Author's response to reviews

Title: Efficacy of dietary prebiotic supplementation on advanced glycation, insulin resistance and inflammatory biomarkers in adults with pre-diabetes: a study protocol for a double-blind placebo-controlled randomised crossover clinical trial

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Author's response to reviews: see over
24 September 2013

Dear Editors

Re: Efficacy of dietary prebiotic supplementation on advanced glycation, insulin resistance and inflammatory biomarkers in adults with pre-diabetes: a study protocol for a double-blind placebo-controlled randomised crossover clinical trial

We wish to submit the above protocol article for consideration for publication in BMC Endocrine Disorders.

Excessive accumulation of advanced glycation endproducts (AGEs) within the body contribute to the development of diabetes and its vascular complications. AGEs are formed endogenously but also enter the body through cigarette smoking and ingestion of foods containing AGEs. The widespread consumption of high fat, heat processed foods containing large quantities of AGEs warrant simple interventions to reduce AGE-mediated damage. While there is some evidence to support the use of short-term low-AGE diets to attenuate AGE-related pathology in people with diabetes, an AGE-restricted diet is difficult to maintain for long periods of time as AGEs contribute to the favourable flavour, colour and aroma of many foods.

Dietary modulation of the human colonic microbiota using prebiotic supplements is a simple therapeutic strategy which can potentially improve the metabolic health of individuals with diabetes or those at risk of developing the condition. This article describes the first prebiotic intervention study we are aware of which examines the effect of changes in gut bacteria on the advanced glycation pathway in adults with prediabetes. Prebiotic dietary supplements capable of beneficially altering the gut microflora may prove to be an effective strategy for preventing or slowing the development of type 2 diabetes.

Thank you for considering this article and we look forward to hearing from you in the near future.

Yours sincerely

Nicole Kellow
Melinda Coughlan
Chris Reid
Gayle Savige
1) Evidence of Ethics Approval: Monash University Human Research Ethics Committee certificate of approval (attached).

2) External Funding: Nil.

3) Trial Registration: Australia and New Zealand Clinical Trials Register (ANZTR) Number: ACTRN12613000130763.

4) Recruitment of participants for this study is expected to commence: December 2013.

5) Other manuscripts produced based on this study protocol: Nil.

1) We have added “External Funding: Nil” at the end of the manuscript.
Human Ethics Certificate of Approval
Date: 5 February 2013
Project Number: CF12/2690 - 2012001452
Project Title: Dietary prebiotic supplementation in adults with prediabetes
Chief Investigator: Dr Gayle Savige
Approved: From: 5 February 2013 To: 5 February 2018

Terms of approval
1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. Amendments to the approved project (including changes in personnel): Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. Future correspondence: Please quote the project number and project title above in any further correspondence.
8. Annual reports: Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. Final report: A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. Monitoring: Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. Retention and storage of data: The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

Professor Ben Canny
Chair, MUHREC

cc: Dr Naiyana Wattanapenpaiboon, Mrs Nicole Kellow