Insights from a general practice service evaluation supporting a lower carbohydrate diet in patients with type 2 diabetes mellitus and prediabetes: a secondary analysis of routine clinic data including HbA1c, weight and prescribing over 6 years

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ABSTRACT

Background In a single general practice (GP) surgery in England, there was an eightfold increase in the prevalence of type 2 diabetes (T2D) in three decades with 57 cases and 472 cases recorded in 1987 and 2018, respectively. This mirrors the growing burden of T2D on the health of populations round the world along with healthcare funding and provision more broadly. Emerging evidence suggests beneficial effects of carbohydrate-restricted diets on glycaemic control in T2D, but its impact in a ‘real-world’ primary care setting has not been fully evaluated.

Methods Advice on a lower carbohydrate diet was offered routinely to patients with newly diagnosed and pre-existing T2D or prediabetes between 2013 and 2019, in the Norwood GP practice with 9800 patients. Conventional ‘one-to-one’ GP consultations were used, supplemented by group consultations, to help patients better understand the glycaemic consequences of their dietary choices with a particular focus on sugar, carbohydrates and foods with a higher Glycaemic Index. Those interested were computer coded for ongoing audit to compare ‘baseline’ with ‘latest follow-up’ for relevant parameters.

Results By 2019, 128 (27%) of the practice population with T2D and 71 people with prediabetes had opted to follow a lower carbohydrate diet for a mean duration of 23 months. For patients with T2D, the median (IQR) weight dropped from of 99.7 (86.2, 109.3) kg to 91.4 (79, 101.1) kg, p<0.001, while the median (IQR) HbA1c dropped from 65.5 (55, 82) mmol/mol to 48 (43, 55) mmol/mol, p<0.001. For patients with prediabetes, the median (IQR) HbA1c dropped from 44 (43, 45) mmol/mol to 39 (38, 41) mmol/mol, p<0.001. Drug-free T2D remission occurred in 46% of participants. In patients with prediabetes, 93% attained a normal HbA1c. Since 2015, there has been a relative reduction in practice prescribing of drugs for diabetes leading to a T2D prescribing budget £50 885 per year less than average for the area.

Conclusions This approach to lower carbohydrate dietary advice for patients with T2D and prediabetes was incorporated successfully into routine primary care over 6 years. There were statistically significant improvements in both groups for weight, HbA1c, lipid profiles and blood pressure as well as significant drug budget savings. These results suggest a need for more empirical research on the effects of lower carbohydrate diet and long-term glycaemic control while recording collateral impacts to other metabolic health outcomes.

Type 2 diabetes (T2D) is a growing problem with an estimated worldwide prevalence of 9.3% (463 million people) for 2019.1 In the UK, the burden on the National Health Service (NHS) is illustrated by the growing cost of drugs prescribed for T2D; in 2018, these made up 11.4% of total primary care net costs and 4.9% of all prescription items.2 In the North of England, the Norwood general practice (GP) practice, which has been serving a stable population of approximately 9800 patients, experienced an eightfold

What this paper adds

- For those choosing a lower carbohydrate dietary approach for an average of 23 months it is possible to achieve a 46% drug-free T2D remission rate in UK primary care whilst also achieving significant improvements in weight, blood pressure and lipid profiles.

- In patients with prediabetes (HbA1c 42 to 48 mmol/ mol), a LCD approach reduced HbA1c to within a non-diabetic threshold in 93% of patients.

- Our audit showed participants who started with the worst blood sugars (HbA1c) saw the greatest improvements in diabetic control.
increase in T2D cases recorded, rising from 57 in 1987 to 472 in 2019. This increase in prevalence translates into an increased morbidity and mortality for patients, as well as increasing pressure on limited healthcare resources.

INTRODUCTION
Several systematic reviews and meta-analyses of randomised control trials (RCTs) suggest beneficial effects of carbohydrate-restricted diets in T2D on glycaemic control, triglyceride and HDL cholesterol profiles.4,5 Between 2018 and 2020, consensus reports by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes acknowledged low-carbohydrate diets as appropriate dietary options.6 In 2020, ADA standards of care for T2D report stated: ‘for individuals with type 2 diabetes not meeting glycaemic targets or for whom reducing glucose-lowering drugs is a priority, reducing overall carbohydrate intake with a low-carbohydrate or a very-low-carbohydrate eating pattern is a viable option’.7 However, there is still some debate about sustainability (particularly in terms of long-term adherence) and safety of lower carbohydrate diets. For example, an RCT comparing a low-carb diet to a low-fat diet in people with T2D8 found a similar 3.4% weight reduction in both dietary groups and no significant change in A1c in either group at 1 year. Also in 2018, the British Dietetics Association (BDA) stated: ‘more research is needed to ascertain the long-term health impacts of low-carbohydrate diets, including on heart health’.9 Beyond this uncertainty, little is known about the best methods of implementing advice on lower carbohydrate diets in primary care practice.

