Author’s response to reviews

Title: Advice or Exercise for Chronic Whiplash Disorders? Design of a randomized controlled trial.

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PDF covering letter
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Emma Veitch
Assistant Editor
BMC Journals
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Dear Emma,

Please find below our response to reviewers comments for our manuscript “Advice or Exercise for Chronic Whiplash Disorders? Design of a randomised controlled trial”.

The necessary changes have also been made to the submitted manuscript. As requested, we have been through the formatting checklist to ensure that manuscript conforms to your guidelines. The revised version will be uploaded today.

If you have any questions or queries, could you please direct these to Associate Professor Chris Maher at C.Maher@fhs.usyd.edu.au as I will be on leave from the 11/7/03 until the 14/8/03.

Many Thanks

Mark Stewart

Review #1 – Robert Ferrari

Compulsory Revisions

1. The impression is that the authors perceive their subjects to have neck pain only. Since a sizeable portion of whiplash patients (at least in my country) also have back pain, the researchers should include subjects with low back pain and pay as much attention to documenting low back pain and measuring back-specific disability.

We agree with the reviewer that a sizeable portion of whiplash patients also have low back pain. Such patients are not excluded from the present study. Low back pain symptoms will be noted in the initial assessment and we have chosen a disability measure designed for patients with neck and/or back pain (Functional Rating Index). Appropriate changes have been made to the body of the text to reflect the importance of low back pain problems. It should be noted however that the main outcome of interest is neck pain and disability.

Further, where they have statements like “that physical activity…is unlikely to further damage the neck”, they should include “neck and back”

We agree with the reviewers comment and have made appropriate changes to the text.
Where the researchers indicate they will assess upper body mobility, will they also not include an assessment of lower body mobility?

We agree that an assessment of lower body mobility is appropriate and a statement to indicate this has been included in the text.

2. A certain percentage of the subjects will have tendinitis of the limbs or things like trochanteric or anserine bursitis. Will the researchers screen for these things? Will these subjects be excluded? Or will their limb problems also be treated? One wonders what the outcome would be for people who have neck pain and shoulder tendinitis, but have no treatment prescribed for the shoulder tendinitis like a corticosteroid injection and rotator cuff exercises. At least the researchers need to identify any non-spinal injuries that could affect overall outcomes.

This is essentially a different research question that the reviewer is proposing. We are not proposing to screen for co-existing musculoskeletal conditions such as rotator cuff pathology and to also treat these conditions. The patients main concern is their whiplash and we propose to treat this condition, this approach is common to most clinical trials for musculoskeletal conditions.

We will however screen for serious pathology that may contraindicate treatment eg undiagnosed cancer. We will do this using a “Red Flags” questionnaire. Where ‘Red flags’ are identified the patient is reviewed by a physiotherapist and if necessary their general practitioner to determine whether more appropriate medical intervention is required other than what is offered in the trial. A complete list of questions asked may be seen below:

1. Is your general health good? yes No If no, what problems do you have?

2. Do you have any current disease process such as arthritis or cancer? Yes No If yes, specify (eg, where):

3. Have you ever been treated for cancer? Yes No If yes, specify:

4. Have you lost more than 4kgs (10lbs) in the last 6 months? Yes No If yes, specify:

5. Do you have any numbness or tingling in your back or genital region? Yes No If yes, specify:

6. Have you recently noticed any bowel or bladder problems? Yes No If yes, specify:

7. Do you have pain, swelling or redness in other joints Yes No If yes, specify:

8. Do you have any skin rashes? Yes No If yes, specify:

9. Do you have any eye discomfort, watery eyes or eye pain with light? Yes No If yes, specify:

10. Do you have any weakness in your upper limbs? Yes No If yes, specify:
11. Do you experience pins and needles or numbness in your upper limbs?  
Yes  No
If yes, specify:

