



NHS Innovation Accelerator

Economic Impact Evaluation Case Study: Low Carb Program

Final version

Summary

The Low Carb Program is a digital behaviour change platform for people with Type 2 diabetes, providing goal-focused education, personalised resources and support to adopt a lower carbohydrate lifestyle. The programme is provided through licences for participants paid for by CCGs, with primary care staff trained in the recruitment of participants and other aspects of the programme. A trial has demonstrated benefits for participants in terms of weight loss, remission from Type 2 diabetes, reduced HbA1c levels and elimination of medications. The latter two metrics are used in this case study to estimate the net benefits and return on investment (ROI) of the Low Carb Program over a period of five years. There is uncertainty over the drop-out rate for the programme over this period, so a sensitivity analysis is included. The results estimate the net saving over five years to be between £673,108 and £509,435 for a CCG which contracts for 3,000 licences. This results in an ROI of between 2.38 and 1.98. These results are based on a number of assumptions and extrapolations from different sources and care should be taken in their interpretation.

1. BACKGROUND

The Low Carb Program is a behaviour change platform aimed at helping patients with Type 2 diabetes, pre-diabetes (diabetes prevention), obesity, non-alcoholic fatty liver disease and polycystic ovarian syndrome. The programme, developed by Diabetes Digital Media (DDM), is delivered through a web site and smartphone app, and aims to help people to adopt and sustain healthier habits. The platform provides education related to the conditions and, for patients with Type 2 diabetes and pre-diabetes, provides the following types of support:

- Daily education and guides
- Coaching from behaviour change coaches
- Peer-to-peer community support from peers with like-minded goals
- A food diary
- Meal plans tailored to dietary preferences, culture and goals
- A recipe library updated daily (which is tailored with artificial intelligence (AI) to a user's dietary preference, allergies, ethnicity, budget, time to cook, and preferred meals)
- Health tracking (blood glucose, HbA1c, mood, medications, ketones, cholesterol, blood pressure, activity)

- AI-led engagement through in-app and email notifications to maintain engagement and behaviour changes
- A team of behaviour change mentors, supported by nutritionists and psychologists

The Low Carb Program can be commissioned by CCGs, with payment for an agreed number of licenses. The aim of the programme is to help participants to achieve sustainable weight loss, lower their blood glucose and reduce their use of diabetes-related medications. The nutrition syllabus is based on the low carbohydrate diet guidelines of 130g per day in line with guidance on low carbohydrates for weight loss from the National Institute for Health and Care Excellence (NICE),¹ Scottish Intercollegiate Guidelines Network (SIGN)² and Diabetes UK.³ The education and coaching elements of the programme are carried out over an initial 12-week implementation period. Following that, users can continue to access health tracking and support.

The Low Carb Program is currently in use in University College Hospital, Coventry (part of University Hospitals Coventry and Warwickshire NHS Trust) and eight CCGs, as well as a number of private, commercial organisations that are not health care commissioners or providers.

This analysis was developed in spring/summer 2020 and was based on the information and evidence available at the time. The limitations of the analysis are as follows:

- Data come from single-arm studies which did not allow for counterfactuals or control groups and data have been drawn from different reports.
- Trial participants were not randomly selected so actual participation rates could be different to those used in the calculations reported here.
- Health outcomes in a trial (weight, glycaemic control, and medication changes) were measured using patient self-reporting.
- The future benefits estimated in this case study are based on the extrapolation of short-term outcomes and we do not know for certain if or how these outcomes would be sustained in practice.
- Maintenance of health behaviours and drop-out rates will have an impact on future benefits and they have had to be assumed in the absence of data on drop-out rates – a sensitivity analysis is included to test this assumption.
- Training costs have been assumed on the basis of assumptions as to which staff would participate.

