Supplemental material

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Supplementary File. 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. Unwin D. et al.

Includes 6 items:

Item 1. Doctor/Nurse protocol Norwood Surgery: T2D, prediabetes, lower carb dietary option

Doctor/Nurse protocol Norwood Surgery: T2D, prediabetes, lower carb dietary option (this document is under regular review, please let DJU know if it can be improved).

At the first appointment for those people interested in this approach:

- Explore possible benefits/ risks of a lower carb approach to T2diabetes (eg medications, risk of hypo) and make a start on motivation. The idea of diabetes remission or coming off meds is very motivating for many people.
An example of the type of question you can ask.

'You have a range of different possible futures WRT to your diabetes, which will you choose?' 'In this clinic to date the average weight loss on low carb is 9Kg, is this of interest to you?' etc..,

- Check are the patients interested in the low carb approach, there are others (eg VLCD)?

-Visit basic physiology of sugar starting with the fact that 'your HbA1c shows how sugary your diet has been in the last few months', and explaining sugar can almost be seen as a metabolic poison to someone with T2D.
Ask 'where do you think the sugar has come from in your diet?'

- Explain dietary sources of glucose with Nice endorsed sugar equivalence infographics.

- Give the Norwood standard diet sheet for low carb approach.

- Establish baseline data; Wt., waist, height, bloods; HbA1c, renal, fasting lipids, FBC.

-Enter EMIS computer code 'low carbohydrate diet'.

-Medications
? Risk of hypoglycaemia (Insulin, gliclazide) reduce dose/stop but monitor
? Risk of DKA (SGL2Inhibitors). Stop, but monitor blood glucose.
? 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)
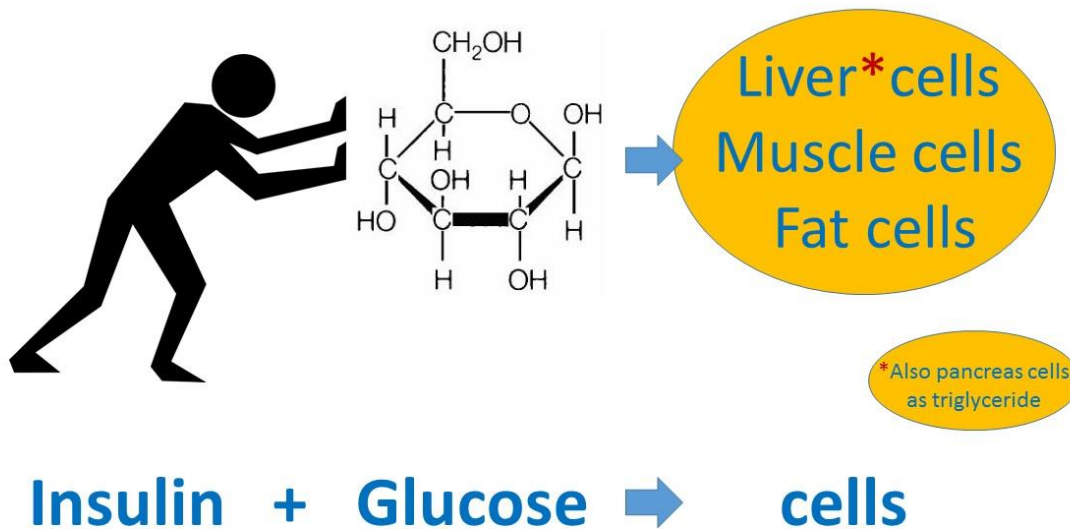
Finally NICE UK guidelines 1.3.6 Individualise recommendations for carbohydrate and alcohol intake, and meal patterns. **Reducing the risk of hypoglycaemia should be a particular aim for a person using insulin or an insulin secretagogue. [2009]**
Often this is achieved by increasing dietary carbs at 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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1.   Unwin DJ, Tobin SD, Murray SW, Delon C, Brady AJ. Substantial and Sustained Improvements in Blood Pressure, Weight and Lipid Profiles from a Carbohydrate Restricted Diet: An Observational Study of Insulin Resistant Patients in Primary Care. International Journal of Environmental Research and Public Health. 2019;16(15):2680.
2.   Gjuladin-Hellon T, Davies IG, Penson P, Amiri Baghbadorani R. Effects of carbohydrate-restricted diets on low-density lipoprotein cholesterol levels in overweight and obese adults: a systematic review and meta-analysis. Nutr Rev. 2018.

