Logo of the Scientific Advisory Committee on Nutrition

Consultation on the draft report:

Lower carbohydrate diets for adults with type 2 diabetes

Comments Form

Organisation	
Name of commentator and contact details	Keith Hulme

- Please do not PDF the form.
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General comments	**Comments** Please insert each new comment in a new row *Example: Please check that referencing is consistent across all the chapters.*
Comments on SACN Draft Report "Lower Carbohydrate diets for adults with Type 2 Diabetes" I have three key comments. In summary: 1. The eligibility criteria used to select evidence means the question asked by the PHE brief remains only partially answered. Some high quality evidence has been excluded, despite being	

compelling. It should be taken into account.

2. The findings relating to reduced medications with lower carbohydrates have been downplayed. These findings are strengthened by the excluded evidence.

3. SACN team risk exposure to criticism and undermining of their credibility by taking such a narrow view of the evidence.

1. My first comment relates to the eligibility criteria used to include and exclude various types of evidence.

As a direct consequence of the criteria some strong evidence on the impact of a very low carbohydrate diet on Type 2 Diabetes has been excluded. This is a significant exclusion and has affected the integrity of the SACN findings.

The included studies were limited to Systematic Reviews, Meta Analyses and pooled analyses of RCTs and prospective cohort studies (para 5.3). Whilst these studies may well be considered the strongest type of evidence, this obviously depends on the availability of high quality well controlled studies clearly focussed on common objectives. Meta Analysis can surely only add value rather than dilute findings if the studies included are strictly homogeneous. In the current study these strengths have been substantially undermined by the limitations identified by SACN in their

findings.
Paras 6.62 to 6.81 and 7.21 to 7.29 of the SACN report summarise some of the limitations of the included evidence base. These include

- Significant heterogeneity in the definition and level of carbohydrate considered

- Poor control of dietary adherence and maintenance

- Inconsistent assessment and reporting of medication adjustment and its effect on one of the primary outcomes HbA1c

- An assessed high risk of bias.

These limitations of the evidence base mean the outcome assessment could only be described in terms of ‘lower vs higher carbohydrate diets’. The approach taken of grouping all forms of low carb diets into a single “lower” category is flawed. It has failed to address the type of diets that PHE referred to as “...gaining attention and increasingly being promoted.” (para 1.1). These diets are predominantly low or very low carbohydrate diets. The included studies were unable to satisfactorily differentiate between the effects of the different carbohydrate levels. As a consequence the brief from PHE remains only partially answered by the present SACN study.
In view of the recognised deficiencies in the eligible studies, consideration could, and should have been taken of other evidence, some of which is

compelling despite not satisfying the inclusion criteria.
An example of compelling available evidence is the ongoing clinical trial conducted by Virta Health specifically addressing treatment of Type 2 diabetes. The protocol features very low carbohydrate diets combined with ongoing medical support and advice. This clinical trial has so far published peer reviewed papers covering results from 10 weeks, 12 months and 2 years, including an assessment of effect on cardiovascular risk factors. (refs 1-4).
The results of the excluded study are spectacular compared with expectation from standard care for Type 2 Diabetes. Results show:

- Substantial reductions or complete elimination of diabetes medication

- Substantial improvement in HbA1c - often to non diabetic levels

- Sustained weight losses

- Improvements in cardiovascular risk factors

The Virta Health study and others specifically addressing low or very low carbohydrate diets and their corresponding impact on Type 2 diabetes and cardiovascular risk factors provide important strong evidence and should be reconsidered for inclusion. Inclusion would demonstrate that SACN has taken reasonable account of a broader evidence base and more fully

responded to the PHE brief.
Virta Health studies have been explicitly excluded. The stated rationale for exclusion (see para 5.9, referring to one of the Virta Health papers) is based on several "key limitations" specifically:

- lack of randomisation
- lack of a comparator arm
- self-selection

I consider that these 'limitations' are not significant when compared to the limitations identified by SACN for the included studies.
Randomisation is clearly important when it can be difficult to account for potential confounding factors. However when the outcomes are so compelling compared with expectation from usual standard of care where the expectation can be deduced from the National Diabetes Audit (ref 5) which has zero targets or measurement for medication reduction or normalisation of HbA1c, but checks whether the NICE care processes are met. The only measure of diabetes control target is an HbA1c level of < 58 mmol/mol, compared with a non-diabetic level of < 48 mmol/mol. This is surely an effective 'comparator arm' for the Virta Health study and negates the need for randomisation.

