



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

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| Topic: | Low carbohydrate dietary interventions for people with type 2 diabetes, as part of a structured education programme. |
| Topic exploration report number: | TER128 |

Introduction and aims

We searched for evidence on low carbohydrate dietary interventions for people with type 2 diabetes, as part of a structured education programme.

Summary of findings

No guidance/guidelines or HTAs were identified on low carbohydrate dietary interventions for people with type 2 diabetes, as part of a structured education programme.

A large body of evidence on low-carbohydrate diets in type 2 diabetes was identified. The direction and size of the direction is unclear. Furthermore, the evidence varied considerably in terms of the how the intervention was delivered: whether this was as part of structured education (and the precise definition of this term) and also whether the intervention was delivered face to face or virtually.

No systematic reviews or RCTs were identified specifically on low-carbohydrate or diet-based digital health technologies (DHTs) for people with type 2 diabetes.

Low carbohydrate dietary interventions for people with type 2 diabetes, as part of a structured education programme includes are, **but not restricted to**, a DHT and was determined to be a Tier 3a technology according to the [Evidence Standards Framework for Digital Health Technologies](#). Technologies within this classification are DHTs for preventative behaviour change, or which allow self-management of a diagnosed condition. For technologies of this classification, it is recommended that high quality comparative observational or quasi-

experimental studies demonstrating relevant outcomes are produced to demonstrate effectiveness of the technology.

Evidence

Guidance and HTAs

No guidance/guidelines or HTAs were identified which evaluate low-carbohydrate dietary interventions for type 2 diabetes. NICE and SIGN guidance on the management of type 2 diabetes is available (NICE NG28 and SIGN 116, respectively), however these do not specifically cover the use of low-carbohydrate dietary interventions.

Systematic reviews

A 2007 Cochrane review identified 36 articles assessing the effects of type and frequency of different types of dietary advice for adults with type 2 diabetes; this included high-fat/low-carbohydrate diets. No high quality data on the efficacy of the dietary treatment of type 2 diabetes were identified in this review.

A Medline search for systematic reviews retrieved the following:

- 32 systematic reviews for low-carbohydrate diet interventions in type 2 diabetes, several of which included meta-analyses of RCTs. The recent and relevant review (McArdle et al. 2019) aimed to evaluate the effect of carbohydrate restriction on glycaemic control in Type 2 diabetes. The review included 25 RCTs on 2132 participants and found no pooled effect on HbA1c in favour of restricting carbohydrate. Another systemic review (10 RCTs with 1376 participants), Snorgaard et al. (2017), found “low to moderate carbohydrate diets have greater effect on glycemic control compared with high-carbohydrate diets in the first year of intervention. The greater the carbohydrate restriction, the greater glucose lowering...Apart from this lowering of HbA1c over the short term, there is no superiority of low-carbohydrate diets in terms of glycemic control, weight, or LDL cholesterol”. No economic evaluations were identified.
- 1 systematic review of digital app-based interventions for management of type 2 diabetes. Some of the included apps had a diet monitoring function, but the systematic review did not specifically look at dietary interventions (Fu et al. 2017).
- No systematic reviews, meta-analyses, or economic evaluations specifically on low-carbohydrate or diet-based digital health technologies for people with type 2 diabetes. This search was therefore followed up with a search for primary studies (see below).

Evidence on specific technologies

Two apps were described by the topic referrer were Low Carb Program and Our Path. The manufacturer website for the “Low Carb Program” cited Saslow et al. (2018) and Hallberg et al. (2018). Saslow et al. (2018) is an open-label, single-arm, pre-post intervention using a sample of convenience for adults with type 2 diabetes who had joined the program and had a complete baseline dataset. Hallberg et al. (2018) is an open-label, non-randomized, controlled, before-and-after 1-year study. These studies may meet the minimum evidence standard for this DHT.

Studies cited on the “Our Path” website are unpublished conference proceedings.

Areas of uncertainty

There is a large evidence base for the effectiveness of low-carbohydrate diets in people with type 2 diabetes. However, it is unclear what evidence exists on delivering these as part of structured education, either face to face or virtually. Compared to low-carbohydrate diets in general, there is relatively limited evidence on the use of DHTs for delivering low-carbohydrate dietary interventions; no randomised controlled trials of this intervention were identified, or any evidence on their cost effectiveness compared to other methods of delivery.

Conclusions

A large body of evidence exists on the effectiveness of low-carbohydrate dietary interventions in type 2 diabetes, but further evidence is needed to clarify the effectiveness of implementing a low-carbohydrate diet as part of structured education, and the effectiveness of different methods of delivery, including by virtual/digital means.

