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Acceptance and commitment therapy for mild traumatic brain injury (ACTion-mTBI): a quasiexperimental feasibility study

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ABSTRACT

Objectives This study aimed to determine the feasibility of recruiting, implementing and delivering an acceptance and commitment therapy (ACT) intervention for mild traumatic brain injury (mTBI) (ACTion-mTBI) within a multidisciplinary outpatient mTBI rehabilitation services. The study also aimed to conduct a preliminary investigation of group differences between ACTion-mTBI and an equivalent cognitive behavioural therapy (CBT) intervention on various outcome measures and psychological treatment targets.

Design A two-arm quasiexperimental feasibility study.

Setting Five mTBI rehabilitation clinics throughout New Zealand.

Intervention Psychologists working in mTBI rehabilitation clinics throughout New Zealand were trained to deliver ACTion-mTBI or CBT. Eligible participants were assigned to either of these interventions based on the psychologist available at the clinic they were referred to. ACTion-mTBI is a five sessions intervention that incorporates all six components of the ACT model. The CBT intervention is an equivalent intervention and incorporating all four components of the CBT model. Both interventions are adapted for an mTBI context.

Primary outcome measures The primary outcomes were related to the feasibility of ACTion-mTBI. This included recruitment, retention and treatment adherence of participants, study procedure and fidelity of treatment delivery.

Secondary outcome measures To explore group differences between ACTion-mTBI and CBT on functional disability, postconcussion symptoms, mental health, valued living and psychological flexibility.

Results The intervention proved feasible to implement with community-based mTBI rehabilitation services. Attrition rates were comparable between the two psychological interventions and fidelity to the treatments was high. At post-treatment, when covarying pretreatment scores, ACTion-mTBI had a significantly greater improvement in functional disability than CBT (moderate effect). ACTion-mTBI also had a significantly greater reduction in postconcussion symptoms, anxiety and stress. Promisingly, significant improvements in psychological flexibility was also found post-treatment. There were no group differences on depressive symptoms and valued living.

Conclusion We conclude that a full clinical trial of ACTion-mTBI for individuals with mTBI is feasible and warranted.

Trial registration number ACTRN1262100059482.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first study to examine the feasibility of a clinical trial of acceptance and commitment therapy (ACT) in mild traumatic brain injury (mTBI).
⇒ We developed an protocol that can guide the delivery of ACT specifically for individuals with mTBI and compared it to an equivalent cognitive–behavioural therapy intervention.
⇒ The study occurred with an mTBI rehabilitation service illustrating that it is feasible to conduct a clinical trial within current health services; however, to enable this to occur, a quasiexperimental design is needed.
⇒ A consequence of this design, and embedding the trail within health services, is that it was not possible to randomise to each of the intervention arms.
⇒ Conclusions regarding the effectiveness of ACTion-mTBI should not be made; however, preliminary group differences on specific outcome measures justify proceeding with a full clinical trial.

A mild traumatic brain injury (mTBI) results from a transfer of mechanical energy to the brain from external forces (eg, the head being struck by an object), which results in acute physiological disruption.[1] According to the American Congress of Rehabilitation Medicine (ACRM), the term 'concussion' is synonymous with mTBI so long as structural abnormalities are neither suspected nor detected on neuroimaging.[1] Following mTBI individuals may experience postconcussion symptoms (PPCS) which can be somatic symptoms (eg, nausea, dizziness, headache, blurred vision, auditory disturbance and fatigue), cognitive complaints (concentration and memory difficulties), emotional and/

or behavioural (eg, low mood and emotional lability). It is well established that PPCS can persist beyond the acute period following injury;[2–5] commonly referred to as persistent PPCS.[6] In a recent systematic review and meta-analysis, Cancelliere and colleagues[3] concluded that after controlling for participant attrition, one-sixth of adults who present to an emergency department or trauma centre with mTBI report ongoing PPCS 3–6 months later. The burden of PPCS can be substantial resulting in reduced functioning,[7] vocational participation,[8] increased healthcare utilisation[9] and decreased quality of life.[9]

Psychological factors, when considered alongside demographic variables and clinical indicators of brain injury severity, have consistently emerged as robust predictors of PPCS.[10–13] As a result, it has been argued that PPCS have a biopsychosocial conceptualisation.[14–17] Such models emphasise the role of preinjury vulnerabilities, early physiological effects from the mTBI and over time, an increasing role of other factors such as psychological reactions, psychosocial and environmental stressors, coping strategies and medicolegal issues.[18–21] As a result, clinical practice guidelines for mTBI underscore the importance of multidisciplinary rehabilitation of PPCS including the provision of mental health treatments, such as psychology.[22–24] These interventions are particularly important in considering the high prevalence of mental health difficulties in PPCS.[12 25 26] For example, a recent review reported prevalence rates of depression and anxiety in adults with PPCS of 44% and 24%, respectively.[25]

A common approach to address mental health difficulties in following mTBI is cognitive–behavioural therapy (CBT).[27–29] CBT explores the relationship between thoughts, emotions and behaviours, identifying those that are unhelpful and changing these with various techniques.[30 31] Applied to mTBI, CBT may focus on identifying thoughts or emotions that an individual has about their PPCS or injury (ie, feeling fearful of getting a headache or exacerbating symptoms) and supporting individuals to understand how these experiences influence behaviour (ie, avoiding tasks that could trigger a headache). A CBT approach would then introduce techniques to challenge these unhelpful cognitions (ie, cognitive restructuring) in the hope that they will result in more adaptive behaviour. Evidence of the effectiveness of CBT in mTBI is mixed.[27 28 32 33] For example, in a recent systematic review, Chen *et al*[27] found that CBT was an effective treatment for anxiety, depression and social integration after mTBI. Additionally, Silverberg *et al*[32] presented preliminary evidence to show that CBT may be beneficial in addressing fear avoidance and endurance behaviours after mTBI. However, two systematic reviews[27 34] both found no support for the effectiveness of CBT on PPCS and functional disability. Consequently, there is a need to explore the efficacy of other psychotherapeutic modalities for mTBI rehabilitation.

