Author's response to reviews

Title: The 5x1 DAFNE Study Protocol: A cluster randomised trial comparing a standard 5 day DAFNE course delivered over 1 week against DAFNE training delivered over 1 day a week for 5 consecutive weeks

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Version: 2 Date: 26 October 2012

Author's response to reviews: see over
We thank the reviewers for their comments, and as a result have made some changes to the manuscript as outlined by the responses in red below.

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Reviewer’s report
Title: The 5x1 DAFNE Study Protocol: A cluster randomised trial comparing a standard 5 day DAFNE course delivered over 1 week against DAFNE training delivered over 1 day a week for 5 consecutive weeks
Version: 1 Date: 28 July 2012
Reviewer: Jyothis George
Reviewer’s report:
Elliot and co-workers describe the protocol for a cluster randomised trial, comparing a standard 5 day DAFNE course delivered over 1 week against DAFNE training delivered over 1 day a week for 5 consecutive weeks. In addition, there are several sub studies that are included in the manuscript including a preference survey, health economics analysis and a qualitative study.
By packaging these few studies together, the readability of the protocol is certainly compromised and a diagram or a table listing out these substudies would help the reader. The substudies are listed in the objectives section at the beginning of the Methods / Design section, page 6.
Some of the text here is written in future tense and the rest in past tense which makes the manuscript harder to read. Please try to ensure consistency. Minor amendments have been made.
Major Comments
There has already been a randomised trial of an education intervention in the UK, looking at a less intensive schedule spread over weeks [Biophysical and Psychological effectiveness of a Brief Educational Intervention for Self-Efficacy in Type 1 Diabetes - (BITES): A randomised control trial. Diabetic Medicine 25 (12); 1447-1453]. Please discuss how the present trial design is different. If the results of the present study and the BITES trial are divergent, it would certainly be of interest to researchers and practitioners. This paper is now referenced, page 4.
Minor Comments
1) "seven out of a possible 74 DAFNE centres volunteered to take part." Why was the uptake low? Did the centres find it easier to do 1-week long DAFNE sessions? Not many centres would have the staff resources to conduct a clinical trial alongside routine clinical commitments. We were pleased that 7 centres agreed to take part, running both 1 week and 5 week courses obviously takes a lot of time, and organisation. The ease of running 1 week as opposed to 5 week courses is one of the outcomes to be determined as already mentioned, page 18.
2) "The exclusion criteria were as follows: severe diabetic complications." Please specify what is meant by ‘severe diabetic complications’. E.g., requiring haemodialysis, or blind, page 8 has been altered accordingly.
3) There are a few other minor grammatical and spelling errors, but I haven’t listed them all in the absence of line or page numbers in the manuscript. Here are a few examples: ‘we need 150 participants to complete the study’ and "to CE the project manager", "teaching style of an Educator, "not consented to the Trial", "HbA1c will be measured at local laboratories DCCT aligned". Now corrected
Structured comments
1. Will the study design adequately test the hypothesis?
Yes
2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
   A key study missed - as above
3. Does the manuscript adhere to the relevant standards for reporting and data deposition: if not, in what ways?
   Yes
4. Is the writing acceptable?
   Scope for improvement, as above
Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published
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

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Reviewer's report
Title: The 5x1 DAFNE Study Protocol: A cluster randomised trial comparing a standard 5 day DAFNE course delivered over 1 week against DAFNE training delivered over 1 day a week for 5 consecutive weeks
Version: 1 Date: 21 September 2012
Reviewer: Monica DiNardo
Reviewer's report:
Overall, I find the purpose of this study protocol to test for non-inferiority of a 5 week X 1 hour diabetes education program of intensive insulin management compared to a proven intensive 1 week method is important. The protocol is well described and carefully designed to meet the stated objectives, and would readily allow for replication by other researchers. Inclusion of the cost effectiveness and qualitative substudies and duration of follow-up strengthens the design. The sample size and multi-site orientation may yield generalisable results; however, the randomization procedure stratified only by centre may produce non-equivalent groups.
Major Compulsory Revisions:
1. Please provide some preliminary data especially comparing the demographics of the 1-week and 5X1 week groups. As stated by the editor, no preliminary data is to be included.
Minor Essential Revisions:
1. Use of consistent terms for the 1 week and 5X1 week groups would add clarity to the manuscript. Now clearly defined, and consistent use of the terms 1 week and 5 week for the two arms.
2. Please describe how you plan to analyze and interpret the primary and secondary outcomes for HbA1C. This is explained on pages 11 and 14.
3. Please provide a citation for the statement about duration of recall for severe hypoglycemic episodes. Reference now provided.
**Reviewer's report**

