Reviewer's report

Title: The efficacy of a comprehensive lifestyle modification programme based on yoga in the management of bronchial asthma: a randomized controlled trial

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Reviewer: Sat Bir Khalsa

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In general, this is a well-designed and well-executed study that provides support for the efficacy of a yoga-based lifestyle intervention for asthma and deserves to be published. Although the use of a randomized controlled trial design is a strength of the study, the use of a wait-list control is not particularly effective at controlling for the non-specific effects of the extensive intervention, and therefore the potential significance of the positive outcomes must be tempered by this fact. There are a number of mostly minor weaknesses and errors in the manuscript itself which need to be adequately addressed before this paper can be accepted.

Major Compulsory Revisions

1) In the Discussion the authors claim that "Since the only built–in difference between the two groups was the yogic intervention during 8 wk of the study, any difference in the outcome during this period may be reasonably attributed to yoga." This sentence is not completely accurate and needs to be revised. The control condition in this study controlled only for the effects of participation in the study (Hawthorne effect), regression to the mean and changes due to natural history of the disease. A wait-list control group does not control for non-specific effects of the treatment including expectation, belief, subject investment in time and effort, change in the subjects’ daily routine (particularly in this extensive intervention), investigator interaction, social interaction and support, and placebo effect all of which could be substantial in this intervention. The more extensive the intervention, the more that non-specific effects could be involved, and the weaker the interpretation of the study and the attribution of benefit to the yoga practices themselves. This appears to be discussed somewhat in subsequent text in the Discussion but should be rewritten and acknowledged more cohesively and more explicitly given that this is the most serious weakness of the study.

2) The fact that the subjects underwent 4 hours per day of intervention for 2 week requires elaboration. How were the subjects able to devote this degree of time daily? Were they unemployed or disabled? This could be important information if the subjects were atypical from normal asthmatic patients in some way. If this is due to a cultural difference between India and Western countries this should be addressed, because many of the readers will be Western scientists. It would be a challenge for most asthma patients in Western countries to be able devote 4 hours per day for 2 weeks unless they were unemployed, disabled or retired.
3) Who instructed the yoga sessions; was it by a qualified yoga instructor? How long were the yoga practice sessions during the 2 week training period and during the 6 week home practice? What was the proportion of content of the 4-hour sessions to the different components of the intervention? Were the subjects required to do the home practice daily? If so, this should be explicitly stated. What was the content of the daily home practice sessions? Were these sessions the same every day? The characteristics of the "session of individualized counseling" need to be described in detail as to the content, duration, and therapist. How frequent was the telephonic support?

4) Please check the calculations of the probability of difference in gender between groups; should the p-values not be the same for both men and women?

5) Is there any adjustment necessary to the between-subjects statistical comparisons of improvements in the 3 variables that were shown to be different between groups at baseline (e.g. if ANOVA was the statistical method then an ANCOVA would be used to correct for this)? There should be a statement of how this was or was not handled statistically.

6) In the Discussion the authors state: "Thirdly, in a disorder which impairs respiratory function, using only a technique which primarily silences the mind in the absence of any breathing exercises is inappropriate." This is overstated. It is well-known that meditation practices alone (such as Transcendental Meditation and Vipassana) can have significant effect on central nervous system activity, autonomic nervous system activity and physiology and therefore may well have utility in asthma. The authors should either delete this argument or substantially rephrase it to account for this.

Minor Essential Revisions

1) In the Abstract the authors state: "The present RCT has demonstrated that adding the mind-body approach of yoga to the predominantly physical approach of conventional care results in measurable improvement in subjective as well as objective outcomes in bronchial asthma." This is too strongly worded given that not all of the outcomes measured showed improvement. It would be better to state that there was improvement in "some" subjective and objective outcomes.