Acceptance and commitment therapy (ACT) is based on Relational Frame Theory with philosophical roots in functional contextualism, the idea that the function of behaviour changes based on the context and situation in which it is occurring.[35] Hence, it is considered to be a contextual-based CBT and is commonly referred to as part of the 'third wave cognitive behavioural therapies'.[36] The focus of change with ACT is on the context of the distress rather than the content. Emotional problems are acknowledged as an inevitable part of living, and therefore deemed to be a universal human experience. ACT aims to cultivate psychological flexibility by strengthening the following six core skills: acceptance, cognitive defusion, self as context, being present, values and committed action.[37] ACT adheres to a health rather than illness model.[35] Accordingly, the core goal of ACT is to facilitate individuals to live a purposeful and meaningful life by focusing and engaging with their values despite their personal circumstances.[37] ACT has a well-established evidence base for improving functioning and well-being in a variety of populations with psychological difficulties and/or medical problems[38–40] (eg, cancer,[41] chronic pain,[42] tinnitus[43] and chronic fatigue[44]). In the context of mTBI, ACT might be better at improving functional disability because it focuses on acceptance of persistent symptoms, fostering psychological flexibility, encouraging value-driven action even if symptoms are still present and reducing avoidance behaviours. This would have the potential at facilitating a increased activity, behavioural activation and increased mood, supporting habituation and desensitisation which are well known to improve PPCS.[22]

The evidence pertaining to the effectiveness of ACT in traumatic brain injury (TBI) is limited and has produced mixed results. There is some work that this psychological intervention reduces anxiety and depression,[45–47] cognitive fusion (being overly attached to and dominated by thoughts), quality of life[46] and psychological flexibility.[47] Whereas, other studies have shown no improvements in psychological flexibility[45 46] or value-driven behaviour.[46] In addition, the literature has predominately focused on the effectiveness of ACT in severe TBI or mixed acquired brain injury cohorts. It is important to examine the effects of ACT exclusively in mTBI, given its unique pathophysiology, diversity of symptom presentation in terms of severity and duration, as well as recovery trajectories. In addition, the focus of treatment is likely to differ, for mTBI, therapy strives to return an individual to their baseline functioning.[48] In more severe injuries, treatment often focuses on adjusting and living with the permanent consequences of an injury.[49] Faulkner and colleagues[50] found that psychological flexibility (the core focus of the ACT approach) significantly contributed to mTBI outcomes and the development of persistent symptoms and functional disability over time. Thus, given the current paucity of empirical evidence, there is a clear rationale for examining ACT in mTBI. However, to ensure that the treatment is acceptable and feasible to implement within the context of mTBI, a feasibility study is needed before clinical effectiveness can be determined.

The present study aimed to achieve this by embedding an ACT informed intervention for mTBI (ACTion-mTBI) into multidisciplinary outpatient mTBI rehabilitation services. As this study occurred within a health service, allocation to a waitlist condition was not appropriate and therefore ACTion-mTBI was compared with an equivalent CBT intervention. The primary objective of this study was to determine outcomes related to the feasibility of ACTion-mTBI. This included recruitment, retention and treatment adherence of participants, study procedures and fidelity of treatment delivery. The second objective was to explore possible group differences in various outcomes between ACTion-mTBI and CBT post-treatment. As a primary objective of rehabilitation is to improve functional status (ie, engagement in functional activities), this was the primary outcome used for this purpose. Group differences on secondary outcome measures post-treatment: PPCS, mental health, valued living and ACT targeted treatment processes (psychological flexibility) were also explored.

METHOD

All reporting is in accordance with Consolidated Standards of Reporting Trials (CONSORT).[51]

Design

The study was initially designed as a randomised feasibility trial, with pretest–post groups, within mTBI rehabilitation services in NZ (commonly referred to as 'concussion services'). Embedding the study within current healthcare practice, enabled evaluation of the feasibility of delivering ACTion-mTBI as part of real-life routine rehabilitation practice. This enhances the real-world applicability of the study findings, as well as increasing the ease in which the intervention can be rolled out into clinical practice if found to be effective in a future full-scale clinical trial. There are, however, ethical and practical considerations that need to be considered when adopting such a design. Concussion services in NZ specify that individuals referred for psychological treatment must be seen within 4 weeks. Consequently, it was not appropriate to adopt a waitlist-controlled study design. Instead, the two arms of the study were ACTion-mTBI and CBT to ensure that all participants enrolled in the study were provided with a psychological treatment.

Randomisation by random number generation into the ACT or CBT or treatment arms was initially planned to be conducted on a 1:1 basis. This design was adopted as the study was going to be conducted at one clinic with multiple clinicians available to deliver either ACTion-mTBI or CBT. However, due to unforeseen circumstances, it was not plausible to conduct the study at one clinic, as it eventuated that only one clinician at the original site was available to deliver the intervention. Consequently, a quasiexperimental feasibility study with pretest–post-test non-equivalent groups design was adopted. More specifically, to ensure adherence to a two-arm design and to support adequate recruitment, four clinics from different geographical locations were added into the study. This enabled additional psychologists within these clinics to deliver the interventions. ACTion-mTBI was offered in two clinics and CBT was offered in three. Thus, participants were assigned to the intervention offered by the psychologist at the clinic they were referred to. Clinics were similar in that each one was contracted by ACC to provide concussion rehabilitation and therefore service provision occurred under the proviso of these contracts. Differences between clinics occurred based on clinician experience and training in mTBI. However, due to the feasibility objective of this study and the small sample sizes required to meet these objectives, controlling for these nuance differences in clinics was not conducted.

