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Trauma-focused cognitive behavioural therapy and exercise for chronic whiplash with comorbid posttraumatic stress disorder: a randomised controlled trial

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The authors report no conflict of interest.

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Abstract

Many people with chronic whiplash associated disorders (WAD) also have symptoms of posttraumatic stress disorder (PTSD), but this is rarely considered in usual predominantly exercise based interventions. We aimed to investigate the effectiveness of combined trauma focused cognitive behavioural therapy (TF-CBT) and exercise compared to supportive therapy (ST) and exercise for people with chronic WAD and PTSD. A randomised controlled multi-centre trial with concealed allocation, assessor blinding, and blinded analysis was conducted. 103 participants with chronic WAD (>3 months and <5 years, grade II) and PTSD were randomised to TF-CBT and exercise (n=53) or ST and exercise (n=50). Both interventions comprised 10 weeks of TF-CBT or ST followed by 6 weeks of exercise. Outcomes were measured at baseline, 10 weeks, 16 weeks, 6 months, and 12 months post-randomisation. Analysis was intention to treat using linear mixed models. There was no difference between the interventions on the primary outcome of neck pain related disability at any time point. At 16 weeks, the treatment effect on the 0-100 Neck Disability Index was 0.59 (95% CI 5.51 to -4.33), at 6 months 1.18 (6.15 to -3.78), and at 12 months 1.85 **(**6.81 to -3.11**)**. In addition, there was no difference between the interventions for the majority of secondary outcomes at any time. Exceptions were in favour of TF-CBT and exercise, where improvements in PTSD symptoms were found at 16 weeks. From 16 weeks onwards, both groups achieved a clinically important improvement in neck pain related disability. However, both groups remained moderately disabled.

Keywords: whiplash associated disorders; post-traumatic stress disorder; psychology; exercise

1. Introduction

Whiplash is the most common non-hospitalized injury after motor vehicle crashes (MVCs) [10] with an annual incidence of up to 300 per 100,000 [16]. Recovery is highly variable [1; 29] with up to 50% continuing to report ongoing pain and related symptomatology one-year post-injury [8]. While clinical guidelines recommend exercise and activity maintenance for whiplash associated disorders (WAD) [eg, [27]], effects are modest [20; 28; 31; 38].

One factor that may compromise physical treatment effects is comorbid psychological distress. In particular, being involved in an MVC is associated with more severe disorders such as posttraumatic stress disorder (PTSD) or symptoms hereof [14]. In WAD, cohort studies have found that approximately 15% follow a moderate-severe PTSD symptomatology trajectory with initial high levels of PTSD symptoms and no recovery 6-months post-injury [25; 29], with these people also reporting higher levels of pain-related disability compared to trajectories without ongoing PTSD symptoms [29]. Further, a recent systematic review found that initial PTSD symptomatology is a prognostic factor for chronic pain in WAD [7]. These findings demonstrate relationships between comorbid PTSD and pain in WAD, supporting the mutual maintenance model of pain and PTSD [26].

Despite this, only a single pilot randomised controlled trial targeting PTSD exists in chronic WAD [12]. Comparing 10 sessions of trauma-focused cognitive behavioural therapy (TF-CBT) with wait-list controls in 26 participants, moderate reductions in both neck pain related disability and PTSD symptoms were found [12]. To the best of our knowledge, only two additional trials exist in other chronic pain populations targeting comorbid PTSD [2; 3]. Comparing the effect of group CBT with a minimal contact condition in a pilot study with patients with MVC related pain and comorbid PTSD, Beck et al.[3] found moderate reductions in PTSD symptoms in the CBT group, but no group differences for pain. Similarly, in a trial for chronic low back pain and comorbid

PTSD, only PTSD symptoms were reduced when adding a brief trauma intervention with somatic experiencing to supervised exercises for low back pain, while no additional effects were achieved on pain nor disability [2]. While all three studies found a significant effect on PTSD symptoms, only Dunne et al. [12] found an effect on pain outcomes, making it difficult to draw definite conclusions regarding the effect of trauma-focused therapy in the comorbidity of chronic pain and PTSD. Also, Dunne et al. [12] was the only study in WAD utilizing an evidence-based intervention for PTSD (prolonged exposure) and a diagnostic interview to assess PTSD, however also with a passive control group and a small number of participants. In addition, participants still experienced significant levels of pain and disability post-intervention [12]. Hence, there is a strong need for a randomized controlled trial with increased statistical power, an active control group, gold standard clinical assessment of PTSD, and the combination of physiotherapy in chronic WAD. Therefore, we aimed to investigate the effectiveness of combined TF-CBT and exercise compared to supportive therapy (ST) and exercise for people with chronic WAD and comorbid PTSD.

2. Methods

2.1. Study Design

This was a parallel randomised controlled multi-centre trial with 1:1 allocation. It evaluated the effect of 10 weeks of TF-CBT followed by a 6-week physiotherapy exercise program compared to 10 weeks of ST followed by the same 6-week physiotherapy exercise program. Both psychological interventions were carried out by a licensed clinical psychologist. In addition to baseline assessments, outcomes were measured at 10 weeks (post-psychotherapy), 16 weeks (post-physiotherapy), and at 6- and 12-months follow-up post-randomisation. The trial was prospectively registered (Australian New Zealand Clinical Trials Registry ACTRN12615000547549) and the protocol published [7]. Ethical approvals were obtained from Griffith University Human Research

Ethics, Australia #AHS/15/14/HREC); The University of Queensland Human Research Ethics Committee, Queensland, Australia (#2014000144) and from the Danish Regional Science Ethics Committee (trial number J.nr. S-20130103).

2.2. Participants and Study Settings

Participants were recruited from Southeast Queensland in Australia and the region of Zealand in Denmark between May 2015 and August 2018 through advertisements and clinical practices. In Denmark, advertisements were also sent directly by post to potentially eligible patients as identified through the Danish National Health Registry after a visit to the emergency department with a neck trauma. Interested individuals contacted the research team for further information, after which a telephone screening interview was conducted. Relevant individuals were then invited for a face-to-face diagnostic interview with a licensed psychologist to determine the presence of PTSD. Prior to this interview, oral and written information were given, and all gave written consent.

