Author's response to reviews

Title: The effect of a sports chiropractic manual therapy intervention on the prevention of back pain, hamstring and lower limb injuries in semi-elite Australian Rules footballers: A randomized controlled trial

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Author's response to reviews: see over
Response to Reviewer Comments

In the abstract, we notice you have included extra information regarding trial registration. Please could you remove the sentence 'As the study commenced when trial registry was not mandatory in Australia, it has been listed retrospectively.' and simply list your trial registry, along with the unique identifying number, e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Please note that there should be no space between the letters and numbers of your trial registration number.

The changes have been made as asked.
Reviewer 1 Ian Horsley

Reviewer's report

Although the background to the nature of the sport is well documented, there is no explanation as to what defines a “semi-elite” player. Is it that these players play at a lower level, but are still full time athletes, or are they part time athletes? I feel that this needs some clarification within the manuscript.

Agree. Although we have stated that the semi-elite Victorian Football League (VFL) is state based in the protocol section of methods, we have now added the sentence: “VFL players train and play in the same competition as elite AFL players not selected for first grade competition and receive financial remuneration without being full time in their playing and training commitments.”

Within the Methods section, under assignment, I feel that there is too much information regarding the composition of the assessment tools. A copy of each questionnaire could be place in the appendix to circumvent this.

We have cut out the non-relevant information on assessment tools, which has shortened this section. However, there is difficulty in reproducing the standardized questionnaires (the McGill Pain Questionnaire and the 39 item Health Status Questionnaire). These questionnaires are in common usage in research and clinical practice and most readers should be familiar with them. We hope the compromise we have made will satisfy the reviewer.

Also in the Methods section, did all the subjects receive the same “best practice”, and how was this determined?

We have now included at the beginning of this section that: “All of the players in both the intervention and control group……” As is mentioned in this sentence, this approach was directed by club staff. The next sentences state that: “All treatment from club staff was independently administered without restriction or interference from the study authors. All staff were employed by the club and had no limitation in the number or type of treatment they could render.” We believe this covers how the “best practice” was determined. As we also state in the limitations section of the discussion: “future research would benefit from the recording of the nature of the control intervention.” This is a limitation of the study.

How the decision of the frequency of the scheduling was decided on in the intervention group, and did all subjects receive the same number of interventions?

We have added a statement into the discussion on the frequency of treatment scheduling which reads: “The decision on the minimum scheduling of treatment decided upon for the intervention group was made such that there
would be a likely treatment effect. Treatment scheduling in this pragmatic arrangement was then based upon current and previous player medical history, examination findings, practicality, player preference and practitioner experience. As the intervention was provided by a single practitioner, this removed issues associated with inter-practitioner reliability.”

With regards to the number of treatments, the following comment has been added to the discussion: “as mentioned in the results there was an average of 17 treatment consultations administered per player in the intervention group, but due to the pragmatic nature of the design, not all players received the same amount of treatment”

How were muscle injuries diagnosed; were they diagnosed by clinical assessment of by ultrasound or MRI imaging. If imaging was utilized, were the grades of the injuries recorded, and the extent of the muscle damage assessed? If no imaging techniques were utilized, there is a possibility of some of the “hamstring pain” being referred from the lumbar spine, hip and pelvis- which would respond well to manipulative therapy.

As is stated in the manuscript, for all injuries (including hamstring injuries): “diagnoses were determined by club medical staff who were blinded to group allocation using either clinical features of injury, advanced imaging or both at their discretion with blinded club recorders completing the injury surveillance.”

To cover the concerns of the reviewer, the following discussion has been added related to the diagnosis of hamstring injuries: “The diagnosis of hamstring strains is usually made on clinical grounds (Verrall et al. 2001). Hamstring strains are commonly diagnosed through history (acute onset, non-contact mechanism) and examination (local tenderness, reproducible pain on straight leg raise testing and/or resisted knee flexion) (Gibbs et al. 2004). In professional sport, MRI assessment is often used to support the clinical diagnosis and provide further assessment of the extent and severity of the injury. However, costs and availability preclude the use of this modality for routine assessment outside of professional sport. Additionally, both clinical examination and MRI findings are strongly correlated with the time required to return to competition, suggesting MRI is not required for estimating the duration of rehabilitation of an acute minor or moderate hamstring injury (Schneider-Kolsky et al. 2006). MRI imaging to confirm diagnosis of hamstring strains was not routinely performed in this study. There are limitations in relying on both clinical methods of diagnosis and MRI as hamstring injuries can appear clinically but not on MRI, but they also may appear on MRI but not clinically (Schneider-Kolsky et al. 2006). As MRI was not routinely used, there is a possibility that some of the hamstring injuries in this study may have been MRI negative which are often considered “back related”. There is some controversy regarding “back related” hamstring injuries as to whether a muscle strain is the cause, particularly for minor strains where causes for the pain may include referred pain from neuromeningeal or myofascial structures such as the lumbar spine and sciatic nerve or from nearby muscles such as the gluteal and piriformis (Verrall et al. 2001). However, “back related”
hamstring injury is an undefined term generally signifying both local hamstring signs and positive lumbar signs (Verrall et al. 2001). It should be noted that none of the hamstring injuries in the study had positive lumbar signs present at the time of diagnosis, but the lack of MRI diagnosis remains as a limitation of the study.