Participants and procedure

All participants were recruited from Accident Compensation Cooperation (ACC) funded concussion services. In NZ, the no-fault insurer, ACC, contracts specialty clinics to provide mTBI rehabilitation for people post-mTBI. To be eligible for these services, individuals must have sustained an mTBI within the past year, have ongoing PPCS and have at least one additional risk factor (eg, inability to return to work or school for more than a week, have a high functioning job, a pre-existing psychiatric condition). Referral pathways to this tertiary service are generally from a primary care provider (ie, Hospital ED, Primary Care) and take on average 60 days from time of injury to first engagement with a concussion service provider.[52] Consequently, individuals who engage in this service are beyond the acute phase of injury and experiencing functional impacts due to symptom persistence. These services take a multidisciplinary approach to assessment and treatment of mTBI. All individuals referred receive occupational therapy and physiotherapy input, and may also have any of the following: neuropsychological screening assessment, specialist medical review and clinical psychology treatment. The only clinical psychology treatment provided for participants in our study was either ACTion-mTBI or CBT. Recruitment took place between August 2021 and June 2023 and concluded due to study funding requirements. However, the study was paused between January 2022 and August 2022 due to COVID-19 and the periods of government-imposed lockdowns during this time. Five participants completed the study prior to these lockdowns. Given this small number, we were not able to examine the effects of COVID-19 on the study outcomes.

Individuals engaged in concussion services were informed about the study by a clinician. Potential participants who consented to be involved were screened for eligibility based on the following criteria: (1) a clinical diagnosis of mTBI by a medical specialist predominately using the ACRM[53] or WHO[54] criteria which include those with or without CT abnormalities (ie, complicated and uncomplicated), (2) adults between 16 years and 65 years of age, (3) engaged in a multidisciplinary concussion

rehabilitation service and (4) had elevated levels of PPCS as indicated by a score on the Rivermead Post-Concussion Questionnaire of 16 or greater[55] or had elevated distress as indicated by a score in the moderate range or greater on at least one subscale of the Depression Anxiety and Stress Scale (DASS-21). Participants were excluded if they had an unstable or severe comorbid mental or physical health condition which could affect participation in the intervention or reporting on the outcome measures. Participants engaged in the study continued to receive multidisciplinary input as part of the concussion service rehabilitation.

Intervention

In many mTBI rehabilitation settings, only a limited number of psychological services are funded and available. For example, in NZ, only 5 hours of psychological services are funded by the national ACC. Consequently, to aid in the implementation of an ACT approach into clinical practice, there is also a need for ACT to fit within current mTBI service provision and be redesigned and tested within a shorter intervention timeframe. As a result, we developed an ACT-based intervention for mTBI (ACTion-mTBI), a five-session treatment which aims to apply the ACT model to improve recovery after mTBI. The ACTion-mTBI and the CBT interventions consisted of five 1 hour sessions delivered by a Registered Psychologist trained in the specific intervention approach.

Acceptance and commitment therapy intervention for mild traumatic brain injury

The development of the ACTion-mTBI programme was informed by focused ACT[56] and modified to fit the time-limit on psychological services within concussion services. The treatment manual was designed in consultation with a trained facilitator and expert in ACT with extensive experience in mTBI (JM). ACTion-mTBI incorporates all six components of the ACT model and adapts experiential exercises, metaphors, discussions and homework to an mTBI context. This aims to: (a) cultivate awareness and acceptance of thoughts and emotions about mTBI, (b) recognise the impact that rigid thoughts/beliefs, behaviours and responses to emotions have on mTBI recovery, and create a more flexible response to such experiences and (c) clarify personal values and commit to pursuing meaningful activities aligned with these values while recovering from mTBI. A summary of the ACTion-TBI protocol is presented in table 1. A recent report by the Association for Contextual Behavioural Science (ACBS) task force[57] stated: 'It is unhelpful to allow applied psychological science to remain at the level of extensive intervention protocols, when the spirit of ACBS idiographic functional analysis linked to processes of change requires a more personalized approach' (p.176). In accordance with this recommendation, ACTion-mTBI was delivered with flexibility based on clinical judgement according to the participant's presentation. For example, if a central feature was severe fusion with unhelpful cognitions driving the presenting issues, then session 3 'unhooking from the mind' was delivered earlier in the intervention. What is critical in the delivery of ACTion-mTBI is that the therapist adopts an ACT stance, using the ACTion-mTBI manual to guide delivery of the intervention and that all aspects of the ACT model are covered within the five sessions. ACTion-mTBI was delivered by JF a board registered Clinical Psychologist and Neuropsychologist who has 8 years of clinical experience working with mTBI and advanced-level training in ACT.

CBT intervention

The CBT protocol was informed by brief CBT therapeutic intervention protocols.[58] The treatment manual (see table 1) was designed in consultation with a clinical neuropsychologist who is trained in CBT with extensive clinical experience with mTBI (LD). The CBT intervention protocol incorporates all four components of the CBT model. It aims to: (1) educate participants on how each component of this model is linked and the role these connections have within an mTBI context, (2) identity unhelpful thinking patterns as they pertain to mTBI recovery and (3) learn a range of CBT-informed skills that can mitigate the influence that each component of the CBT model has on mental well-being. Consistent with ACTion-mTBI, the CBT manual was also delivered flexibly based on clinical judgement, what is critical in the delivery of this intervention is that the clinician adopts the CBT therapeutic model.

It was initially planned that the CBT intervention would be delivered by one clinician in the same manner as the delivery of ACTIon-mTBI. However, due to unforeseen circumstances with clinician availability, the CBT intervention was delivered by three clinicians: LD (three participants), DP (17 participants) and DA (three participants). All clinicians are board-registered Clinical Psychologists with over 10 years of experience with mTBI.

Patient and public involvement

Patients and members of the public were involved throughout the design and implementation of this study. During the development phase, input from individuals with lived experiences of mTBI was sought to ensure that the intervention was relevant and met the needs of patients receiving concussion services. Stakeholder feedback informed the adaptation of the ACTion-mTBI intervention to align with the time constraints and funding limitations of the New Zealand ACC framework.

Patients contributed to refining the recruitment materials and processes to ensure clarity and accessibility. During the implementation phase, patient representatives were consulted to monitor the appropriateness of the interventions and facilitate iterative improvements where necessary. While patients were not involved in conducting the statistical analyses, their feedback will be sought for interpretation and dissemination of findings in a manner that is meaningful and accessible to individuals with mTBI.

