Physiotherapist-delivered stress inoculation training integrated with exercise versus physiotherapy exercise alone for acute whiplash-associated disorder (StressModex)

Physiotherapist-delivered stress inoculation training integrated with exercise versus physiotherapy exercise alone for acute whiplash-associated disorder (StressModex): a randomised controlled trial of a combined psychological/physical intervention

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ABSTRACT

Objective There are few effective treatments for acute whiplash-associated disorders (WAD). Early symptoms of postinjury stress predict poor recovery. This randomised controlled trial (StressModex) investigated whether physiotherapist-led stress inoculation training integrated with exercise is more effective than exercise alone for people with acute WAD.

Methods 108 participants (<4 weeks) at risk of poor recovery (moderate pain-related disability and hyperarousal symptoms) were randomly assigned by concealed allocation to either physiotherapist-led stress inoculation training and guideline-based exercise (n=53) or guideline-based exercise alone (n=55). Both interventions comprised 10 sessions over 6 weeks. Participants were assessed at 6 weeks and at 6 and 12 months postrandomisation. Analysis was by intention to treat using linear mixed models.

Results The combined stress inoculation training and exercise intervention was more effective than exercise alone for the primary outcome of pain-related disability at all follow-up points. At 6 weeks, the treatment effect on the 0–100 Neck Disability Index was (mean difference) −10 (95% CI −15.5 to −4.48), at 6 months was −7.8 (95% CI −13.8 to −1.8) and at 12 months was −10.1 (95% CI −16.3 to −4.0). A significant benefit of the stress inoculation and exercise intervention over exercise alone was also found for some secondary outcomes.

Conclusion A physiotherapist-led intervention of stress inoculation training and exercise resulted in clinically relevant improvements in disability compared with exercise alone—the most commonly recommended treatment for acute WAD. This contributes to the case for physiotherapists to deliver an early psychological intervention to patients with acute WAD who are otherwise at high risk of a poor outcome.

Trial registration number ACTRN12614001036606.

What are the findings?

- Physiotherapist-delivered stress inoculation training integrated with guideline-based exercise results in greater and clinically relevant improvements in pain-related disability compared with guideline-based physiotherapy exercise alone.
- The treatment benefit was maintained at 12-month follow-up.
- Physiotherapist-delivered stress inoculation training integrated with guideline-based exercise results in clinically relevant improvements in stress, depressive symptoms, pain self-efficacy, perceived recovery and pain compared with guideline-based physiotherapy exercise alone.

How might it impact on clinical practice in the future?

- These results support the use of physiotherapist-delivered stress inoculation training and exercise for people with acute whiplash-associated disorders at risk of poor recovery.
- Physiotherapists are the most commonly used practitioner delivering care to patients with acute whiplash-associated disorder, and with some additional training this approach to early management could be considered for all whiplash-injured patients at risk of poor recovery.

INTRODUCTION

Whiplash-associated disorders (WADs) are the most common non-hospitalised injuries following a road traffic crash (RTC)[1] and are a large public health problem in Western countries incurring significant economic and social costs.[1 2] Systematic reviews have demonstrated that approximately 50% of those injured will continue to report symptoms years after the injury, with 30% having moderate to severe pain and disability.[3 4] As most recovery, if it occurs, takes place in the first 2–3 months postinjury,[4] appropriate early treatment may prevent later chronic pain and disability.

Current clinical guidelines recommend exercise and activity for acute WAD,[5] but several systematic reviews conclude that exercise/activity-based interventions provide only small effects.[6–8] Those interventions have followed a traditional biomedical

approach and not addressed psychological responses to the injury. WADs are heterogeneous conditions and patients present with varying levels of pain, disability and psychological distress. Acute symptoms of postinjury stress predict poor recovery at long-term follow-up,[9 10] and these symptoms may contribute to pain developing and persisting.[11 12] We postulated that targeting early stress symptoms in patients identified at risk of poor recovery[13] might limit disability and alleviate pain compared with exercise alone.

Non-psychologist practitioners such as physiotherapists are increasingly being used to deliver psychological interventions for musculoskeletal pain. Most trials using physiotherapists in this role have focused on already chronic conditions such as chronic WAD,[14] chronic low back pain and arthritis, and have targeted mainly pain-related cognitions.[15 16] Few trials have investigated physiotherapists delivering a psychological intervention in the acute stage of injury and none have addressed stress-related symptoms. Stress inoculation training is a cognitive behavioural approach that facilitates general problem solving and coping strategies to manage stress-related anxiety.[17] It has shown positive effects in randomised trials of sexual assault victims and orthopaedic inpatients.[17 18]

Therefore, we tested a physiotherapist-delivered stress inoculation training integrated with guideline-based exercise compared with guideline-based exercise alone for people with acute WAD at risk of poor recovery.

METHODS

StressModex is a parallel-group, assessor-blinded, randomised controlled trial with participants recruited from sites in Queensland, Australia, between 3 October 2014 and 23 January 2017, and follow-up at 6 weeks and at 6 and 12 months. The trial was prospectively registered at the Australian New Zealand Clinical Trials Registry, and the study protocol has been previously published.[19]

Two protocol deviations were made. The original protocol specified that the Acute Stress Disorder Scale (ASDS) was to be used as a screen for inclusion/exclusion and as a secondary outcome measure at each follow-up point. Due to its overlap with the Posttraumatic Stress Diagnostic Scale (PDS) and to reduce participant burden, the ASDS was only used for inclusion/exclusion and not as a secondary outcome. The sample size proposed in the original protocol included a 15% loss to follow-up. We decided prior to the trial commencement to increase this to 20%, and this increased the sample size from 100 to 108.

Setting and participants

Community-dwelling participants were recruited by advertisement in local and metropolitan newspapers, radio and online media, from primary care practices (general practitioner and physiotherapy) as well as from the Emergency Department of the Gold Coast University Hospital.

Participants were eligible for inclusion if they met all of the following criteria: grade 2 or 3 WAD less than 4 weeks in duration; currently experiencing at least moderate pain-related disability (Neck Disability Index [NDI]: ≥32%) and hyperarousal symptoms (≥3 hyperarousal subscale of the PDS)[13 20]; not currently receiving care for whiplash (excluding medications); aged 18–65 years; and proficient written and spoken English.