12. Do you have any balance problems?  
Yes  No
If yes, specify:

13. Do you suffer from dizziness?  
Yes  No
If yes, specify:

14. Have you had a recent fever (not including flu or cold)?  
Yes  No
If yes, specify:

15. Have you had a recent infection?  
Yes  No
If yes, specify:

16. Are you currently taking any medication?  
Yes  No
If yes, specify:

17. Is there any chance that you may be pregnant?  
Yes  No

18. Have you had any surgery for your neck or low back?  
Yes  No
If yes, specify:

19. Have you ever been diagnosed with a neurological disorder  
by a specialist / GP?  
Yes  No
If yes, specify:

20. Have you had any cervical x-rays since your accident?  
Yes  No

If no, X-rays need to be organised for participation.
If yes, do you know if these highlighted any major structural  
problems such as a fracture or dislocation? (exclude if positive)  
Yes  No

This screening questionnaire combined with questions relating to contraindications to exercise testing (see point 3 below) will exclude subjects who we believe are at risk of physical deterioration from participation in the trial. A complete history will be taken by the treating physiotherapist and due regard will be paid to co-existing conditions. It is the view of the authors that subjects gained by such a process will reflect the population of whiplash sufferers being treated with programs similar to that offered in this trial without being deleterious to participants. It is outside the scope of the trial to treat all coexisting conditions.

3.  I suggest a full symptom checklist be obtained at the onset. It is important to know if these patients have  
things like cognitive symptoms, jaw pain, chest pain, dizziness etc and to see if any of these additional  
symptoms affect outcome measures. It may be that subjects with multiple non-pain symptoms, for example  
have a different response to treatments. Also, this data will let the rest of us know what kind of patients  
entered the study.

We agree with the reviewer and a full symptom checklist will be obtained by way of red-flag screening (see  
above), via questioning about contra-indications to exercise testing (see questions asked below) and via the  
history taken by the treating physiotherapist. Additionally each subject is screened for the potential for  
depression via the DASS21 (Depression Anxiety Stress Scale) which will help highlight any cognitive  
symptoms that may co-exist. Appropriate changes to the text have been made to highlight this point.
Physical Activity Readiness Questionnaire

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐ 1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 2. Do you feel pain in your chest when you do physical activity?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 3. In the past month have you had chest pain when you were not doing physical activity?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 4. Do you lose your balance because of dizziness or do you ever lose consciousness?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 5. Do you have a bone or joint problem that could be made worse by a change in physical activity?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 6. Is your doctor currently prescribing drugs (for example water pills) for your blood pressure or heart condition?</td>
</tr>
<tr>
<td>☐</td>
<td>☐ 7. Do you know of any other reason why you should not do physical activity?</td>
</tr>
</tbody>
</table>

1. Taken from the American College of Sports Medicine Guidelines for Exercise Testing and Prescription 1995

4. The litigation status as well as any sources of monetary compensation including private insurance schemes needs to be known for each subject and reported. The researchers may question the relevance of this, but there are enough reasons to have concerns about confounding factors that one thing that must be shown to have been successful in randomization is randomization for litigation / compensation status.

We agree with the reviewer’s comments and this information will be recorded. A statement to this effect has been included in the text.

Review #2 – Silvano Mior

Discretionary Revisions

1. RE: Baseline Measures: It would be helpful to readers if the authors had provided further information justifying their use of the primary outcome scales that were selected and why, rather than simply including the references. It is appreciated that psychometric testing of some of the scales is limited but work has been published in regard to the scales, especially the primary ones, alluded to in the proposal.

Whiplash Associated Disorders incorporate a wide array of symptoms and a number of primary outcome measures will be used to cover the pain, disability and quality of life changes experienced by such a population. The scales chosen are simple to score, relevant to this population and cover the aspects of WAD highlighted above. The Neck Disability Index is the most established of the scales and there is much known about the psychometric properties of this instrument thanks to the research of Dr Mior and his colleagues. The pain scales we will use are used widely and also have acceptable test properties. The SF36 is the most widely used generic health measure at present. It is easy to administer and score and has Australian Normative data for the general population. We agree with the reviewers comment and appropriate changes to the text have been made outlining why the appropriate scales were selected.

Compulsory Revisions

1. RE: Consent: In the study population section, the authors indicated that they will recruit subjects with the assistance of the MAA and send a letter inviting participation. It is unclear at what stage the authors will obtain consent from the subjects for their participation and if there are any concerns relating to matters of confidentiality in accessing names of claimants from the MAA without claimant authorization.
This study has ethics approval from the Human Ethics Committee of the University of Sydney and we see no concerns related to the invitation of clients to participate in the trial. Verbal consent will be obtained from the client over the phone to establish whether the client is appropriate for the trial. Written consent will be obtained at the initial assessment prior to obtaining any further information from the subject. Appropriate changes have been made to the text to clarify these issues.

