Critique author	Linda Metzger

Bibliographic Data	
Authors	Zoe A Michaleff , Chris G Maher, Chung-Wei Christine Lin, and et al.
Title	Comprehensive physiotherapy exercise programme or advice for chronic whiplash (PROMISE): a pragmatic randomized controlled trial
PMID	24703832
Citation	*Lancet* 2014; 384: 133–4.
Other information if relevant	TRIAL REGISTRATION Australian New Zealand Clinical Trials Registry, number ACTRN12609000825257

Methods	
Aim of study	To compare the difference in clinical effectiveness of a comprehensive exercise program delivered by physiotherapists with advice in people with a chronic whiplash-associated disorder
Design	Assessor single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Participants were recruited in Sydney and Brisbane Australia by advertisements in local and metropolitan newspapers, radio, and online media. The Motor Accidents Authority of New South Wales Australia, Motor Accident Insurance Commission Queensland Australia, QBE Insurance, and trial clinics assisted with recruitment by inviting by mail potentially eligible clients to participate.
Setting (location and type of facility)	20 private physiotherapy clinics in Sydney and Brisbane
Age	adults 18 to 65 years of age, mean age 42.8 years
Sex	62 men, 108 women, total 172 at baseline
Total number of participants for whom outcome data were reported	At the primary endpoint of 14 months, 170 were analyzed. Outcome data were reported on 157 participants (91%) at 14 weeks, 145 (84%) at 6 months, and 150 (87%) at 12 months.
Inclusion criteria	1. Grade I or II whiplash of at least 3 months duration but less than 5 years duration. 2. Currently experiencing at least moderate pain OR moderate activity limitation due to pain (modified items 7 & 8 of SF36). 3. Not currently receiving care for whiplash. 4. Aged between 18 years and 65 years old. 5. Proficient in written and spoken English.

Exclusion criteria	1. Known or suspected serious spinal pathology (e.g. metastatic disease of the spine). 2. Confirmed fracture or dislocation at time of injury. 3. Nerve root compromise. 4. Spinal surgery in the past 12 months. 5. Any coexisting medical condition which would severely restrict participation in the exercise program e.g. traumatic brain injury. 6. Any of the contraindications to exercise listed in the American College of Sports Medicine (ACSM) guideline screened using the Physical Activity Readiness Questionnaire (PAR-Q).
Other information if relevant	No minimum pain intensity specified. There were no significant differences between groups in participants' baseline sociodemographic, clinical characteristics, or outcome measure scores. Participants had their whiplash associated disorder symptoms for an average of 21.5 months.

Intervention Groups

Group 1	
Group name	Comprehensive physiotherapy exercise program group
Number in group	85 at baseline
Description of intervention	Participants received 20 individually tailored and supervised exercise sessions lasting 1 hour for 12 weeks. The comprehensive exercise program began with 4 weeks of specific cervical spine exercises, consisting of craniocervical flexion training, neck extensor training, scapular training, posture re-education, and sensorimotor exercises (kinesthetic sense, balance and eye movement control). By week 7, all participants had started the graded activity program of functional whole body exercise, an individually designed program aimed to help achieve functional goals. Exercises in this stage consisted of upper and lower limb muscle strength and endurance exercises, specific functional task practice, and progression of the aerobic, neck flexor, and neck extensor endurance exercises.
Duration of treatment period	12 weeks, 1 hour for 12 weeks (2 physiotherapy sessions per week for 8 weeks; one session per week for 4 weeks).
Co-interventions if reported	A copy of the booklet "Whiplash injury recovery: a self-management Guide" was provided that gave information about whiplash-associated disorders, advice on how to manage the symptoms, and outlined a simple exercise program to help with reduction of associated neck pain. A maximum of two sessions of manual therapy (excluding manipulation) could be used by physiotherapists to correct any underlying musculoskeletal problems. Also, aerobic exercise was prescribed from week 1 to week 12 in a submaximum and progressive way. Specific cognitive-behavioral therapy strategies were used by the physiotherapists, to encourage skill acquisition, setting progressive goals, and self-monitoring, and to positively reinforce progress. Participants were provided with a 12 week home exercise program that was to be completed on days they did not attend the treatment clinic.
Additional information if relevant	

Group 2	
Group name	Advice Group

Number in group	85 at baseline
Description of intervention	A copy of the booklet "Whiplash injury recovery: a self-management Guide" was provided that gave information about whiplash-associated disorders, advice on how to manage the symptoms, and outlined a simple exercise program to help with reduction of associated neck pain. Participants received one 30 minute consultation with a physiotherapist during which time they read the booklet, practiced the exercises with minimum guidance, and had any questions or concerns clarified. Participants were then required to implement the advice provided and practice the exercises independently at their own discretion. No additional supervision was provided except they could contact the physiotherapist by telephone on 2 occasions if they needed further explanation of the information covered in the consultation.
Duration of treatment period	12 weeks
Co-interventions if reported	
Additional information if relevant	