Table 1 A summary of the ACTion-mTBI and CBT manual content

Session number	ACTion-mTBI protocol			CBT manual content		
	Session title	ACT therapeutic process	Content	Session title	CBT component	Content
1	Dropping the struggle	Acceptance contact with the present moment	Snapshot of life Identifying the main problem Dropping the struggle/creative hopelessness Opening up and acceptance (dropping anchor) Homework	Thinking, feeling and behaving are linked	Introduce the link between thoughts, emotions, behaviour and physiology. Focus on physiology.	Agenda Snapshot of life Identifying the main problem Concussion psychoeducation Brief introduction to CBT Relaxation technique (diaphragmatic breathing)
2	Moving towards	Acceptance contact with the present moment Values committed action	Dropping anchor exercise Recap and review of the main problem Values exploration Choice point model Homework	Thinking can have errors	Education on the link between thoughts, feelings, behaviour and physiology with functional examples. Focus on physiology and thoughts.	Agenda Review session 1 Education on the CBT model (with reference to the mood monitoring worksheet) Education on thinking styles Relaxation technique (progressive muscle relaxation)
3	Unhooking from the mind	Acceptance contact with the present moment Defusion	Mindfulness exercise Recap and review of main problem Functional analysis of choice point model Defusion education and exercise Homework	Restructuring	Physiology, feelings and thoughts.	Relaxation technique Agenda Review session 2 Main focus on thoughts and how this impacts mood Use homework to complete seven part thought record—challenge with alternate thought
4	The noticing self and committing	Acceptance contact with the present moment Self as context values committed action	Mindfulness/self as context exercise Recap and review of the main problem Self as context education and excise Values bullseye exercise and SMART goals	Engaging in what is rewarding	Physiology, feelings and behaviour.	Relaxation technique Agenda Review session 3 Main focus on behaviour and how this impacts mood Review behaviour activity to facilitate positive event scheduling
5	Review and relapse prevention	Acceptance contact with the present moment Diffusion Self as context Values committed action	Mindfulness/self as context exercise Review of presentation Recap on intervention and experiential exercises Relapse prevention Discharge planning	Review and relapse prevention	Physiology, feelings, thoughts and behaviour.	Relaxation technique Agenda Review session 4 Review activity schedule—increase activities that bring sense of pleasure and achievement Recap and review intervention Relapse prevention Discharge planning

ACTion-mTBI, acceptance and commitment therapy intervention for mild traumatic brain injury; CBT, cognitive behavioural therapy.

Outcome measures

To assess the group differences between the interventions, outcome measures were administered by a research assistant at pretreatment (T1) and immediately post-treatment (T2).

Primary clinical outcome

Functional status: functional disability was assessed using 12-item WHO Disability Assessment Schedule (WHODAS V.2.0). The WHODAS V.2.0 evaluates disability based on the International Classification of Functioning activity and participation: cognition, self-care, mobility, interpersonal functioning, life activities and participation.[59 60] The WHODAS V.2.0 asks respondents how much difficulty they have had in the past 30 days in relation to all their health problems for each of the 12 items. The rating scale options are as follows: 0=none, 1=mild, 2=moderate, 3=severe and 4=extreme/cannot do (higher scores represent greater disability). Scores on each item were summed

and total scores were used. Snell *et al*[61] showed that the 12-item WHODAS V.2.0 had high internal consistency in mTBI (Cronbach's alpha=0.92).

Secondary clinical outcomes

PPCS: the Rivermead Post-Concussion Symptom Questionnaire (RPQ) is a 16 item self-report questionnaire that assesses common symptoms following mTBI (Cronbach's alpha=0.90).[62] The RPQ consists of somatic symptoms (headaches, dizziness, nausea and vomiting, noise and light sensitivity, sleep disturbance and double vision); cognitive symptoms (forgetfulness/poor memory, poor concentration and taking longer to think) and emotional symptoms (being irritable/easily angered feeling depressed or tearful, feeling frustrated or impatient). Participants are required to rate the presence and problem status of these symptoms on a scale of 0–4 (0=not experienced at all; 1=no more of a problem than before injury; 2=a mild problem; 3=a moderate problem; 4=a severe problem). Scores of 1 ('no more of a problem than before injury') were recoded to 0 as per the recommendation of King *et al*.[62]

Depression, anxiety, stress: the Depression, Anxiety and Stress Scale-21 (DASS-21[63]) is a 21 item self-report with three subscales that measure depression, anxiety and stress over the previous week. It uses a 4-point Likert scale with 0=never, 1=sometimes, 2=often and 3=always. Higher scores on this measure are indicative of elevated levels of depression, anxiety and stress symptoms. A score of at least 7 on the depression scale, 6 on the anxiety scale and 10 on the stress scale were classified as moderate in severity and used for participant inclusion. The DASS-21 has good psychometric properties (Cronbach's alpha=0.73–0.81[63]) and is a valid measure of depression, anxiety and stress symptoms in people with ABI.[64]

Valued living: the Valued Living Questionnaire (VLQ) is a two-part instrument designed to assess valued living.[65] In the first part, participants rate the importance of 10 domains of living on a 10-point Likert scale. These domains are family, couples' relations, parenting, friendship, work, education, recreation, spirituality, community life and physical well-being. In the second part, participants rate, using a 10-point Likert scale, how consistently they had lived by the valued behavioural pattern within each domain over the past week. Responses from both parts are used to calculate a valued living composite (VLC), which quantifies the extent to which one is living out particular values in everyday life. An overall VLC is calculated, as well as for each valued domain within the VLQ. The VLQ has demonstrated adequate interitem consistency (α=0.77) and test–retest reliability (r=0.75).[65] The VLQ has been used to measure valued living in a range of clinical populations including anxiety, chronic pain, depression and TBI.[66 67]

Treatment process measures

Psychological flexibility: when measuring psychological flexibility, it has been recommended that both a context-specific and a more generic measure of psychological flexibility should be used.[68] Consequently, the Action and Acceptance Questionnaire Acquired Brain Injury (Reactive Avoidance) (AAQ-ABI (RA) and the Acceptance and Action Questionnaire Second Edition (AAQ-II)) were administered.