2. RE: Sample: In the inclusion section, it is unclear if subjects who may be undergoing any type of care for their WAD condition, either from physician or others, are eligible to participate. And if they are undergoing care, how this will be accounted for in the study?

Subjects will be excluded from the study if they are currently undergoing treatment for their whiplash condition. Subjects will be asked to refrain from current treatment for the duration of the trial. This will eliminate confounding factors relating to treatment. Appropriate changes have been made to the text to clarify this issue.

In the exclusion section, there is no mention if subject’s who may be involved in litigation will be allowed to participate or if this is an issue in NSW?

Subjects will be allowed to participate regardless of whether they are involved in litigation. Subjects’ litigation status will be recorded at the initial assessment. Appropriate changes have been made to the text to clarify this issue.

Subjects will also have to undergo a cervical x-ray but it is unclear if films that have already been taken will be used and if not, what is the rationale for taking a new x-ray study?

Subjects will only have to undergo an x-ray investigation if films have not already been taken since the accident. Such x-rays are used to rule out potentially serious complications such as fracture or dislocation. Appropriate changes have been made to the text to clarify this issue.

Also, inclusion will include subjects with WAD I-III. Has consideration been given that numbers in each category to be included in the study would be representative of a similar percentage in the general population? Will the authors control for WAD type in their analysis?

We agree with the reviewers comment however and WAD type will be controlled for during data analysis (via ANCOVA).

3. RE: Treatments: In the advice group, it would be helpful if the authors define what they meant by “standardized education and….resume light activity”. In the same section, the authors suggest that they will encourage subjects to return to “normal activities” but it is unclear how this differs from encouraging them to” resume light duties”. In the physical activity programme group, subjects “explore and discuss….understanding of whiplash and attitudes…” consistent to CBT principles; will the nature of this information differ significantly from that provided to the advice group? If so could this potentially confound the outcomes in that the physical activity programme now involves much more than an exercise programme? Could the authors explain why they have not elected to provide advice as per CBT principles to both groups but exercise only to the second group, which may perhaps better answer their research question as to the role of exercise?

It is the authors intention that both groups be treated the same with regard to advice received. Indeed groups will be randomized after standardized advice has been received. This advice will be consistent to CBT principles regardless of group. Appropriate changes to the text have been made to reflect this point. Subjects in both groups will be taught the basics of pacing with regard to resumption of pre-injury activity. Resumption of light activity reflects the fact that we wish subjects to start at a relatively low level and slowly build up activity. Normal activity refers to a resumption of activities that they may have ceased as a result of the injury but are however normal in terms of pre-injury status.

Also in this section, only the physical activity program group will undergo an assessment at the first visit to determine “…current and pre-injury ability to perform work and home activities…”; why is this also not done for the advice group? This could provide comparative functional data between the groups and also identify if such factors may impact on response.

Both groups will undergo the same assessment prior to randomisation, which will include a determination of current and pre-injury ability to perform work and home activities. The exercise group will however have an assessment at their first gym session to determine a baseline for their programme. It is outside the scope of this trial to provide further assessment of the advice group in this way. The text has been corrected to highlight these points.
At the 6 week study point, subjects will be asked to record “type and amount” of treatments that they may use until the end of the 12 month review. Will they be provided a diary or recommendations on how to record such data because relying on accurate recall 12 months later may pose to be a problem?

Subjects will be given recommendations to formally record the amount and type of treatment they may receive as we acknowledge the potential for recall bias in terms of this information. A statement reflecting this point has been added to the text.

4. **RE: Conclusion:** As mentioned above, if the rationale and design of this RCT is to assess the “effects of advice and exercise programmes” it is suggested that both groups be provided a similar advice strategy but only one group would be provided the exercise strategy.

As noted above, it is the authors intention that both groups be treated the same with regard to advice received. Appropriate changes to the text have been made to reflect this point.