**Title:** The 5x1 DAFNE Study Protocol: A cluster randomised trial comparing a standard 5 day DAFNE course delivered over 1 week against DAFNE training delivered over 1 day a week for 5 consecutive weeks

**Version:** 1  
**Date:** 17 September 2012  
**Reviewer:** Thomas Kubiak

**Reviewer's report:**

**Discretionary Revisions:**
1. Just a question out of curiosity: Why is structured diabetes education to be offered to all people with T1DM in England and Scotland, but apparently not in Wales? From page 4 we assume you mean why not Scotland? The department of health covers England and Wales, but Scotland has its own guidelines set by the Scottish Health boards.

2. The description of the two treatments is a bit confusing. Suggestion: Briefly mention key characteristics in the text, contents etc. could then displayed in a table.

**Minor Essential Revisions**
3. Please provide some more information on the randomisation procedure. Random blocks are fine but details are missing on how the blocks were generated... **The computer program used is now detailed on page 9.**
4. I applaud the authors for the analytical approach with GEE. Is it a part of the plan to examine between centre variance? Please comment. GEE treats the between group variance as a ‘nuisance’ and so doesn't explicitly produce it. However we will estimate the intracluster correlation coefficient (ICC) using the method of moments, page 14 revised.
5. How did the authors check the exclusion criteria? Some of them seem a bit nebulous to me. What exactly were the severe diabetic complications? How was the participants’ "enthusiasm" to adopt SBGM on a regular basis judged? Examples of exclusions are given on page 8. "Enthusiasm" is judged on an individual basis, someone who refuses to measure their BG several times a day is unlikely to benefit from DAFNE education.

**Major Compulsory Revisions**
6. The authors line of reasoning pertaining to possible (dis)advantages of the 5 week DAFNE needs to be backed up by references. For instance, is peer support...
really a key factor for the programme's success and is it reasonable to assume that a 5 week DAFNE format could be problematic at all? The tight one week format may indeed bolster group coherence and identity - however, again, is this an evidence-based factor for the programme's success? We cannot answer these questions at this time as evidence is lacking, and hence the study design includes qualitative research to try to answer these points. Moreover, from an educational psychology perspective the less tight format spread over 5 weeks should be definitely be superior due to the room it gives to gain hands-on experience between lesson, as the authors correctly point out. However, there is already evidence for the effectiveness of weekly delivered format in T1DM patient education. E.g., that's the way the Dusseldorf programme (which is essentially DAFNE) is delivered in many European countries. Same with the MEDIAS2 programme. There are also studies published that demonstrate the effectiveness of the format (admittedly, not compared to a tight format but, in case, of MEDIAS2 compared to one-to-one education). The authors should at least acknowledge this evidence. We have acknowledged the Dusseldorf programme on which DAFNE is based. MEDIAS2 is a study in Type 2 diabetes and the paper was published after the protocol was designed, therefore we have not referenced it.

7. I feel a bit uncomfortable about the way the qualitative part of the study is placed in the manuscript. It is only briefly mentioned in the abstract (without the authors making clear what the objectives of the sub-study were), followed by a lengthy description in the main text body. This description, however, lacks some relevant details (e.g., analytical approach). As main results of the qualitative sub-study have already been published, I suggest cutting down this suggest, merely briefly mentioning the sub-study’s objectives and recruitment in the main text body. Definitely, the objectives should also go into the abstract if the sub-study is mentioned there. The method of data analysis is described on page 20.

The objectives of the qualitative study are now mentioned in the abstract, and some of its description has been removed from the main text.

**Level of interest:** An article of importance in its field

**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.