Participants were eligible for inclusion if they had chronic WAD grade II (no neurological deficit or fracture) [30] for at least 3 months but less than 5 years and met all the following criteria: Comorbid PTSD as according to full criteria in DSM-5 [4] related to the WAD-causing MVC, moderate pain and disability $\geq$30% on the NDI, aged between 18 and 70 years old, and proficient in oral and written English or Danish (depending on the country of participation). In turn, the following exclusion criteria were applied: Known or suspected serious spinal pathology (e.g., metastatic, inflammatory or infective diseases of the spine), confirmed fracture or dislocation in the neck at the time of injury (WAD Grade IV), nerve root compromise (at least 2 of the following signs: weakness/reflex changes/sensory loss associated with the same spinal nerve), spinal surgery in the last 12 months, and a history or current presentation of psychosis, bipolar disorder, organic brain disorder, or severe depression. In Denmark, all interventions were conducted in a specialized

rehabilitation hospital. In Australia, the interventions were delivered in private psychology and physiotherapy practices.

2.3. Randomization and Blinding

Participants were randomly allocated to treatment group using block randomization generated by a study biostatistician using blocks of 4 to 8 and generated prior to the trial commencement. To ensure allocation was concealed, participants were randomly assigned by opening the next sealed, sequentially numbered, opaque envelope. After determination of eligibility, participants were randomized and were scheduled to receive their first session of the psychological treatment within one week of randomization. Participants were deemed to have entered the study at the time that the envelope was opened. A non-blind research assistant arranged all appointments with treating practitioners and informed psychologists of group allocation. Physiotherapists were blind to the psychological treatment group. The staff, who were involved in the baseline and follow-up assessments, were blinded to the treatment allocation of the participants.

2.4. Outcome Measures

All primary and secondary outcomes as well as descriptive characteristics such as age, gender, level of education, accident-related information, and early whiplash-related symptoms were collected at baseline prior to randomization and start of treatment. All outcome measures were collected again at 10 weeks (post-psychotherapy), at 16 weeks (post-physiotherapy), at 6 months, and at 12 months post-randomisation. All outcomes were collected by paper questionnaires.

2.4.1. Primary Outcome

The primary outcome was the Neck Disability Index (NDI). The NDI is a reliable and valid measure of neck pain related disability[32] with 10 items scoring from 0 to 5, which is rescaled to a 0 to 100 score. A higher score is indicative of more neck pain related disability. The NDI is recommended for use in chronic musculoskeletal pain [18].

2.4.2. Secondary Outcomes

The secondary outcomes included all of the following:

1. Average neck pain intensity over the past 24 hours and the past week was measured by two separate 11-point Numerical Rating Scales ranging from 0 (“no pain”) to 10 (“worst imaginable pain”) [23].
2. Self-rated posttraumatic stress symptoms were measured using the PTSD Checklist for DSM-5 (PCL-5)[5]. Symptomatology was reported on 20 items representing the four symptom clusters: (B) Intrusion (5 items), (C) avoidance (2 items), (D) negative alterations in cognitions and mood (7 items), and (E) alterations in arousal and reactivity (6 items). All items are scored from 0 (“not at all”) to 4 (“extremely”), leaving a total score from 0 to 80 with a higher score indicating a higher level of PTSD related symptomatology.
3. Diagnostic presence of PTSD criteria was measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) [36]. The CAPS-5 is a 30-item diagnostic interview that corresponds to the full diagnostic criteria according to DSM-5 (criteria A to F) and was carried out by licensed psychologist. In Australia, the interviews were conducted by a research psychologist and in Denmark, by the treating clinical psychologist (with a cross-over, so they did not, in majority of cases, assess the patients that they would be treating). In this study, the diagnostic presence as a binary outcome (yes/no) was applied based on fulfilment of all criteria.
4. Symptoms of depression, anxiety, and stress were measured using the Depression, Anxiety, and Stress Scale 21 (DASS-21) [17]. Each of the three constructs is measured by 7 items scored from 0 to 3, which are summed up and multiplied by two, leaving a total score for each construct ranging from 0 to 42 with a higher score indicating higher symptom severity.

5. SF-12 was applied as a generic measure of health status [34]. The SF-12 measures the same eight domains as the SF-36 and a higher score indicates a better health status.
6. The Patient-Specific Functional Scale was applied to measure patient-specific disability [37]. Respondents choose relevant activities and rated their ability to perform them on a scale from 0 ("unable to perform") to 10 ("able to perform at prior level"), leaving a higher score to indicate better functional level.
7. Pain catastrophizing was measured by the Pain Catastrophizing Scale (PCS)[30], which consists of 13 items with a 5-point Likert scale ranging from 0 ("not at all") to 4 ("all the time"), thereby adding to a total score between 0 and 52. A higher score indicates a higher level of pain-related catastrophizing.
8. The Pain Self Efficacy Questionnaire (PSEQ) was used to measure the confidence the participants have in performing activities while in pain [22]. Total scores range from 0 to 60 with a higher score indicating a higher level of pain self-efficacy.
9. The Tampa Scale for Kinesiophobia (TSK) was used to measure fear of re-injury due to movement, which is a 17 items scale scored from 1 ("strongly disagree") to 4 ("strongly agree"), thereby having a total score ranging from 17 to 68 with a higher score indicating higher levels of kinesiophobia / fear of re-injury due to movement [21].
10. The patient's self-rated global impression of recovery was measured using an 11-point scale ranging from -5 ("vastly worse") to +5 ("completely recovered") [23]. This was only included at 10 and 16 weeks to avoid recall bias when administered over longer periods [16].

In addition to the above-mentioned outcome measures, participants also completed a process measure, the Credibility Expectancy Questionnaire (CEQ), at the first and last week of each of the

treatments (thereby completing it four times in total) [11]. The CEQ provides a measure of how the participant thinks and feels about the treatment.

As per protocol, perceived working alliance as measured by the Working Alliance Inventory [13] was completed by the clinician and the patient in the first and last session of each intervention (both psychotherapy and physiotherapy) for later secondary analyses. This data is therefore not included in this paper.

2.5. Interventions

The treatments were carried out by licensed psychologists and physiotherapists experienced in the management of musculoskeletal pain. Prior to starting the trial, all psychologists and physiotherapist received appropriate protocols and training in the trial interventions and received continuing supervision. For the psychological interventions, specific manuals were developed with checklists of adherence to protocol, and sessions were recorded. Brief handover documents from psychologist to physiotherapist were also developed.