In the Results section, the results are presented for low back pain which is beyond the scope of this study, unless the title is refined accordingly.

We agree with the reviewer and have added low back pain into the title. We believe all the results recorded for the primary and secondary outcome measures should be presented in this manuscript. The title now reads: The effect of a sports chiropractic manual therapy intervention on the prevention of back pain, hamstring and lower limb injuries in semi-elite Australian Rules footballers: A randomized controlled trial.

**Major compulsory revisions**

I general I feel that this could be a body of work which would be of interest, although I feel that there needs to be some work carried out to clarify the diagnosis of the injuries- if possible.

We agree with the reviewer and believe that the section added to the discussion (see comments above) should satisfy this.

**Minor essential revisions**

Label for figure 1 on page 22, and actual figure is on page 32.

As the figure is an attachment, it is added to the end of the manuscript, whereas the manuscript requires the figures section (and label) to be listed before the tables section. This has been corrected.

**Discretionary Revisions**
I would like to see a breakdown, if possible, analysing which HVLA were utilized and comparing with outcomes, in order to identify any possible associations.

At the moment we have listed in the results section the following: “Of the manipulation and/or mobilisation delivered to the joint based regions of the body, 56% was HVLA manipulation only, 36% a combination of HVLA manipulation and mobilization and 8% mobilization only. Therefore, 92% of the total joint based treatment involved some form of HVLA manipulation technique.” We also give a break down of where this treatment was delivered: “Of the manipulation and/or mobilisation provided, 21% was to the thoracic spine, 18% to the knee, 18% to the hip, 15% to the lumbar spine and 12% to the sacroiliac joint.”

At the end of the discussion we also state: “Due to constraints in manuscript size, we are unable to describe the entire treatment provided in this study… which will be the subject of a subsequent publication.” The analysis of the treatment is the subject of a more focussed second paper currently in draft.

Data was not collected on the manipulation or mobilization provided outside of the intervention group. As we mention in the limitations section: “Future research would benefit from recording the nature of the control interventions in order to clarify the differences between interventions or to specifically address the role of HVLA based manipulative techniques”. Because we do not have the data on the treatment provided outside of the intervention, we can not answer the reviewers questions specifically. Because of this we have strengthened our calls for future research and now state: “future studies could specifically document the scope of the manual treatment delivered by all treating practitioners in both groups which would assist in comparing outcomes”
Reviewer's report

1. Is the question posed by the authors well defined?
Yes, it was “...to investigate whether a sports chiropractic manual therapy intervention protocol provided in addition to the current best practice management could prevent the occurrence of and weeks missed due to hamstring and other lower-limb injuries at the semi-elite level of Australian football.”

2. Are the methods appropriate and well described? The methods are well described. The authors have relied on previous work on the expected incidence of hamstring injuries to base their comparison of injury rates on in their current study, which is a reasonable comparison given that such data existed.

3. Are the data sound? Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data? Yes

6. Are limitations of the work clearly stated? Yes

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Yes

8. Do the title and abstract accurately convey what has been found? Yes

9. Is the writing acceptable? Yes the manuscript is well written

Major Compulsory Revisions

The authors have based their power calculation as such “historical AFL data [3] the assumed hamstring incidence level for the null hypothesis is 15%. For a 5% significance level and 80% power, a sample size of at least 63 and less than 117 is required to detect a 50% reduction in the incidence of hamstring injuries.” This is an appropriate way to base their calculation. However although they only had 59 subjects they then report that the chiropractic management “resulted in the prevention of primary lower limb muscle strain injuries, although no statistical significance was noted for hamstring injury and primary non-contact knee injury.”

The level of significance for both of these was p=0.051. Given that they were short on the number of subjects required, I would like to see the
authors acknowledge the strong likelihood of a type two error especially given how close each of these results were to p<0.05, but far more appropriately, I would like to see them provide effect size and power calculations based on these results for how many subjects would be required for further studies.

