Reviewer's report

Title: Randomized Trial of a Mind and Body Technique for Weight Loss Maintenance

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Reviewer: Jeffrey Greason

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Overview
This rigorously designed, well written paper presents findings from a relatively large 2-arm RCT that compared a professionally facilitated energy psychology group-based intervention (Tapas Acupuressure Technique, TAT) against a professionally facilitated support group with the goal of maintaining weight loss following a 6-month behavioral weight loss program. Whereas the study design and size of the trial were strengths, 11 of the 19 items on the CONSORT checklist for non-pharmacological (behavioral) trials were either missing and/or unclear, thus compromising the quality of the report as currently written. As detailed below, my major concerns are that the primary conclusions do not follow from the data, and there are several alternative explanations and confounding factors that merit discussion in interpreting these results, including clinical implications for health care (if any).

Discretionary Revisions
1. References: #6-9 are not current. For example, see Tapper et al. 2009 Appetite, and other RCTs published since 2005.

Minor Essential Revisions
2. Title: To help identify the specific objective of the trial, use the term “TAT” rather than the more vague “Mind and Body Technique” in the title.
4. Table 2: Change title from Regression Models to ANCOVA Models. Add effect sizes and confidence intervals.
5. Table 3: Add effect sizes and confidence intervals.
6. Background: In my view, the Background section lacks a compelling theoretical or empirical basis for the TAT intervention. I read the authors’ prior publications on this topic (2007 and 2009, J Altern Complement Ther), and I encourage elaborating on the theoretical mechanisms of how TAT may work in this paper, as well. This can be a couple of additional sentences in 4th paragraph.
7. Background: My review of the authors’ prior publications also revealed that there are numerous potentially active ingredients of TAT, few of which are
discussed in interpreting the results of this trial. For example, TAT not only involves acupressure (which could ostensibly influence or unblock chi, should chi exist), but it also involves several other therapeutic elements that could conceivably help reduce stress, negative mood, sleep disturbance, quality of life, and ultimately, weight, in their own right. These techniques include visualization, asking for forgiveness, thanking God (or some other higher power) for the requested/expected healing response (a call for religious or spiritual healing of sorts), and drinking 6-8 glasses of water on the days TAT is practiced (which could help maintain a sense of fullness during the day, thereby mitigating excessive eating, and in turn helping to maintain weight loss). Although I can respectfully consider the Chinese medicine/chi/meridian theory of how TAT purportedly works, any or all of these constituent processes could very well explain any potential therapeutic effects of TAT on stress-related mental or physical health conditions. The contribution of the paper would be strengthened (more balanced and even handed, and less potentially biased and driven by non-significant results) by presenting this issue – and these alternative explanations or theories – in both the Background and Discussion.

Major Compulsory Revisions

1. Abstract, Results: Primary statistical test of efficacy is misinterpreted. There is no significant difference between groups. Please state as such. Do not say “arms differed by 1.24 kg” and “more weight loss was maintained in the TAT group” when these primary statements about efficacy are not supported by the data (p=.097). The way the primary result is currently written is fundamentally misleading and misrepresents the major trial outcome.

2. Abstract, Conclusions: The main conclusion does not accurately reflect the test of the primary or secondary hypotheses, but rather focuses on the results of a secondary, subgroup analysis based on questionable methodology. An equally plausible interpretation of the trial data, from both the R21 and the R01 grants, is that TAT is simply no more effective in maintaining weight loss than facilitated peer group support. In my view, the findings, and health care implications, would be more accurately presented as such. See additional comments/concerns below about multiple confounding factors that could alternatively explain TAT effect.

3. Methods, Weight-loss maintenance interventions: The issue of clustering (i.e., patients are clustered within group facilitators) needs to be addressed, methodologically and statistically, per CONSORT guidelines. The current statistical model is misspecified without taking clustering [aka nesting, or hierarchical data] into account, which can produce biased estimates of treatment effects.

4. Methods, Weight-loss interventions, TAT: Briefly describe what is involved in TAT certification (# of hours of training, # of hours of supervision, # of TAT sessions performed, and verified outcomes obtained [if possible]).