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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
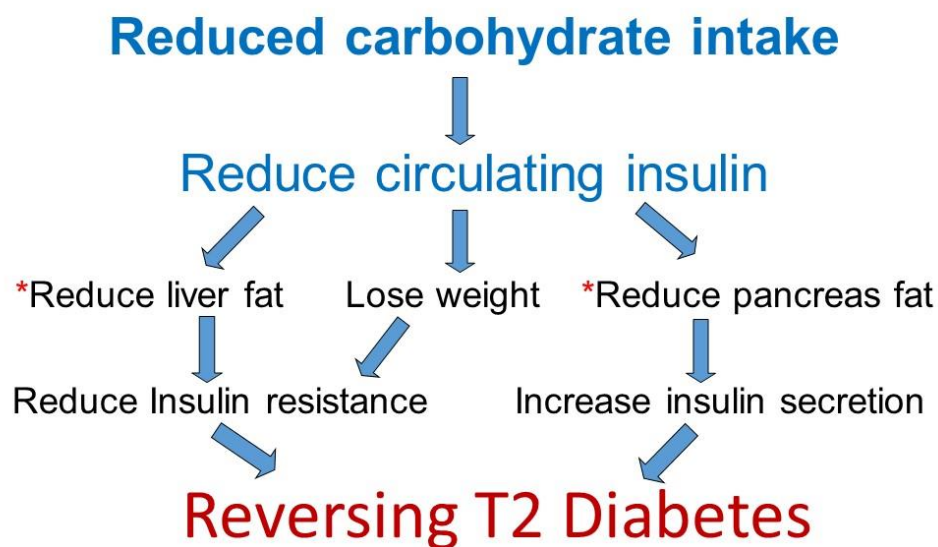

Liver*cells
Muscle cells
Fat cells

*Also pancreas cells as triglyceride

Insulin + Glucose ➡ cells

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

Triglyceride

Liver fat: linked to insulin resistance

Pancreatic fat: inhibits B cell function -cannot produce enough insulin
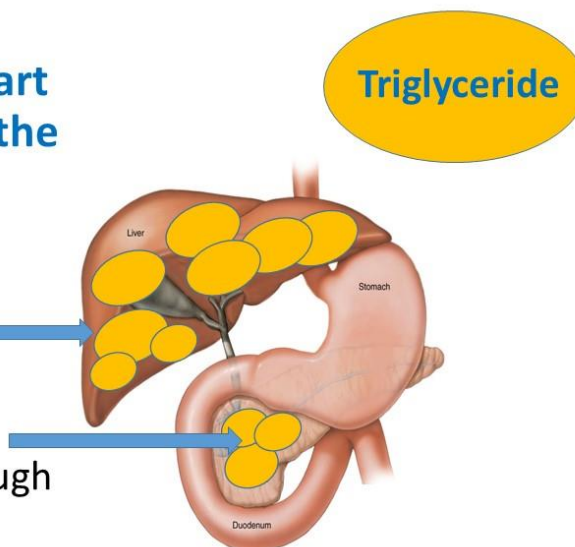
Reversal of type 2 diabetes: Normalisation of beta cell function in association with decreased pancreas and liver triacylglycerol. Lim EL1, Hollingsworth KG, Taylor R. Diabetologia. 2011 Oct;54(10):2506-14. doi: 10.1007/s00125-011-2204-7.

