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.

Minor Essential Revisions:
1. Use of consistent terms for the 1 week and 5X1 week groups would add clarity to the manuscript.
2. Please describe how you plan to analyze and interpret the primary and secondary outcomes for HbA1C.
3. Please provide a citation for the statement about duration of recall for severe hypoglycemic episodes.

Discretionary Revisions:
1. Although a high degree of detail is necessary for a study protocol, less detail regarding certain non-essential aspects of the study may improve the flow of the manuscript.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
**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.