

Development of novel low- and high-emulsifier diets for trial in Crohn's disease management

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Individual emulsifiers have been implicated in the pathogenesis of Crohn's disease in pre-clinical models,⁽¹⁾ yet little is known about the quantity of emulsifiers in the food supply. Before high-quality human trials are implemented to assess the therapeutic effects of emulsifiers in food, development of high- and low-emulsifier diets that adjust for confounding dietary variables are needed. To design two novel diets for use in feeding trials, based on existing food, matched in nutrients and ingredients, except emulsifiers, and to evaluate the adherence to, and palatability, tolerance and blinding of the diets in healthy volunteers. A database of qualitative emulsifier content of food categories was developed based on visits to seven supermarkets and reading labels of all available food packaging. Two 7-day diets were developed using this database and knowledge of natural emulsifiers in whole foods.⁽²⁾ The diets met Australian healthy eating guidelines and were matched for energy, macro- and micronutrients, and fibre, and only varied in emulsifier content. 20 recipes were developed, cooked, portioned and vacuum-sealed with dry goods and delivered to participants. Ten healthy participants were recruited to receive both diets in a single-blinded, randomised, cross-over feeding trial with a 3-week washout. Daily food records were kept by participants to assess adherence and intake. Participants completed electronic surveys to assess the tolerability, palatability, satiation and ease of following the diets using a 100 mm visual analogue scale on completion, the results being compared using paired t-tests. They were asked to identify the intervention diet for Crohn's disease and why, for which qualitative analysis was performed. Ten participants (seven male) completed the trial with high adherence (only one participant consumed disallowed food). Palatability of the high-emulsifier diet was mean 68 mm (95% CI [48, 88]), which was similar to 62 mm (95% CI [28, 96]) for the low-emulsifier diet ($p = 0.55$). Likewise, tolerability (41 mm, CI [12, 70] v. 55 mm, CI [30, 80]) and satiety (57 mm, CI [23, 91] v. 49 mm CI [15, 83]) were similar between high- and low-emulsifier diets, respectively ($p > 0.10$). The diets were rated easy to follow at 82 mm (CI [61, 100]). All participants accurately chose the low emulsifier diet as the intervention diet, citing it as "less sweet and less processed". The qualitative feedback highlighted that some participants found the diets high in complex carbohydrates and lentils making them feel bloated and gaseous, whilst others felt hungry. Novel diets, matched in all but emulsifier content, were successfully designed and found to be palatable with excellent adherence but easily identifiable. Improving and re-evaluating the diets for blinding and tolerability are required before implementing in a larger feeding trial. This highlights the importance of conducting pilot studies to assess novel interventional diets for use in trial.

References

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