Primary outcome	
Outcome name and criteria for definition	The primary outcome measure was the average pain intensity during the preceding week measured on the numerical rating scale (0-10 pts) at 14 weeks follow-up.
Time points measured and/or reported	At baseline, 14 weeks, 6 months, and 12 months after randomization by a blinded assessor.
Differences between groups	1) At the 14-week end point, results showed improvements over time for the pain scale in both groups. The exercise group reduced their pain by 1.6 points and the exercise group reduced pain by 1.5 points. All scores improved between baseline and all follow-up points for both groups. These improvements did not meet the pre-specified clinically worthwhile effect of 2 points. 2) The comprehensive exercise program did not provide a benefit over advice. There were no statistically significant differences between groups in the pain change scores from baseline at all 3 follow-up points, and the associated between group effect sizes were very small (all ≤ 0.20) and clinically unimportant. The point estimates of the effects of treatment were close to zero and the 95% CIs did not include a clinically worthwhile effect on pain reduction. The effect at 14 weeks was 0.0 (−0.7 to 0.7) on a 0–10 pain intensity scale. Treatment effects did not meet the pre-specified clinically worthwhile effect of 2.0 points.
Additional information if relevant	No serious adverse effects were reported. Adverse effects were recorded for 5 patients who received the comprehensive exercise program and 4 who received advice.

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were: 1) average pain intensity over the past 24 h, 2) self-rated recovery 3) disability measured with the 10 item Neck Disability Index (0–100) 4) Whiplash Disability Questionnaire (scale range 0–130) 5) quality of life measured with the Short Form 36 6) functional ability measured with the Patient-Specific Functional Scale (scale range 0–10) and 7) cervical spine range of motion measured with an inclinometer.
Time points measured	At baseline, 14 weeks, 6 months, and 12 months after randomization by a blinded assessor.
Differences between groups	- No statistically significant differences between groups were found for the secondary outcomes, except for self-rated recovery at all follow-up points and functional ability at 14 weeks, but treatment effects did not reach clinical significance.
Additional information if relevant	ITT analysis results were reported.
Conclusions	
Key Conclusions Of Study Authors	- An intensive 12 week comprehensive exercise program delivered by physiotherapists for people with chronic whiplash-associated disorders did not provide additional benefit over advice for the primary outcome of average pain intensity in the preceding week. - Simple advice is equally as effective as a more intense and comprehensive physiotherapy exercise program. - The results of the study noted a significant, although clinically unimportant, benefit for 2 of the secondary outcome measures (self-reported recovery and functional ability). - The study did not find any evidence to support the hypothesis that differential responses to treatment arise in individuals with chronic whiplash-associated disorders. - This trial provides a credible assessment of the two study treatments with important implications for clinical practice and for the management of people with chronic whiplash-associated disorders. - Education and advice is as effective as more costly interventions, but how to deliver these interventions to patients in the most effective manner needs to be better understood. - Future avenues of research might include improving understanding of the mechanisms responsible for persistent pain and disability, and investigating the effectiveness and timing of drugs.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	A computer-generated randomization schedule, stratified for recruitment site (Sydney and Brisbane), was produced before the trial start by the study statistician who was also in charge of randomly assigning recruited patients.
Allocation concealment *(selection bias)*	Low	Allocation was concealed, participants were randomly assigned immediately after baseline assessment by opening the next sealed, sequentially numbered, opaque envelope.
Blinding of participants and personnel *(performance bias)*	High	Because of the nature of the interventions, it was not possible to blind participants or physiotherapists.The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome measures were obtained by an investigator who was unaware of group allocation. All authors were masked to group allocation as well for analysis and interpretation of results.
Incomplete outcome data *(attrition bias)*	Low	Loss to follow up (no longer interested) was relatively equal between groups. All participants lost to follow-up were included in the ITT analysis.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12609000825257.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	The sponsors of the study (The National Health and Medical Research Council of Australia, Motor Accidents Authority of New South Wales, and Motor Accident Insurance Commission of Queensland) had no role in study design, data collection, data analysis, data interpretation, or writing of the report.	
Possible conflicts of interest for study authors	None declared	
Notes:		

Comments by DOWC staff

- This study found no significant difference in the average pain intensity during the preceding week over the 12 month study period of a 12-week, 20-session comprehensive exercise program delivered by physiotherapists with an advice program that included an unsupervised, simple exercise program in people with a mild chronic whiplash-associated disorder.

- The findings of this study showed that there were small improvements in the average pain intensity during the preceding week over the 12 month study period for both groups, but these reductions in pain were clinically unimportant.

- In reality this study is comparing a comprehensive supervised exercise program delivered by physiotherapists to an unsupervised, simple exercise program with advice independently executed by the participants. The conclusion is that a supervised exercise program is no more effective than an unsupervised exercise program for people with a chronic whiplash-associated disorder.

- The findings are only generalizable to people with a mild (Grade 1 or 2), chronic whiplash-associated disorder who had no neck fractures or neurological involvement.

- There was a significant difference of direct participant to therapist contact and attention between groups (20 sessions vs one session), but this attention bias did not seem to affect the results.

- Study strengths included a large sample size with adequate statistical power to detect clinically meaningful effects, trial registration, a pre-specified protocol, design features known to minimize bias such as assessor blinding, concealed allocation, an intention-to-treat analysis, and a long-term follow-up with high rates of follow-up.

- The authors reported that compliance with treatment was good for both intervention groups, but they failed to report adherence with the home exercises for both groups.

- The main limitations were lack of blinding of therapists and patients, the high number of treating therapists that may have confounded treatment fidelity, and unequal matching of the interventions in format and time.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that there is no significant difference in the effectiveness of an 12-week, 20 session comprehensive supervised exercise program, and an unsupervised simple exercise program with advice, for improvement in average pain intensity in the preceding week in people with a mild chronic whiplash-associated disorder even though both interventions resulted in small reductions of pain over 12 months.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
-