Author's response to reviews

Title: Acupressure for smoking cessation - a pilot study

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Response to reviewers

Reviewer: George Lewith
Comment: outcomes for the main feasibility items should be placed in the first paragraph of the discussion
Response: first paragraph modified to read:
This pilot study found that about half the smokers that were seeking help from a local smoking advice service were willing to try acupressure beads as an adjunct to usual treatment, but the dropout rate during the five week study was 84%. Compliance with instructions to press the bead was good for the first week but then deteriorated. Adverse events were minimal.

Comment: need for preliminary data for the treatment methodology.
Response: I have now included references to justify use of Lung and Shenmen points, including my own MSc thesis and a recognised manual.

Comment: there is no formal CONSORT diagram which would be very useful.
Response: thank you, now included as Figure 1.

Reviewer: Janneke Kaper

Comment: the title suggests the manuscript is about the effectiveness of acupressure but it is about the feasibility of the trial.
Response: our intention in placing the formal term 'pilot' in the title was to indicate to readers not to expect the report to provide any evidence of effectiveness. We regret that it did not achieve this, and considered revising the title. However, 'feasibility' does not cover the trial fully, it was more than a feasibility study. Also, we think that the title meets BMC's request to be as concise and informative as possible; perhaps the editors could advise us if they believe it should be changed.

Comment: With NRT and group behavioural therapy, there is little room for improvement. What were the expectations about the effect [acupressure].
Response: the potential expectations of how acupressure could contribute to smoking cessation, (stated in the penultimate paragraph of the Introduction), are: reduction of withdrawal symptoms and increase quite rate, or reduce the use of NRT and possibly minimise the total cost of the intervention. We did not have any information on which to estimate an effect size.

Comment: what can be done in future studies to equal the use of NRT and the number of therapy sessions?
Response: individual smoker's requirements for NRT will vary and cannot be standardised; but the recommendation for each individual is varied according to a fairly standardised procedure at the Smoking Advice Service. Text modified to read:
given a letter to the GP recommending the dose of NRT or, more rarely, bupropion tailored to the individual according to their smoking history.
Each smoker is invited to attend the whole course of six therapy sessions. The number actually attended by each smoker is a feature of dropout, which we counted as relapse.

Comment: the manuscript would benefit from adding a paragraph regarding recommendations for future studies ... the points for improvement of methodology should be made more clear. The methodological consequences of for example an open ... study instead of a blinded ... study can be discussed.
Response: further research questions and study designs in this area could be the subject of a discussion paper on its own, and we wanted to avoid extensive arguments here. So we have simply highlighted some of the main issues that led to the present design with new text:

Future studies could profitably explore the effectiveness of acupressure in smokers who have chosen acupressure in preference to NRT or bupropion using a patient preference design. Dalal et al 2007 High levels of expectation could in themselves increase the effectiveness of acupressure, and may improve compliance with instructions to stimulate the bead. Open studies should be conducted first to determine whether an effect exists, then by blinded studies using a placebo intervention, to test the causal relationship. We have not been able to design a convincing placebo for acupressure beads. Placebo-controlled studies of acupressure in smoking cessation require careful consideration of the ethical aspects: in view of the proven benefits of certain interventions, and the life-threatening consequences of failure, smokers should not be offered only a control intervention which the researcher expects to be ineffective. This is why we initially sought a dose-related effect in our design, and why we offered acupressure as an adjunct to known effective treatment.

Comment: in the introduction, I interpreted that the effectiveness of the intervention can be up to 72% after 6 months. The effectiveness in this trial is difficult to interpret from the results section. Is it 7 of 19 (39%) after 6 weeks? Can this difference be explained?
Response: thank you for that comment, and this is a question that concerned us too: did the addition of acupressure actually reduce the effectiveness of the Smoking Advice Service from 72% to 33% (four from twelve who received acupressure)? We think the explanations are (i) our group sizes were too small to support drawing valid conclusions about results (ii) the 72% success rate was obtained by telephone interview, and so is open to considerable bias. To avoid this confusion for the reader, we have now removed the reference to the success rate from the introduction. Text now reads:

Data available for the clinic in Plymouth show that over 300 patients attended courses of these interventions in 2003 (Smoking Advice Service report April 2004).

Comment: Abstract background: ‘there is evidence to support the effectiveness of two of these’. This suggests that these are the only two effective treatments available.
Response: indeed, advice and bupropion are also effective, thank you. The text has been modified to read: Smokers who approach publicly funded stop-smoking clinics in the UK are currently offered nicotine replacement therapy (NRT) or bupropion, and group behaviour therapy, for which there is evidence of effectiveness.

Comment: For future studies the cut off point for CO measurement can probably be lowered. It is even better to use urinary cotinine.
Response: we agree that there is some uncertainty over the interpretation of levels of expired CO between 7 and 10 ppm; urinary cotinine may be better at differentiating smokers from non-smokers but urine tests are relatively intrusive and open to substitution unless carefully monitored. This study does not add to the understanding of verifying cessation, therefore we would regard it as rather presumptuous for us to make recommendations on this subject.

Comment: the structure of the results section can be improved.
Response: we agree that the results section appears to be rather formalised, and we struggled with this during the preparation of the manuscript. However, the natural sequence of the study set the order for the research questions and this in turn determined the order of the results section. We have looked again at this problem but cannot resolve it.