The exclusion criteria were known or suspected serious spinal pathology (eg, metastatic disease of the spine); confirmed fracture or dislocation at time of injury (WAD grade 4);[21] fracture or injuries to other body regions; spinal surgery in the past 12 months; meeting the criteria for probable acute stress disorder diagnosis on the ASDS [22]screening positive for a current major depressive episode on the Patient Health Questionnaire-9 (PHQ-9); and a history of psychosis, bipolar disorder or depression.

Randomisation and masking

Volunteers were screened by telephone by a research physiotherapist. If eligible they completed baseline assessment via online forms sent via the RedCap (Research Electronic Data Capture) program. Participants were mailed the forms to complete if they did not have internet access. After baseline assessment, eligible participants were randomised using a computer-generated randomisation schedule consisting of random permuted blocks of 4–8, produced before the trial start by an independent statistician, to receive one of the following interventions:

- Stress inoculation training and guideline-based exercise delivered by a physiotherapist.
- Guideline-based exercise alone delivered by a physiotherapist.

To ensure allocation was concealed, participants were randomly assigned immediately after baseline assessment by opening the next sealed, sequentially numbered, opaque envelope. Participants were deemed to have entered the study at the time that the envelope was opened.

The research staff who were involved in the baseline and follow-up assessments were blinded to the treatment allocation of the participants.

Study interventions

All participants were provided with the patient educational booklet entitled whiplash injury recovery: a self-management

Table 1 Outline of interventions

Week	Sessions/ Week	SIT and physiotherapy exercise	Standard physiotherapy exercise
1	2	*Session 1*: Introduction to SIT, theories of stress and pain, abdominal breathing exercises. Physiotherapy exercise. *Session 1b*: Physiotherapy exercise.	*Session 1*: Physiotherapy exercise. *Session 1b*: Physiotherapy exercise.
2	2	*Session 2*: Muscle relaxation training (body scan). Physiotherapy exercise. *Session 2b*: Physiotherapy exercise.	*Session 2*: Physiotherapy exercise. *Session 2b*: Physiotherapy exercise.
3	2	*Session 3*: Problem solving for stressful situations. Physiotherapy exercise. *Session 3b*: Physiotherapy exercise.	*Session 3*: Physiotherapy exercise. *Session 3b*: Physiotherapy exercise.
4	2	*Session 4*: Use of positive coping statements. Physiotherapy exercise. *Session 4b*: Physiotherapy exercise.	*Session 4*: Physiotherapy exercise. *Session 4b*: Physiotherapy exercise.
5	1	*Session 5*: Applying SIT to the real world. Physiotherapy exercise.	*Session 5*: Physiotherapy exercise.
6	1	*Session 6*: Coping skills maintenance. Physiotherapy exercise.	*Session 6*: Physiotherapy exercise.

Therapist contact time was a maximum of 50 min per session for both groups.
SIT, stress inoculation training.

guide which provides information and advice about WAD and self-management.[23]

Participants in both groups were asked not to seek other treatments and where possible not to change current medications for the 6-week intervention period. The participants' nominated general practitioner was notified in writing of the individual's participation in the trial. The general practitioners were asked within reason to refrain from referring or suggesting additional or alternative treatments for the initial 6 weeks after randomisation.

Guideline-based exercise

The exercise programme adheres to the recommendations of the current Australian guidelines for the management of acute whiplash.[17] The 6-week (10 sessions) exercise programme was carried out under the supervision of the physiotherapist (2 sessions/week in weeks 1–4 and 1 session/week in weeks 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 submaximum and progressive manner. Participants were encouraged to perform the exercises at home, once per day. Written and illustrated exercise instructions were provided. A logbook was completed by participants to record compliance with the exercises. At the physiotherapist's discretion, manual therapy (but not grade V manipulation) was allowed, but it was emphasised that this was not a major component of the intervention. The exercise programme has been described in detail elsewhere[19] and is available in online supplementary appendix 1.

Stress inoculation training and exercise

The exercise programme provided was identical to that described above.

In addition, the physiotherapist provided six sessions (one per week) of stress inoculation training, teaching strategies to assist participants in managing acute stress responses. It consisted of three phases: (1) identify and understanding stress—identifying specific stressors and how these affect pain, behaviour, emotions, physical performance and thoughts; (2) developing skills for managing stress, such as relaxation, problem solving and helpful coping self-statements; and (3) applying skills in various stressful situations to develop tolerance and confidence. Participants were encouraged to practise these skills on a weekly basis with home practice. Further details of the stress inoculation training intervention are provided in online supplementary appendix 1.

For both study arms, all sessions were for a maximum of 50 min.

An overall outline of the week-to-week delivery of the interventions is illustrated in table 1, with full details available in online supplementary appendix 1.

Physiotherapist training and treatment fidelity

To avoid contamination, different physiotherapists were used to deliver the stress inoculation training and exercise (10 physiotherapists) or standard physiotherapy exercise (11 physiotherapists) interventions. Those who delivered the exercise-alone intervention had never been trained in the stress inoculation training intervention.

All treatments were delivered by physiotherapists with experience in the delivery of treatments as part of clinical trials and in the delivery of the exercise programme used in the trial. Before the start of the trial, physiotherapists were again trained in the exercise intervention with a half-day workshop, with the physiotherapists who delivered the combined intervention receiving an additional 1.5 days training in stress inoculation. The exercise training was provided by MS, an experienced musculoskeletal physiotherapist, and the stress inoculation training by JK, a clinical psychologist, and RS, a rehabilitation physician. After the training, the physiotherapists delivering the stress inoculation intervention audiotaped the practice sessions of each of the six components. These were audited by JK and RS and the physiotherapists provided with feedback. The physiotherapists could not commence delivering the trial treatments until it was deemed that they could successfully deliver the intervention. Midway through the trial, a refresher training session of 1 day was provided to the physiotherapists delivering the combined intervention.

The physiotherapists completed a session-by-session checklist of adherence to protocol and were required to provide audio recordings of their stress inoculation sessions, a random sample of which was formally evaluated by an independent psychologist. The physiotherapy exercise sessions were audited twice per physiotherapist (MS) to check for adherence.

