Author's response to reviews

Title: Community based yoga classes for type 2 diabetes: An exploratory randomised controlled trial

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Author's response to reviews: see over
Response to reviews of paper on RCT of yoga in diabetes

REVIEWER 1 Lisa Bernardo

Why did we screen for exercise tolerance?

We did this mainly because the yoga did include some exercises (see response about ‘yoga therapy’ below), but also because the local research ethics committee is (in my view) overcautious. We have to get the study approved by a local ethics committee which includes lay members and is infamous for turning down studies. We decided that since we could not PROVE that yoga was not dangerous in diabetic people with cardiovascular disease, we would have no defence if they suggested it would be! But also, since we asked the yoga teachers to use their judgement on what to do in the classes, we would have been liable if one of them had instigated strenuous exercise which had an adverse effect on a person with known major risk factors. Given that this was research, we would have had to have a clinician present at all sessions, which was impractical.

Did we use standard criteria for exercise tolerance?

No. We used data on the patients electronic medical record – if they had any evidence of cardiovascular disease, we excluded them.

Why did we not recruit from faith based organisations or newspapers?

The sampling frame was designed to mirror existing ‘prescription for exercise’ schemes in the UK, where people are referred by their GPs or practice nurses. Also, the inner city areas we were recruiting from are very multi-faith and multi-ethnic. There isn’t a single ‘faith based organisation’ – indeed, a quick search of one of the two localities on Google turned up 42 ‘faith based organisations’. So I don’t think this would have helped much in such a small study. (In a different study, in China, we’re recruiting very successfully through a faith based organisation and I fully support this as a general strategy – it just wasn’t appropriate here).

We didn’t recruit through newspapers as this is not generally considered to be a robust approach. Those who answer newspaper ads may differ systematically from those who don’t read newspapers or who choose not to respond.

I agree that there is “freedom from being away from the medical model” when you don’t go through GPs. Robin Monro, a yoga therapist who was on our steering group, did a previous RCT on a hospital population in whom the yoga was “prescribed” by the consultant. This is bad news for those who seek (as I do) to de-centre the medical expert in lifestyle interventions, but we can’t ignore the findings. As we said in our paper, “Whether yoga should be ‘medicalised’ (e.g. as a ‘prescription for exercise’ intervention) to increase the priority given to it by patients is not an easy question to answer. Whilst this move may improve attendance, it also sits oddly with the ethos of a ‘holistic’ intervention intended to transform mind, body and spirit.”
What were the qualifications of the yoga teachers? Did they have training in yoga therapy? [...] You make reference to the subjects treating the yoga practice like 'going to the gym'. Did they realize they were in therapy? You seem to go back and forth with yoga as exercise and yoga as therapy; if you aren't clear, perhaps your subjects weren't.

I think we've inadvertently introduced an ambiguity into our paper. When we talked of 'yoga therapy' we meant 'yoga [as] therapy [for diabetes]'. From this referee's comment it would seem that the term 'yoga therapy' has a very specific meaning and is a different intervention, involving just breathing and no exercise. We have removed the word 'therapy' throughout the paper and called it either 'yoga classes' or 'yoga intervention'. The nature of the intervention is described briefly in the paper under 'intervention'.

Referee suggests that personalisation of the yoga is an essential element of the intervention

We agree. No change to paper needed.

What kind of incentives/assistance were given to subjects to practice at home--audio tapes of their practice sessions, a booklet, email reminders, etc?

We gave a mat, belt, and audiotape. We've included this in the description.

I disagree that a promise to practice at home should be a study inclusion criteria. Remember, by simply breathing and focusing the mind one is practicing yoga!

I'm afraid I'm looking at this as a scientific intervention, hence feel it would be reasonable to assume that if there is any impact at all there is likely to be a dose-response effect. Hence if 'low dose' yoga has been shown to have no impact on the outcome measures used, we're suggesting 'high dose' yoga. Incidentally, what we actually said in our paper was “[the yoga teachers] felt that in future research, agreement to practise regularly at home should be a precondition for inclusion in the trial”. Whether the referee agrees with this statement or not, we feel we should report that that was what the yoga teachers said!

Each subject should have served as his/her own control. I didn't see where you compared each subjects' pre/post scores. Maybe something would turn up if this were done?

We did do this, but I agree we weren't very clear in the first draft of the paper. There was no significant difference in the pre and post scores. I've made it clearer in the data analysis section that the 'paired' data relate to before vs after in each participant.
It might be appropriate to consider that yoga may be a worthwhile intervention for those who choose it or are likely to choose it, and will be ineffective in those who do not choose it.

We agree, and have now included this as a suggestion. A recurring comment amongst the research team here was 'you can lead a horse to water…'. The only problem with this is that several people we approached said they couldn’t do our study because they were already in a yoga class!

The study might have more to say about the effect of yoga on T2D if a per protocol analysis was done, i.e., what was yoga’s effect on HbA1c among the adherent?

The problem here is that ‘adherence’ isn’t a dichotomous variable. What do you call a person who attended one or two sessions? So we can’t compare ‘adherent’ with ‘non adherent’, though we could plot change in primary endpoint against number of sessions attended. We did do the latter on the ‘back of an envelope’ – but the numbers were small and whilst there was a ‘trend’ towards a dose response effect, as I recall the result was not statistically significant [NB our statistician is sadly very ill at the moment so I can’t ask her – if this analysis were crucial I could get another statistician to re-do it]. But more importantly I’m not sure this is a valid thing to do given that we did not stipulate this analysis in advance. The purpose of this study is to get the process right prior to a larger study. I have however suggested in the paper that a per-protocol analysis might be included in a definitive trial.

Minor discretionary revisions

We thank the reviewer for pointing out come typos and grammatical errors which we’ve corrected.