Author's response to reviews

Title: The effects of changing dairy intake on trans and saturated fatty acid levels - results from a randomized controlled study

Authors:

jocelyne r benatar (jbenatar@adhb.govt.nz)
ralph ah stewart (rstewart@adhb.govt.nz)

Version: 8 Date: 25 February 2014

Author's response to reviews: see over
26 February 2014

The Editors
Nutrition Journal

To Whom It may concern

Re: The effects of changing dairy intake on trans and saturated fatty acid levels- results from a randomized controlled study

To Whom it may concern

Thank you to the reviewers who commented on this study. Several changes are made to the manuscript in response and these. Reviewer’s 1 has accepted the manuscript. Reviewer’s 2 comments are listed below.

<table>
<thead>
<tr>
<th>Reviewer comments</th>
<th>Response</th>
</tr>
</thead>
</table>
| Page 4, paragraph 4: Given the aim was to evaluate the effects of dietary advice to increase, decrease or not change dairy food intake, why did the authors ask those who reduced dairy to also eliminate red meat? How can the authors attribute changes to change in dairy intake rather than changes in red meat intake. What were the results from the FFQ with regards to changes in red meat consumption between groups? Could this have influenced the results? | Added to Page 4, paragraph 4
‘This was to ensure that participants did not increase uptake of alternative sources of ruminant trans fatty acids’

On page 7 it is stated
‘There was no significant change in intake of food from ruminant sources such as meat or goat milk and cheese by randomized group.’

It is therefore clear this did not influence result |
| Page 4: The authors’ comments in their rebuttal regarding why a food diary was not used is confusing. Why would informed consent be different than obtaining consent from collecting FFQ data? Was the FFQ used validated for assessing intake both over a 3-day period and over 1 month? Is an FFQ sensitive enough to pick up changes over only 3 days? | To use a one month diary we would have had to consent patients, administer the diary, and then randomize participants 1 month later. The FFQ was a 3 day recall of what participants have consumed prior to randomization and therefore can be administered on the day of randomization. The FFQ used has been validated [1] by the National Cancer Institute. Patients are unlikely to recall more than 3 days of intake, and the reviewer is correct, there is a danger of inaccuracy. However all FFQ and diaries have been shown to be relatively inaccurate[2]. Changes in intake as measured by the FFQ were not a primary or secondary objective of the study. |
| Page 5, paragraph 2: I am unclear regarding the comments on the CV for fatty acid analysis. Can the authors please add the CV values to this section? | The questions we asked was whether randomizing patient to changed dairy intake affected fatty acid levels. The FFQ was a simple and practical way to evaluate change in food intake. Added to page 5- ‘The coefficient of variation for each fatty acids at this laboratory is presented in table 1. Each CV is added to the table to make interpretation easy.’ |
| Page 6, paragraph 2: The authors need to state why analysis used was not intention-to-treat. This is the usual analysis for a clinical trial where the question of whether advice to change dietary intake has an effect on outcomes. | This was not done as this is a surrogate marker outcome study. ITT was not done as there is no outcome measure available. Added to page 6 ‘Analysis was done only on those participants who completed the study, as no measurable outcomes were available on those who did not return at one month.’ |
| It is stated that participants had normal weight. Although mean weight was within the healthy weight range, the SD suggests that there were some participants who were overweight and possibly obese. This description needs to be modified. | Results page 6 has been modified to ‘The average body mass index was 24.5 (SD 4.0) and participants were normotensive with an average blood pressure (BP) 110/70 (SD10/8) mmHg’ |
| Page 7, paragraph 2: Please add the overall p-value for difference in change in dairy fat between groups. | P value added page 7 Change in dairy fat for the reduced dairy diet was -10.4 (10.1) g/day, no change was -3.4 (7.9) g/day, and increased dairy was +12.5 (15.7) g/day, p<0.001. |
| Page 7, paragraph 4: Given no change in total saturated fat between the groups, do you think that the low dairy food group compensated with other high saturated fat foods that were not picked up by the FFQ? | This is likely hence the comment in the discussion page 9 para 2: ‘Moreover, reducing dairy food intake had no effect on plasma levels of these fats suggesting that these may be present in other food sources’ |
| Page 8, paragraph 4: The authors state “intake of dairy food significantly changed for all randomized groups”. However the results sections states that change in dairy food was not significant for the no change group, p=0.78. Please clarify. | This has been amended on page 8, paragraph 4: ‘Intake of dairy food significantly changed for all those randomized to increase and decrease dairy food intake’, |
| Suggest adding limitations inherent with using FFQ to assess dietary intake. | Added to limitation page 10 Food frequency questionnaires may not accurately reflect dietary intake [3, 4]. Studies comparing food frequency measures with repeated dietary recalls generally show correlations of the order of 0.4–0.7 [1] |
| Table 3: There is no comparison for reduced vs. increased. Could the authors provide an overall p-value for differences between the 3 groups and then pairwise comparisons if any of the overall p-values are statistically significant? | We used ANCOVA as it is a more robust statistical test to assess treatment effect. Analyzing controlled trials with baseline and follow up measurements the use of an analysis of covariance (ANCOVA), despite its name, is a regression method that takes into account unknown imbalance at baseline between the group [5]. With ANCOVA the analysis is done across the groups hence only 1 p value |
| The referencing within the text is still inconsistent. There are sometimes spaces between the text and the reference and sometimes not. Please ensure | Thank you- the references have been checked again and corrected |
The authors have used both English and American spelling. E.g. Randomized" and "randomised" Please be consistent.

We have made 5 changes to the American spelling

Page 3; paragraph 1: “poly unsaturated” should read “polyunsaturated”

changed

Page 4; paragraph 2: There should be a space between “…volunteers (n=180)”

changed

Page 7, paragraph 3: The word “acid” needs to be added to the first sentence. Also “table” should read “tables”.

changed

Page 9, paragraph 3: Suggest rewording first sentence to “did not change significantly between groups”. This paragraph also needs a full stop at the end.

changed

Journal titles are sometimes abbreviated and sometimes not. Please be consistent as per journal guidelines.

The references are done using endnote using the nutritional journal style and are therefore consistent with the journal requirements. All citations are downloaded and software automatically changes the style- it cannot be manually changed.

We hope this manuscript is more suitable for publication in the Nutrition Journal.

Yours sincerely,

[Signatures]

Dr Jocelyne Benatar
Clinical Research Doctor

Professor Ralph Stewart
Cardiologist