The UK National Institute for Health and Care Excellence T2D guidelines, although not currently advising a low-carbohydrate diet specifically, do advise low Glycaemic Index (GI) foods as part of the multicomponent management of T2D.10 Observations from an earlier service improvement pilot at the Norwood surgery suggested patients with T2D might achieve a clinically significant improvement in glycaemic control by restricting carbohydrate intake.11 In addition, dietary carbohydrate restriction may positively benefit other aspects of the metabolic syndrome, including central obesity, hypertriglyceridaemia and non-alcoholic fatty liver disease.12 13 Encouraged by the emerging body of evidence and patient demand for more effective lifestyle guidance in T2D, the Norwood surgery started routinely offering dietary advice on lower carbohydrate diets to all patients with T2D and prediabetes from March 2013 to date (September 2020).

The purpose of this secondary analysis of routine clinic data was to evaluate the effects of advising a lower carbohydrate diet for patients with T2D or prediabetes. Specifically, we hoped to answer the following question: for those patients choosing a lower carbohydrate diet to manage their T2D or prediabetes, when we compare ‘baseline data’ to ‘latest follow-up’ what are the outcomes in terms of body weight, glycaemic control and effect on diabetes medication prescribing (British National Formulary Chapter 6.1.2.)? Given the BDA concern over heart health, additional clinical variables were included relating to cardiac risk, namely lipid profile and blood pressure (BP). The Diabetes Remission Clinical Trial (DiRECT)14 recently investigated a very-low-calorie diet (VLCD) to achieve weight loss and subsequent drug-free improvement in T2D, including T2D remission. Raising the possibility of T2D remission through dietary intervention has given hope to many people affected by T2D. Yet, the exclusion criteria for the DiRECT study included patients over 65 years old and patients who have had T2D for over 6 years (72 months). We, therefore, decided to include analysis of these specific subcohorts in our service evaluation.

METHODS
Advice on lowering dietary carbohydrate was offered routinely by trained GPs and practice nurses to patients with T2D and prediabetes (defined as a haemoglobin A1c [HbA1c] from 42 to 48 mmol/mol) from March 2013 (online supplemental file 1. Low-carb protocol). The lower carbohydrate diet was introduced as an option alongside clear and simplified explanations of key physiological principles; including how glucose and insulin levels change in response to different foods; starchy carbohydrates comprise many glucose molecules; and the concept that foods can have either a low or high GI and glycaemic load (online supplemental file 2).

For patients who opted to try a lower carbohydrate diet, dietary advice was given as part of routine GP or practice nurse consultations. The level of ongoing support was tailored to patient choice and clinical need. In addition to 10 min ‘one-to-one’ appointments (we estimate an average of 3 appointments per patient, per year were required), the practice offered access to optional 90 min evening group sessions that ran approximately once every 6 weeks. Group sessions included a psychologist who facilitated behaviour change by encouraging participants to consider their individual health goals, the resources available to them, setting realistic steps and enabling the individual to notice what works for them.15 Patient relatives and carers were encouraged to attend as some patients relied on others for food shopping or cooking. Group sessions also provided a forum for patients to offer practical support to their peers and for the training of new staff. On average, 25 patients attended each session.

Several educational resources were produced to support patients and staff. The lower carbohydrate diet sheet (figure 1) outlines low GI sources of food in the diet. Glycaemic load data, derived from the GI, were also presented to encourage a reduction in the intake of sugary and starchy foods, for example, sugary breakfast cereals, rice or potatoes, by replacing them with, for example, green leafy vegetables, full-fat dairy, eggs, meat, fish, berries and nuts, with sensitivity to each patient’s sociocultural dietary needs and preferences. A set of
A lower carb diet for type 2 diabetes:

In this condition your metabolism can no longer deal with sugar, which becomes almost a poison—so its consumption needs cutting back dramatically.

Sugar, cut it out altogether. Although it will be in the blueberries, strawberries and raspberries you are allowed to eat. Cakes and biscuits are a mixture of sugar and starch that make it almost impossible to avoid food cravings; they just make you hungrier!

Reduce starchy carbs a lot. Remember they digest down into surprising amounts of sugar. If possible cut out the ‘White Stuff’ like bread, pasta, rice and breakfast cereals

All green veg/salads are fine—eat as much as you can. Turn the white stuff green

So that you still eat a good big dinner try substituting veg such as broccoli, courgettes or green beans for your mash, pasta or rice—still covering them with your gravy, Bolognese or curry!

Tip: try home-made soup—it can be taken to work for lunch and microwaved. Mushrooms, tomatoes, and onions can be included in this. Aldi and Tesco now sell cauliflower rice!

Fruit is trickier...

