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Trauma-focused cognitive behaviour therapy and exercise for chronic whiplash: protocol of a randomised, controlled trial

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Abstract

Introduction: As a consequence of a road traffic crash, persistent pain and disability following whiplash injury are common and incur substantial personal and economic costs. Up to 50% of people who experience a whiplash injury will never fully recover and up to 30% will remain moderately to severely disabled by the condition. The reason as to why symptoms persist past the acute to sub-acute stage and become chronic is unclear, but likely results from complex interactions between structural injury, physical impairments, and psychological and psychosocial factors. Psychological responses related to the traumatic event itself are becoming an increasingly recognised factor in the whiplash condition. Despite this recognition, there is limited knowledge regarding the effectiveness of psychological interventions, either delivered alone or in combination with physiotherapy, in reducing the physical and pain-related psychological factors of chronic whiplash. Pilot study results have shown positive results for the use of trauma-focused cognitive behaviour therapy to treat psychological factors, pain and disability in individuals with chronic whiplash. The results have indicated that a combined approach could not only reduce psychological symptoms, but also pain and disability. **Aims:** The primary aim of this randomised, controlled trial is to investigate the effectiveness of combined trauma-focused cognitive behavioural therapy, delivered by a psychologist, and physiotherapy exercise to decrease pain and disability of individuals with chronic whiplash and post-traumatic stress disorder (PTSD). The trial also aims to investigate the effectiveness of the combined therapy in decreasing post-traumatic stress symptoms, anxiety and depression. **Participants and setting:** A total of 108 participants with chronic whiplash-associated disorder (WAD) grade II of > 3 months and < 5 years duration and PTSD (diagnosed with the Clinician Administered PTSD Scale (CAPS) according to the DSM-5) will be recruited for the study. Participants will be assessed via phone screening and in person at a university research laboratory. Interventions will take place in southeast Queensland, Australia and southern Denmark. **Intervention:** Psychological therapy will be delivered once a week over 10 weeks, with participants randomly assigned to either trauma-focused cognitive behavioural therapy or supportive therapy, both delivered by a clinical psychologist. Participants will then receive ten sessions of evidence-based physiotherapy exercise delivered over a 6-week

period. **Outcome measures:** The primary outcome measure is neck disability (Neck Disability Index). Secondary outcomes focus on: pain intensity; presence and severity of PTSD (CAPS V and PTSD Checklist 5); psychological distress (Depression, Anxiety Stress Scale 21); patient perceived functionality (SF-12, Tampa Scale of Kinesiophobia, and Patient-Specific Functional Scale); and pain-specific self-efficacy and catastrophising (Pain Self-Efficacy Questionnaire and Pain Catastrophizing Scale). After psychotherapy (10 weeks after randomisation) and physiotherapy (16 weeks after randomisation), as well as at the 6-month and 12-month follow-ups, a blind assessor will measure the outcomes. **Analysis:** All analyses will be conducted on an intention-to-treat basis. The primary and secondary outcomes that are measured will be analysed using linear mixed and logistic regression models. Any effect of site (Australia or Denmark) will be evaluated by including a site-by-treatment group-by-time interaction term in the mixed models analyses. Effect modification will only be assessed for the primary outcome of the Neck Disability Index. **Discussion:** This study will provide a definitive evaluation of the effects of adding trauma-focused cognitive behaviour therapy to physiotherapy exercise for individuals with chronic WAD and PTSD. This study is likely to influence the clinical management of whiplash injury and will have immediate clinical applicability in Australia, Denmark and the wider international community. The study will also have implications for both health and insurance policy makers in their decision-making regarding treatment options and funding.

Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR). **Registration number:** ACTRN12615000547549. **Was this trial prospectively registered:** Yes. **Date of trial registration:** 28 May 2015. **Funded by:** National Health and Medical Research Council and the Danish Victims Fund. **Funder approval number:** NHMRC 569803 and DVF 14-910-00013. **Anticipated completion date:** December 2018. **Provenance:** Not invited. Peer-reviewed. **Corresponding author:** Michele Sterling, Menzies Health Institute Queensland, Griffith University, Gold Coast, Australia 4022. Email: m.sterling@griffith.edu.au

Full protocol: Available on the eAddenda at [doi:10.1016/j.jphys.2015.07.003](https://doi.org/10.1016/j.jphys.2015.07.003)