5. Methods, Weight-loss interventions, SS: Briefly describe degree of experience, training, and qualifications of SS group facilitators.

6. Methods: Please add section on how fidelity to TAT protocol was assessed
during the trial. Method of TAT quality assurance (adherence to protocol)? Consistent quality or delivery across interventionists?

7. Methods: The 2009 JACM paper mentions that an expectancy to benefit scale would be administered to both the TAT and the SS groups, however, this is not described in the current manuscript. Please add and discuss relevance, since non-specific effects (like expectancy) are known to largely explain many CAM intervention effects, including acupuncture and hypnosis among others.

8. Methods, Statistical methods: No statistical power analysis or sample size determination is presented in either the 2009 design/rationale paper, or in this manuscript. Please add, and frame in the context of your specified models. In this description, please address statistical power (what it was & how it was calculated) for the augmented model, which includes interaction terms that require greater power than main effects.

9. Methods, statistical methods: Alpha levels are described for main effects (.05) and interactions (.10), however, many statistical tests were performed and several data-driven model modifications were made without discussing the issue of multiple testing. Please address the multiple testing issue, including the role of taking a data-driven versus a theory-driven approach to testing your augmented and final models. How does multiple testing and data-driven analytic approach influence the reliability (or spuriousness) of the trial findings? This is an important topic to address in both the Methods and Discussion/Limitations.

10. Methods, statistical methods: Per CONSORT guidelines, please add estimates of effect size and confidence intervals for ANCOVA and regression derived parameter estimates.

11. Results, Change in weight: The description of results must be consistent with statistical tests. Please correct misleading use of language here when describing tests of main effects. It is not accurate to say “…a difference favoring the TAT arm…” when the p-value is not significant. It is accurate to simply say “change in weight did not significantly differ between the TAT and SS groups (p=.098).” The first line of the Discussion, for example, does a good job in this regard.

12. Results, Secondary outcomes: First, please show results of secondary outcomes in a table, even though they are not statistically significant. Second, given numerous dramatic case reports and anecdotes, and the purported theory of how TAT unblocks chi, why were none of the secondary outcomes significantly improved in the TAT group? (Topic for Discussion)

13. Results, Exploratory analyses: Why wasn’t TAT practice significantly associated with weight change outcomes? (Again, good topic of Discussion, given theory and presumed necessity of self-practice to elicit a healing response with TAT.)

14. Discussion: The result of the secondary, subgroup analysis – despite questionable subgroup splitting by 20/80%ile – is interesting from the perspective of “what works best for whom” with CAM therapies. I would strongly suggest doing a sensitivity analysis to more closely examine the robustness of this potential secondary/exploratory finding. For instance, I would suggest repeating the analysis you did but using different sets of %iles to compare (e.g., top 10%
vs. bottom 90%; top 25% vs. bottom 75%; top 33% vs. bottom 67%, top 50% vs. bottom 50%). If you can create a sensitivity analysis table to substantiate and build a greater degree of confidence around the 20/80%ile analysis, it would strengthen the contribution of this paper.

15. Discussion, 2nd paragraph: Please do not present new data in the Discussion. Figure 4 data should be moved to Results, and only interpretation discussed in Discussion section.

16. Discussion, 3rd paragraph: Greater initial weight loss is confounded by younger age, fewer depressive symptoms, and less perceived stress. These factors alone could explain greater weight loss, and subsequent between-group differences in weight regain, irrespective of TAT. Please add this point to a general, more even handed discussion of alternative explanations for this trial’s null effects and secondary/exploratory findings.

17. Discussion, 3rd paragraph, last sentence: Please give at least one specific example of how a future trial could be designed to capitalize on the lessons learned from this trial.

18. Conclusions: Again, please lead with statement of primary (null) trial finding, then present secondary/exploratory findings. Please emphasize how your conclusions may be confounded/biased/spurious/unreliable given (a) the number of statistical tests performed, (b) unclear statistical power, (c) a multitude of alternative explanations for how TAT could exert a therapeutic effect, and (d) the fact that two NCCAM-funded RCTs have now documented that TAT is not superior to group support in maintaining weight loss.

**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.