The TF-CBT intervention comprised an adapted protocol of prolonged exposure therapy. It consisted of 10 weekly 60-90-minute sessions of individually delivered TF-CBT. The intervention focused on providing PTSD related psychoeducation, teaching anxiety management strategies such as progressive muscle relaxation, initiating cognitive restructuring of unhelpful thoughts and assumptions, and applying prolonged imaginal and in-vivo exposure. Finally, relapse prevention was included in the final sessions. Home exercises were outlined from session to session and involved listening to recordings of imaginal exposure and doing in-vivo exposure.

ST was applied as an active control intervention. The intervention was given in 10 weekly 60-minute individual sessions. Similar to TF-CBT, the first session was used for psychoeducation about PTSD symptomatology and the rationale for ST. The following session included discussion of current issues and general problem-solving skills. Home exercises involved diary keeping of

current problem and mood states. Of importance, this supportive intervention would specifically avoid exposure, cognitive restructuring, and anxiety management techniques.

After receiving either one of the psychological interventions outlined above, all participants received the same exercise program. The exercise program was delivered by physiotherapists and comprised 10 sessions of over six weeks with two weekly sessions in week 1-4 and one weekly session in week 5 and 6. The physiotherapists first assessed the participant and then tailored the exercises for each individual. The programme comprised specific exercises to improve movement, strength and endurance of the neck and shoulder girdle muscles, as well as exercises to improve eye/head coordination. The exercises were progressed by the physiotherapist in terms of increasing difficulty and load. At the same time, the physiotherapist advised and guided the participant's return to normal activities, including work and on undertaking general aerobic exercise in a sub-maximum and progressive manner. Participants were also encouraged to perform the exercises at home. Written and illustrated exercise instructions were provided, and participants' compliance with exercises were evaluated.

Full details of the interventions are provided in Appendix 1 (available online as supplemental digital content at http://links.lww.com/PAIN/B208) and in the protocol [6].

2.6. Statistical Analysis

An independent study statistician undertook the analyses and was blinded to group allocation. A sample size of 108 participants was calculated a priori. Based on a two-sided t-test, a sample of 86 (43 per group) would provide 80% power to detect a significant difference at alpha 0.05 between the group means of 10 points on the 100-point NDI (assuming a SD of 16, as outlined in the protocol [6]). Effects smaller than this are unlikely to be considered clinically worthwhile. Allowing for a 20% loss to follow up by 12 months, we required 54 participants per treatment group, leaving a total sample size of 108.

Statistical analyses were conducted on an intention-to-treat basis using. To account for repeated outcome measurement, and to make use of all available data, a linear mixed modelling approach was used. The effect of the intervention was analysed separately for each outcome with time as a repeated factor, treatment condition, as a fixed factor and an unstructured covariance matrix used to specify the within-participant correlation over time. Because the study recruited from two sites, and differences in the characteristics of the patients, delivery of the treatment, or health system context may affect effectiveness, we assessed potential site-effects by including a treatment-site interaction term to each model. For each continuous outcome, the difference in estimated marginal means (95% CI) between the groups was obtained at each time point, after adjustment for baseline measurement. For CAPS-5 PTSD diagnosis (dichotomous data, diagnosis present/absent), at each follow up time point, risk ratios and 95% confidence intervals were calculated. The null hypothesis that the proportions of participants with a PTSD diagnosis were the same in each treatment group was tested using the chi-squared test for association. A p-value <0.05 was used to define statistical significance. All analyses were conducted in Stata 15.

3. Results

3.1. Protocol Deviations

There were two deviations from the trial protocol. Due to recruitment difficulties and time constraints, recruitment was ceased at 104 participants. For logistical reasons, the psychologist conducting the CAPS-5 was, in some cases, not blinded to the participants' group allocation.

3.2. Enrolment and Follow-up

All participants were classified as Grade II WAD. Figure 1 outlines the flow of participants through the trial.

[Insert Figure 1 about here]

A total of 104 participants consented and were randomised. One participant withdrew after randomisation but before providing any data, leaving 103 participants in the analysis. Of the 53 participants randomised to the TF-CBT and exercise group, the primary outcome measure (NDI) was completed by 43 (81%) participants at 10 weeks, 38 (72%) at 16 weeks, 38 (72%) at 6 months, and 36 (68%) at 12 months. Of the 50 participants randomised to ST and exercise, the NDI was completed by 46 participants (92%) at 10 weeks, 43 (86%) at 16 weeks, 40 (80%) at 6 months and 43 (86%) at 12 months. There was some variation in the number of participants completing the secondary outcome measures over time in both groups. Three psychologists and 6 physiotherapists delivered the interventions in Australia, while three psychologists and two physiotherapists delivered the interventions in Denmark.

3.3. Baseline Characteristics

Table 1 shows the baseline characteristics for both groups. Participants were mainly middle-aged and predominantly female; the mean (sd) time since MVC injury was 2.49 (1.93) years for the TF-CBT group, and 3.33 (4.15) years for the ST group. Sixty-six percent of the TF-CBT group and 78% of the ST group had lodged a compensation claim, with approximately 23% of both groups reported having settled their claim. Forty-two percent of the TF-CBT group and 58% of the ST group had engaged a solicitor. Queensland operates under a fault-based third-party compensation scheme, where only those deemed not at fault for the MVC can claim for compensation. Those deemed at fault for the MVC can seek care through the public health care system or through private health insurance. In Denmark, people can seek care through the public tax-funded health care system regardless of fault. In addition, compensation can be claimed through private insurances. Of most relevance to the participants in this study, two types of compensations can be claimed. First, it is mandatory by law to have private liability insurance on motor vehicles. In cases with several motor vehicles involved, fault does not have to be proven, and the person's own fault is only taken

into account in cases of severe negligence. Second, many Danes hold one or several private accident insurances, which provides the right to compensation in cases with personal injury causing a certain amount of ongoing invalidity. The circumstances for this compensation depend on the specific insurance terms, but compensation can be reduced or lapsed in cases of severe negligence.

Almost all participants had received treatment prior to entry to the trial, with physiotherapy being the most common type of treatment provided. Scores on all items of the CEQ were the same for both groups (Table 1).

[Insert Table 1 about here]

3.4. Compliance and Adherence

Participant compliance with treatment was fair. The median (interquartile range; IQR) number of sessions attended in the TF-CBT and physiotherapy exercise groups were 10(3) for TF-CBT and 10(1) for physiotherapy. In the ST and exercise group, the median (IQR) number of sessions were 10 (0) for ST and 10 (1) for physiotherapy. In the TF-CBT group, 23 patients did not attend the full 10 TF-CBT sessions with the mean (SD) attendance being 5.6 (2.8), and 21 did not attend all 10 physiotherapy sessions but attended 3.5 (3.8) sessions. In the ST group, 12 patients did not attend all 10 ST sessions but attended 6.3 (3.3) sessions, and 16 did not attend all 10 physiotherapy sessions with attendance at 6.3 (3.6) sessions.

