is "A Single-Case Evaluation of a New Group-Based Intervention to Enhance Adjustment to Life with Acquired Brain Injury: VaLiANT (Valued Living After Neurological Trauma)" (page 1).
2	Abstract	*Summarise the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions* Abstract outlines required information (pages 2).
3	Scientific background	*Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base* Information contained in introduction (pages 3-6).
4	Aims	*State the purpose/aims of the study, research question/s, and, if applicable, hypotheses* Information contained in final paragraph of introduction (page 6).
5	Design	*Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined a priori or data-driven) and, if applicable, criteria for phase change* Information contained in section titled 'design' under the methods section (page 7).
6	Procedural changes	*Describe any procedural changes that occurred during the course of the investigation after the start of the study* There were no procedural changes during the course of investigation.
7	Replication	*Describe any planned replication* Details of replication across participants is included under the section titled 'design' under the methods section (page 7).

8	Randomisation	*State whether randomisation was used, and if so, describe the randomisation method and the elements of the study that were randomized* Details of randomisation are included under the sections titled 'design' and 'procedure in the methods section (pages 7 and 11 respectively).
9	Blinding	*State whether blinding/masking was used, and if so, describe who was blinded/masked* Details of blinding are contained under the 'procedure' section (page 12).
10	Selection Criteria	*State the inclusion and exclusion criteria, if applicable, and the method of recruitment* Information contained under 'participant selection' section (page 7).
11	Participant characteristics	*For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured* Details of participant characteristics can be found in-text in the results section (page 15-19), and in Table 1 (page 22).
12	Setting	*Describe characteristics of the setting and location where the study was conducted* Details of setting are in the section titled 'intervention' (page 11).
13	Ethics	*State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained* Information on ethics approval and consent is listed at the beginning of the methods section (page 6)
14	Measures	*Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured* Target behaviour is defined under the section 'Target behaviour (primary outcome)' (page 8). All other measures are outlined under the section 'secondary outcomes' (pages 8-9). Details of when measures were administered is under the section 'procedure' (page 12).
15	Equipment	*Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material*

		resources) used to measure target behaviour/s and other outcome/s or deliver the interventions Details regarding the intervention manual can be found in Appendix C (page 46).
16	Intervention	*Describe intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication* Descriptions of the intervention can be found in Appendix C (page 46) and under the section titled' Intervention' (pages 10-11) in the methods section. Information on the control condition in the 'procedure' section (pages 14-15).
17	Procedural fidelity	*Describe how procedural fidelity was evaluated in each phase* Details regarding treatment fidelity can be found under the section 'fidelity and acceptability of the intervention' (page 9).
18	Analyses	*Describe and justify all methods used to analyse data* Justification of data analysis methods can be found under the section 'data analysis' (pages 12-15).
19	Sequence completed	*For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons* Details on discontinuation, missed sessions, and number of trials in each phase for each participant can be found under the 'results' section (pages 15-19), and in figure 2 (page 22).
20	Outcomes and estimation	*For each participant, report results, including raw data, for each target behaviour and other outcome/s* Results and raw data are included (pages 16-19, and 22-26)
21	Adverse events	*State whether or not any adverse events occurred for any participant and the phase in which they occurred* No adverse events were identified in the study (page 15).
22	Interpretation	*Summarise findings and interpret the results in the context of current evidence* Interpretation of results is included in the discussion (pages 27-31).

23	Limitations	*Discuss limitations, addressing sources of potential bias and imprecision* Discussion of limitations can be found on pages 30-31.
24	Applicability	*Discuss applicability and implications of the study findings* Applicability of findings discussed page 31
25	Protocol	*If available, state where a study protocol can be accessed* N/A
26	Funding	*Identify source/s of funding and other support; describe the role of funders* Funding information can be found on the title page (page 1).