¹ NICE. Type 2 diabetes in adults: management . NICE guideline Published: 2 December 2015
<https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-pdf-1837338615493>

² SIGN 116. Management of diabetes A national clinical guideline. March 2010 Updated November 2017.
<https://www.sign.ac.uk/assets/sign116.pdf>

³ Diabetes UK. Evidence-based nutrition guidelines for the prevention and management of diabetes March 2018.
https://diabetes-resources-production.s3.eu-west-1.amazonaws.com/resources-s3/2018-03/1373_Nutrition%20guidelines_0.pdf

2. INPUT COSTS

The Low Carb Program can be commissioned by CCGs on the basis of three-year licenses, which cost £90 per person (equivalent to £30 per person per year). For the purpose of this case study, a scenario has been developed where a CCG wishes to use 3,000 licenses across 25 GP practices over five years. Practice staff are trained to identify potential programme participants, or staff can be supported in identifying participants based on goals. The latest national figure for prevalence of diabetes in England is 3,319,266,⁴ around 90% of whom will have Type 2 diabetes. Based on 135 CCGs in England, the average prevalence of Type 2 diabetes per CCG is 22,128. On that basis, 3,000 licenses would enable targeting of around 14% of an average CCG Type 2 diabetes population.

The license cost includes:

- Collaboration to identify local needs and to design a tailored implementation plan
- A dedicated account manager for programme implementation and integration into the local care pathway
- Collaborative modelling and stratification for the commissioner to target primary care practices and patient cohorts
- A comprehensive training plan at practice level on the low carbohydrate diet, de-prescribing, patient onboarding and other aspects of the programme
- Ongoing training through the Low Carb Program's digital platform
- A patient enrolment and engagement support plan
- KPI engagement dashboards to enable understanding of the engagement and progress of patients that are participating in the programme
- Optional monthly drop-in sessions during lunchtimes with clinical teams to answer queries or questions

The total cost of these licenses would be equivalent to £90,000 per year. To estimate the savings over five years, an average annual inflation rate of 1.5%⁵ is applied, as is a discounting rate of 3.5%.⁶ In a published report on a trial of the Low Carb Program, it is reported that 70.8% of participants remained engaged at one year, although 52.8% of participants completed the education and coaching element of the programme (100% of modules).⁷ For the purposes of this analysis, we are conservatively including only the 52.8% of participants who completed all education modules – this is used as the drop-out rate for year one. For subsequent years, a drop-out rate of 5% is assumed, which would result in 1,358 people from the initial cohort of 3,000 completing five years, as illustrated in Table 2.1. This is a very conservative assumption of drop-out, based on the possibility that those who complete the education and coaching are highly committed to persevering with the rest of the programme.

⁴ Based on Quality and Outcomes Framework (QOF) data for 2018/19:

<https://www.diabetes.org.uk/professionals/position-statements-reports/statistics/diabetes-prevalence-2019>

⁵ Based on: PSSRU. Unit Costs of Health & Social Care. 2019. Inflation indices. 10-year average of NHSCII pay and prices (2019/20 & 2020/21 are estimated).

⁶ Based on: HM Treasury (2013, updated 2015). The Green Book: appraisal and evaluation in central government. Standard social discount rate.

⁷ Saslow LR, Summers C, Aikens JE & Unwin DJ (2018) Outcomes of a Digitally Delivered Low-Carbohydrate Type 2 Diabetes Self-Management Program: 1-Year Results of a Single-Arm Longitudinal Study. *JMIR Diabetes*: 3; 3.

It should be noted that the costs are based on the number of people who are using the programme at the start of each year, as these are the people for whom a contract will be agreed. In the outcomes section, below, the numbers at the end of year are used as the basis for calculating benefits, as only the people who complete each element of the programme will be expected to demonstrate the full benefits of the programme.