Psychologist adherence to the trial protocol was generally good based on a random audit of 20 participants based on content checklists. In 78% of the cases, the psychologists fully adhered to the protocol, in 17% of the cases they mostly adhered but missed one or two sessions, and for 5% (2 psychologists, one at each site) no information on adherence was available. Physiotherapist adherence to the trial treatment protocol was also good based on an independent review of randomly selected session's treatment notes. 87.5% were fully compliant, one (2.5%) did not adhere due to the patient's avoidance behaviour, and notes were unavailable for four (10%).

No serious adverse events were reported during the trial.

3.5. Primary Outcome

In the primary analysis, the TF-CBT and exercise intervention did not provide a benefit over ST and exercise at 16 weeks follow-up (estimated mean difference 0.59 on the 100% NDI, 95% CI, 5.51 to -4.33), at 6-month (estimated mean difference 1.18, 95% CI, 6.15 to -3.78), or at 12-month (estimated mean difference 1.85, 95% CI, 6.81 to -3.11) follow-ups. There was no significant treatment-by-site interaction. Table 2 and Figure 2 show the unadjusted NDI scores for each group and Table 3 shows the treatment effect for the TF-CBT and exercise group compared with the ST and exercise group at each follow-up time point.

[Insert Table 2 and 3 + Figure 2 about here]

3.6. Secondary Outcomes

For the majority of secondary outcomes, no effect was observed at any time-points, and no significant treatment-by-site interactions were observed. The few significant between-group differences in secondary outcomes were in favour of TF-CBT and exercise and were the following: At 16 weeks, the PCL-5 total symptom score (estimated mean difference -6.24, 95% CI, -0.54 to -11.94), the PCL-5 avoidance symptom cluster (C) (estimated mean difference -1.38, 95% CI -0.55 to -2.21), and the rumination subscale of the Pain Catastrophizing Scale (estimated mean difference -1.54, 95% CI, -0.05 to -3.02) were lower in the TF-CBT and exercise group. At 12 months, the Tampa Scale of Kinesiophobia (estimated mean difference -3.32, 95% CI, -0.51 to -6.13) was lower in the TF-CBT and exercise group. Table 2 shows the unadjusted scores for each outcome and Table 3 the treatment effects at each time point.

For the dichotomised CAPS-5 results, there was no significant difference in the proportion of participants diagnosed with PSTD between the intervention groups at any time point. At 16 weeks follow-up after either combined TF-CBT and exercise or combined ST and exercise, respectively

85% and 72% no longer fulfilled the diagnostic criteria for PTSD. See Table 4 for Risk Ratios at all time points.

[Insert Table 4 about here]

3.7. TF-CBT alone compared to ST

Comparing TF-CBT to ST at 10-weeks (immediately after the psychological treatment but prior to commencement of physiotherapy), there was equally no effect for the primary outcome measure of neck pain related disability (estimated mean difference 0.28, 95%, CI 5.08 to -4.52) nor for any of the secondary outcomes. Again, Table 2 shows the unadjusted scores for each outcome, and Table 3 shows the treatment effects at each time point.

4. Discussion

4.1. Summary of Findings

Combined TF-CBT and exercise did not provide additional benefit over combined ST and exercise for the primary outcome of neck pain related disability for people with chronic WAD and comorbid PTSD at any time point. Similarly, there were no significant differences in the effect between the treatment groups on the majority of secondary outcomes measures. The exceptions revealed a small but significant benefit of TF-CBT and exercise on three of the secondary outcomes at 16 weeks (total PTSD symptoms, the avoidance subscale of PTSD, and the rumination component of pain catastrophizing) and on one of the secondary outcomes at 12 months (kinesiophobia). Comparing only TF-CBT and ST prior to commencing physiotherapy, there was also no additional benefit of TF-CBT on any outcome. Attrition was higher in the TF-CBT group. It is possible that participants found this intervention more confronting and it therefore, may not be feasible for some patients.

4.2. Discussion of Findings

Previous trials have indicated that TF-CBT is superior to ST for PTSD symptoms [4; 19; 35].Whilst we found the combination of TF-CBT and exercise improved some PTSD symptoms to a greater extent than ST and exercise, there was no difference between the two interventions on the primary outcome of pain related disability, nor on the majority of other secondary outcome measures. There may be several reasons for this. First, it may be due to the exact content of ST in the present study. While ST did not contain any exposure or cognitive restructuring techniques, emotional stress related to the trauma was addressed in the ST if brought up by the participants themselves. Furthermore, the goal of ST was to provide education about trauma symptoms, provide unconditional emphatic support, improve problem-solving skills towards current issues, and thereby improve self-efficacy. This is indeed some of the core components of psychotherapy that have proven effective for psychological distress [33]. Second, PTSD assessment may have been compromised due to symptom overlap between chronic pain and PTSD. If this is the case, the included participants may have been more generally distressed and hyperaroused rather than fulfilling all the diagnostic criteria for PTSD. In this case, it would make sense that ST works equally well as TF-CBT, as these overlapping symptoms may represent more general distress that does not need to be targeted by trauma-focused therapeutic interventions. It is also possible that the exercise component of both interventions may have served as an exposure treatment.

Despite the lack of group differences between the two interventions in the present trial, participants still benefitted from the treatments. While participants only gained a change of 2.8-3.1 percentage points on the primary outcome of NDI after psychological therapy alone, they gained between 8.4 and 10.7 percentage points' change after the combined interventions (either TF-CBT and exercise or ST and exercise). Several studies have indicated that a minimum change of 7 percentage points on the 0-100 NDI is required for the change to be clinically relevant [9; 15; 24],

leaving the NDI changes in both groups at 16 weeks, 6 months, and 12 months to be clinically relevant. Of note, however, we deemed a minimum change of 10% to be clinically worthwhile in our protocol. Using this criterion, only ST and exercise at 6 and 12 months provided changes in NDI of clinical importance. Comparing this to existing trials, these changes in pain related disability were better than the effects found in Dunne et al. [12], who compared TF-CBT to waitlist control, and Beck et al. [3], who compared group CBT to a minimum contact condition, indicating an additional effect of the combined interventions of psychological therapy and exercise. Moreover, the finding that our study positively affected both neck pain-related disability and PTSD, which was not the case in Beck et al. [3], where only PTSD symptoms improved, also indicate that the combined interventions may be more effective compared to psychotherapy alone. On the contrary, the combined somatic-experiencing and exercise intervention by Andersen et al. [2] also only improved PTSD symptoms. However, the study by Andersen et al. [2] was in low back pain and not utilizing an evidence-based treatment for PTSD. Hence, future studies should assess the effects of combined evidence-based interventions and assess the potential mechanisms of change to further improve interventions for chronic WAD with comorbid PTSD. Moreover, the reduction in PTSD cases in the TF-CBT were comparable with Beck et al. [3].