Some tropical fruits like bananas, oranges, grapes, mangoes or pineapples have too much sugar in and can set those carb cravings off. Berries are better and can be eaten; blueberries, raspberries, strawberries, apples and pears too.

Eat healthy proteins...

Such as in meat. eggs (three eggs a day is not too much), fish—particularly oily fish such as salmon, mackerel or tuna—are fine and can be eaten freely. Plain full fat yoghurt makes a good breakfast with the berries. Processed meats such as bacon, ham, sausages or salami are not as healthy and should only be eaten in moderation.

Seven broadly indicative infographics were generated, for example, figure 2. These help people make wiser dietary choices by representing the glycaemic load of example food portions alongside an equivalent number of standard (4 g) teaspoons of table sugar.16 From 2018, staff training was formalised through completion of a Royal College of General Practitioners e-learning module on T2D and the GI, written by one of the authors.17

Our paper is part of an ongoing audit of service provision. Practice patients who have either T2D or prediabetes and choose the low-carb approach are coded within the practice computer system. The relevant records can then be easily retrieved and interrogated to produce the data which is presented as ‘baseline’ (that is before the code was put on) and ‘latest follow-up’ (self-explanatory). The metrics we measured (weight, BP, lipid profile, HbA1c) are part of the routine care for this group of patients at the Norwood GP practice. Exclusion criteria were severe mental illness, terminal illness and eating disorders. We also examined the effects of this intervention in those over 65 years and those with T2D for longer than 72 months. These groups were excluded from the DiRECT study.14

Routine clinical data were collected between March 2013 and March 2019. Baseline measurements of weight and BP were done at the surgery and blood tests (HbA1c, lipid profiles) by the local NHS phlebotomy clinic. The frequency of blood tests depended on clinical need and risk assessment as part of standard care. As some patients found it challenging to fit fasting blood tests into their lifestyle patterns, the results included a greater number of incomplete data sets for lipid profiles than other measures.

Statistical analyses were performed with R V.3.6.1. Summaries of baseline and follow-up data are shown as median and the IQR (25th percentile, 75th percentile) for non-normally distributed continuous variables (age, weight, HbA1c, lipid profile and BP) and more normally distributed continuous variables are presented as median (SD) (duration of diet). Comparisons between baseline and latest follow-up continuous variables were made using the Wilcoxon signed rank test for paired samples. A p value<0.05 was considered statistically significant.
Baseline and latest follow-up distributions of patient data are presented with box and whisker charts, the box represents the median value and the IQR, the red dot indicates the mean value and the upper and lower whiskers indicate either, the minimum/maximum value, or 1.5 times the IQR (outliers are not shown).

Data are presented for patients with T2D, and for two subgroups: for patients with T2D and aged 65+ years; and for patients with T2D having had this diagnosis for 72 months or longer at the start of the intervention (6 years). Data are presented for patients with prediabetes (HbA1c of 42–47 mmol/mol).

Linear regression models were fitted with HbA1c reduction as the outcome and weight loss, age, duration of T2D and baseline HbA1c as predictors. The NHS in England publishes monthly data about the drugs prescribed by every GP in the country. Data on items prescribed and costs are processed and organised by GP practice and British National Formulary (BNF) chapter by the OpenPrescribing website. These data enable analysis comparing prescribing costs in one practice (Norwood) to local, regional and national averages. The site also generates graphs such as the figure discussed in the Results below.

RESULTS

By the end of March 2019, there were 199 patients with T2D (N=128) or prediabetes (N=71) who had both persisted with the lower carbohydrate programme, and for whom service evaluation data had been collected. The number of routine (10 min) appointments patients attended varied depending partly on risk assessment and approximately half of the cohort attended the additional group sessions on one or more occasion. Table 1 shows statistical analysis of the cardiometabolic variables measured at baseline and the end of the service evaluation period.

At the end of the evaluation period, the Norwood GP practice register for T2D had a total of 473 patients, this cohort of 128 represents 27%. Of these, 83 (63%) were male, and the mean age was 63 years. They were recorded as being on the lower carbohydrate programme for a mean (SD) duration of 23 (16.8) months. For those with T2D, there was a statistically significant reduction in all variables of interest other than a statistically significant increase in high density lipoprotein (HDL) cholesterol. The most prominent changes at the follow-up were a reduction in the observed weight from the median (IQR) of 99.7 (86.2, 109.3) kg to 91.4 (79, 101.1) kg, p<0.001, and for HbA1c from the median (IQR) of 65.5 (55, 82) mmol/mol to 48 (43, 55) mmol/mol, p<0.001 (table 1 and figure 3). Overall, 121 of the 128 patients (94.4%) lost weight. Seven patients either lost no weight or gained weight, yet these seven individuals had a mean improvement in HbA1c of 21.1 mmol/mol, similar to the average for the whole group. Regression analysis showed little overall relationship between the magnitude of weight loss (predictor) and improvement in HbA1c (outcome), $R^2=0.0058$, p=0.402, $\beta=0.234$ mmol/mol/kg, (95% CI: −0.317 to 0.785) (online supplemental file 3). Table 1 and figure 4 demonstrate the significant reduction in total and LDL cholesterol, triglycerides and total/HDLC ratio and a significant increase in HDLC cholesterol seen in patients with T2D. A median reduction in systolic and diastolic BP occurred of 11 and 5.1 mm Hg, respectively, p<0.001.