Table 2.1: Cost of annual participant numbers based on 52.8% completion of education and coaching and a subsequent 5% annual drop-out rate

Cohort year	Number of people	Cost of cohort
Year 1 - initial cohort	3,000	£90,000
Year 2 (number completing year 1)	1,584	£46,544
Year 3 (number completing year 2)	1,505	£44,880
Year 4 (number completing year 3)	1,430	£43,275
Year 5 (number completing year 4)	1,358	£41,728
Number completing year 5	1,290	-
Cumulative costs over 5 years		£266,428

Whilst the cost of training is included in the license, there is an opportunity cost to GP practices for the time of staff to attend training. Based on the information provided, an assumption has been made that, for each participating practice, one GP, one practice nurse and half of a whole time equivalent (wte) pharmacist is trained (i.e. one pharmacist for every two practices). The costs of training are set out in Table 2.2.

Table 2.2: Cost of staff time in training for one GP practice

Participant	Cost per hour of working time	Multiplier	Cost per practice
GP ^a	£112	0.5 day (3.75 hours) for 1.0 wte	£420.00
Practice Nurse ^b	£37	0.5 day (3.75 hours) for 1.0 wte	£138.75
Pharmacist ^c	£45	0.5 day (3.75 hours) for 0.5 wte	£84.38
Total			£643.13

Sources:

- ^a PSSRU Community-based Health Care Staff. General practitioner. Per hour of GMS activity. Excluding direct care staff costs. Without qualification costs
- ^b PSSRU Community-based Health Care Staff. Nurse (GP practice)
- ^c PSSRU Community-based Health Care Staff. Scientific and professional staff. Band 6

For a CCG adopting the Low Carb Program across 25 CCGs, the total training cost would be £16,078. Adding the license costs to this, the total cost for the CCG, with 3,000 licences (£90,000) would be £106,078 for one year and £282,506 over five years (taking into account drop-off, inflation and discounting). This assumes that no additional, compulsory training is provided after the initial programme start-up (which does not include the discretionary, drop-in training sessions facilitated by the Low Carb Program clinical team).

3. OUTCOMES

For the Low Carb Program, a single-arm trial was carried out among 1,000 participants with results published in 2018.⁸ A range of results was reported among participants, at 12 months from the start of the programme, which include:

- Weight loss
- Reduction in HbA1c
- Elimination of diabetes medications and reduction or elimination of insulin
- Remission of Type 2 diabetes

At the date of preparing this case study, however, detailed economic data was available only for the elimination of medications and not for the other benefits. There would also be a risk of double-counting benefits if the economic benefits were estimated for each of these different areas. As a result, this case study considers the economic benefits of a reported reduction in medications and it uses published literature to estimate the economic benefits that would result from a sustained reduction in HbA1c levels. First, the impact of reduced HbA1c levels are estimated, then the benefits of reduced medications are calculated, and these are summed to produce total estimated benefits.

Evidence that can be used to assess the economic benefits from the reduced risk of complications of diabetes, resulting from lower levels of HbA1c, comes from Baxter *et al.*⁹ This paper assessed the potential reduction in incidence of diabetes-related complications and associated costs, if HbA1c levels could be reduced to and maintained at targets recommended in the NICE guideline for Type 2 diabetes.¹⁰ The authors considered the cumulative reductions in incidence and cost of complications if an 11 mmol/mol reduction in HbA1c is sustained among patients over five-year periods.

Table 3.1 shows the estimated reductions in the incidence and cost of complications, over five years, as calculated by the Baxter *et al* paper.

⁸ Saslow LR, Summers C, Aikens JE & Unwin DJ (2018) Outcomes of a Digitally Delivered Low-Carbohydrate Type 2 Diabetes Self-Management Program: 1-Year Results of a Single-Arm Longitudinal Study. *JMIR Diabetes*; 3; 3.

⁹ Baxter *et al.* (2016) Estimating the impact of better management of glycaemic control in adults with Type 1 and Type 2 diabetes on the number of clinical complications and the associated financial benefit. *Diabet Med*. Nov;33(11):1575-1581

¹⁰ The National Collaborating Centre for Chronic Conditions. Type 2 Diabetes. National Clinical Guideline for Management in Primary and Secondary Care (update). London: Royal College of Physicians, 2008.