Although both groups in the present trial achieved reductions in neck pain-related disability (primary outcome), participants remained moderately disabled at all follow-ups. Thus, interventions for chronic WAD and comorbid PTSD still need to be improved. The participants in the present study were patients with chronic WAD and comorbid PTSD. Cohort studies have consistently demonstrated that this WAD subgroup follows a severe trajectory following injury, characterized by little or no recovery over time in both pain-related disability and PTSD symptoms [1; 25; 29]. Therefore, our findings indicate that the improvements in disability were due to the trial treatments

and this is a promising result in a usually treatment resistant group. However, without the inclusion of a no-treatment control group, we cannot definitively rule out some natural recovery over time.

4.3. Clinical and Research-related Implications

Although no group differences were found in relation to improvement in pain related disability and PTSD, the results are still promising and indicate that patients with chronic WAD and comorbid PTSD may benefit from intervention targeting both PTSD symptoms and pain related disability. As TF-CBT and exercise were equally effective as ST and exercise, both intervention combinations are equally recommended. As ST and exercise are easier to apply and commonly more comfortable for the patients, this may be most relevant. However, as patients remained moderately disabled, and other current approaches to chronic WAD also has proven to be only marginally effective, future research needs to further test potential optimized interventions. Future studies should investigate relevant moderators of the effects of combined interventions to decipher who may better respond to either intervention.

4.4. Strengths and Limitations

The present trial has several strengths and limitations. The randomised controlled design, the pre-specified protocol, and the assessment of comorbid PTSD by a gold standard diagnostic interview are major strengths of the present study. Also, the homogenous population of MVC related WAD and PTSD due to the same traumatic event is a strength. Moreover, the study aimed to stratify intervention by selecting a poorly recovering group of patients with chronic WAD and comorbid PTSD and is – to our knowledge – the first study to do so. However, a number of limitations should also be mentioned. First of all, two deviations from the protocol were made. The first was that the recruitment was ceased at 104 participants due to logistical constraints instead of at the a priori calculated 108. This may have had implications for the study power, but it would seem unlikely that four more participants would markedly have changed the results. The second

was that it was not possible to uphold blinding of group allocation of all assessing psychologists conducting the PTSD interviews due to practical reasons. This may have influenced the results on this outcome measure. Secondly, the methodology of the study could have been strengthened by the inclusion of a third intervention arm of exercise alone and or a wait-list control group. Thirdly, due to the large symptom overlaps between PTSD and chronic pain, PTSD assessment can have been challenged. This may have caused some issues in the present study both with regards to the included participants and the outcome of PTSD due to artificial inflation of symptoms reports and false positives.

4.5. Conclusions

Combined TF-CBT and exercise was found to be equally effective as ST and exercise for people with chronic WAD and comorbid PTSD. While both groups gained improvements in the primary outcome neck pain related disability, participants remained moderately disabled. Similar improvements were seen on a number of secondary outcomes. A combined intervention of psychotherapy and exercise could be beneficial for chronic WAD patients with comorbid PTSD, but our study does not allow comparison with natural recovery. Future research needs to establish more effective interventions and whether some patients benefit more from one intervention over the other.

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Conflict of Interest Statement

All authors have completed the ICMJE disclosure form and disclose the following financial support for the submitted work. The authors have no conflict to disclose. The funders had no role in the data collection, analysis, interpretation, nor reporting of results.

Registration and Protocol

The trial was registered a priori in the Australian New Zealand Clinical Trial Registry (ACTRN12615000547549) on May 28th, 2015, and the protocol was published in the Journal of Physiotherapy in October 2015 [7].

Registration and Protocol

The investigators will share data (with associated coding library) used in developing the results presented in this manuscript on request to the corresponding author. Anonymised record-level data will be made available on proposal for analysis by those who have received ethical clearance from their host institution.

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Figure Legends

Figure 1. Flow of participants through the trial

Figure 2. Primary outcome measure, mean Neck Disability Index (0–100) at baseline, 10 weeks, 16 weeks, 6 and 12 months for the intervention groups. 95% CI also shown. Trauma focussed cognitive behavioural therapy (CBT) or supportive therapy were delivered in the first 10 weeks, followed by 6 weeks of exercise in both groups.