Outcome measures

All outcome measures were completed online through the RedCap platform or via mail. Investigators following up participants in any way to complete outcome measures were blinded to group allocation. Demographic characteristics such as age, educational level, working status, medical history, present medications, previous investigations and treatment, as well as information about symptoms, injury event and compensation status, were obtained at baseline.

The primary outcome measure was the NDI,[24] a valid, reliable and responsive measure of neck pain-related disability,[24] scored 0–100, with a higher score indicating greater disability.

Secondary outcomes included the following: PDS[25]; the Depression, Anxiety and Stress Scale (DASS)[26]; the Pain Catastrophizing Scale[27]; the Pain Self-Efficacy Questionnaire (PSEQ)[28]; the Coping Strategies Questionnaire[29]; self-rated global impression of recovery measured using an 11-point scale that ranges from −5 (vastly worse) to +5 scale (completely recovered), with 0 indicating unchanged[30]; the average pain intensity over the last week and the last 24 hours measured with 0 (no pain) and 10 (worst possible pain) in a Numeric Rating Scale and the physical and mental subscales of the Short-Form 36.[31] All secondary measures are described in online supplementary appendix 2.

Participants also completed a process measure, the Credibility/Expectancy Questionnaire (CEQ)[32 33] following the initial session with the treating physiotherapist. The CEQ provides a measure of how the participant thinks and feels about the treatment (online supplementary appendix 2).

We identified serious adverse events (defined as an event that is life-threatening, requires inpatient hospitalisation, or will result in persistent or significant disability or incapacity) and adverse effects (defined as an exacerbation of a pre-existing condition such as neck pain or headache) of treatment with open-ended questioning at the 6-week follow-up assessment.

Statistical analysis

An independent study statistician undertook the analyses and was blinded to group allocation. Sample size calculations were based on the ability to detect a clinically important difference of 10 points[24 34] on the 100-point NDI between the two treatment groups. This was determined using a two-sided t-test with a type 1 error rate of 0.05, power of 0.80 and allowing for 20% loss to follow-up by 12 months with an assumed SD of 16, based on previously collected pilot data and data from recent trials. Using these parameters, the calculated total sample size was 108 participants (54 participants per group).

Statistical analyses were conducted on an intention-to-treat basis using IMB SPSS Statistics V.24. To account for repeated outcome measurement, a linear mixed modelling approach was employed. 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. For each outcome, the difference in estimated marginal means (95% CI) between the groups was obtained at each time point, after adjustment for baseline measurement. All outcomes were continuous. A p value <0.05 was used to define statistical significance. Effect sizes (Cohen's D) were also produced for all continuous outcomes at each time point.

Additional analyses were undertaken at 6 weeks, with a Fisher's exact test used to determine group differences in self-rated global impression of recovery when dichotomised into success defined as much to very much improved (score +4 or +5).[35]

Patient involvement

A patient representative of the National Health and Medical Research Council of Australia (NHMRC) Centre of Research Excellence in Road Traffic Injury Recovery was involved in the initial discussions of the intervention to be tested. They were not involved in the development of the plans for recruitment, design, outcome measures or the conduct of the study. No patients were asked to advise on the interpretation or writing of results. The burden of the intervention was not assessed, but patients were asked at each follow-up if they had any concerns with the treatment and we also assessed the credibility of the interventions and patient expectations of outcome. We intend to disseminate the trial results to the participants and will pursue patient and other relevant stakeholder involvement in the development of a dissemination plan.

RESULTS

Enrolment and follow-up

All participants were classified as grade 2 WADs. Figure 1 outlines the flow of participants through the trial. A total of 108 participants consented and were randomised. Of the 53 participants randomised to the stress inoculation and exercise group, the primary outcome measure (NDI) was completed by 51 (96%) participants at 6 weeks, 49 (92%) at 6 months and 50 (94%) at 12 months. Of the 55 participants randomised to the exercise-only group, NDI was completed by 51 participants (93%) at 6 weeks, 49 (89%) at 6 months and 48 (87%) at 12 months. There was some variation in the number of participants completing the secondary outcome measures over time in both groups, with these differences noted in table 3. Twenty-one physiotherapists (10 delivered the integrated intervention and 11 the standard exercise) delivered the trial treatments across 12 private physiotherapy clinics.

Table 2 shows the baseline characteristics for both groups. Participants were mainly middle-aged and predominantly female. The average time since their RTC injury was 16.4 (7.7) days. In both groups, approximately one-third of the participants had lodged a claim for compensation, with a compulsory third-party motor vehicle claim being the most common claim type. Twenty per cent of participants had engaged a solicitor. Queensland operates under a fault-based third-party compensation scheme, where only those deemed not at fault for the motor vehicle crash (MVC) can claim for compensation. Participants reported moderate levels of pain and disability and lower quality of life than Australian norms (table 3). Scores on all items of the CEQ were the same for both groups (table 2).

No serious adverse events were reported. One participant in each group recorded an adverse effect in the form of neck pain exacerbation. Neither of these participants withdrew from the trial because of adverse effects.

Adherence with treatment was good, with the median (IQR) number of sessions attended for both the stress inoculation and exercise and exercise-only groups being 10[9 10] out of a maximum of 10 sessions. Eight participants in the exercise-only group did not attend the full 10 sessions but attended a mean (SD) of 6.5 (2.4) sessions. Nine participants in the stress inoculation and exercise group did not attend the full 10 sessions, with the mean (SD) attendance being 6 (2.2). Physiotherapist adherence to the trial treatment protocols was excellent based on independent review of randomly selected sessions. For the audiotaped stress inoculation training sessions, 10% of the sessions were audited and adherence to the protocol was 94.6%±10.6%. For the completed proformas of the exercise sessions, adherence was 93%±4%.

Primary outcome

In the primary analysis, the stress inoculation and exercise group improved significantly more than the exercise-alone group at each time point (estimated mean difference between groups at 6 weeks=−10.0 points [95%CI −15.5 to −4.48, Cohen's D=−0.7, p<0.01]; at 6 months=−7.8 points [95%CI −13.8 to −1.8, D=−0.52, p<0.05]; at 12 months=−10.1 points [95%CI −16.3 to −4.0, D=−0.66, p<0.01]). Based on an estimated minimal clinically important difference for the NDI of 7–10 percentage points,[24 34 36] the difference between the interventions is clinically important at each time point. Table 3 and figure 2 show the unadjusted NDI scores for each group, and table 4 shows the treatment effect for the stress inoculation and exercise group compared with the exercise-alone group at each follow-up time point.