Table 3.1: Cumulative reductions in incidence and cost of complications if an 11 mmol/mol reduction in HbA1c is sustained over a five-year period, for people with diabetes in England

Complications	Cohort n= 2,223,654 ^a	
	Incidence (cases)	Cost (all cases) ^b
Eye Disease	30,009	£14,300,000
Renal Disease	20,422	£6,200,000
Foot & Nerve Disease	64,639	£68,400,000
CVD	16,088	£70,800,000
Total	131,158	£159,700,000

Source: Baxter et al.¹¹

^a People with diabetes in England, 2015

^b The costs estimated in this paper were not discounted as the study was a budget impact analysis

In a trial of the Low Carb Program, 52.8% of the initial cohort completed the education and coaching element of the programme. Of the completers, an average reduction in HbA1c of 1.17% was reported at 12-month follow-up¹² (lower reductions were reported for participants who only partially completed this part of the programme). Using a conversion calculator,¹³ this translates to a 12.8 mmol/mol reduction, which makes it comparable to the impacts estimated by Baxter *et al*, based on an assumption that participants were able to maintain their lower HbA1c levels for five years.

Dividing the total cost by the number in the cohort in Table 3.1 gives a cumulative saving per person of £71.82 at five years. Based on a cohort of 3,000 people, with 52.8% completing education and coaching in year one, then an annual drop-out rate of 5%, this would result in a total saving for this cohort of £92,659 (based on 1,290 completing year 5, from Table 2.1).

The evidence on reduction in medication use is based on the same cohort of 1,000 people with Type 2 diabetes as that in the Saslow paper, on which the completion rates are based. Medication use for this cohort was measured at the start of the Low Carb Program and again one year later. Table 3.2 shows the reduction in numbers and annual cost of medications taken, at 12-month follow-up. In this cohort many people were taking several different medications, so the numbers do not relate to numbers of individuals.

¹¹ Baxter *et al. op cit*. The estimated costs in this paper were not discounted as the study was a budget impact analysis.

¹² Saslow LR, Summers C, Aikens JE & Unwin DJ (2018) *op. cit*.

¹³ Based on the conversion calculator here: <https://www.diabetes.co.uk/hba1c-units-converter.html>

Table 3.2: Number and costs of medications eliminated at 12 months from a cohort of 1,000 people with Type 2 diabetes

Drug Group	Medications eliminated ^a	Average cost per year	Savings at 12 months
Biguande (AA)	211	£50	£10,550
Sulphonylureas	99	£50	£4,950
Meglitinides	2	£380	£760
Thiazolidinedione	9	£33	£297
DPP4	25	£430	£10,750
SGLT2	12	£476	£5,712
GLP1	81	£950	£76,950
Insulin	38	£200	£7,600
Total	477		£117,569

Source: data provided by Diabetes Digital Media

^a A 'medication' is one person using that medication, but each person may use more than one medication.

These results are based on the cohort of 1,000 participants in the programme. For a CCG with 3,000 licenses, it is assumed that the results at the end of one year would be three times that, i.e. a total saving of £352,707 (an average of £117.57 per participant).

In order to estimate the costs over five years, the same inflation and discounting rates are used as for the licence costs (1.5% and 3.5% respectively). In addition, it is assumed that 52.8% complete the education and coaching in year one and there is a subsequent, annual drop-out rate of 5%. This gives a cumulative, adjusted saving over five years of £862,955, relating to 1,290 individuals who complete year five, from the initial cohort of 3,000 licences.

4. ECONOMIC ANALYSIS

For this case study scenario a cohort of 3,000 people starting the programme is followed-up over five years. A drop-out rate is assumed for both the benefits and the costs: 52.8% of participants complete the education and coaching in year one, following which there is an annual drop-out rate of 5%. This results in a total of 1,290 people participating in the programme at the end of five years, (with 1,358 at the beginning of year five and thereby incurring costs for that year). All costs and benefits in this economic analysis are based on these assumptions. A sensitivity analysis is included below, to test the assumption of the 5% drop-out rate.