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. Lim EL1, Hollingsworth KG, Taylor R. Diabetologia. 2011 Oct;54(10):2506-14. doi: 10.1007/s00125-011-2204-7.
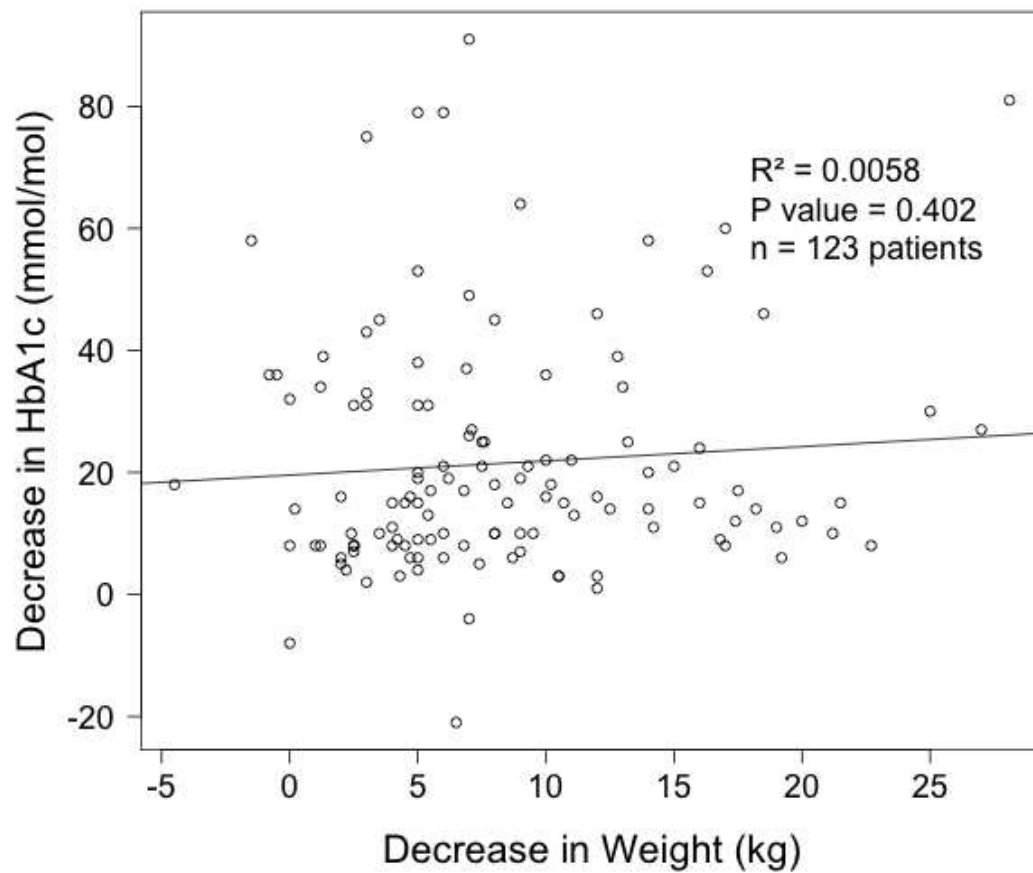
A Starch Molecule
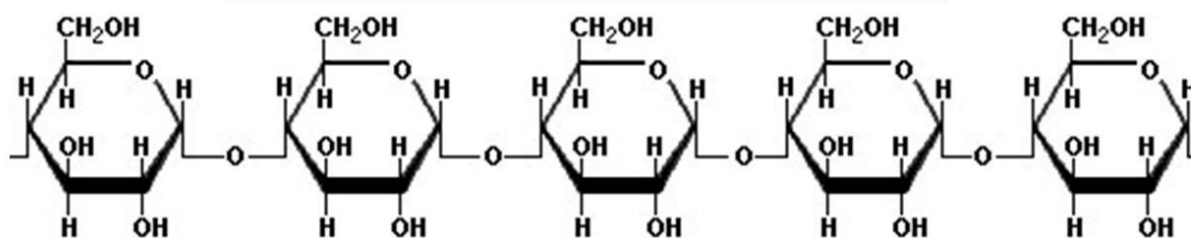
Many glucose molecules are linked together – enzymal digestion will break them up again

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, β=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*

LOCAL, REGIONAL or NATIONAL	Year to April 1st 2020				Prescribing trends 2015 – 2020					
					Items per patient			Cost per patient		
	Patients	Spend/Patient	Items/Patient	Possible saving*	2015	2020	Change In%	2015	2020	Change In%
NORWOOD SURGERY, SOUTHPORT	9,749	£ 4.91	0.40		0.36	0.40	+12%	£ 3.64	£ 4.91	+35%
SOUTHPORT AND FORMBY CCG	125,509	£ 10.13	0.76	£655,257	0.64	0.76	+18%	£ 6.62	£ 10.13	+53%
NORTH WEST COMMISSIONING REGION	7,544,547	£10.67	0.76	£43,506,050	0.67	0.76	+14%	£ 7.48	£10.67	+43%
NATIONAL EXPENDITURE FOR ENGLAND	60,086,632	£9.52	0.71	£277,045,236	0.61	0.71	+16%	£ 6.53	£9.52	+46%

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

*OpenPrescribing.net, EBM DataLab, University of Oxford, 2020. Accessed August 2020 with thanks to W Dale.
*The possible savings if all GP practices prescribed like Norwood
Table contains rounded numbers