Secondary outcomes

The stress inoculation and exercise group also improved significantly more than the exercise-alone group on several secondary outcomes at various time points. Tables 3 and 4 show the results for the secondary outcomes. A significantly greater proportion of participants in the stress inoculation and exercise group (41%, n=21) reported that their condition was improved/much improved compared with the exercise-only group (18%, n=9) (Fisher's exact test $\chi^2=8.01$, p<0.05).

Some of these effects are clinically important, although it should be noted that the minimal clinically important differences have been defined in conditions other than WAD. These include DASS stress scores at 6 weeks and DASS depression scores at 6 weeks and 6 months (minimal clinically important difference—DASS stress score of 5.55 and DASS depression score of 3.86[21]);

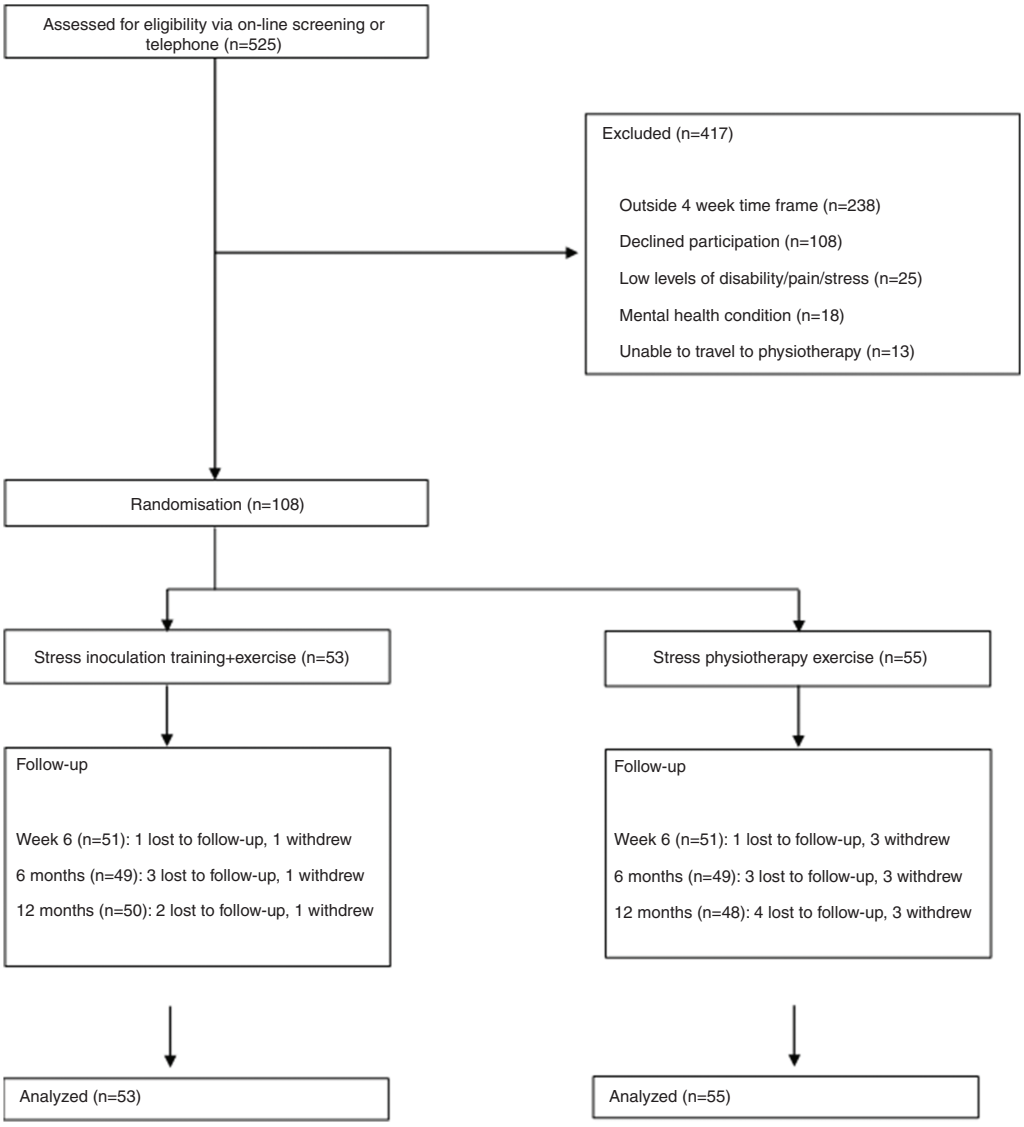

Figure 1 Flow of participants through the trial.

PSEQ scores at 12 months (PSEQ minimal clinically important difference is 5.5[22]); and global perceived recovery at 6 weeks (minimal clinically important difference is 1.35[37]). Group differences in Mental Health Component Scores (MCS) at 6 weeks and 6 months were greater than 4.95 (ie, half the SD seen in the Australian population[38]) and may reflect a clinically important difference.

DISCUSSION

Principal findings

The StressModex trial found that physiotherapist-led stress inoculation training and exercise results in greater improvements in neck pain-related disability compared with exercise alone for patients with acute WAD. Clinically relevant benefits of the combined intervention were found for the primary outcome (NDI)[24 34] in the short (6 weeks), medium (6 months) and long (12 months) term, indicating a sustained effect of the intervention over time. Significant effects of the combined intervention were also found for many secondary outcomes, including pain and mental health outcomes. No serious adverse events related to the interventions were reported.