Table 1. Baseline characteristics of trial participants by treatment group

Characteristic	**TF-CBT (n=53)**	**ST (n=50)**
Age in years; mean (SD)	39.71 (13.3)	44.49 (11.6)
Missing	1 (1.89)	2 (4.00)
Female	39 (73.6)	36 (72)
Level of education completed		
School years	10 (18.9)	12 (24)
Technical training	22 (41.51)	14 (28)
Higher education	20 (37.74)	23 (46)
Missing	1 (1. 9)	1 (2)
Working status		
Employed[a]	32 (60.4)	34 (68)
Self-employed	6 (11.3)	8 (16)
Home duties	2 (3.8)	1 (2)
Unemployed	12 (22.6)	5 (10)
Retired and early pension	1 (1.9)	2 (4)
If employed, are you working usual hours?		
Yes, working usual hours	20 (37.7)	18 (36)
Working reduced hours	13 (24.5)	16 (32)
Not working	8 (15.1)	7 (14)
Missing*	12 (22.6)	9 (18)
Role in the crash		
Driver	43 (81.1)	44 (88)
Back seat passenger	0 (0)	1 (2)
Front seat passenger	7 (13.2)	3 (6)
Other (eg, passenger in bus)	3 (5.7)	2 (4)
Years since accident (SD)	2.49 (1.9)	3.33 (4.2)
Knew the accident was coming	20 (37.7)	7 (14)
Missing	2 (3.8)	3 (6)
Type of collision		
Rear end	21 (39.6)	22 (44)
Front end	9 (17)	10 (20)
Rear and front end	5 (9.4)	6 (12)
Side impact	9 (17)	5 (10)
Other (eg, multiple directions)	9 (17)	5 (10)
Missing	0 (0)	2 (4)
Vehicle was stationary at time of impact	22 (41.5)	21 (42)
Missing	9 (17)	8 (16)
How soon following the accident did your neck pain start?		
Immediately	20 (37.7)	22 (44)
Within 24 hours	28 (52.83)	18 (36)
After 24 hours	5 (9.4)	9 (18)
Missing	0 (0)	1 (2)
Was your neck movement restricted following the accident?		
Not at all	7 (13.2)	3 (6)
Mildly	12 (22.6)	7 (14)
Moderately	10 (18.9)	18 (36)
Severely	24 (45.3)	22 (44)
Hospital admission following the accident	24 (45.3)	17 (34)
Missing	1 (1.9)	1 (2)
History of major surgery or other injuries	30 (56.6)	28 (56)
Missing	3 (5.7)	0 (0)
Fractures/dislocations following the accident	7 (13.2)	7 (14)
Missing	2 (3.8)	1 (2)
Current compensation claim	27 (51)	28 (56)
Compensation claim has settled	12 (22.6)	12 (24)
No compensation claim lodged	14 (26.4)	10 (20)
A solicitor has been engaged	22 (41.5)	29 (58)
Missing	9 (17)	6 (12)

Investigations		
X-rays	36 (67.9)	26 (52)
Missing	5 (9.4)	2 (4)
MRI	23 (43.4)	25 (50)
Missing	9 (17)	1 (2)
CT scan	23 (43.4)	19 (38)
Missing	6 (11.3)	2 (4)
Present drugs for whiplash-associated disorder		
Simple analgesics and antipyretics	26 (10.3)	40 (15.9)
Nonsteroidal anti-inflammatory agents	29 (11.5)	28 (11.1)
Narcotic analgesics	28 (11.1)	22 (8.7)
Combination simple analgesics	8 (3.2)	9 (3.6)
Muscle relaxants	7 (2.8)	4 (1.6)
Antidepressants	5 (2)	5 (2)
Dietary supplements or herbal medicines	3 (1.2)	5 (2)
Anticonvulsants, simple analgesics, and antipyretics	4 (1.6)	4 (1.6)
Other medications[b]	14 (5.6)	20 (7.9)
Previous treatment		
Physiotherapy	44 (83.)	41 (82)
Chiropractic	14 (26.4)	17 (34)
Massage	29 (54.7)	34 (68)
Acupuncture	22 (41.5)	23 (46)
Surgical procedures	2 (3.8)	1 (2)
Psychological treatment	3 (5.7)	10 (20)
Other (eg, osteopathy)	8 (15.1)	8 (15.1)
No treatment	0 (0)	2 (4.)
Neck pain intensity over the past week, 0–10, mean (SD)	6.64 (1.8)	6.28 (2.)
Neck pain intensity over the past 24 hours, 0–10, mean (SD)	6.51 (1.7)	5.96 (2.1)
Credibility/Expectancy Questionnaire, mean (SD)		
Treatment credibility, 3–27	21.34 (4.6)	21.11 (5.4)
Missing	3 (5.7)	3 (6)
Treatment expectancy, 3–27	18.56 (5.7)	17.47 (5.4)
Missing	2 (3.8)	3 (6)

Data are expressed as n (%) except where indicated.

[a] This includes studying, sick and maternity leave from current employment, and the Danish possibility of "flexible job"

[b] This includes antianxiety agents, antimigraine preparations, anticonvulsants, combination simple analgesics, nonsteroidal anti-inflammatory agents, sedatives, hypnotics, adrenal steroid hormones, antihistamines, and antipsychotic agents.

Table 2. Unadjusted mean (SD) for outcome by treatment group and time point

	Baseline		10 weeks		16 weeks		6 months		12 months	
	*TF-CBT (n=53)**	*ST (n=50)*	*TF-CBT (n=43)*	*ST (n=46)*	*TF-CBT (n=38)*	*ST (n=43)*	*TF-CBT (n=38)*	*ST (n=40)*	*TF-CBT (n=36)*	*ST (n=43)*
Primary outcome										
NDI (0-100)	50.40 (12.54)	49.48 (13.62)	47.29 (14.76)	46.66 (15.94)	41.93 (18.44)	41.09 (17.49)	42.04 (19.65)	39.07 (17.90)	41.68 (21.52)	38.78 (17.98)
Secondary outcomes										
CAPS-5										
Total (0-80)	33.60 (11.56)	31.64 (8.15)	21.23 (12.11)	20.71 (10.59)	15.97 (11.75)	17.86 (11.57)	14.50 (12.68)	15.70 (12.25)	13.81 (11.30)	14.60 (10.76)
CAPS-5 Cluster B	8.75 (3.60)	7.74 (2.72)	5.58 (4.09)	5.39 (3.54)	3.73 (3.69)	4.20 (3.47)	3.76 (4.31)	3.08 (3.37)	3.36 (3.59)	3.23 (3.13)
CAPS-5 Cluster C	4.11 (1.46)	3.82 (1.35)	2.23 (2.18)	1.91 (2.09)	1.62 (1.96)	1.55 (1.45)	1.26 (1.91)	1.65 (2.06)	1.06 (1.82)	1.00 (1.41)
CAPS-5 Cluster D	11.02 (5.52)	10.44 (3.90)	6.30 (4.81)	6.62 (4.89)	4.65 (4.67)	5.57 (4.79)	3.82 (4.40)	5.58 (5.21)	3.94 (4.50)	4.67 (4.47)
CAPS-5 Cluster E	9.55 (3.10)	9.18 (2.72)	7.12 (3.24)	7.07 (3.08)	6.03 (3.93)	6.57 (3.71)	5.66 (3.63)	5.4 (3.24)	5.56 (3.57)	5.77 (3.54)
PCL-5										
Total (0-80)	41.58 (12.41)	43.90 (12.43)	30.63 (15.60)	31.72 (14.34)	18.95 (12.20)	26.74 (17.23)	17.32 (14.26)	22.20 (15.29)	19.58 (14.34)	21.19 (15.10)
PCL-5 Cluster B	10.17 (3.57)	10.30 (4.16)	7.49 (4.68)	7.28 (4.22)	4.08 (3.09)	5.35 (4.11)	4.16 (4.42)	4.83 (3.78)	4.03 (3.93)	4.16 (3.55)
PCL-5 Cluster C	4.56 (1.99)	4.26 (2.30)	3.07 (2.20)	3.02 (2.09)	1.50 (1.72)	2.67 (2.07)	1.50 (2.09)	1.95 (2.22)	1.64 (2.07)	1.58 (1.87)
PCL-5 Cluster D	13.92 (5.72)	15.38 (5.55)	9.98 (5.95)	10.85 (5.59)	6.42 (4.96)	9.40 (7.22)	5.16 (5.11)	7.80 (6.06)	6.58 (5.69)	7.58 (6.20)
PCL-5 Cluster E	13.02 (4.40)	13.96 (3.85)	10.09 (4.74)	10.57 (4.75)	6.95 (4.22)	9.33 (5.60)	6.68 (4.88)	7.63 (4.99)	7.33 (4.59)	8.05 (4.94)
DASS										
Depression (0-42)	16.60 (10.64)	19.12 (9.33)	11.30 (9.00)	15.04 (10.03)	7.84 (7.49)	11.58 (10.50)	8.16 (8.19)	11.70 (10.55)	9.11 (9.31)	12.28 (10.79)
Anxiety (0-42)	15.28 (9.54)	16.24 (10.57)	9.67 (8.23)	12.22 (9.29)	7.21 (6.87)	10.14 (9.82)	6.53 (6.72)	9.60 (9.98)	6.89 (7.67)	9.07 (9.64)
Stress (0-42)	22.72 (9.03)	24.60 (9.15)	16.98 (7.53)	19.00 (9.71)	13.11 (7.30)	15.91 (9.89)	12.37 (6.85)	14.95 (10.02)	13.67 (8.85)	15.07 (10.34)
SF-12										
PCS	33.75 (8.41)	34.62 (8.89)	37.26 (8.96)	37.12 (9.42)	36.63 (10.09)	37.91 (10.27)	38.82 (10.13)	40.45 (7.97)	39.59 (12.49)	40.90 (9.17)
MCS	36.48	35.93	39.78	37.39	44.87	43.49	44.11	41.60	43.10	43.79

