Reviewer's report

Title: Preliminary Examination of the Efficacy and Safety of a Standardized Chamomile Extract for Chronic Primary Insomnia: A Randomized Placebo-Controlled Pilot Study

Version: 1 Date: 23 June 2011

Reviewer: Ka Fai Chung

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This is an important study looking at the efficacy and safety of chamomile for the treatment of chronic insomnia.

Major Compulsory Revisions

I am most concern with the study conclusion which states that there is a modest and mixed clinical benefit of chamomile for treating insomnia. It seems that the baseline severity of insomnia may be significantly higher in the chamomile group, resulting in a moderate within-group effect size after treatment. When the baseline severity of insomnia is controlled for, there is no significant group by time interaction. It is possible that the improvements in the chamomile group are due to events unrelated to treatment, such as natural course of illness and regression toward the mean.

It may be worthwhile to provide more information of the allergic reactions and adverse effects of chamomile (references 14 and 15) and present in more details the two previous studies of chamomile that have included sleep-wake measures (references 16 and 17). For example, what is the sample size, is chamomile used as a single herb or in herbal mixture, what are the sleep-wake measures used, and what are the dosages of chamomile?

Please clarify whether individuals with depressive disorder are excluded and how the investigators determined the participants were in remission (Methods, 3rd paragraph).

The authors are encouraged to briefly describe the outcome measures used in the study and their range of scores (the paragraph before the Objectives and Outcomes section). Please also provide references of the scales. Explanation of the outcome measures can be grouped into a section. There are some repetitions in the paragraph before the Objectives and Outcomes section and the Intervention section.

Please explain the rationale for adjusting the baseline values in statistical analysis and whether there are significant differences between treatment groups at baseline. Why not using ANOVAs with repeated measures if there are no baseline differences? Please present more clearly whether there is time effect, group effect, and time by group interaction. The authors may need to explain
whether the effect size refers to within-group or between-group effect size and provide a clearer definition of the term. When the authors used the term “effect size”, it is better to state whether it is within-group or between-group.

The authors are encouraged to present the RCT in the CONSORT format. It is necessary to revise Figure 1. Please present the demographics and clinical characteristics of the treatment groups in a Table and the percentage of missing data in Figure 1 and Table 1. The frequency of the adverse events in the treatment groups could also be presented in a Table, otherwise, it should be presented in greater details. Please explain more clearly the answers to the question on blinding in each treatment group (Results last paragraph).

The authors are encouraged to omit the Cohen’s d values in the Discussion section (first paragraph) and rewrite the sentence “However, only differences in the FSS approached statistical significance” and “These measures of sleep quality …. 0.79” in the same paragraph. It is hard to say what level of p value can be regarded as being close to statistical significance. Please specify whether the pooled effect sizes ranging from 0.38 to 0.79 refers to sleep quality and fatigue. Sentences with unclear meanings are common in the manuscript. It is unwise to speculate that greater improvements could be attained if a sample with more severe insomnia were used (Discussion second paragraph). It is difficult to say that the study findings are similar to those of previous studies (Discussion third paragraph). In fact, the lack of significant difference between the treatment groups is contrary to the previous findings. It seems unclear only STAI-T, but not both STAI-T and STAI-S were presented. Since the authors discussed the treatment of anxiety disorder using chamomile, it is useful also to analyze the changes in STAI-S with treatment.

The authors are encouraged to provide a definitive discussion on the dose and duration of chamomile for the treatment of insomnia and comment on whether a higher dose of chamomile and longer treatment duration should be used in future studies.

There are many grammatical mistakes and typo errors that require correction. Effect size is not a primary outcome measure (Abstract section). When the p value is provided in the Abstract, either all p values be presented or not to present the p values.

**Level of interest:** An article of importance in its field

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.