Comparison with other trials

Previous trials of treatment for acute WAD have predominantly focused on exercise treatments and found mostly small effects.[6 7] One large high-quality trial conducted in the UK (Managing Injuries of Neck Trial (MINT) trial) showed a small effect of a six-session physiotherapy exercise package over advice alone at 4 months' follow-up (NDI −3.7 [−6.1 to −1.3]) but not in the longer term of 8 and 12 months.[39] Much greater effects were found for the same outcome in the StressModex trial. This might be due to our objective of specifically targeting stress-related symptoms, a known risk factor for poor recovery after whiplash injury.[9] The MINT trial intervention included simple strategies for dealing with psychological factors where the physiotherapists questioned patients to identify treatment targets, such as beliefs about pain and coping strategies. Subsequent management included goal setting, pacing, education about pain and recovery, facilitation of effective coping strategies, and reassurance. Physiotherapists also screened for post-traumatic stress symptoms and referred when necessary, although details of how decisions around this process were made were not explained.[40] It is possible that the approach used in the MINT trial was too

Table 2 Baseline characteristics of trial participants, by treatment group

Characteristic	Stress inoculation training and exercise (n=53)	Standard exercise (n=55)
Age, years, mean (SD)	43.4 (14.3)	39.3 (13.9)
Female	36 (67.9)	31 (56.4)
Highest education level*		
Year 9 or 10	12 (22.6)	6 (10.9)
Year 11 or 12	10 (18.9)	15 (27.3)
Technical/Trade qualification	11 (20.8)	14 (25.5)
Undergraduate	10 (18.9)	10 (18.2)
Postgraduate	10 (18.9)	9 (16.4)
Working status*		
Employed	34 (64.2)	30 (54.5)
Self-employed	6 (11.3)	14 (25.5)
Home duties	3 (5.7)	3 (5.5)
Unemployed	5 (9.4)	4 (7.3)
Retired	5 (9.4)	3 (5.5)
If employed, are you working usual hours?		
Yes, working usual hours	17 (42.5)	30 (68.2)
Working reduced hours	13 (32.5)	9 (20.5)
Not working	10 (25.0)	5 (11.4)
Role in the crash*		
Driver	37 (69.8)	45 (81.8)
Back seat passenger	1 (1.9)	1 (1.8)
Front seat passenger	12 (22.6)	4 (7.3)
Motorbike rider	3 (5.7)	4 (7.3)
Knew the accident was coming*	6 (11.3)	12 (21.8)
Type of collision*		
Rear end	19 (35.8)	22 (40.0)
Front end	17 (32.1)	15 (27.3)
Rear and front end	7 (13.2)	8 (14.5)
Side impact	10 (18.9)	9 (16.4)
Vehicle was stationary at time of impact*	19 (35.8)	23 (41.8)
How soon following the accident did your neck pain start?*		
Immediately	26 (49.1)	27 (49.1)
Within 24 hours	19 (35.8)	25 (45.5)
After 24 hours	8 (15.1)	2 (3.6)
Compensation claim lodged*	17 (32.1)	18 (32.7)
What type of compensation claim?		
Compulsory third-party claim	10 (58.8)	15 (83.3)
Worker's compensation	5 (29.4)	3 (16.7)
Other	2 (11.8)	0 (0.0)
Compensation claim has settled	3 (17.6)	2 (11.1)
A solicitor has been engaged*	10 (18.9)	11 (20.0)
Investigations*		
X-rays	25 (47.2)	25 (45.5)
MRI	6 (11.3)	10 (18.2)
CT scan	16 (30.2)	19 (34.5)
Present drugs for whiplash-associated disorder*		
No drugs	8 (15.1)	12 (21.8)
NSAIDs only	12 (22.6)	10 (18.2)
Paracetamol only	14 (26.4)	15 (27.3)
Paracetamol and opioid	4 (7.5)	2 (3.6)
Opioid only	4 (7.5)	4 (7.3)
Benzodiazepine only	2 (3.8)	2 (3.6)
Other drugs/combinations	9 (17.0)	9 (16.4)
Previous treatment*		
Physiotherapy	6 (11.3)	11 (20)
Chiropractic	4 (7.5)	2 (3.6)
Massage	11 (20.7)	14 (25.4)
Acupuncture	5 (9.4)	4 (7.2)
Other (eg, osteopathy)	4 (7.5)	4 (7.2)
No treatment	31 (58.5)	27 (49)
Neck pain intensity over the past week, 0–10*, mean (SD)	5.8 (1.7)	5.4 (1.5)
Neck pain intensity over the past 24 hours, 0–10*, mean (SD)	5.4 (1.8)	5.2 (1.9)
Credibility/Expectancy Questionnaire*, mean (SD)		
Treatment credibility, 3–27	22.8 (3.5)	21.9 (3.4)
Treatment expectancy, 3–27	21.3 (3.5)	21.6 (4.0)

Data are expressed as n (%) except where indicated.
*Missing data for one participant in the exercise-alone group.
NSAIDs, non-steroidal anti-inflammatory drugs.

broad, and although attempted to address psychosocial factors lacked the specificity to be effective. Physiotherapists report difficulty identifying and lack confidence to manage psychological factors in people with musculoskeletal pain,[41] most likely due to a lack of training in these aspects. The fact that our trial specifically targeted one psychological risk factor and trained physiotherapists in its management as opposed to a more broad approach may be the reason for the stronger effects seen.

Additionally, all clinical trials to date have considered the condition as homogeneous and included all patients regardless of their presentation. However, there are consistent data to show WAD, particularly grade 2 disorders, is heterogeneous with varying levels of pain, disability and psychological factors,[4] with some of these factors being prognostic for poor recovery.[9] In StressModex, we specifically included patients at risk of poor recovery.[13 20] Those with good potential for recovery (eg, lower levels of pain, disability and stress) would be unlikely to benefit from strategies to target stress-related symptoms that they do not report, and we propose that these low-risk patients will recover well with less intensive intervention. Further to this, a greater number of treatments provided to people with acute WAD may lead to poorer outcomes,[42] indicating the importance of differentiating patients on their risk or not of developing chronic pain. By providing more concerted targeted treatments to those who need them most (patients at risk of poor recovery), the iatrogenic effects of providing the same treatment to those who do not need it may be avoided.