2) The incorporation of dietary recommendations, counseling sessions, lectures and health education into this intervention distinguish it substantially from what is more commonly viewed as "yoga" in most yoga research studies, i.e. postures, breathing techniques and meditation. Although the title of this manuscript "comprehensive lifestyle modification programme based on yoga" accurately reflects this, most of the text in this manuscript describes the intervention as simply "yoga". This is potentially misleading. The authors should adopt another more accurate term (e.g. yoga-based mind-body intervention, yoga-base lifestyle intervention, etc.) throughout the manuscript to avoid this.

3) The authors have chosen to present all of the data in a large number of tables - this makes reading the manuscript somewhat tedious. The authors should
present some of the more compelling results in a few graphs (and perhaps replace some of the tables) to make the paper more readable. Perhaps some tables could be combined, or some of the tables with insignificant results can simply be described in the text in the Results section.

4) There appears to be inconsistency in the reporting of statistical significance in Tables 3 to 8. Either within-group statistics (repeated measures; over time) are presented or between-group statistics or no statistics are included. Tables 3 and 4 appear to within-group statistics but not between-group statistics, Tables 5 and 6 have no statistics, and Tables 7 and 8 appear to have between-group statistics but not within-group statistics.

5) In the Discussion the authors state "However, in practice the drop-outs increase steeply, particularly from the control group, as the duration of the study increases." What is the justification for this statement? Are there supporting data for this in previous studies?

6) In general, the language in the Discussion is often too strong. For example, the authors argue that "...in the process of testing a holistic treatment using a design which is ideal for testing a drug, the holistic treatment should not be reduced to one of its components" but later on state "...it would help to integrate mind-body approaches like yoga into the practice of scientific medicine if the trials not only show that these approaches work, but also how they work in terms of measurable basic mechanisms.". These are inherently contradictory; determining mechanism requires dismantling of the therapy to determine which are the effective components (e.g. meditation, postures, breathing, etc.). The authors should tone down the strength of these kinds of arguments or rephrase them in the Discussion.

7) The Conclusion is somewhat poorly constructed and written and has a number of grammatical errors and should be revised.

8) There are many spelling, grammatical and formatting errors. The authors should proofread their manuscript more carefully. Below are examples of some of the errors followed by corrections.

The word “yoga” is sometimes capitalized and sometimes not; it should be used consistently throughout.

The acronym for the quality of life questionnaire is AQOL in the Abstract and Tables but AQLQ in much of the text; there should be consistent use of only one of these.

“There is substantial body of evidence on yoga and…”
“There is a substantial body of evidence on yoga and…”

“However, none of these studies has investigated…”
“However, none of these studies have investigated…”

“…done on 57 adult patients having mild or moderate bronchial asthma…”
“…done on 57 adult patients with mild or moderate bronchial asthma…”
“…in addition to conventional care, also an intervention based on yoga”
“…in addition to conventional care, also received an intervention based on yoga”
“…the change being statistically significant in case of forced vital capacity…”
“…the change being statistically significant for forced vital capacity…”
“…referred to the Integral Health Clinic (IHC) by physicians of All India Institute of Medical Sciences (AIIMS) or came to IHC in response to posters in AIIMS or newspaper advertisements.”
“…referred to the Integral Health Clinic (IHC) of the All India Institute of Medical Sciences (AIIMS) by AIIMS physicians or came to the IHC in response to posters at AIIMS or newspaper advertisements.”
“…at the beginning of the study to summon up how many times they had used an inhaler or bronchodilator during preceding 2 wk…”
“…at the beginning of the study to add up how many times they had used an inhaler or bronchodilator during the preceding 2 wk…”
"…had at least one session of individualized counselling."
"…had at least one session of individualized counseling."
"…previous RCTs on the efficacy of yoga which are arrived at similar conclusions."  
"…previous RCTs on the efficacy of yoga which have arrived at similar conclusions."  
"…some of the recent studies are overlooked some basic features of yoga."  
"…some of the recent studies have overlooked some basic features of yoga."

Level of interest: An article of importance in its field

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests