Reviewer’s report

Title: Effectiveness of the National Program of Complementary Feeding for older adults in Chile on vitamin B12 status in older adults; secondary outcome analysis from the CENEX Study (ISRCTN48153354)

Version: 1 Date: 24 January 2013

Reviewer: mary rose sweeney

Reviewer’s report:

1. Is the question posed original, important and well defined?
There is limited data on the impact of adding vitamin B12 to foodstuffs so the information gathered in this study is of value particularly as the timescales is over 24 months allowing both for an acute and a long-term effect.

2. Are the data sound and well controlled?
I would like to know more about the sample – how representative are they of the older Chilean population? – can you provide some data from a national study for example to demonstrate that the biomarker data at baseline is typical of that from a larger Chilean study.

3. Is the interpretation (discussion and conclusion) well balanced and supported by the data?
I think the discussion and conclusions are fine but there is no enough information in the sections prior to this.

4. Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?
I feel the authors have been rather sketchy with the information they have provided. I would need to see more information on the intervention itself, in terms of where they accessed the foods, how often they consumed them, what amount they consumed at any one time, what opportunity they had to ask questions and engage with the research team before and during the intervention, method of cooking, how they accounted for foods not consumed. Also the authors mention supplements – were the foods fortified with synthetic sources of B12 or were the sources natural or were they given supplements with B12. This is confusing. Also it would be important to establish how often participants were contacted (either face to face or by phone) to monitor progress, compliance, motivation levels etc. No information is provided on whether the participant’s were current or previous supplement users. No information was provided on their typical diet and intake of fortified foodstuffs either actively or passively. No information is provided on whether participants changed their diet with the advent of the survey.

5. What are the strengths and weaknesses of the methods?
It is difficult to judge whether the methods are robust as no enough information is provided on the methodology.
6. Can the writing, organization, tables and figures be improved?
The tables and graphs appear to be well laid out

7. When revisions are requested.

8. Are there any ethical or competing interests issues you would like to raise?
None

9. Reviewers are reminded of the importance of timely reviews.
No issues with this

10. Confidentiality
Understood

11. Are the included additional files (supplementary materials) appropriate?
Online publishing enables the inclusion of additional files with published articles. Additional files of many types can be submitted, including movies, tabular data and mini-websites. Reviewers are encouraged to comment on the appropriateness of the types of additional files, included with the manuscript, for publication with the final article. Additional files pertaining to original/raw data files that support the results reported in the manuscript can be included. It is not expected that reviewers should re-analyze all supporting data as part of their peer review, but the availability of supporting data enables more detailed investigation of particular aspects of the study if the reviewer or editor feels it is necessary.

Major Essential Revisions

No dietary intake data is provided at collection at baseline or throughout the study. This would really have helped with the interpretation of the data particularly as the intervention did not achieve an increment in B12 status but rather the opposite occurred.

No blood sampling with B12 measurement was conducted at intervals during the study to examine what was happening to B12 status during the study period.

Not enough information is provided on the intervention itself, what it was, how subjects were supposed to take it, how often, how waste was accounted for

No mention of how compliance was monitored – it sounds like the subjects were not contacted for the 24 month period

I would like to see some data from a wider population study illustrating that this group are representative of the Chilean older population – the authors should provide some comparative data.

The authors mention in the introduction that folic acid is supplied in the PACAM programme – is B12 also added in this intervention as it is also mentioned that the primary objective of the study was to measure impact on B12 levels.
At one point the authors mentions that 125 participants are randomly selected but then goes on to say that blood was taken from 491 individuals – this is very unclear and very confusing. Please clarify.

The authors say 1kg per month was supplied of a dried soup and 1kg of a powdered milk per month. This is very vague. The authors should provide more details of the intervention and supply a copy of the instructions given to participants.

As this group are an older cohort presumably they would have needed extra attention when it comes to ensuring that they were complying and that issues of cognition did not interfere with compliance.

How did the authors address these issues?

I am not sure what the authors mean by the sentence on paragraph 2 on page 4 which states “The recommended supplement intake provides ……. please clarify this sentence and the relevance of it.

Were all the samples (at both time points) included in the same batch laboratory assay?

Statistical analysis – the first mention of a “Health Centre” is made – what is the role of the health centre in the study? The authors should elaborate on this.

Please explain what is meant by “SHR”

What instrument captured SHR responses? – there is no previous mention of this in the manuscript. Please clarify.

Under the RESULT section define what you mean by “supra physiological levels”.

**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:**

None