One previous trial found no effect of an early multidisciplinary (medication, physiotherapy and psychology according to their presentation) versus usual care for acute WAD.[43] In this trial, patients in the multidisciplinary arm were less compliant with psychology treatment compared with physiotherapy. Patients in the acute stage of a physical injury may not see the relevance of seeing a psychologist for what they perceive is a physical injury. This factor may also explain the smaller effects found in the MINT trial, where patients with post-traumatic stress symptoms were referred to a psychologist.[40] The StressModex trial attempted to overcome these barriers by using physiotherapists to deliver early psychological care, and we have demonstrated greater effect on later disability, pain and mental health

Table 3 Unadjusted mean (SD) for each outcome by treatment group and follow-up time point

	Baseline		6 weeks		6 months		12 months	
	SIT + exercise (n=53)	Standard exercise (n=55)	SIT + exercise (n=51)	Standard exercise (n=51)	SIT + exercise (n=49)	Standard exercise (n=49)	SIT + exercise (n=50)	Standard exercise (n=48)
Primary outcome								
NDI (0–100)	44.9 (13.9)	41.7 (11.2)	25.5 (18.5)	33.1 (16.4)	24.8 (19.9)	27.9 (16.2)	23.6 (20.2)	28.7 (17.1)
Secondary outcomes								
PDS (0–51)	20.9 (12.2)	16.0 (10.3)	12.1 (12.0)	13.1 (10.3)	9.5 (12.2)	10.2 (10.3)	11.2 (12.4)	10.7 (9.6)
DASS-Stress (0–42)	15.8 (10.1)	14.2 (9.6)	10.5 (8.7)	15.4 (9.4)	11.0 (9.7)	13.7 (8.5)	12.4 (10.1)	13.1 (8.9)
DASS-Anxiety (0–42)	12.0 (10.3)	7.6 (8.3)	7.0 (8.4)	7.0 (7.9)	7.5 (7.8)	7.5 (7.7)	9.3 (9.8)	7.0 (6.9)
DASS-Depression (0–42)	12.7 (10.7)	9.4 (9.3)	7.8 (8.8)	9.7 (8.7)	8.0 (9.1)	9.7 (8.6)	9.7 (10.5)	9.7 (9.9)
PCS (0–52)	17.5 (12.8)	16.7 (13.2)	8.8 (9.7)	11.3 (11.3)	9.9 (13.1)	10.7 (10.5)	10.0 (12.1)	10.6 (12.4)
PSEQ (0–60)	27.5 (14.0)	32.8 (13.7)	41.5 (15.4)	41.7 (15.1)	38.4 (19.5)	41.6 (15.0)	41.1 (18.4)	39.5 (15.8)
CSQ (−72 to 180)	44.4 (29.5)	41.8 (23.5)	64.0 (36.4)	48.5 (31.2)	54.6 (38.3)	41.6 (28.8)	61.2 (36.5)	43.7 (31.8)
SF-36-PCS	36.5 (8.4)	38.4 (7.8)	43.0 (10.6)	45.2 (9.7)	43.7 (11.5)	46.7 (9.2)	44.7 (11.1)	45.1 (9.8)
SF-36-MCS	33.2 (12.7)	37.8 (11.3)	40.1 (12.6)	35.5 (13.1)	40.9 (13.6)	38.3 (11.3)	40.6 (13.5)	39.5 (11.5)
Average pain intensity in the past 24 hours (0–10)	5.4 (1.8)	5.2 (1.9)	2.5 (2.2)	3.7 (2.4)	2.6 (2.4)	3.4 (2.5)	2.9 (2.3)	3.7 (2.7)
Global recovery (−5 to +5)	NA	NA	2.9 (1.8)	1.3 (2.5)	2.5 (2.3)	1.8 (2.4)	2.5 (2.3)	1.5 (2.3)

Each column n primarily reflects the number of participants with primary outcome data. For the secondary outcomes, differences in n were noted for (1) baseline (exercise alone, n=54), (2) 6 weeks (exercise alone, n=50), (3) 6 months (SIT + exercise [n=47 for PDS, PSEQ and average pain intensity; n=46 for PCS and SF-36; and n=45 for DASS and CSQ] and exercise alone [n=47]); and (4) 12 months (SIT + exercise [n=48 except for global recovery where n=49] and exercise alone [n=46 except for PCS where n=47]).
CSQ, Coping Strategies Questionnaire; DASS, Depression Anxiety and Stress Scale; NA, not available; NDI, Neck Disability Index; PCS, Pain Catastrophizing Scale; PDS, Posttraumatic Stress Diagnostic Scale; PSEQ, Pain Self-Efficacy Questionnaire; SIT, stress inoculation training; SF-36, Short-Form 36.

outcomes. We have also shown that with training, physiotherapists can successfully and effectively deliver a psychological type of intervention.

The stress inoculation intervention included sessions to recognise the effect of stress on pain, strategies to modulate stress, problem solving and coping skills, and focused on the transfer of these skills to daily life. The significant effects on stress symptoms (DASS) at all time points suggest that it was effective in improving patients' stress symptoms. Whether or not the reduction in stress acts as a mediating variable for the effect on disability cannot be determined from the results of this trial but would warrant further investigation.

Strengths and limitations

The StressModex trial has several strengths and limitations. The trial followed a prespecified protocol and included design features to minimise bias, including assessor blinding, concealed allocation and intention-to-treat analysis. Participant retention was high, participants complied with treatment attendance, and physiotherapists adhered to the treatment protocol. The participants represented people with acute WAD and compared well with cohorts of previous studies.[39 43]

Strengths also included direct comparing of two non-drug treatments—the exercise component is the most commonly recommended and used treatment for acute WAD.[5] What was our innovation? We added a treatment that targeted a known risk factor for poor recovery (stress) in patients with complex whiplash, which is usually resistant to treatment. The number of treatments and the treatment time per session in both interventions were equal.

There are some limitations. Participants were aware of their treatment group assignment. The nature of the intervention also meant that it was not possible to blind the physiotherapist providers. However, treatment expectations were no different between the two groups. In terms of generalisability, participants with a history of mental health diagnoses were excluded as were those who scored highly on the ASDS and the depression screen, the PHQ-9. Thus our findings are not generalisable to those with a diagnosable mental health condition. In these cases, patients would require assessment by a qualified mental health professional, and it was certainly not our aim for physiotherapists to provide treatment to such patients.