Agree. At the end of the second paragraph of the discussion we have now added: “As the level of significance for prevention of hamstring injuries and primary non-contact knee injuries was p=0.051, given that the study was short of the number of subjects required by the power analysis, there is a strong likelihood of a type two error, especially considering how close each of these results were to p<0.05.”

With regards to the quandary of effect size, we consulted our statistician who has said: “Effect sizes make sense for comparing mean differences across trials, because they are standardised with respect to within-trial variation and allow for comparison of effects across trials. For log-linear models (which includes 2 x 2 contingency tables as a special case, as used in this study) we are interested in the probability of an event (call this p), which is a parameter taking values in the range 0 to 1. It is therefore standardised across trials, so plays the role of an effect size for a log-linear model. The odds is a value defined as p/(1-p), and is therefore in a form that also allows comparisons across trials. In particular, p is obtained from the odds using the formula odds/(1+odds).” Therefore, our statistician has suggested not including an effect size calculation, largely because no single effect size is widely used in 2-way contingency tables. Furthermore, effect sizes are not really used in the sports medicine or low back pain literature (perhaps more common in the psych literature).

Regarding the power analysis, again we consulted the statistician and the belief is that we should stick with the historical data as the basis of the calculation. This data has been collected for 17 continuous years, with 100% compliance. It collects data for approximately 700 footballers for over 22 games per season which allows the data to account for fluctuations in injury. This is more accurate than basing a power analysis on a small study.

Also they did not make it clear if their original power calculation was based on the size of single group compared to the AFL rate of 15% injury. If this is the case they in fact only had half the number of participants needed and still managed to show very strong effects.

Agree. We have reconsulted our statistician and repeated the power analysis and clarified the issues. The section now reads: Based on historical AFL data [4] the assumed hamstring incidence level for the null hypothesis is 15%. For a 5% significance level and 80% power, a total sample size of 117 is required to detect a 50% reduction in the incidence of hamstring injuries.
Reviewer 3 Stephen Perle

Reviewer’s report

Major Compulsory Revisions

1. If this manuscript was submitted to a chiropractic publication the readers might be likely to understand the distinction between manual and mechanically assisted techniques. However as this journal is geared to a more heterogeneous population a short explanation of the differences in these interventions are in order.

Agree. In the intervention section of the methods section we have added the following: According to Mierau et al. (1999), manual manipulation involves a brief, shallow, sudden carefully administered thrust (high velocity in nature). Mechanically assisted manipulation is performed through the assistance of devices (for example drop pieces) or impulse type instruments, being non-cavitational and high velocity in intent. Mobilisation occurs when a joint is passively moved within its normal range of motion (usually a slow oscillatory movement).


2. The results section of the paper is inconsistent in what details it provides in text and what only in tabular format. For example when talking about Injury Surveillance the authors, appropriately I believe, provide chi squared values and probability of type I errors (p=...). However, for low back pain and health status the authors note statistical significance without reporting the probabilities.

Agree. We have edited the results sections for low back pain and health status and have now included p values within the text where appropriate.

Minor Essential Revisions

3. The information presented on what types of treatment were provided to the subjects would be easier to understand if it was also in tabular form.

We agree with the reviewer and have added a table to replace the paragraph in the results section. The new table is:

Table 5: Description of the treatment rendered to the intervention group

<table>
<thead>
<tr>
<th>Number of treatments</th>
<th>Intervention group (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of treatments</td>
<td>487 (mean per player 17)</td>
</tr>
<tr>
<td>Amount of manipulation and/or mobilization to joint regions</td>
<td>2000 (47% total treatment, mean 4 per treatment)</td>
</tr>
<tr>
<td>Location of manipulation and/or mobilization</td>
<td>Thoracic spine 21%, knee 18%, hip 18%, lumbar spine 15%, sacroiliac joint 12%</td>
</tr>
<tr>
<td>Manipulation and mobilization breakdown</td>
<td>HVLA manipulation only 56%, HVLA manipulation and mobilization 36%, Mobilization only 8%</td>
</tr>
<tr>
<td>Amount of soft tissue techniques to soft tissue regions</td>
<td>2258 (53% total treatment, mean 4 per treatment)</td>
</tr>
<tr>
<td>Location of soft tissue techniques</td>
<td>Gluteal region 22%, lumbar spine 12%, hip flexors 10%, knee 9%, posterior thigh 6%</td>
</tr>
</tbody>
</table>

* Soft tissue structures are defined as surrounding the involved joint (muscle, tendon, ligament, fascia etc.)