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

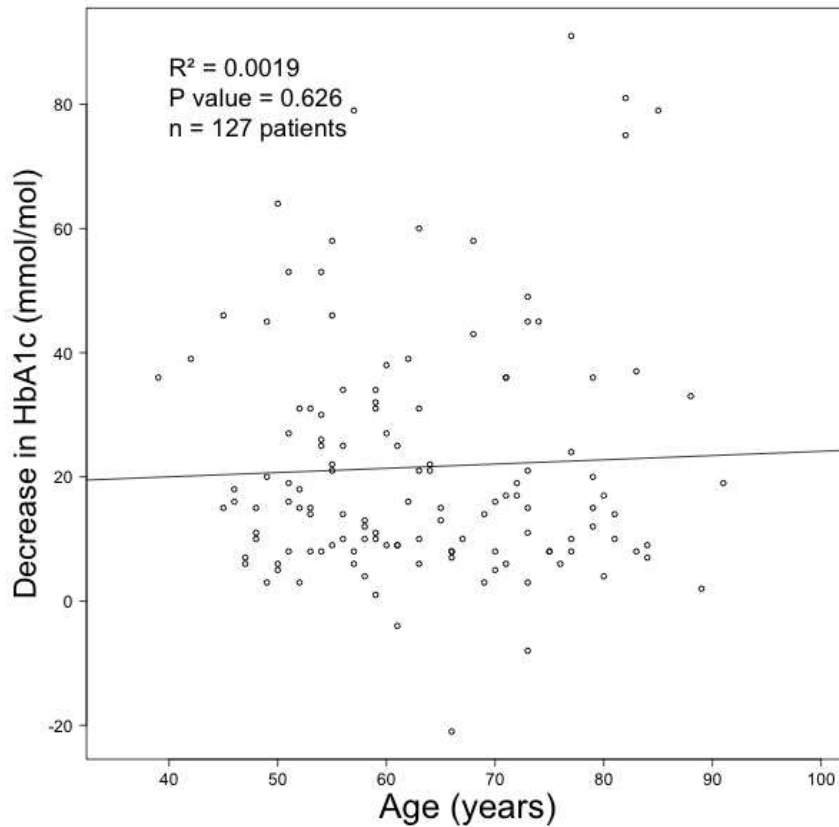Norwood average spend on drugs for diabetes per patient for the year ending April first 2020 was £4.91

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**

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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.**
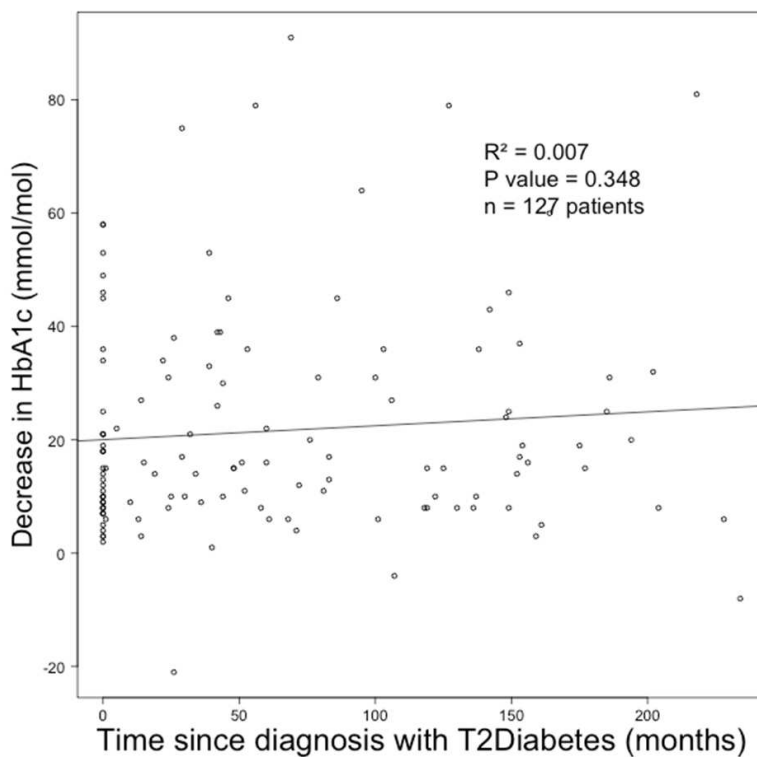
A linear regression model fitted with HbA1c reduction as the outcome and time (months) since diagnosis with T2D as the predictor, $\beta=0.025$ (95%CI -0.027, 0.076). The small R^2 value and large P value suggest a poor correlation between improvement in Hba1c and how long participants had been diabetic 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.

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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, β=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.