The AAQ-ABI (RA) uses a 5-point Likert scale (0= 'never true' to 4 = 'always true') with scores ranging from 0 to 36; higher scores indicate greater reactive avoidance associated with an ABI. The measure has been developed and validated in an undifferentiated sample of ABI (Cronbach's alpha 0.89[69]). In the current study, items within the questionnaire were modified by replacing 'brain injury' with 'concussion'. Faulkner and colleagues[70] found that the AAQ-ABI (RA) has one distinct underlying factor in mTBI and strong internal consistency (Cronbach's α=0.87).

The Acceptance and Action Questionnaire Second Edition (AAQ-II) is a 7-item questionnaire utilising a 7-point Likert scale (response format, 1 = 'never true' to 7 = 'always true') with scores ranging from 7 to 49. Higher scores are indicative of greater experimental avoidance a component of psychological flexibility.[67] The AAQ-II has been found to have good reliability and validity, with the Confirmatory Factor Analysis of this measure in supporting a one-factor model (Cronbach's alpha ranging from 0.78 to 0.88[71]).

Statistical analysis

A per protocol analysis was conducted and Shapiro-Wilk tests found no evidence against an assumption of normality in the data. Independent-sample t-tests and χ^2 tests were first conducted to examine potential differences in the demographic and injury characteristics between the two groups. Descriptive statistics were used to describe the measures at pretreatment and independent-sample t-tests were computed to determine any differences between groups. χ^2 was also used to determine any differences in attrition between the two treatment groups. To examine group differences between the two interventions on the primary and secondary outcomes measures, analysis of covariance (ANCOVA) was used. Analyses included post-treatment scores as the outcome variable, pretreatment scores as a covariate and a between-subjects factor (group: CBT or ACTion-mTBI). By assessing the difference in post-test means while accounting for pretest values, ANCOVA provides more statistical power.[72 73] Effect sizes (Cohen's d) were also calculated and interpreted according to standard conventions (<0.50 = small; 0.50–0.80=medium; >0.80 = large[74]). Alpha levels of 0.05 alpha without correction for multiple comparisons were applied, given that the analyses are exploratory and each outcome is best considered as individual tests rather than disjunction tests.[75] Analyses were performed using SPSS V.29.0 (IBM, USA).

RESULTS

Recruitment and retention feasibility

Sixty-one individuals who expressed interest in the study and were deemed eligible provided written informed

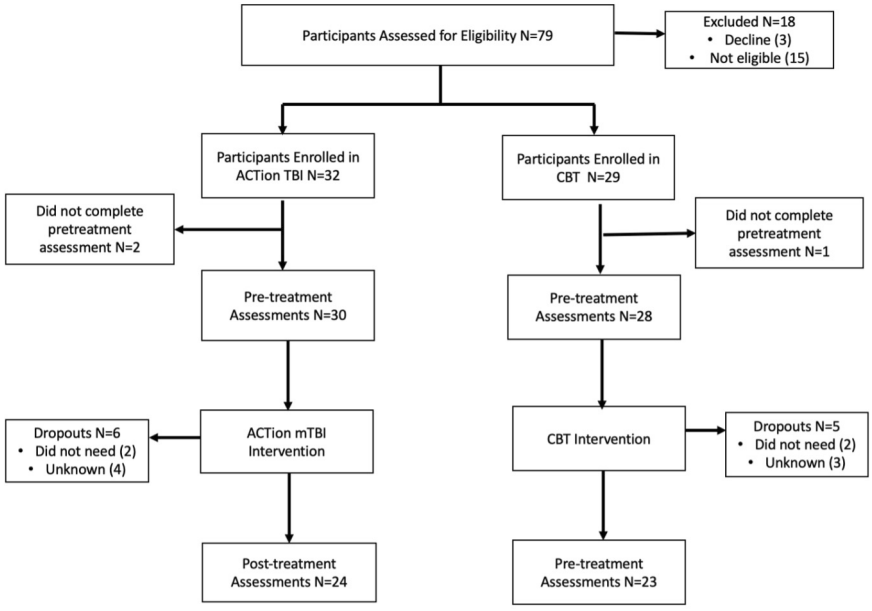

Figure 1 Overview of participant involvement in the study. An illustration of participant recruitment into the two arms of the current study. The direction of flow in the illustration depicts participant enrolment in the two intervention conditions, pretreatment assessment, engagement in the intervention and post-treatment assessment. ACtion-mTBI, acceptance and commitment therapy intervention for mild traumatic brain injury; CBT, cognitive–behavioural therapy.

consent to participate. As shown in figure 1, of those allocated to ACTion-mTBI, 75.0% completed the intervention. 79.3% allocated to the CBT intervention completed the intervention, with no significant difference in attrition ($\chi^2(1) = 0.01$, p=0.95). In the ACTion-mTBI group, 30 participants (92.86%) attended at least one session. Those who did not attend treatment were unable to do so because of illness (n=1) or unknown (n=1). Twenty-four participants (80.0%) attended all five sessions of ACTion-mTBI. Of the six who did not attend all sessions, two participants did not require all treatment sessions and four disengaged from treatment for unknown reasons. This sample size was consistent with sample sizes of 24–35 participants conventionally recommended for pilot and feasibility studies.[76–78] In the CBT group, 28 of the 29 participants enrolled in this treatment attended at least one session. Twenty-three participants completed the intervention (82.1%). Of the five who did not attend all sessions, two did not require all treatment sessions and three disengaged from treatment for unknown reasons. Recruitment proved to be feasible with an average of six participants recruited into either treatment arm per month (in the last 8 months of the study where there were no COVID impacts on service access).

