Reviewer's report

Title: Bach Flower Remedies for psychological problems and pain: a systematic review

Version: 1 Date: 5 February 2009

Reviewer: Harald Johan Hamre

Reviewer's report:

This is a systematic review comprising six studies (four placebo-controlled RCTs and two case series) of Bach Flower Remedies (BFR) for two clinical domains. Compared to a previous review from 2002 it adds at least four studies, published 2004-2007.

Major Compulsory Revisions

Background: Has a lengthy section on BFR, but the following is missing and could be relevant: Therapy setting (Who prescribes BFR? Self-treatment? Non-medical practitioners? Physicians?) Extent of use? Cost? Any relevant pre-clinical or observational data? Results of previous systematic reviews? Why was this review undertaken?

Efficacy of BFRs for stress: Cram 2004 is included, but the only outcomes of this study cited in the present review are EMG, skin temperature and skin conductance. So apparently none of the outcomes specified in the eligibility criteria in Table 2 (pain reduction, improvement of symptoms, adverse events) were used in the study. If this is correct, the study should not be included in the review, although it might be mentioned in the Backgrounds section.

Four times (Conclusions in Abstract, Summary of findings in Discussion, Comparison with existing literature in Discussion, Conclusions) the authors state "BFR are not efficacious, "evidence for lack of efficacy" and similar. Isn't rather a statement such as "no evidence of efficacy" or "no evidence of benefit compared to placebo" justified? Absence of evidence is not necessarily evidence of absence, and especially so in this review: The authors comment on the high risk of bias in the studies (dropout rates of 42.5% and 55%, n=10 in a study they excluded for other reasons but nevertheless described) which would seemingly not allow for any firm conclusion about lack of efficacy. Moreover, although the authors refer to the discussion of suitability of CAM therapies for RCTs, they do not assess whether the RCTs were adequately designed to enable any effects of BFR, if present, to be demonstrated (risk of false-negative results): Were the indications appropriate for ordinary BFR practice? (E.g. experimentally induced anxiety in one study). Was the selection of individual BFR among the 38 herbs adequate regarding the symptoms treated? (Background section: "The ... patient is prescribed remedies... which should be individually tailored and adjusted during the course of therapy." Was this implemented in the studies?) Were the psychological symptoms and states allegedly affected by BFR (Table 1) reflected in the outcome measures used in the studies? Was the follow-up period
adequate to assess clinically relevant effects? (Background section: "therapy …
typically over weeks to months". Table 3: Duration of treatment: 10 minutes, 3
hours, 7 days…)  

Minor Essential Revisions  
Methods/Study selection: 1st paragraph should probably read: "we included
randomised controlled trials…"

Efficacy of BFRs for stress: One study was excluded because the intervention
was not just a BFR but also a non-Bach flower remedy. However, this
combination is not specified as an exclusion criterion in Table 2.

Discussion and Conclusion: Any clinical implications of these findings? Any
concrete suggestions for future research? (Suggestions for clinical domains and
outcomes? Individualised or fixed BFR therapy? Suggestions for designs, e.g.
placebo control or pragmatic studies?)

Discretionary Revisions

Background, last paragraph: The present review is limited to two clinical
domains. The authors mention a corresponding review from 2002 which,
according to the title, was apparently not restricted to specific indications, and
which comprised only four studies. Accordingly, a small number of studies would
be expected also for the present review. It is therefore unclear why this review
was limited to only two clinical domains.

Level of interest: An article whose findings are important to those with closely
related research interests

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare that I have no competing interests.