With regards to self selection, this adds to the likelihood of protocol adherence, which has proved to be a limitation of the included studies.

In addition randomisation would deny some patients the benefits that are well established with the clinicians involved. Indeed it could be argued that randomisation would be unethical.

2. **My second comment relates to the downplaying of the reduced medications**

Reducing (or de-prescribing) medication is clearly a highly desirable outcome and the data reported in the included studies, although limited, is highly supportive of low carbohydrates and should be highlighted rather than downplayed.

- The Huntriss (2018) paper includes the quote ‘From all 14 papers that included participants on diabetes medication at trial start and reported changes in diabetes medication, there was a unanimous report of the superior effect of medication reduction in the LCIA (low carbohydrate intervention arm) in comparison to the control group, with nine out of 11 studies that discussed statistical significance of the difference between groups, finding a statistically significant reduction in diabetes medication in the LCIA.’

- This finding is reinforced in the Virta Health papers which quantifies the dramatic reductions in diabetes medication with the low carbohydrate diet. In fact part of the protocol is to reduce medication very early in the protocol to limit potential hypoglycaemic events.

- The evidence for this outcome was not graded in the SACN report because a meta analysis was not performed (para 7.44) although it was mentioned in para 7.45.

- In the summary table (table 7.2) the comment was ‘no evidence’ with no mention of the qualitative benefit with low carbohydrate.

This is an important outcome and should not be ‘disregarded’ or downplayed due to lack of quantification in the studies considered. Further evidence is provided in the excluded studies.

Arguably reduction in medication should have been a primary outcome, more important than weight loss per se.

3.My third comment relates to the SACN team risking exposure to criticism and an undermining of their credibility by taking such a narrow view of the evidence.

The failure to include a broader evidence base, taking account of much available clinical and other evidence has resulted in a paucity of good quality data and enabled rather weak conclusions to be drawn. These conclusions tend to support the status quo, reinforcing previous SACN reports and could be considered to be suggestive of bias on the authors behalf.

- Long standing guidelines from PHE and Diabetes UK encourage high (50%) levels of carbohydrates for the general population including those with Type 2 diabetes.

- New and good evidence has emerged which challenge these long established guidelines and provide support for low or very low carbohydrate diets for those with Type 2 Diabetes

- By choice of eligibility criteria these studies have been excluded and assessment limited to heterogeneous studies with admitted serious limitations

- Other bodies around the world (including the NHS) have begun to include a low carbohydrate diet as one option for the care of T2DM as described in para 3

- As new data has become available since the SACN literature search

it may be appropriate for them to reconsider both this new data and the breadth of evidence considered.

- There is a swelling tide amongst clinicians that substantially reducing carbohydrates is an effective treatment for T2DM especially since the evidence against dietary fat is proving to be less than convincing.

- The discussion in paras 2 and 3 of the SACN report clearly show the case that with T2DM there is the inability to manage blood glucose, high levels of which are caused by dietary carbohydrates.

By ignoring the broader evidence base, SACN risk criticism of bias in their assessment which may be seen as an attempt to maintain their previous conclusions on carbohydrates

Keith Hulme
5 Saswick Court
Roseacre
Preston PR4 3XD

Refs

1. A Novel Intervention Including Individualized Nutritional

Recommendations Reduces Hemoglobin A1c Level, Medication Use, and Weight in Type 2 Diabetes. McKenzie et al 2017 https://diabetes.jmir.org/2017/1/e5/

2. Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study. Hallberg et al 2018. https://doi.org/10.1007/s13300-018-0373-9.

3. Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-Year Non-randomized Clinical Trial . Athinarayanin et al 2019. https://doi.org/10.3389/fendo.2019.00348

4. Cardiovascular disease risk factor responses to a type 2 diabetes care model including nutritional ketosis induced by sustained carbohydrate restriction at 1 year: an open label, non-randomized, controlled study. Bhanpuri et al 2018. https://cardiab.biomedcentral.com/articles/10.1186/s12933-018-0698-8

5.National Diabetes Audit, 2017-18 Report 1: Care Processes and Treatment Targets
England and Wales 13th June 2019 https://files.digital.nhs.uk/88/F1E544/National%20Diabetes%20Audit%2017-18%20Full%20Report%201%2C%20Care%20Processes%20and%20Treat

ment%20Targets.pdf

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Comments by paragraph	Comments
Example: 1.2	Please insert each new comment in a new row *Example: Missing reference and statement unclear*

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