Brief literature search results

| Resource | Results |
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| HTA organisations | |
| Healthcare Improvement Scotland | We did not identify any relevant guidance from this source. |
| Health Technology Assessment Group | We did not identify any relevant guidance from this source. |
| Health Information and Quality Authority | We did not identify any relevant guidance from this source. |
| UK guidelines and guidance | |
| SIGN | SIGN 116: Management of diabetes (2010) http://www.sign.ac.uk/pdf/sign116.pdf No recommendations about intervention of interest. |
| NICE | NICE Guideline NG28. Type 2 diabetes in adults: management (NG28). https://www.nice.org.uk/guidance/ng28 Section 1.3 makes a range of recommendations on dietary advice but does not make any specific recommendations on use of low-carbohydrate diets or how these should be implemented. |
| Secondary literature and economic evaluations | |
| EUnetHTA | We did not identify any relevant guidance from this source. |
| Cochrane library | Nield L, Moore H, Hooper L, Cruickshank K, Vyas A, Whittaker V, Summerbell CD. Dietary advice for treatment of type 2 diabetes mellitus in adults . Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004097. DOI: 10.1002/14651858.CD004097.pub4. |
| Medline | <p><u>Results for low-carbohydrate or diet-based digital health technologies</u> No systematic reviews, meta-analyses, or economic evaluations were found.</p> <p><u>Results for digital health technologies (not specific to diet) - 1 systematic review identified</u> Fu, H., McMahon, S. K., Gross, C. R., Adam, T. J., & Wyman, J. F. (2017). Usability and clinical efficacy of diabetes mobile applications for adults with type 2 diabetes: a systematic review. Diabetes research and clinical practice, 131, 70-81.</p> <p><u>Low-carbohydrate diet interventions more generally - Approx 32 systematic reviews (selection included below)</u> McArdle, P. D., Greenfield, S. M., Rilstone, S. K., Narendran, P., Haque, M. S., & Gill, P. S. (2019). Carbohydrate restriction for glycaemic control in Type 2 diabetes: a systematic review and meta-analysis. Diabetic Medicine, 36(3), 335-348.</p> <p>Ajala, O., English, P., & Pinkney, J. (2013). Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes. The American journal of clinical nutrition, 97(3), 505-516.</p> |

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| | <p>Snorgaard, O., Poulsen, G. M., Andersen, H. K., & Astrup, A. (2017). Systematic review and meta-analysis of dietary carbohydrate restriction in patients with type 2 diabetes. <i>BMJ Open Diabetes Research and Care</i>, 5(1), e000354.</p> <p>Meng, Y., Bai, H., Wang, S., Li, Z., Wang, Q., & Chen, L. (2017). Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: a systematic review and meta-analysis of randomized controlled trials. <i>Diabetes research and clinical practice</i>, 131, 124-131.</p> <p>Castañeda-González, L. M., Gascon, M. B., & Cruz, A. J. (2011). Effects of low carbohydrate diets on weight and glycemic control among type 2 diabetes individuals: a systemic review of RCT greater than 12 weeks. <i>Nutricion hospitalaria</i>, 26(6), 1270-1276.</p> |
| Primary studies | |
| Medline | A search for primary studies on digital applications for the delivery of low-carbohydrate or other diet interventions in type 2 diabetes retrieved 169 hits. Restricting this to the term “low-carbohydrate” revealed 4 hits, none of which were relevant. |
| Cochrane library | |
| Ongoing primary or secondary research | |
| PROSPERO database | 21 review protocol records were retrieved on low-carbohydrate dietary interventions in type 2 diabetes with an “on-going” status. 10 of these protocols were registered within the last 2 years. |
| Clinicaltrials.gov | Not searched |
| Other | |
| | <p>From “Low Carb Program” website.</p> <p>Saslow, L. R., Summers, C., Aikens, J. E., & Unwin, D. J. (2018). Outcomes of a Digitally Delivered Low-Carbohydrate Type 2 Diabetes Self-Management Program: 1-Year Results of a Single-Arm Longitudinal Study. <i>JMIR diabetes</i>, 3(3), e12.</p> <p>Hallberg, S. J., McKenzie, A. L., Williams, P. T., Bhanpuri, N. H., Peters, A. L., Campbell, W. W., ... & Volek, J. S. (2018). 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. <i>Diabetes Therapy</i>, 9(2), 583-612.</p> <p>References from “OurPath” website were for conference proceedings only and therefore not cited here.</p> |

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| Date of search: | November 2019 |
| Concepts used: | Low-carbohydrate diet AND diabetes (AND (app OR application OR digital)) for increased specificity |

