Technoleg Iechyd Cymru
Health Technology Wales

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.

Topic:	**Low Carb Program**
Topic exploration report number:	TER121

Introduction and aims

Health Technology Wales researchers searched for evidence on the Low Carb Program, a structured education and behaviour change platform available via a website or mobile application. The platform is intended for people with type 2 diabetes, prediabetes and obesity (not intended for people with type 1 diabetes). The program aims to support people to implement a lower carbohydrate lifestyle with the goal of improving blood glucose control, facilitating sustainable weight loss and reducing dependency on diabetes medication.

The Low Carb Program is part of the NHS National Innovation Accelerator and has been approved for inclusion in the NHS Apps Library in the United Kingdom. The platform is an MHRA-regulated Class I Medical Device.

Summary of findings

The Low Carb Program is a digital health technology and was determined to be a Tier 3a technology according to the NICE Evidence Standards Framework for Digital Health Technologies. This indicates that the technology Is used for preventing and managing diseases and will likely have measurable user benefits. Based on this classification, there is a requirement to demonstrate effectiveness using comparative evidence from high quality observational or quasi-experimental studies demonstrating relevant outcomes.

The topic proposer provided supporting evidence from an open-label, single-arm study (Saslow 2018). Of the 1,000 study participants, 708 (70.80%) reported outcomes at 12 months and 528 (52.80%) completed all program lessons. Medication use was reduced in 40.4% of participants who were taking at least one hypoglycemic medication at baseline. Glycaemic control and weight loss improved, particularly in people who completed the full program (mean body weight change of –7.45 kg and HbA1c change of –1.17% at one year).

The topic proposer also provided evidence from a poster which described a primary care NHS pilot in Wincanton which used lower grade staff (health coaches) to work weekly with patients

engaging with the Low Carb Program. The study demonstrated a 97% uptake of the Low Carb Program, 86% completion rate and average 8.7% weight loss at three months.

The cost of the technology is listed on the website as £14.99 per month or £69.99 when purchased as an annual subscription. The cost is lower when delivered through the NHS with a cost of £90 per patient licence, with each licence providing unlimited access to the Low Carb Program for three years. This upfront cost may be offset, at least partially, by a reduction in medication use. The topic proposer provided evidence from a poster which described a health economic analysis, which estimated a saving of £835 per patient per year as a result of a reduction in medication use.

No further clinical or economic evidence was identified through searches undertaken by HTW.

Areas of uncertainty

No comparative evidence was identified which investigated the use of the Low Carb Program. There is also limited evidence on the long term clinical and economic implications of the Low Carb Program. As such there is uncertainty around the effectiveness and cost-effectiveness of the Low Carb Program.

Conclusions

Some evidence has been identified demonstrating the potential benefits of the Low Carb Program. However, the evidence may not be of sufficient quality to draw firm conclusions about its benefits compared to current standard care.

Brief literature search results

Resource	Results
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	We did not identify any directly relevant guidance from this source which considered the specific intervention. Guidance on 'Management of Diabetes' includes section on low carbohydrate diets as one of many dietary recommendations in people diagnosed with type 2 diabetes
NICE	We did not identify any relevant guidance from this source
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant evidence from this source
Cochrane library	We did not identify any relevant evidence from this source
Medline	We did not identify any relevant evidence from this source
Primary studies	
Medline	One directly relevant study was identified which considered the specific technology under consideration: Saslow L, Summers C; Aikens J, Unwin D. Outcomes of a Digitally Delivered Low-Carbohydrate Type 2 Diabetes Self-Management Program: 1-Year Results of a Single-Arm Longitudinal Study. JMIR Diabetes 2018; 3(3): e12. This study was also submitted by the topic proposer on Health Tech Connect
Cochrane library	We did not identify any relevant evidence from this source

Date of search:	October 2019
Concepts used:	Low Carb Program, low carbohydrate programme, type 2 diabetes, pre-diabetes, obesity