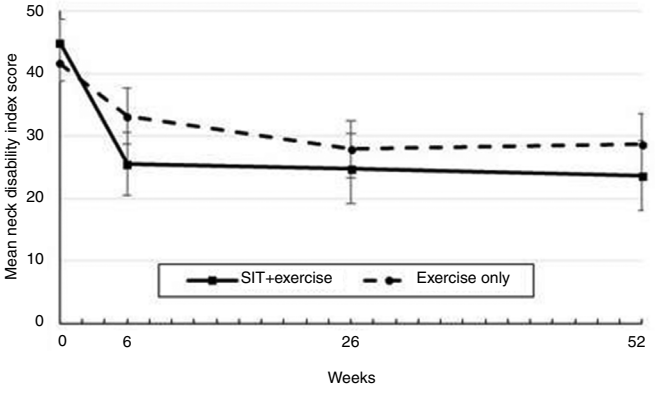

Figure 2 Primary outcome measure, mean Neck Disability Index (0–100) at 6, 26 (6 months) and 52 (12 months) weeks for each patient group. 95% CI also shown. SIT, stress inoculation training.

Clinical implications

When physiotherapists deliver a combined stress inoculation training and exercise, patients report clinically relevant reductions in pain-related disability compared with when physiotherapists deliver guideline-based exercise alone. Our format of integrating stress inoculation training with the guideline-recommended treatment of exercise over 10 sessions fits well with usual care for acute WAD commonly provided throughout the world.

Our results apply to the many jurisdictions worldwide that wrestle with the health burden of WAD. Our findings will interest insurance stakeholders and health insurance policymakers. Physiotherapists are the most commonly used practitioner delivering

Table 4 Treatment effects expressed as adjusted mean differences (95% CI) between SIT + exercise and standard exercise group at 6 weeks, 6 months and 12 months

	6 weeks	6 months	12 months
Primary outcome			
NDI (0–100)	−10.0 (−15.5 to −4.48)**	−7.8 (−13.8 to −1.8)*	−10.1 (−16.3 to −4.0)**
Secondary outcome			
PDS (0–51)	−3.7 (−6.9 to −0.5)*	−4.7 (−8.6 to −0.8)*	−3.2 (−6.7 to 0.4)
DASS-Stress (0–42)	−5.6 (−8.4 to −2.8)***	−4.2 (−7.3 to −1.1)**	−2.2 (−5.1 to 0.8)
DASS-Anxiety (0–42)	−2.3 (−4.6 to 0.1)	−2.9 (−5.5 to −0.2)*	−0.8 (−3.7 to 2.1)
DASS-Depression (0–42)	−3.8 (−6.5 to −1.1)**	−4.1 (−6.9 to −1.3)**	−2.5 (−5.8 to 0.9)
PCS (0–52)	−2.5 (−5.6 to 0.5)	−1.3 (−4.9 to 2.2)	−1.2 (−4.8 to 2.4)
PSEQ (0–60)	3.9 (−1.2 to 9.0)	2.6 (−2.9 to 8.1)	6.7 (1.3 to 12.0)*
CSQ (−72 to 180)	12.9 (0.8 to 25.0)*	11.2 (−1.1 to 23.5)	16.8 (4.8 to 28.8)**
SF-36-PCS	−0.1 (−3.4 to 3.2)	−0.1 (−3.6 to 3.3)	2.0 (−1.7 to 5.8)
SF-36-MCS	6.6 (2.1 to 11.2)**	6.1 (1.8 to 10.4)**	4.5 (0.2 to 8.7)*
Average pain intensity in the last 24 hours (0–10)	−1.5 (−2.3 to −0.6)**	−1.0 (−1.8 to −0.1)*	−1.0 (−2.0 to −0.1)*
Global recovery (−5 to +5)	1.6 (0.7 to 2.4)*	0.7 (−0.27 to 1.6)	0.9 (−0.1 to 1.8)

*P<0.05, **p<0.01, ***p<0.001.
Results have been adjusted for baseline values. Differences are calculated as SIT + exercise minus standard exercise; therefore, a negative difference favours the SIT + exercise group for NDI, PDS, DASS, PCS and pain intensity. A positive difference favours the SIT + exercise intervention for PSEQ, SF-36, CSQ and global recovery.
CSQ, Coping Strategies Questionnaire; DASS, Depression Anxiety and Stress Scale; NDI, Neck Disability Index; PCS, Pain Catastrophizing Scale; PDS, Posttraumatic Stress Diagnostic Scale; PSEQ, Pain Self-Efficacy Questionnaire; SIT, stress inoculation training; SF-36, Short-Form 36.

care to patients with acute WAD, and if they receive some additional training in delivering stress inoculation this approach to early management could be widely feasible in whiplash-injured patients at risk of poor recovery (ie, those who have high levels of stress). We plan to explore the barriers and facilitators to implementing this discovery across health sectors and jurisdictions. With an eye on scaling up the reach of our intervention, we will investigate delivering it in group settings and supplementing it with online delivery of some components.

Correction notice This article has been corrected since it published Online First. The CI −15.5 to −9.0 has been corrected to −15.5 to −4.48 in the abstract, results and table 4.

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Patient consent for publication Not required.

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REFERENCES

1 Connelly LB, Supangan R. The economic costs of road traffic crashes: Australia, states and territories. *Accid Anal Prev* 2006;38:1087–93.
2 Dyer C. Ministers consider measures to reduce UK's 1500 daily claims for whiplash. *BMJ* 2012;344:e3226.
3 Carroll LJ, Holm LW, Hogg-Johnson S, *et al*. Course and prognostic factors for neck pain in whiplash-associated disorders (WAD): results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine* 2008;33:583–92.
4 Sterling M, Hendrikz J, Kenardy J. Compensation claim lodgement and health outcome developmental trajectories following whiplash injury: a prospective study. *Pain* 2010;150:22–8.
5 SIRA. *Guidelines for the management of acute whiplash-associated disorders – for health professionals*. Sydney: State Insurance Regulatory Authority (NSW), 2014:16.
6 Southerst D, Nordin MC, Côté P, *et al*. Is exercise effective for the management of neck pain and associated disorders or whiplash-associated disorders? A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Spine J* 2016;16:1503–23.
7 Teasell RW, McClure JA, Walton D, *et al*. A research synthesis of therapeutic interventions for whiplash-associated disorder (WAD): part 2 - interventions for acute WAD. *Pain Res Manag* 2010;15:295–304.
8 Wiangkham T, Duda J, Haque S, *et al*. The effectiveness of conservative management for acute Whiplash Associated Disorder (WAD) II: a systematic review and meta-analysis of randomised controlled trials. *PLoS One* 2015;10:e0133415.
9 Campbell L, Smith A, McGregor L, *et al*. Psychological Factors and the Development of Chronic Whiplash-associated Disorder(s): a systematic review. *Clin J Pain* 2018;34:1.
10 Sarrami P, Armstrong E, Naylor JM, *et al*. Factors predicting outcome in whiplash injury: a systematic meta-review of prognostic factors. *J Orthop Traumatol* 2017;18:9–16.
11 Jenewein J, Wittmann L, Moergeli H, *et al*. Mutual influence of posttraumatic stress disorder symptoms and chronic pain among injured accident survivors: a longitudinal study. *J Trauma Stress* 2009;22:540–8.
12 Ravn SL, Sterling M, Lahav Y, *et al*. Reciprocal associations of pain and post-traumatic stress symptoms after whiplash injury: A longitudinal, cross-lagged study. *Eur J Pain* 2018;22:926–34.
13 Ritchie C, Hendrikz J, Kenardy J, *et al*. Derivation of a clinical prediction rule to identify both chronic moderate/severe disability and full recovery following whiplash injury. *Pain* 2013;154:2198–206.
14 Ludvigsson ML, Peterson G, O'Leary S, *et al*. The effect of neck-specific exercise with, or without a behavioral approach, on pain, disability, and self-efficacy in

