

Consultation on the draft report:

Lower carbohydrate diets for adults with type 2 diabetes

Comments Form

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General comments	Comments
Methods	<p>Please insert each new comment in a new row</p> <p>This report provides a helpful overview of 4 main systematic reviews and meta-analyses of randomised controlled trials comparing lower- to higher- carbohydrate diets for people with type 2 diabetes. It follows a slightly unusual methodological process, which means that some studies which are in more than one review are 'double-counted' and it is not clear why a new meta-analysis of studies identified in the reviews was not conducted. However, the findings are fairly consistent with the findings of individual reviews with our understanding of the literature. Since there are no sub-group analyses it is hard to know who these dietary interventions may work for, and how.</p> <p>It is important that the report appropriately focusses on "higher quality" evidence provided by systematic reviews and meta-analyses of randomised controlled trials, in order to address the stated aim to review the evidence on lower carbohydrate diets compared to current UK government advice (high carbohydrate diets) for adults with type 2 diabetes. It broadly concludes an absence (or absence of evidence) of superiority at 1 year, for the pre-specified outcomes. However, it is important to distinguish between the question of superiority (is it the best approach), and effectiveness (does it work for some people); and the focus on comparative trial data risks overlooking effectiveness outcomes. This could be brought out more clearly in the report.</p> <p>Much of excluded observational literature (and within-group analyses reported in the supplementary appendix) do demonstrate the potential for clinically significant improvements in weight and HbA1c reduction (for example), suggesting some short-term effectiveness (though not superiority) of low-carbohydrate approaches for some patients. This is reflected in the reported UK and international dietary recommendations for type 2 diabetes, many of which now include low carbohydrate diets as one option (that are "safe and effective in the short term") to consider as part of an individualised approach. This more nuanced approach is not addressed in the conclusions of the report.</p> <p>Additionally, the majority of studies included were comparing two programmes in which people were advised and supported to consume (on average) a lower-energy diet without carb restriction, or a diet using carb restriction as an additional or alternative means to reduce energy intake. Few comparisons were made to true "usual care", i.e. current UK government advice and how this is routinely delivered, or in "healthy" individuals with type 2 diabetes. So while a lack of superiority of low-carbohydrate (or higher-carbohydrate) diets shows that either may be equally valid in the context of a weight loss programme, the results of this report do not currently tell us whether healthy people with type 2 diabetes, who are not explicitly aiming to lose weight, should be advised to lower their carbohydrate intake or not.</p>

General limitations in the evidence base	<p>This review appropriately highlights several important points in this area:</p> <ul style="list-style-type: none"> • Despite the large numbers of publications in the field, there remains limited robust evidence comparing objectively low- and high- carbohydrate diets for people with type 2 diabetes. This is in large part due to the variability in prescribed (and achieved) carbohydrate proportions (and absolute amounts consumed) in the studied diets. Most comparisons made were between moderate- and high- carbohydrate diets, with relatively little data on very-low and low-carbohydrate diets; this limited absolute difference in intake between groups may contribute to the limited differences in outcomes seen. Improved consistency of reporting in future studies, and the use of the now widely accepted criteria for very low- and low- carbohydrate diets, should be encouraged. • The confounding effects of medication changes are highlighted here. With inconsistent and very variable reporting of medication changes throughout the studies, it is impossible to assess the impact of either the different diets, or potential reduction in medications, on glycaemic control. • There is a paucity of research in ethnic groups other than white populations; and in people with type 2 diabetes but without overweight or obesity (who make up a small, but significant, proportion of people with type 2 diabetes), limiting the application and generalisability of these conclusions in routine care settings.
Primary outcomes	<p>The rationale for reporting BMI only at 12 months, but HbA1c from 3 months, is not clear. The report states that “many short-term interventions are able to achieve weight loss but the maintenance of weight loss is challenging”; however the same could be argued for HbA1c (it is difficult to sustain improvement over time). Weight loss interventions that lead to short-term weight loss also lead to longer-term weight loss, compared to control groups. There currently is no evidence that any particular type of intervention, with different trajectories of weight loss, change the trajectory of weight regain. Additionally, there are recognised cardiometabolic and general health benefits seen with weight loss that persist even beyond the time of any potential weight regain. In this context, the decision to discount weight loss outcomes at less than 12 months in case they are not sustained does not seem clinically justified, and examining the evidence of short- as well as longer-term effects would be valuable. As is recognised in the results, sensitivity analyses within the meta-analyses (e.g. Sainsbury et al 2018) suggest that a significant proportion of the HbA1c improvements may be due to weight loss; and the conclusions again re-state that it is difficult to separate the effect of weight change on the outcomes. It is therefore hard to interpret the reported HbA1c results (and other outcomes) for shorter-term studies (3-12 months) without reporting the corresponding weight losses.</p>
Conclusions and Recommendations	<p>1) This report highlights the need to achieve consistency in definitions and reporting standards. Adopting consistent definitions of very low-, low-, moderate- and high carbohydrate diets, such as those used in</p>

	<p>this report, and quantitative reporting of medication changes throughout studies, would enable more robust comparisons and conclusions to be drawn in future reviews and reports.</p> <p>2) The report highlights several significant gaps in the evidence. Further research into the effects, and effectiveness, of low-carbohydrate diets for people with type 2 diabetes is needed in ethnic groups other than white populations, and in those populations in whom the effects of LCDs are relatively under-researched but the burden of T2DM is high (e.g. the South Asian population); and in people with type 2 diabetes with a normal BMI (both in the context of weight loss and weight maintenance).</p> <p>3) Additionally, the existing studies, and this report, cannot answer the question of whether UK government advice for people with type 2 diabetes should advise them to reduce their carbohydrate intake, outside the context of weight loss and weight loss programmes. There is an important evidence gap in understanding what the optimal diet for standard “healthy eating” with type 2 diabetes should be.</p> <p>4) This report recognises that UK and international recommendations endorse an “individualised” approach to weight loss and dietary change for people with type 2 diabetes, which may include low-carbohydrate diets (as being safe and effective in the short term). There is currently little evidence to inform how a person may be assessed or supported (particularly in routine care, where 90% of the management of type 2 diabetes is conducted) to determine which dietary management strategy may be most appropriate, or effective. While an “individualised” approach and patient choice fits with the UK model of patient-centred care, it is important to understand whether this approach to dietary management improves patient outcomes, and how this could be operationalised in routine consultations.</p>
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Please add extra rows as needed

Comments by paragraph	Comments
	Please insert each new comment in a new row
Table 3.1 (p.19)	Diabetes Australia row – Carbohydrate content – “low carbohydrate diets” should be followed by 2 asterisks ** (referring to definition of low carb diets) rather than 1 * (referring to NICE guideline)

Please add extra rows as needed