Medication use: 40 of the T2D participants were newly diagnosed with diabetes and so not on any medications for T2D at baseline. There were a further 34 participants with more established diabetes managed by diet alone. Metformin was started in just four of these patients. The remaining 54 people were on medication for T2D at baseline. Twenty-nine medications were stopped in this group, sometimes more than one drug in any particular patient. As a result of this 19 of the 54 patients previously on medication became medication free, making a total of 89 people with T2D managed without medication at latest follow-up (table 2). Of these, 59 were both free of medication and had an HbA1c<48 mmol/mol.

Figure 5 demonstrates that the Norwood GP practice had the lowest prescribing costs for antidiabetic medications (BNF 6.1.2) in the local area. According to OpenPrescribing.net, by April 2020, Norwood spent £50 885 less per year than is average for the area. Further interrogation of this resource, looking at overall practice prescribing for T2D against regional and national figures, indicates a 35% increase in Norwood prescribing compared with a 53% rise in the local area for the 5 years from March 2015 (online supplemental file 4).

Table 1 and figure 6 show regression analysis of the improvement in HbA1c with respect to baseline HbA1c on the programme for the entire T2D cohort. It shows a positive relationship ($R^2=0.752$, p<0.001, $\beta=0.806$, 95% CI: 0.724 to 0.888) between higher initial HbA1c (worse diabetic control) and greater improvements in diabetic control on the programme. A subcohort of interest to clinicians is patients with poor glycaemic control. Of the 128 participants, 40 patients had a baseline HbA1c of 80 mmol/mol or greater (mean 97.3 mmol/mol). The average reduction in HbA1c for this subcohort was 41.9 mmol/mol, more than double the overall average improvement. The average HbA1c of this group at latest follow-up had improved to 55.4 mmol/mol. Regarding medications in this subcohort who started with very poor diabetic control; two patients were started on metformin, and the following medications were deprescribed in five patients; metformin in two, gliclazide in three, lipraglutide in one and insulin in one.

Analysis of the results from the two subcohorts of interest (time since diagnosis of diabetes and age) is shown separately in table 1. There was the same trend in cardiometabolic variables that occurred in the entire cohort. The results for these subcohorts are:
In the 45 patients with T2D for over 72 months at the introduction to this service, the median (IQR) weight reduced from 96.2 (86.2, 106.0) kg to 86.9 (76.9, 95.4) kg, p<0.001, and median (IQR) HbA1c reduced from 73 (62, 84) mmol/mol to 49 (45, 56) mmol/mol, p<0.001. Regression analysis showed little overall relationship between the duration of diabetes at initiation of the programme (predictor) and improvement in HbA1c (outcome) for the main T2D cohort (n=127), R²=0.007, β=0.025 mmol/mol/month (95% CI: −0.027 to 0.076) (online supplemental file 5).

Of the 53 patients over 65 years old with T2D at the introduction to this service, 11 were over 80 years old, and the average age was 75 years.
who chose the approach. However, the methodological
profiles) for the 27% of the practice T2D population
all the metrics evaluated (HbA1c, weight, BP and lipid
Analysis of our data shows significant improvements in
DISCUSSION
the same pattern as described in patients with T2D.

The 71 patients with prediabetes represent 11.1%
of the 637 people on the practice prediabetes register,
35 (49%) were male, and the mean age was 65 (59,73)
years. They were recorded as being on a lower carbohy-
drate diet during this period of time. The 27% adopted a lower carbohydrate diet during this
in clinical practice, avoiding in-depth discussions around portion sizes and carbo-
hydrate counting has been patient friendly and time
efficient.