Table 4.1 presents the costs and benefits for the Low Carb Program, based on an initial cohort of 3,000 people, over five years, with a 5% drop-out rate.

Table 4.1: Costs and benefits of the Low Carb Program for a cohort of 3,000 people over five years

Element	Value
Licence costs	£266,428
Training costs	£16,078
Total costs	£282,506
Reduced medications	£862,955
Reduced HbA1c levels	£92,659
Total benefits	£955,614
Net cost/benefit	£673,108

On the basis of the data provided, a return on investment (ROI) can be calculated using the formula:

$$\frac{\sum \text{Total discounted benefits} - \sum \text{discounted costs}}{\sum \text{Total discounted costs}}$$

ROI over 5 years: $\frac{£955,614 - £282,506}{£282,506}$ ROI: 2.38

Sensitivity Analysis

Outcomes showed 70.8% of participants remained engaged with the programme at one year. However, for the purposes of this analysis, we are conservatively including only those people who completed all of the education and coaching modules, which is 52.8% of participants.

The drop-out rate in the above analysis may have an important impact on the results. It is, however, based on an assumption, in the absence of evidence. To test this assumption, the following table shows the costs and benefits that would result from a 10% and 15% drop-out rate from years two to five, along with the ROI for each case.

Table 4.2: Costs and benefits over five years, with drop-out rates of 10% and 15%

Element	Value with a 10% drop-out rate	Value with a 15% drop-out rate
Licence costs	£253,382	£241,234
Training costs	£16,078	£16,078
Total costs	£269,461	£257,312
Reduced medications	£781,076	£707,363
Reduced HbA1c levels	£74,639	£59,384
Total benefits	£855,715	£766,747
Net cost/benefit	£586,254	£509,435
ROI	2.18	1.98

5. CONCLUSIONS

The calculations presented here indicate a net saving from the use of the Low Carb Program over five years of between £673,108 and £509,435 for a CCG which contracts for 3,000 licences. This relates to an ROI of between 2.38 and 1.98.

The sensitivity analysis indicates that variations in net benefits result from modest (5%) changes in the assumptions about drop-out rates in the cohort. Outcomes showed 70.8% of participants remained engaged at one-year. For the purposes of this analysis, we have used the 52.8% of participants who completed all of the education and coaching modules as the basis of the drop-out rate for year one. Longer term data from a trial would provide a more robust indication of the long term health benefits and how this affects the economic results. It may be that certain elements of support provided by the Low Carb Program (education, coaching, peer-to-peer support, recipes, food diaries, health tracking etc.) are most effective in achieving the benefits, and these could be enhanced in future developments of the programme.

The benefits used in these calculations do not include all of the possible economic benefits resulting from the programme. However, care has to be taken in trying to estimate any additional benefits from weight loss or remission from diabetes, for example, as doing so may result in double-counting benefits included here, i.e. those that result from reduced HbA1c levels and elimination of medications.

As the Low Carb Program is provided digitally, we assume that it can be scaled up relatively easily, with the main limit being the need for training and support to CCGs. As there are currently 135 CCGs in England, a simple multiplication indicates that net savings could be around £67million to £91million nationally over five years.

As previously mentioned, there are some limitations within the analysis, relating to the fact that participants in a trial were not randomly selected and health outcomes were measured using self-report. Both of these mean that the reported benefits may not reflect the results that would be found in real life implementation of the programme. The estimated future benefits are based on the extrapolation of short-term outcomes and the maintenance of health behaviours and medication elimination will have an impact on future benefits. For this case study, some assumptions have had to be made, some of which have been tested in sensitivity analysis. Any assumptions have been clearly stated.

York Health Economics Consortium, September 2020