Treatment fidelity feasibility

Fidelity checks of the ACTion-mTBI delivery were completed by JM on 10% of sessions to ensure adherence to the ACT model, using the ACT fidelity checklist measure (ACT-M).[79] The average rating on the ACT-M was 34.0 out of a total score of 36 indicating high consistency with the ACT model. 10% of CBT sessions by different psychologists were independently assessed to ensure adherence to the CBT therapeutic model using the Comparative Psychotherapy Process Scale-External Rater form (CPPS).[80] The CPPS assesses the degree to which a therapist uses techniques of cognitive–behavioural psychotherapy. Fidelity measures were completed by AT a Registered Psychologist with training and expertise in CBT. The average rating on each on the CBT subscale was 5.42 out of 6 indicating high adherence to the CBT therapeutic model.[81]

Group differences

Data on the demographic and clinical characteristics of the groups are summarised in table 2. There were no significant differences in the demographic and clinical characteristics of the ACTion-mTBI group and CBT groups except on age; the ACTion-mTBI group were, on average, significantly younger. Scores on the outcome measures at pretreatment assessment were also compared between the ACTion-mTBI and CBT groups. As shown in table 2, there were no significant differences in the outcome measures and treatment processes at pretreatment assessment.

Figure 2 shows the mean scores for functional disability at pretreatment and post-treatment for each group. Based on an ANCOVA accounting for pretreatment scores, there was a significant difference between the groups (F (1,46) = 9.84, p=0.003) at post-treatment assessment with a medium effect size (d=0.58). More specifically, the ACTion-mTBI group had significantly lower scores on functional disability (M=10.25, SE=1.22) than the CBT group (M=14.91, SE=1.22) at post-treatment.

Secondary clinical outcomes were PPCS, depression, anxiety, stress and valued living. Based on an ANCOVA, covarying pretreatment scores, a significant difference between the treatment groups was found in PPCS with

Table 2 Demographic and injury characteristics of participants at pretreatment assessment

	ACTion-mTBI (n=24)	CBT (n=23)	P value
Demographic characteristics			
Age	31.65 (11.84)	39.70 (16.90)	0.04*
Gender			
Male	9 (37.50%)	11 (47.83%)	0.47
Female	15 (62.50%)	12 (52.17%)	
Ethnicity			
Māori†	2 (8.33%)	5 (21.74%)	0.14
NZ European	17 (70.83%)	17 (73.91%)	
Other	5 (20.83%)	1 (4.35%)	
Education history			
High school or less	6 (25.00%)	5 (21.74%)	0.79
University/ tertiary	18 (75.00%)	18 (78.26%)	
Preinjury employment			
Working	23 (95.83%)	21 (91.30%)	0.53
Not working	1 (4.17%)	2 (8.70%)	
Medical history			
Yes	8 (33.33%)	11 (47.83%)	0.25
No	16 (66.67%)	12 (52.17%)	
Previous concussion(s)			
Yes	12 (50.0%)	12 (52.17%)	0.88
No	12 (50.0%)	11 (47.83%)	
Mental health history			
Yes	15 (62.50%)	12 (52.17%)	0.39
No	9 (37.50%)	11 (47.83%)	
Injury characteristics			
Time since injury (weeks)			
Pretreatment	25.58 (18.83)	25.09 (19.95)	0.47
Post-treatment	33.68 (14.04)	37.86 (22.05)	0.61
Mechanism of injury			
Motor vehicle accident	2 (8.33%)	4 (17.39%)	0.58
Fall	9 (37.50%)	11 (47.83%)	
Assault	5 (20.83%)	2 (8.70%)	
Hit by object	8 (33.33%)	5 (21.74%)	
Additional injury			
Yes	13 (54.17%)	16 (69.57%)	0.28
No	11 (45.83%)	7 (30.43%)	
Pretreatment outcome measures			
RPQ	34.42 (10.48)	30.35 (13.00)	0.12
DASS-D	9.04 (4.72)	9.78 (9.63)	0.37
DASS-A	6.50 (4.17)	7.00 (4.48)	0.35
DASS-S	11.21 (4.32)	10.35 (5.14)	0.27
WHODAS V.2.0	20.79 (7.98)	19.17 (8.42)	0.25
AAQ-ABI (RA)	18.83 (6.48)	18.65 (6.64)	0.46
AAQ-II	29.17 (7.82)	27.39 (7.80)	0.22
VLQ	41.29 (15.03)	40.87 (14.85)	0.46

*P<0.05.
†Māori are the indigenous population of NZ.
AAQ-ABI (RA), Action and Acceptance Questionnaire Acquired Brain Injury (Reactive Avoidance); AAQ-II, Action and Acceptance Questionnaire Second Edition; DASS-A, Depression, Anxiety and Stress Scale-21-Anxiety Subscale; DASS-D, Depression, Anxiety and Stress Scale-21-Depression Subscale; DASS-S, Depression, Anxiety and Stress Scale-21-Stress Subscale; RPQ, Rivermed Post Concussion Questionnaire; VLQ, Valued Living Questionnaire; WHODAS V.2.0, WHO Disability Assessment Schedule V.2.0.

small effect size (F (1,46) = 8.02, p=0.007, anxiety with medium effect size (F (1,46) = 5.35, p=0.025) and stress with small effect size (F(1,46) = 4.24, p=0.045) at post-treatment assessment. The ACTion-mTBI group had significantly lower scores on each of these secondary clinical outcome measures than the CBT group (see table 3). No significant group differences were found on post-treatment scores, while covarying pretreatment scores, on depression (F (1,47) = 0.66, p=0.421) and valued living (F (1,47) = 1.07, p=0.307)).

Treatment processes included context-specific measures of reactive avoidance (AAQ-ABI(RA)), and a general measure of experiential avoidance (AAQ-II).