Of all the patients with T2D at the Norwood GP prac-
tice, 27% adopted a lower carbohydrate diet during this
service evaluation period. The approach was not adopted by all patients, which is a reminder of the importance of individual choice in diet and lifestyle matters. The
same might also be said for healthcare professionals as
the level of interest, commitment and confidence in this
dietary approach to T2D varied between the 10 clinicians
limitations of this service evaluation must be considered
in the interpretation of these results. Our audit reports
results from people who chose to take up this interven-
tion and who persisted with it. It is a practice-based service
evaluation not a prospective research study so lack of
randomisation introduces the possibility of selection bias.
The absence of a control group also means we cannot
compare the dietary intervention directly with routine
care. However, some idea of the results one might expect
from routine care can be derived from the control arm of
the DiRECT study, discussed below.19 Lack of randomi-
apart from individualised follow-
care. However, some idea of the results one might expect
from routine care can be drawn from the control arm of
the DiRECT study, discussed below.19 Lack of randomi-
sation also risks confounding. For example, individuals
who chose the diet may have other unique characteristics
or behaviours that confer benefit. Co-intervention bias
is another possibility, where for example other medica-
tions or exercise recommendations may have conferred
benefit that were not included in the analysis. Despite
this, the wide IQR of baseline HbA1c (55–82 mmol/mol)
and an overall average of 65 mmol/mol (suggesting rela-
tively poor glycaemic control) indicates that a ‘real-world’
cross section of patients was included. Another limitation
is relying on the patients’ word regarding adherence to a
lower carbohydrate diet; hence, we must acknowledge the
risk of reporting bias. Although the average weight loss of
8.3 kg does suggest significant dietary change, we cannot
know with any certainty what has actually happened to
the balance of the different macronutrients in the diet of
the participants. Another limitation concerns the use of
the glycaemic load. It is important to note that this info-
graphic is indicative only and does not represent the true
process of glucose metabolism.20

For several years, a ‘low-carbohydrate diet’ has gener-
ally been accepted to be one containing less than 130 g
of carbohydrate per day.13 But in routine care, it may not
be realistic for patients to count grams of carbohydrate
on a regular basis. Our data suggest a more simple and
practical approach to lowering dietary carbohydrate can
be associated with significant improvements in HbA1c,
weight, lipid profiles and BP without the need for precise
daily carbohydrate or calorie counting. Patients appear
to have benefited from having received clear and simpli-
fied explanations of how sugar and carbohydrates affect
blood glucose levels and how to recognise foods with high
glycaemic loads, as illustrated by infographics (figure
2), in addition to individualised follow-up and multidis-
ciplinary group sessions. In clinical practice, avoiding
in-depth discussions around portion sizes and carbo-
hydrate counting has been patient friendly and time
efficient.

Of all the patients with T2D at the Norwood GP prac-
tice, 27% adopted a lower carbohydrate diet during this
service evaluation period. The approach was not adopted by all patients, which is a reminder of the importance of individual choice in diet and lifestyle matters. The
same might also be said for healthcare professionals
as the level of interest, commitment and confidence in this
dietary approach to T2D varied between the 10 clinicians

Figure 3 Type 2 diabetes box and whisker plots; baseline
and latest follow-up haemoglobin A1c (HbA1c) and weight.

Figure 4 Box and whisker type 2 diabetes; baseline
and latest follow-up lipid results.
involved at the GP practice, especially at the beginning. Still, the number of patients adopting this dietary approach has continued to rise and, as of August 2020, the cohort includes 173 patients with T2D, representing 36% of the practice total.

In our practice, the idea of drug-free remission of T2D has inspired many patients and clinicians. However, at the time of writing there is no internationally agreed definition of T2D remission. The criteria used at Norwood and suggested by Taylor et al.21 are a previous diagnosis of type 2 diabetes by WHO criteria and an HbA1c<6.5% (48 mmol/mol) without antidiabetic medication. Using this definition, the DiRECT study14 showed that a VLCD of <800 calories per day can lead to weight loss and drug-free T2D remission in a UK primary care setting. At 12 months, T2D remission was achieved in 68 of 149 participants giving a remission rate of 46%. When followed up further, at 24 months, the remission rate had dropped to 36%.19 At Norwood, 59 of 128 patients receiving lower carbohydrate dietary advice achieved drug-free T2D remission, giving a rate of 46% at 23 months duration of the approach. As a comparison to illustrate how rare remission is in usual care DiRECT quotes a remission rate at 24 months of just 2% for routine T2D care in the UK, emphasising the potential value in novel dietary approaches to this problem. The DiRECT study excluded patients who, at recruitment, had been diagnosed with T2D for longer than 72 months or were over 65 years old. In our practice, this would have excluded 45 and 53 patients, respectively. Of the over 65-year-old patients at Norwood, 11 were over 80 years, the oldest was 91 years old. The average improvement in HbA1c for this group was 15 mmol/mol. Similarly, in those patients with T2D for over 72 months, the average reduction in HbA1c was 24 mmol/mol, demonstrating a significant improvement. As shown in the results above our findings suggest both older people and those who had had diabetes for longer had good outcomes on a lower carbohydrate diet.