	(9.94)	(10.06)	(11.96)	(10.65)	(11.22)	(9.94)	(9.14)	(12.08)	(11.88)	(10.22)
PSFS										
General (0-80)	3.19 (1.98)	3.29 (1.77)	2.61 (1.27)	3.21 (1.84)	3.30 (1.83)	3.58 (2.06)	3.46 (1.96)	3.98 (1.92)	3.94 (2.15)	3.72 (2.21)
Today (0-80)	3.52 (1.75)	2.94 (1.73)	2.92 (1.59)	3.27 (1.95)	3.68 (1.86)	3.85 (1.69)	3.76 (2.13)	4.21 (1.97)	3.44 (1.99)	3.73 (2.11)
PCS										
Total (0-52)	27.74 (9.28)	26.82 (12.07)	19.74 (9.78)	22.67 (13.50)	14.39 (9.88)	18.43 (12.13)	13.03 (9.16)	15.35 (12.29)	13.00 (11.28)	16.02 (13.00)
Magnification	4.96 (3.11)	5.90 (3.20)	3.44 (2.32)	4.59 (3.24)	1.97 (2.25)	3.07 (2.60)	2.03 (2.37)	2.78 (2.50)	1.92 (2.45)	2.88 (2.70)
Rumination	10.34 (3.52)	8.98 (4.34)	7.16 (3.40)	7.89 (4.71)	5.42 (3.83)	6.88 (4.42)	5.11 (3.64)	5.57 (4.60)	4.64 (4.31)	5.63 (4.78)
Helplessness	12.43 (4.92)	11.94 (5.76)	9.14 (5.17)	10.20 (6.42)	7.00 (5.12)	8.48 (6.22)	5.89 (4.31)	7.00 (6.16)	6.44 (5.38)	7.51 (6.22)
PSEQ (0-60)	28.34 (11.77)	29.74 (11.52)	33.00 (12.87)	32.78 (12.12)	37.66 (12.69)	35.76 (14.65)	37.08 (13.21)	39.53 (13.63)	39.08 (15.15)	38.72 (14.53)
TAMPA (17-68)	47.06 (6.34)	45.98 (7.87)	42.47 (6.73)	44.41 (6.95)	39.05 (7.88)	40.34 (8.19)	38.82 (8.01)	38.78 (8.21)	36.36 (9.65)	39.26 (8.48)
Neck pain intensity, past week (0–10)	6.64 (1.76)	6.28 (2.04)	6.60 (1.72)	6.28 (1.97)	5.81 (2.22)	4.95 (2.08)	5.39 (2.39)	4.90 (2.06)	5.43 (2.21)	4.86 (2.21)
Neck pain intensity, past 24h (0–10)	6.51 (1.71)	5.96 (2.05)	6.77 (1.73)	6.22 (1.80)	5.27 (2.09)	4.74 (2.59)	5.29 (2.51)	4.85 (2.48)	5.22 (2.49)	4.81 (2.51)
Global recovery (-5 to +5)	N/A	N/A	0.73 (1.70)	0.53 (1.60)	1.46 (1.68)	1.58 (1.62)	1.65 (1.87)	1.58 (1.78)	1.51 (1.93)	1.51 (1.75)

*n represents the number of participants with primary outcome data at each time point. TF-CBT, Trauma Focussed Cognitive Behavioural Therapy; ST, Supportive Therapy. NDI, Neck Disability Index; DASS-21, Depression Anxiety and Stress Scale-21; SF-12 PCS, Generic measure of health status – physical component; SF-12 PCS, Generic measure of health status – mental component; ; PSFS, Patient-Specific Functional Scale; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; TAMPA, Tampa Scale for Kinesiophobia; CAPS-5, Clinician Administered PTSD Scale 5; PCL-5, PTSD Checklist.