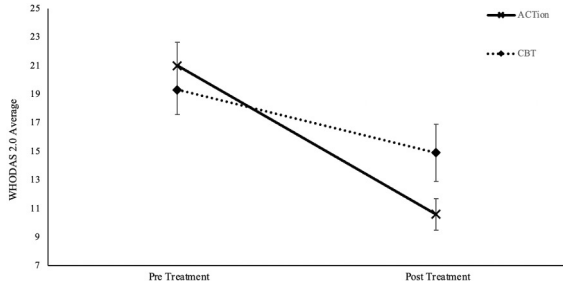

Figure 2 Group differences on self-reported measure of functional disability at pretreatment and post-treatment assessment time points. Line graph describing the changes in functional disability. The X-axis represents pretreatment and post-treatment and the Y-axis represents average scores on the WHO Disability Assessment Schedule (WHODAS V.2.0). The graph shows a decrease in average WHODAS V.2.0 scores from pretreatment to post-treatment across both groups (ACTion-mTBI and CBT) with the most significant decrease in the ACTion-mTBI group.

Table 3 F statistics for post-treatment secondary clinical outcome and treatment process measures from ANCOVA (using the pretreatment scores as a covariate)

	ACTion-mTBI Mean±SE	CBT Mean±SE	Mean difference (ACTion-CBT)	95% CI	F statistic	P value	Cohen's d
Secondary outcomes							
Post-concussion symptoms	15.21±2.23	24.31±2.28	−9.10	−15.58 to −2.63	8.02	0.007	0.47
Depression	4.11±0.66	4.88±0.68	−0.77	−2.68 to 1.14	0.66	0.421	0.21
Anxiety	3.74±0.70	6.06±0.72	−2.32	−4.34 to −0.30	5.35	0.025	0.60
Stress	5.05±0.63	7.35±0.64	−1.84	−3.65 to −0.04	4.24	0.045	0.41
Valued living	49.12±2.54	45.36±2.60	3.63	−3.56 to 11.08	1.07	0.307	0.33
Treatment process measures							
AAQ-ABI (RA)	9.32±1.02	12.58±1.04	−3.27	−6.21 to −0.33	5.04	0.030	0.52
AAQ-II	21.33±1.22	22.92±1.25	−1.59	−5.12 to 1.93	0.83	0.367	0.12

AAQ-ABI (RA), Action and Acceptance Questionnaire Acquired Brain Injury (Reactive Avoidance); AAQ-II, Acceptance and Action Questionnaire Second Edition; ANCOVA, analysis of covariance; CBT, cognitive behavioural therapy.

Based on ANCOVA (see table 3) covarying pretreatment scores, significant group difference was found on the AAQ-ABI (RA) with medium effect size (F (1,47) = 5.04, p=0.030). More specifically, the ACTion-mTBI had significantly lower levels of context specific reactive avoidance (M=9.32, SE=1.02) than the CBT group (M=12.58, SE=1.04). There were no significant group differences at post-treatment on the AAQ-II (F (1,47) = 0.83, p=0.367). Finally, all ANCOVA models were rerun to include age as a covariate given that significant differences in this variable were found between the intervention groups. No significant effects of age were found on the primary, secondary and treatment process post treatment (see online supplemental table 1).

DISCUSSION

The overall objective of this study was to explore the feasibility and group differences of an ACT-informed intervention for mTBI (ACTion-mTBI) embedded within community-based multidisciplinary rehabilitation services when compared with an equivalent CBT intervention. Our first aim was to determine the feasibility of recruitment, retention and treatment adherence of participants, study procedures and fidelity of treatment delivery of ACTion-mTBI within the context of concussion services in NZ. A randomised feasibility trial was initially planned to be conducted at one clinic. This approach was not achievable and to ensure adequate recruitment using the procedure specified, additional clinics and treating psychologists were added to the study. Consequently, the study design shifted to a quasiexperimental design and participants were allocated to either ACTion or CBT based on the treatment that was available at the clinic the participant was referred to. This research design was feasible to conduct within concussion services. Participants were able to engage in the research and intervention protocol while also receiving multidisciplinary rehabilitation. Current consensus guidelines for the treatment of mTBI stipulate the importance of multidisciplinary care to maximise treatment outcomes for this population.[22 24] It is promising that we were able to conduct this quasiexperimental feasibility study within this context to replicate best practice guidelines. It also demonstrates the plausibility of conducting a larger-scale clinical trial using this design. We also found that fidelity to the treatments was very high, which further supports the applicability of delivering these psychological interventions within a concussion service.

To further support feasibility, when removing the impact of COVID-19, we were also able to recruit an average of six participants into either treatment arm per month. This enabled us to achieve the sample size of 24–35 participants per arm conventionally recommended for pilot and feasibility studies.[76–78] Furthermore, there was very high uptake into the treatment arms as part of the recruitment process. Attrition rates were low and comparable between ACTion and CBT with 80.0% of participants attending all five sessions of ACTion-mTBI and 82.1% attending all five sessions of CBT. This provides confidence that recruitment and data collection can be obtained from an adequate sample that would be needed for full-scale trial.

The second aim of this study was to conduct a preliminary test of the trends in effects of ACTion-mTBI comparted to CBT. To achieve this, a range of outcome and treatment process measures completed by the ACTion-mTBI group were compared with CBT. We found that, after covarying pretreatment scores, ACTion-mTBI had a significant reduction in functional disability (medium effect size) and PPCS severity (small effect size) compared with CBT. This finding is somewhat consistent with Dino and Colleagues,[38] who found that veterans with mTBI participating in a 1 day ACT workshop experienced

improvements in functioning and reintegration post-workshop compared with the treatment as usual group. ACT adopts a health model, and has an emphasis on enhancing functioning, life satisfaction and the ability to pursue meaningful goals, rather than focusing on symptom reduction.[82 83] This approach may resonate with individuals who do not recover naturally from mTBI, and they may therefore benefit from adopting an acceptance-based stance. This includes a strong focus on validating and acknowledging the difficulties associated with their mTBI rather than a focus on reframing their thoughts.[84 85] These findings are also consistent with previous evidence suggesting the effects of CBT may be more specific to mental health and do not generalise to improve mTBI outcomes.[27 28 34] Although, replication of these findings is needed in a larger sample, this study provides promising preliminary evidence that adopting an ACT approach in mTBI rehabilitation may have cascading positive effects on improving functioning and reducing PPCS severity.