<table>
<thead>
<tr>
<th>Baseline status</th>
<th>Drugs for diabetes* added + stopped–</th>
<th>Number of people medication free at latest follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed T2D, n=40</td>
<td>0</td>
<td>40</td>
</tr>
<tr>
<td>Diet-controlled T2D, n=34</td>
<td>Metformin +4</td>
<td>30</td>
</tr>
<tr>
<td>T2D on medication, n=54</td>
<td>Gliclazide –12, Metformin –8, Insulin –4, Dapagliflozin –2, Sitagliptin –2, Liraglutide –1</td>
<td>19</td>
</tr>
<tr>
<td>Total=128</td>
<td>–25</td>
<td>89</td>
</tr>
</tbody>
</table>

*Also, Insulin doses were halved in four patients.

T2D, type 2 diabetes.

Figure 5 Data from: OpenPrescribing.net, EBM DataLab, University of Oxford, 2020, accessed July 2020. Prescribing of drugs for diabetes British National Formulary (BNF) 6.1.2 for all the general practice (GP) practices in Southport and Formby Clinical Commissioning Group (CCG).

Figure 6 Initial HbA1c versus improvement in HbA1c for 127 patients with type 2 diabetes on a low-carb diet for an average of 23 months.
Looking at the overall cohort with diabetes, we found very little relationship between duration of diabetes or age of participant at baseline and decrease in HbA1c (online supplemental files 5 and 6). It may be unfortunate to exclude these subgroups from similar avenues of research in the future.

Patients whose T2D is poorly controlled, for example, with HbA1c of 80 mmol/mol and more, may present the clinician with a dilemma as the risks might be considered so high that medication ought to be started or increased immediately. In this service evaluation, 40 patients presented with an HbA1c over 80 mmol/mol. Of those, the highest was 144 mmol/mol. These 40 patients ultimately achieved an average improvement in HbA1c of 41.9 mmol/mol, meaning the best results from this project were achieved in patients who presented with the worst glycaemic control. Figure 6 demonstrates graphically the clear positive relationship between a higher initial HbA1c and the degree of improvement in HbA1c that was observed on our programme. This suggests it may be a reasonable approach (particularly if the patient hopes to avoid medication) to offer a trial of advice on a lower carbohydrate diet for patients who are already on antidiabetic medications, there are three important considerations: whether the drug/diet combination poses a risk of hpyoglycaemia. Insulin is an obvious culprit for this as are some oral agents such as gliclazide. Careful measurement of blood glucose, dose reduction and/or cessation of culprit drugs is crucial to patient safety.

We saw two particular cases where patients had significant weight loss that was not matched by improvements in HbA1c. In one case, the patient had, in fact, developed type 1 diabetes and needed insulin. Further investigation into the other case led to the diagnosis of a hidden malignancy. Another pattern is where both weight and HbA1c rose together, on direct questioning this typically represented higher GI carbohydrate foods ‘creeping’ back into the diet. This prompted the clinician to support the patient back to a lower carbohydrate diet. Our impression is that group sessions were particularly helpful in this scenario as participants did not require an appointment so could access support easily and out of working hours. Quality long-term support is vital to achieving sustained benefits from any approach to managing people with T2D, a point reinforced by the decline in T2D remission rate seen in the DiRECT study follow-up over time. A recent, randomised controlled feasibility study demonstrated it is practical for practice nurses to provide follow-up support as part a low-carbohydrate dietary intervention for patients with T2D in a UK primary care setting.

The lower carbohydrate diet option also appeared to be both an acceptable and effective intervention to the 71 participants with prediabetes (HbA1c from 42 to 48 mmol/mol). After an average duration of 22 months, only five still had an HbA1c of 42 mmol/mol or above. This ‘prediabetes remission rate’ of 93% may provide a further message of hope. In clinical practice, it is encouraging for patients to hear that nearly all who choose a lower carbohydrate diet may see their prediabetes resolve alongside additional improvements in weight, BP and lipid profiles. One notable example of an additional benefit is the improvements seen in serum triglycerides of about 30% (table 1 and figure 4). It is currently challenging for a clinician to know what to suggest when faced with a patient with high triglycerides and obesity. A lower carbohydrate diet may well have a role in this group too and should prompt further research.

In discussions around low-carbohydrate diets, the potential replacement of dietary carbohydrate for fat was a cause for concern around any impact on cardiovascular outcomes. In general, with respect to lipid profiles our findings support the meta-analysis by Gjuladin-Hellon et al who concluded ‘large randomised controlled trials of at least 6 months duration with carbohydrate restriction appear superior in improving lipid markers when compared with low-fat diets’. Given the improved average HbA1c, lipid profiles, weight and BP, we are optimistic of improved cardiovascular risk for our cohort.

For clinicians considering advising a lower carbohydrate diet for patients who are already on antidiabetic medications, there are three important considerations:

1. Whether the drug/diet combination poses a risk of hypoglycaemia. Insulin is an obvious culprit for this as are some oral agents such as gliclazide. Careful measurement of blood glucose, dose reduction and/or cessation of culprit drugs is crucial to patient safety.
It is likely that the reduction in antihypertensive drugs will result in cost savings of £50,885 per year less than the average for the area (figure 2).