4. On page 9 of the manuscript the authors write “all data collected was manually…,” on page 10 “If data was extremely skewed…” and on page 17 “Although data was not recorded…” Data is a pleural word and the verb should agree in number, thus ‘was’ should be replaced by ‘were.’

Agree. Required changes have been made.

5. I think the use of the phrase “based regions” used as “joint based regions” and “soft tissue based regions” is confusing. Does this mean that joint based regional treatment meant that a treatment was provided to the region around, for example, the ankle and soft tissue based regions means that the treatment was applied to all muscles

We agree. The addition of the new table (see comments above), re-wording of the table and the definition: “Soft tissue structures are defined as surrounding the involved joint (muscle, tendon, ligament, fascia etc.)” should satisfy the reviewer.

6. On page 13 the authors write “of the soft tissue therapy provide” should be “provided,”

Agree. Change has been made.

7. The vast majority of the discussion section is an exposition of the literature that supports the theories concerning why chiropractic care might provided added value in preventing hamstring injuries. As this is speculative I think this should be pared down and more time spent on what we do know than what we theorize.

There are only two paragraphs dedicated to the exposition of the literature that supports the theories concerning why chiropractic care might provide added value in preventing. We do not believe that this is excessive and think that it is necessary to discuss and hypothesize what led to the improvement in the intervention group. Although we agree that much of the discussion is speculative, we are providing an important discussion of what is being spoken about anecdotally and that we will rightfully acknowledge the speculative parts
of the discussion. This study adds some information but it raises more areas of possible investigation.

Furthermore, little is known about the true cause of hamstring injuries, which makes discussion beyond speculation difficult. As we state in the discussion of the paper: “For the reversible risk factors that exist for hamstring injury, no definitive evidence exists to support them [6]. It has been suggested that waiting for a substantial body of evidence to exist to support a risk factor in its role in injury before conducting a RCT may be considered unethical [7].”

Please note that the discussion section also includes a thorough section on the limitations of the study, a new added section on the diagnosis of hamstring strains (as per request of reviewer 1) and the mechanism of hamstring injuries.

8. On page 16 the authors imply that manipulative physiotherapists tend to use more slow velocity or mobilization treatments. The reference is a paper by physical therapist educators from the U.S. regarding usage of manipulation in professional education. I do not think that this is good documentation about what manipulative physiotherapists in Australia actually do in practice.

In the Flynn et al. paper that the reviewer is referring to, the authors review the published literature on manipulation utilization rates in physiotherapy. We have added a section which should clarify the reviewers concerns, which reads:

“In the paper by Flynn et al. [24] they state that in the previously reported low back pain literature high velocity spinal manipulation utilization rates for low back pain to be between 2.8% and 8.9%, with rates in a heavily evidence based education system to be 36.2%. Alternatively, in the cited studies low velocity mobilization is used between 27.2% and 72.0% of the time. Despite these figures being the most up to date yet published, these figures represent United States, Ireland and United Kingdom physiotherapists and the figures may not be representative of current practice in those geographical locations or in Australian physiotherapists in particular.”

9. I was really expecting that the authors would discuss what I believe was an unusual outcome in this study. I thought it unusual that lower limb muscle strain injury incidence was significantly lower while the missed weeks was not. Conversely the non-significant difference in incidence of non-contact knee injury incidence but significant reduction in weeks missed for non-contact knee injury.

These perhaps interesting results may be partly explained by the sections we have added to the manuscript explaining the high probability of type two error occurring in the study. The added section reads: “As the level of significance for prevention of hamstring injuries and primary non-contact knee injuries was p=0.051, given that the study was short of the number of subjects required by
the power analysis, there is a strong likelihood of a type two error, especially considering how close each of these results were to p<0.05.”

With regards to the fact that lower limb muscle strain injury incidence was significantly lower while the missed weeks was not, we have added the section to the discussion that: “this implies that many minor grade strain injuries may have been prevented, but the one injury causing 4 missed matches skewed the results and meant the comparison would not be statistically significant. This is important in a small sample study such as the prevention of one serious injury (or not) can significantly alter the weeks lost profile of a particular treatment approach. Only studies with much larger sample sizes can really effectively confirm this important research observation.”

**Discretionary Revisions**

10. Although discussed the authors never actually say that as an under powered study this work is prone to type II error.

Agree. Reviewer 2 made a similar comment and we now state in the discussion that: “given that the study was short of the number of subjects required by the power analysis, there is a strong likelihood of a type two error.”