Table 3. Treatment effects expressed as predicted adjusted mean differences (95% CI) between TF-CBT + exercise and ST+ exercise group at each follow-up time point

	10 weeks			**16 weeks**			**6 months**			**12 months**		
	Mean Difference	*95% CI*		*Mean Difference*	*95% CI*		*Mean Difference*	*95% CI*		*Mean Difference*	*95% CI*	
Primary outcome												
NDI (0-100)	0.28	5.08	-4.52	0.59	5.51	-4.33	1.18	6.15	-3.78	1.85	6.81	-3.11
Secondary outcomes												
CAPS-5												
Total (0-80)	0.07	4.61	-4.48	-2.47	2.16	-7.11	-1.54	3.12	-6.20	-0.43	4.23	-5.09
CAPS-5 Cluster B	-0.15	1.26	-1.56	-0.79	0.66	-2.23	0.29	1.75	-1.16	0	1.46	-1.45
CAPS-5 Cluster C	0.27	1.04	-0.50	-0.10	0.70	-0.89	-0.48	0.32	-1.28	0.07	0.87	-0.74
CAPS-5 Cluster D	-0.42	1.46	-2.29	-1.04	0.89	-2.96	-1.68	0.25	-3.62	-0.42	1.51	-2.36
CAPS-5 Cluster E	0.03	1.31	-1.25	-0.61	0.70	-1.93	0.22	1.54	-1.10	-0.22	1.11	-1.54
PCL-5												
Total (0-80)	0.12	5.70	-5.46	-6.24[a]	-0.54	-11.94	-4.09	1.65	-9.82	-0.48	5.25	-6.22
PCL-5 Cluster B	0.28	1.69	-1.1	-1.00	0.45	-2.45	-0.74	0.72	-2.20	0.02	1.48	-1.44

			4									
PCL-5 Cluster C	-0.14	0.67	-0.94	-1.38[b]	-0.55	-2.21	-0.69	0.15	-1.53	-0.10	0.74	-0.94
PCL-5 Cluster D	-0.38	1.89	-2.64	-2.32	0	-4.64	-2.20	0.14	-4.54	-0.49	1.85	-2.83
PCL-5 Cluster E	0.24	2.03	-1.55	-1.65	0.19	-3.49	-0.43	1.43	-2.28	-0.33	1.52	-2.19
DASS												
Depression (0-42)	-2.77	0.50	-6.04	-2.73	0.64	-6.10	-2.44	0.96	-5.85	-2.58	0.82	-5.97
Anxiety (0-42)	-1.87	0.92	-4.66	-2.05	0.80	-4.90	-2.76	0.11	-5.63	-1.86	1.01	-4.73
Stress (0-42)	-0.72	2.41	-3.85	-1.56	1.66	-4.77	-1.32	1.93	-4.56	-0.12	3.12	-3.37
SF-12												
PCS	0.76	4.13	-2.61	-1.80	1.71	-5.31	-0.59	2.94	-4.12	-0.80	2.75	-4.35
MCS	2.68	6.80	-1.44	1.83	6.13	-2.46	1.27	5.58	-3.05	-1.55	2.79	-5.89
PSFS												
General (0-30)	-0.55	0.16	-1.25	-0.29	0.47	-1.04	-0.41	0.36	-1.18	0.35	1.12	-0.41
Today (0-30)	-0.55	0.40	-1.51	-0.51	0.48	-1.51	-0.30	0.73	-1.34	-0.54	0.54	-1.63

PCS												
Total (0-52)	-2.68	1.24	-6.60	-3.08	0.95	-7.10	-2.47	1.58	-6.51	-2.63	1.42	-6.67
Magnification	-0.78	0.23	-1.78	-0.60	0.43	-1.63	-0.57	0.47	-1.60	-0.52	0.51	-1.56
Rumination	-1.02	0.42	-2.45	-1.54[c]	-0.05	-3.02	-0.69	0.81	-2.18	-1.09	0.40	-2.59
Helplessness	-1.12	0.75	-2.99	-1.22	0.71	-3.15	-1.45	0.50	-3.39	-1.29	0.65	-3.23
PSEQ (0-60)	0.64	4.90	-3.62	1.71	6.09	-2.68	-0.93	3.48	-5.34	1.33	5.74	-3.07
TAMPA (17-68)	-2.55	0.16	-5.26	-1.64	1.16	-4.45	-0.87	1.94	-3.69	-3.32[d]	-0.51	-6.13
Neck pain intensity, past week (0–10)	0.13	0.87	-0.61	0.77	1.54	0	0.27	1.05	-0.50	0.48	1.26	-0.30
Neck pain intensity, past 24hr (0–10)	0.39	1.21	-0.43	0.43	1.29	-0.42	0.24	1.11	-0.62	0.30	1.17	-0.56
Global recovery (-5 to +5)	0.10	0.81	-0.61	-0.22	0.51	-0.95	0.02	0.76	-0.72	-0.17	0.57	-0.91

Results have been adjusted for baseline values. NDI, Neck Disability Index; DASS-21, Depression Anxiety and Stress Scale-21; SF-12 PCS, Generic measure of health status – physical component; SF-12 MCS, Generic measure of health status – mental component; PSFS, Patient-Specific Functional Scale; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; TAMPA, Tampa Scale for Kinesiophobia; CAPS-5, Clinician Administered PTSD Scale 5; PCL-5, PTSD Checklist. Significant positive differences favour TF-CBT; [a]p=0.032; [b]p=0.001; [c]p=0.042; [d]p=0.021.

Table 4 CAPS-5 PTSD diagnosis Contingency Tables and Risk Ratios at each time point

10 Weeks

	PTSD	No PTSD	*Total*
TF-CBT	16	27	*43*
ST	16	29	*45*
Total	*32*	*56*	*88*

RD 0.17 (95% CI -0.18 to 0.22); RR 1.047 (95% CI 0.60 to 1.82); Chi-squared p = 0.872

16 Weeks

	PTSD	No PTSD	*Total*
TF-CBT + Exercise	5	31	*36*
ST + Exercise	12	31	*43*
Total	*17*	*62*	*79*

RD -0.14 (95% CI -0.32 to 0.04); RR 0.50 (95% CI 0.19 to 1.28); Chi-squared p=0.131

6 Months

	PTSD	No PTSD	*Total*
TF-CBT + Exercise	5	33	*38*
ST + Exercise	11	29	*40*
Total	*16*	*62*	*78*

RD -0.14 (95% CI -0.32 to 0.03); RR 0.48 (95% CI 0.18 to 1.25); Chi-squared p=0.117

12 Months

	PTSD	No PTSD	*Total*
TF-CBT + Exercise	6	30	*36*
ST + Exercise	6	37	*43*
Total	*12*	*67*	*79*

RD 0.03 (95% CI -0.13 to 0.19); RR 1.19 (95% CI 0.42 to 3.38); Chi-squared p=0.738

Figure 1. Flow of participants through the trial