For the 17 GP practices in the Southport and Formby region, the average annual cost of antidiabetic medication is £1012.4 million, up by £421.7 million since 2013. In the financial year 2017/2018, there were 20% of the antihypertensive drugs were also stopped due to significant improvements in BP. Finally, over the last 5 years, there has been a relative reduction in antidiabetic medications prescribed by Norwood Practice on hypertension, published separately, shows that 20% of the antihypertensive drugs were also stopped due to significant improvements in BP.

Nationally, prescribing rates for T2D are a huge strain on the NHS budget. In the financial year 2017/2018, there were 53.4 million items prescribed for diabetes at a total net ingredient cost of £1012.4 million, up by £421.7 million since 2007/2008. As outlined in the results above, compared with the 17 GP practices in the Southport and Formby region, the Norwood GP practice spend on antidiabetic medication is £50,885 per year less than the average for the area (figure 5). It is likely that the reduction in antihypertensive drugs will add to the savings which are welcome, considering the extra costs of this service were approximately £9000 per year.

CONCLUSION
This service evaluation found that advising a lower carbohydrate diet approach for patients with T2D and prediabetes can be effectively incorporated into routine primary care over a prolonged period (6 years). The basic model centred on the assumption that, for these individuals, glycaemic control (as measured by HbA1c) is most influenced by the consumption of food with higher GI and glycaemic loads, such as those containing simple sugars and starchy carbohydrates. Advice was given to lower the amount of these foods supported by illustrative infographics. Follow-up largely consisted of regular 10 min appointments with optional group sessions. The role of group sessions was to reinforce diet and lifestyle change, particularly to help ‘rescue’ patients who were struggling to maintain dietary changes. Significant improvements were observed across all cardiometabolic parameters measured: weight, HbA1c, lipid profile and BP with drug-free T2D remission in 46% of all patients with T2D. Of the prediabetic patients, 93% attained a normal HbA1c and similar improvements in cardiometabolic markers as seen in the diabetic cohort. Additional benefits included deprescribing of antidiabetic medications and significant prescribing budget savings.

Due to the practice-specific nature of this evaluation, there is limited external validity. Still, these results could form the basis for similar service improvement projects in primary care. Similar pilots could be designed to test the validity and cost-savings of this approach. At the very least, for patients, clinicians and others affected by T2D and prediabetes, the results might provide hope of better health outcomes in the future. These results highlight a need for more empirical research on the effects of lower carbohydrate diets and long-term glycaemic control while recording collateral impacts to other metabolic health outcomes.

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Contributors DU initiated the approach in the practice, designed the infographics and wrote the initial drafts. JU organised and ran the group consultations, also training all clinical staff in using patients’ own goals and feedback to implement change. AAK did the initial statistics and helped with the later drafts of the paper. DC did a rewrite of the paper in its later stages. CD finished the statistics, produced the table, the box and whisker plots and linear regression models. RG wrote up the results and gave a lot of help to the entire manuscript. KM corrected several drafts and improved the style of the paper. SR found authors, chaired numerous meetings to agree on scope, influenced the style and edited across the manuscript in multiple rounds. RG and SR are joint supervising authors.

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Competing interests SR is co-chair of the Management Board of BMJ Nutrition, Prevention and Health, which is co-owned by the NNEdPro Global Centre for Nutrition and Health of which SR is both chair and executive director.

Patient consent for publication Not required.
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  - **Risk of hypotension**, explain that with weight loss BP may well improve and medications for this may be reduced or cut back

- Salt; Due to the renal sodium retaining properties of insulin(1) for those with T2D going low carb and therefore lower insulin results in considerable loss of sodium and consequently a diuresis. Patients may well need to increase their salt intake –particularly in the first few weeks of the diet.

- Suggest a review date - often 2 or 4 weeks depending on assessed risks. Perhaps longer for pre-diabetes

**On review**

Weigh, measure waist, BP. Do medications need to be changed? See above

How is it going? Problems/suggestions
Remember if both weight and HbA1c are climbing the most common reason is ‘carb creep’ NOT failure of the diet needing medication So check for this by rechecking dietary intakes. Over time many patients drift. It’s better to see this as a learning opportunity. We all learn from our mistakes!

Weight loss alongside a climbing HbA1c is worrying –ask a doctor about this.

HbA1c ‘too good’ e.g. 28mmol/mol could the patient be anaemic?

Produce Emis graphs of Weight., HbA1c etc. as feedback to maintain motivation.

Do they wish to continue?

Are they happy to share anonymised data for our on-going audit of service provision? (please explain what this means) This extra level of patient data protection is not actually needed for audit but Norwood feels it’s good practice.

If so enter Emis GP computer code 'obtaining consent'

Would they like to attend the group sessions –do they know how to find out when the next one is?