chronic whiplash-associated disorders: a randomized clinical trial. *Clin J Pain* 2015;31:294–303.
15 Vibe Fersum K, O'Sullivan P, Skouen JS, *et al*. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: a randomized controlled trial. *Eur J Pain* 2013;17:916–28.
16 Bennell KL, Ahamed Y, Jull G, *et al*. Physical therapist-delivered pain coping skills training and exercise for knee osteoarthritis: randomized controlled trial. *Arthritis Care Res* 2016;68:590–602.
17 Foa EB, Dancu CV, Hembree EA, *et al*. A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. *J Consult Clin Psychol* 1999;67:194–200.
18 Ross MJ, Berger RS. Effects of stress inoculation training on athletes' postsurgical pain and rehabilitation after orthopedic injury. *J Consult Clin Psychol* 1996;64:406–10.
19 Ritchie C, Kenardy J, Smeets R, *et al*. StressModEx--Physiotherapist-led Stress Inoculation Training integrated with exercise for acute whiplash injury: study protocol for a randomised controlled trial. *J Physiother* 2015;61:157.
20 Ritchie C, Hendrikz J, Jull G, *et al*. External validation of a clinical prediction rule to predict full recovery and ongoing moderate/severe disability following acute whiplash injury. *J Orthop Sports Phys Ther* 2015;45:242–50.
21 Ronk FR, Korman JR, Hooke GR, *et al*. Assessing clinical significance of treatment outcomes using the DASS-21. *Psychol Assess* 2013;25:1103–10.
22 Chiarotto A, Vanti C, Cedraschi C, *et al*. Responsiveness and minimal important change of the pain self-efficacy questionnaire and short forms in patients with chronic low back pain. *J Pain* 2016;17:707–18.
23 Jull G, Sterling M. Whiplash injury recovery: a self management guide. 2011 http://www.maic.qld.gov.au/forms-publications-stats/pdfs/whiplash-injury-recovery-booklet.pdf
24 MacDermid JC, Walton DM, Avery S, *et al*. Measurement properties of the neck disability index: a systematic review. *J Orthop Sports Phys Ther* 2009;39:400–C12.
25 Foa E. *Posttraumatic stress diagnostic scale: manual*. Minneapolis: NCS Pearson, 1995.
26 Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Ther* 1995;33:335–43.
27 Sullivan MJL, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychol Assess* 1995;7:524–32.
28 Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain* 2007;11:153–63.
29 Rosenstiel AK, Keefe FJ. The use of coping strategies in chronic low back pain patients: relationship to patient characteristics and current adjustment. *Pain* 1983;17:33–44.
30 Pengel LH, Refshauge KM, Maher CG. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. *Spine* 2004;29:879–83.
31 Ware J, Kosinski M, Dewey J. *How to score version 2 of the SF-36 health survey (standard and acute forms*. Lincoln: Quality Metric Inc, 2000.
32 Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry* 2000;31:73–86.
33 Smeets RJ, Beelen S, Goossens ME, *et al*. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clin J Pain* 2008;24:305–15.
34 Young IA, Dunning J, Butts R, *et al*. Reliability, construct validity, and responsiveness of the neck disability index and numeric pain rating scale in patients with mechanical neck pain without upper extremity symptoms. *Physiother Theory Pract* 2018;28:1–8.
35 Mellor R, Bennell K, Grimaldi A, *et al*. Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial. *BMJ* 2018;361:k1662.
36 Juul T, Søgaard K, Davis AM, *et al*. Psychometric properties of the Neck OutcOme Score, Neck Disability Index, and Short Form-36 were evaluated in patients with neck pain. *J Clin Epidemiol* 2016;79:31–40.
37 Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17:163–70.
38 Hawthorne G, Osborne RH, Taylor A, *et al*. The SF36 Version 2: critical analyses of population weights, scoring algorithms and population norms. *Qual Life Res* 2007;16:661–73.
39 Lamb SE, Gates S, Williams MA, *et al*. Emergency department treatments and physiotherapy for acute whiplash: a pragmatic, two-step, randomised controlled trial. *Lancet* 2013;381:546–56.
40 Williamson E, Williams M, Hansen Z, *et al*. Development and delivery of a physiotherapy intervention for the early management of whiplash injuries: the Managing Injuries of Neck Trial (MINT) Intervention. *Physiotherapy* 2009;95:15–23.
41 Synnott A, O'Keeffe M, Bunzli S, *et al*. Physiotherapists may stigmatise or feel unprepared to treat people with low back pain and psychosocial factors that influence recovery: a systematic review. *J Physiother* 2015;61:68–76.
42 Skillgate E, Côté P, Cassidy JD, *et al*. Effect of early intensive care on recovery from whiplash-associated disorders: results of a population-based cohort study. *Arch Phys Med Rehabil* 2016;97:739–46.
43 Jull G, Kenardy J, Hendrikz J, *et al*. Management of acute whiplash: a randomized controlled trial of multidisciplinary stratified treatments. *Pain* 2013;154:1798–806.