In terms of mental health, for depression, no significant differences between the ACTion-mTBI and CBT groups were found post-treatment. Although, significantly lower levels of anxiety (medium effect size) and stress (small effect size) were found in the ACTion-mTBI group post-treatment after covarying pretreatment scores. It is surprising that ACTion-mTBI and CBT both had a similar effect on depression symptomology, whereas ACTion-mTBI appeared to have a greater impact on reducing anxiety and stress symptoms. Brief psychological interventions either using a CBT or ACT approach have demonstrated similar effects of reducing a range of mental health presentations.[86 87] Given the feasibility nature of this study and limited sample size, replication of this study is needed to confirm the effect that ACTion-mTBI has on specific mental health outcomes. However, these findings do add to an emerging evidence base demonstrating potential benefits of ACT on mental health difficulties in neurological conditions, including TBI.[45–47] Our study provides initial support for clinicians to adopt a wider repertoire of psychological interventions, such as ACT, in mTBI rehabilitation to address mental health difficulties after mTBI.

However, we found no significant difference between ACTion-mTBI and CBT on valued living post-treatment. This was a surprising finding given that there is a focus in ACTion-mTBI to support individuals to identify and increase their engagement in values-based activities. There could be multiple reasons for this finding and further examination in future studies with a larger sample is needed. It may be that as both treatments occurred within a multidisciplinary mTBI where the focus is on a graduated return to activity, that overtime this rehabilitation inadvertently increases valued living engagement. It should also be noted that previous research on the impact of ACT on values-based participation has revealed mixed findings in TBI,[46 47] which may reflect the way in which valued living is assessed in this population. Miller *et al*[88] recently identified validity problems of the valued living questionnaire in a cohort of individuals with ABI. The results of this study could therefore reflect limitations in the way the construct is measured for this population. Future research could address this gap and examine the effects of ACTion-mTBI on valued living using other measures (ie, the Valuing Questionnaire[89]).

The third aim of this study was to explore the effects of ACTion-mTBI on ACT-targeted treatment process. In this study, psychological flexibility was examined in two ways. This included assessing an mTBI context-specific component of psychological flexibility and a general measure of experiential avoidance. At post-treatment, the ACTion-mTBI group had significantly lower mTBI-specific and general experiential avoidance than CBT. No significant differences were found at post-treatment on the general measure of experiential avoidance. Given that ACTion-mTBI aims to specifically target mTBI-related presenting difficulties, it is not surprising that the effects of this intervention appear to be contained to context-specific treatment processes. The core aim of ACT is to increase psychological flexibility and it is therefore promising that there is initial evidence that ACTion-mTBI is targeting a component of its intended process. Furthermore, given evidence that psychological flexibility influences mTBI outcomes and recovery,[90] targeting this process in the ACTion-mTBI intervention may also account for the reduction in PPCS and improvement in functional status observed in this study. However, in this study, only one facet of psychological flexibility was measured and future research would benefit from using a more comprehensive measure of this construct (ie, the Multidimensional Psychological Flexibility Inventory.[91]

The quasiexperimental design of this study enabled feasibility and trends in effect of the intervention to be examined within the clinical environment that it will be delivered in if found to be an effective treatment. However, embedding this study in current practice does have limitations that need to be acknowledged. It is challenging to infer if the effects identified in this study are due to the psychological treatments provided or due to other factors that are less well controlled in this study design. For example, although the influence of engaging in a multidisciplinary rehabilitation service was likely mitigated by including two treatment groups that were both engaged within such a service, the nature of the rehabilitation provided may differ across each group due to the different clinics participants were referred to. Consequently, future research with a larger sample should include site stratification in the analysis of the effects of the treatment to control for these potential confounding effects. Furthermore, ACTion-mTBI was delivered by one clinician across two clinics; whereas the CBT intervention was delivered by three across three clinics. Due to our small sample size, we also could not feasibly account for clinician or clinic effects in our analyses. It is therefore critical that the next step in the evaluation of ACTion-mTBI is to determine that these initial findings generalise to other clinicians and clinics who deliver this intervention.

Post-treatment effects were also only measured at one time and therefore any inferences regarding the sustainability of these effects over time cannot be determined. Future research will need to ensure serial post-treatment assessments to ensure the effects of the treatment are examined over time. Participants in both treatment groups were also more likely to be female, middle age and of European ethnicity; however, this does not represent the most common characteristics of individuals who experience mTBI in NZ.[92] As part of the feasibility analysis of ACTion-mTBI, participants also engaged in an interview post-treatment to ascertain their perception of the intervention.[93] The feedback demonstrated that the ACTion-mTBI approach was highly valued by Māori (indigenous people of NZ), but may reflect that fewer Māori were referred to or chose to access the service where these psychological interventions were delivered, or were less able to access the service. It is imperative that the efficacy of ACTion-mTBI is established with a more diverse and representative sample of individuals who require psychological treatment as part of their mTBI recovery.

In conclusion, we determined feasibility of recruitment and study procedures of a quasiexperimental feasibility study of ACTion-mTBI within concussion services in NZ. ACTion-mTBI was found to significantly reduced functional disability, PPCS, anxiety, stress and a component of psychological flexibility. However, there were no observed effects for depression or valued living. The results indicate that ACTion-mTBI shows promising preliminary effects in not only addressing mental health difficulties in mTBI, but also in improving mTBI-specific outcomes. However, clinical effectiveness of ACTion-mTBI needs to be determined in a large-scale clinical trial, with a larger, more representative sample, with multiple clinicians delivering the intervention, and tracking the impact of outcomes over time. This study illustrates that a full clinical trial is feasible and provides initial evidence that this is warranted for people recovering from mTBI.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Southern Health and Disability Ethics Committee (21/STH/117) and Auckland University of Technology Ethics Committee (21/159). Participants gave informed consent to participate in the study before taking part.

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