Reviewer's report

**Title:** A randomized controlled trial investigating the impact of different modes of vitamin B12 supplementation over subclinical vitamin B12 deficiency on sensory, motor and cognitive function among older people living in Santiago, Chile. A study protocol [ISRCTN 02694183].

**Version:** 1  **Date:** 17 May 2011

**Reviewer:** Mary Ann Johnson

Reviewer's report:

1. The question posed by the authors is of interest and is well defined.
2. The proposed methods appropriate and well described, and are in sufficient detail to replicate the work.
3. This is a proposal, rather than a research report, so there are no data, results, or conclusions to review.
4. The title and abstract accurately convey information about the proposed study.
5. The writing is acceptable.
6. The major compulsory revision is to clearly define how the MMSE will be used as a screening tool and the cut-off to be used. Several statements are problematic and the authors perhaps mean greater than 20 or greater than 24? “Potential participants will be those with an MMSE score of less than 20 (out of a maximum of 30).” Later the authors state, “Those with an MMSE score of below 24 or a Pffefer Test less than 5 (indicator of depression) will not enter the study.”
7. The second compulsory revision is to justify why participants will include those with serum vitamin B12 of up to 700 pmol/L, as this is rather high and participants with this concentration will likely be vitamin B12 sufficient and hence unlikely to respond, neurologically, to high doses of vitamin B12 from fortified foods and supplements.
8. The third compulsory revision is to provide information on the vitamin B12 status of older people in Chile, as well as the expected drop out rate, to help with the power and sample size calculations. For example, if vitamin B12 status, measured by serum vitamin B12, is relatively poor, then the power calculations are probably adequate. However, if vitamin B12 status is relatively good, then this study is probably underpowered. The drop out rate seems very low, so should be justified and/or increased along with the estimated sample size.
9. A minor revision is to clarify how many centers are being held in “reserve,” as it is not clear if 6 are in reserve or just one. If one, then indicate how this one will be selected.
10. Edit the document to correctly spell this author as either “Pfeffer” or “Pfeffer.”

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

**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.