Reviewer’s report

Title: Adverse events after naprapathic manual therapy among patients seeking care for neck and/or back pain. A randomized controlled trial

Version: 1
Date: 16 December 2013

Reviewer: Greg Kawchuk

Reviewer’s report:

ABSTRACT
Terms such as manual therapy and spinal manipulation are used interchangeably – confusing. There is never a definition or hierarchy explaining the terms in the main manuscript.

The first statement indicates there is a need to be more “aware” about this topic – which suggests this is a paper about knowledge translation or will test a hypothesis about awareness - please rewrite to say there is a need for better information about AE rates etc.

There is no evidence that manipulation is provided differently, better, worse etc. between various regulated professional who provide manual therapy. Therefore, the need to describe this as “naprapathic” manual therapy is dubious. It should be described as manual therapy without any reference to a specific profession other than a note in the methods that in this study, the intervention was provided by naturopaths.

BACKGROUND
Not all guidelines that recommend SMT are linked to specific countries. Various guidelines that make this recommendation come from agencies, not countries.

Need to define SMT, manual therapy etc…

Would suggest that Naturopath also be used as a term as it is more common in the Americas than naprapath.

Remove naprapathic as a preface of treatment description (e.g. naprapathic manual therapy) as there is no scientific evidence it differs from any other profession in its delivery.

METHODS
I am unsure why unmasking was completed before treatment. Why was this necessary?

Please change all references in the manuscript from “patients” to “subjects”

If the questionnaire was for AEs in last 24 hours after tx but the subject returned for treatment after a time greater than 24 hours, there is a problem with recall.
Please describe the times of when forms were completed (e.g. the percentage of subjects completing forms within 24 hours, 48 hours, 72 hours etc).

How long could treatment go on for? 1 month? 1 year? How many treatments could be given?

It is unclear if the anonymity of the subject or their comments were kept from the clinician. This is an important consideration as subjects may not report all AEs if they think the clinician would know what they said.

If bothersomeness is the same as severity, then use only 1 term in the paper.

RESULTS
It is unclear how many treatments were given and over what time period. What were the averages at least?

Please explore the effect of the duration of the complaint prior to enrollment in the study with outcomes. Were people with more chronic complaints more likely to report AEs?

Please explore if AEs were more common early in treatment or latter in treatment.

Please explore if AEs were different between different anatomic regions (Cervical, thoracic and lumbar).

DISCUSSION
On the form, how would subjects know if their AE was/was not caused by the treatment? How might this effect the results?

There is a huge consideration here that is not discussed – why data were included from subjects having a minimum of three treatments. Why at least 3 visits? This excludes subjects who had AE say in their first visit then never came back....

Don’t define serious AE but say none were reported.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

None