**Next steps**

Review date and agree next blood test (HbA1c etc.) -usually at 2 months from the start, but this depends on a risk analysis.

**Lipid profiles** Fasting profiles are preferable as triglyceride/HDL ratios are a better predictor of risk than LDL Lipid profiles usually (but not always) improve on low carb(2)

**Finally** NICE UK guidelines 1.3.6 Individualise recommendations for carbohydrate and alcohol intake, and meal patterns. Reducing the risk of hypoglycaemia should be a particular aim for a person using insulin or an insulin secretagogue. [2009]

Often this is achieved by increasing dietary carbs at the expense of weight gain An alternative is to reduce carbs and the drugs involved this has the advantage of weight loss and improvements in BP

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**Item 2.** Four infographics used to help participants understand insulin and glucose

The hormone insulin can be thought of as pushing glucose out of the blood stream and into cells to reduce blood sugar. In some cells it becomes fat.

![Liver, Muscle, Fat cells diagram](image)

**Insulin + Glucose → cells**

Type 2 diabetes results in part from accumulation of fat in the liver and pancreas.

- **Liver fat:** linked to insulin resistance
- **Pancreatic fat:** inhibits B cell function - cannot produce enough insulin

*Also pancreas cells as triglyceride*

**Triglyceride**

Reversal of type 2 diabetes: Normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol.

Reduced carbohydrate intake

Reduce circulating insulin

*Reduce liver fat  Lose weight  *Reduce pancreas fat

Reduce Insulin resistance  Increase insulin secretion

Reversing T2 Diabetes

*Reversal of type 2 diabetes: Normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol.

A Starch Molecule

Many glucose molecules are linked together – enzymal digestion will break them up again
**Item 3. Relationship between decrease in HbA1c with respect to decrease in weight**

A linear regression model fitted with HbA1c reduction as the outcome and weight reduction (kg) as the predictor, $\beta=0.234$ (95%CI -0.317, 0.785). The small $R^2$ value and large P value suggest that magnitude of weight loss for participants does not correlate well with the improvement in diabetic control. Those who lost less weight seem to do as well as those with greater weight loss.
**Item 4. Openprescribing data**

**Comparing the prescribing of NHS antidiabetic drugs, BNF 6.1.2 at Norwood GP surgery to local, regional and National figures. 2015 to 2020**

**Data from Openprescribing**

<table>
<thead>
<tr>
<th>LOCAL, REGIONAL or NATIONAL</th>
<th>Year to April 1st 2020</th>
<th>Prescribing trends 2015 – 2020</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>Spend/Patient</td>
</tr>
<tr>
<td>NORWOOD SURGERY, SOUTHPORT</td>
<td>9,749</td>
<td>£4.91</td>
</tr>
<tr>
<td>SOUTHPORT AND FORMBY CCG</td>
<td>125,509</td>
<td>£10.13</td>
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<tr>
<td>NORTH WEST COMMISSIONING REGION</td>
<td>7,544,547</td>
<td>£10.06</td>
</tr>
<tr>
<td>NATIONAL EXPENDITURE FOR ENGLAND</td>
<td>60,086,632</td>
<td>£9.52</td>
</tr>
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</table>

The Norwood model saves £50,897 in antidiabetic prescribing relative to neighbouring levels of prescribing for the Southport & Formby CCG.


**The calculations that underpin figure 5 on prescribing costs. A detail.**

From Openprescribing.net:

Southport and Formby average spend on drugs for diabetes per patient for the year ending April first 2020 was £10.13

Norwood average spend on drugs for diabetes per patient for the year ending April first 2020 was £4.91

Difference per person per year £10.13 - £4.91 = £5.22

Norwood has 9,748 patients, so total comparison works out at £5.22 X 9,748 = £50,885 per year cheaper on drugs for diabetes compared to the average for the area. These are rounded down figures, **the actual figure is £50,897**
**Item 5.** Relationship between decrease in HbA1c achieved with respect to the number of months since diagnosis of T2D to the start of the intervention.

A linear regression model fitted with HbA1c reduction as the outcome and time (months) since diagnosis with T2D as the predictor, $\beta=0.025$ (95%CI -0.027, 0.076). The small $R^2$ value and large $P$ value suggest a poor correlation between improvement in Hba1c and how long participants had been diabetic before starting the approach. People who have been diabetic for longer still appear to do well. The clustering at time = 0 months is because many newly diagnosed T2D chose the approach as soon as they were diagnosed.
Item 6. Relationship between decrease in HbA1c achieved with respect to the age of participants.

A linear regression model fitted with HbA1c reduction as the outcome and age of the patient as the predictor, \( \beta = 0.068 \) (95% CI -0.209, 0.346). The small \( R^2 \) value and large P value suggest a poor correlation between improvement in Hba1c and increasing age, put another way older people seem to do just as well as the young using our approach.