Author's response to reviews

Title: Acute adverse events from over-the-counter Chinese Herbal Medicines: A population-based survey of Hong Kong Chinese.

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Author's response to reviews: see over
Re: Acute adverse events from over-the-counter Chinese Herbal Medicines: A population-based survey of Chinese adults in Hong Kong

Despite the movement in recent years for greater regulation of alternative and complementary medicines around the world, studies about the safety of these medicines have been limited. A number of countries in the East Asia region are in various stages of implementing formal safety regulations for over-the-counter Traditional Chinese Medicines. To the authors’ knowledge, there have been no population-based studies on adverse events related to alternative and complementary medicine use. The authors feel that our study fills a much needed knowledge gap in the reporting of adverse events among TCM users since previous studies have been primarily based upon emergency room admissions and case reports by clinicians. Hence, the patient-reported adverse events may serve supplement the existing data and provide new insights into the safety of alternative and complementary medicines. This study provides the prevalence of past-year adverse events related to over-the-counter Traditional Chinese Medicine use, the consumer factors associated with adverse events and the description of the types of adverse events and dosage forms responsible for these drug reactions.

This manuscript is not under simultaneous consideration by any other publication or has not already been published. We declare that there are no conflicts of interest. The funding was provided by Health and Health Services Research Fund of Hong Kong government. All the authors agree with the publication of the paper and no person or persons other than the authors listed have contributed significantly to its preparation. All ethical safeguards in accordance with the Declaration of Helsinki have been met.

Furthermore, we have edited the paper abiding by the following guideline:

Editor’s Comments:

The authors have done a thorough job responding to reviewer comments. The manuscript is now ready for publication except for two typos that the authors can be expected to correct without re-review:

1) The incorrect citation is given for SPSS. It is not marketed by SAS Institute, but by IBM.

2) On the Consort flow chart, some lettering is cut off in two of the boxes.

"Serving the community through quality education, caring practice, and advancement of health sciences."
We have now corrected the citation—(Version 16.0 of SPSS was still marketed by SPSS Inc while later versions were marketed by IBM). The flowchart is now revised and is being submitted as a Word and pdf document to facilitate production.

Reviewer: Thomas Ostermann’s report:
The authors have done much effort to improve their manuscript. There are only minor revisions:
Minor revisions:
  1) Still the abstract does not reflect the content of the full text. The method section should include logistic regression analysis. Otherwise it is not clear where the OR come from.

We have now succinctly added (to keep within abstract word limits) that the multivariable logistic regression was used in the analysis in order to clarify the meaning of the Odds Ratios presented in the Results section. We thank the reviewer for his comments to improve the abstract.

  2) The authors have incorporated some articles on ADRs and CAM but state that "these studies were typically conducted on patients who were prescribed complementary and alternative medicine by licensed practitioners and not self-medicating. However some other studies indeed do look at CAM self-medicating and should be introduced and discussed, i.e.

Self-medication and non-doctor prescription practices in Pokhara valley, Western Nepal: a questionnaire-based study

Self-Reported Health Characteristics and Medication Consumption by CAM-Users and Nonusers: A Swiss Cross-Sectional Survey

The use of prescription medicines and self-medication among children—a population-based study in Finland to mention some.

There may also be additional actual papers I am not aware of which might be integrated to discuss the results found here.

We have included these studies into the introduction for thoroughness of the literature review. These studies indicate the self-medication (a predictor of adverse events) is common across the world. We have also added a reference by Consolini & Ramon to the above references.

  3) Regarding Table 4B I would suggest to integrate the different findings in the text and delete table 4b and leave table 4 as it is.

We have deleted Table 4B and have made reference to the findings of table 4b in the results so that readers can be clear that the results do not substantively change. This is probably the most succinct methods presenting the data. We thank the reviewer for this useful insight.
Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

We are submitting this manuscript as Full-Length Paper for consideration of publication in *BMC Complementary and Alternative Medicine.*

Yours sincerely,
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