RESEARCH PROPOSAL
Reversing Type 2 Diabetes

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Long-term improvement in insulin sensitivity in people with type 2 diabetes.

HbA1c below 42 mmol/mol (6%) without taking diabetes medication are said to have reversed or resolved their diabetes – remission.

Loss of body weight can be particularly beneficial in helping to reverse the progression of diabetes. The most common cause of type 2 diabetes is obesity–related, which generally follows a vicious cycle pattern.
High calorie diet high in refined carbs → Rise in insulin blood levels → Central/truncal obesity and weight gain → Insulin resistance – increase in bl sugar → Further weight gain and more insulin resistance → Overeating; lethargy and less physical exercise → Lethargy and increased hunger → Consistent high demand on pancreas – to produce extra insulin & beta cell damage → Cannot produce sufficient insulin – steeper rise in bl sugar → Symptoms of diabetes – thirst; frequent need to urinate → High calorie diet high in refined carbs
Low Carbohydrate Diets

KEY MESSAGES FROM PUBLISHED EVIDENCE

- Low–carbohydrate diets are known for lowering the amount of insulin the body needs to produce, resulting in less insulin resistance.

- A study published in 2014 by the Second University of Naples showed that a low–carbohydrate Mediterranean diet was able to achieve significant rates of remission in people with type 2 diabetes. After one year of following the diet, 15% of participants achieved remission and, after six years, 5% had achieved remission on the diet.

- By comparison, low–fat diets were not as effective in the study. After one year, 4% of participants on a low–fat diet had achieved remission and, after six years, 0% of participants had achieved remission.

- Dr David Unwin, a UK GP, has run studies that have demonstrated reversal of diabetes in a number of his after following a reduced–carbohydrate diet.
Very Low Carbohydrate Diets

- Very low carbohydrate diets (VLCD) have been shown to achieve **significant weight loss**, **reduce insulin resistance** and allow people with type 2 diabetes to **come off their diabetes medication**.

- In 2011, a study was published by researchers at Newcastle University showing that an **8-week 800 kcal per day diet** was able to achieve **remission from diabetes in seven of the 11 participants** that took part. The trial used MRI scans and showed that the reversal of diabetes appeared to be correlated with significant reductions in fat storage within the liver and pancreas.

- Currently, **Newcastle University** are running a study involving **32 participants**. The participants were put on a similar diet for a similar length of time and then followed a low calorie weight maintenance diet.

- The participants will be **reviewed for at least two years** to see how many of the participants can maintain diabetes remission over this period. Initial results show that 40% of participants had achieved and maintained remission from type 2 diabetes six months after completing the diet.
Exercise

- Commitment to exercise has allowed a number of people to successfully reverse their type 2 diabetes.

- Exercise helps the body to become more sensitive to its insulin. In combination with a healthy diet, exercise can reduce the demand for insulin in the body and therefore help reverse diabetes.

- The people that have used exercise to reverse their diabetes have done so by combining exercise with healthy eating. There have been a number of anecdotal accounts showing exercise to be linked with diabetes remission.

- A study published in 2015 showed that 67% of participants were able to achieve partial remission of their type 2 diabetes having taken part in a six-month diet and exercise program. The participants in this study were newly diagnosed with type 2 diabetes.
Local Findings

- A small pilot from a practice in a neighbouring CCG recruited 30 patients with Type 2 Diabetes on a Modified Mediterranean Diet and after 3 months results showed average of 7kg weight reduction and 16mmol HbA1c reduction per patient, plus patients came off their anti-diabetic medications.

- This reflects the findings from Dr Unwin’s practice (9,600 patient list) which saved £38K in 12 months on anti-diabetic drugs. This should also lead to a reduction in admissions/referrals due to better control of diabetes, BP, cholesterol etc.
## Local Diabetes Prescribing Trends

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Local Diabetes Prescribing Trend

Diabetes Prescribing Cost Trend Chart

Annual Cost

£3,500,000
£3,000,000
£2,500,000
£2,000,000
£1,500,000
£1,000,000
£500,000
£0

2014/2015
2015/2016
2016/2017
2017/2018
2018/2019
(5 Months)

- Antidiabetic Drugs
- Diabetic Diagnostic & Monitoring Agents
- Insulin
- Treatment Of Hypoglycaemia
Local Diabetes Prescribing Trend

Diabetes Prescribing Items Trend Chart

- Antidiabetic Drugs
- Diabetic Diagnostic & Monitoring Agents
- Insulin
- Treatment Of Hypoglycaemia
Local Diabetes Prescribing Trend

Diabetes Prescribing Cost per item Trend Chart

- Antidiabetic Drugs
- Diabetic Diagnostic & Monitoring Agents
- Insulin
- Treatment Of Hypoglycaemia

Average Cost per item

£0.00 £5.00 £10.00 £15.00 £20.00 £25.00 £30.00 £35.00 £40.00 £45.00

(5 Months)
To recruit patients with Type 2 diabetes registered with GP practices in primary care to participate in a qualitative study using reduced calorie/low carbohydrate diets over a period of 6–12 months with weekly/monthly/quarterly follow ups to establish progress and offer support, mentorship and advice where required.
Proposed Monitoring

Patients will be monitored at regular intervals against the following criteria:

- Weight Loss – Bi-weekly
- Support and mentorship – 1–2 weekly
- BP – Bi-weekly
- Cholesterol – monthly
- HbA1c – quarterly
- Medication review – quarterly
Potential Outcomes

- % change in weight from baseline
- % BP change from baseline
- % change in cholesterol from baseline
- % change in HbA1c from baseline
- Changes in medication from baseline
- Qualitative analysis on support and mentorship required
Findings

- A longitudinal analysis will capture not only the quantitative % changes in clinical markers but also the qualitative impact on individual patients in terms of their personal experiences, challenges and goal-setting.
- The latter aspect is crucial given this is a key driver for achieving the clinical outcomes.
Implications

- The model could be scaled up across practices/organisations depending on outcomes.

- The model can be adopted to suit different populations that enable alternative methods to be carried out. This may include comparisons to explore interventions that work for minority ethnic groups; social deprivation and/or rural isolation to ensure the wider determinants of health are captured.

- Involvement of multi-disciplinary teams including patients is essential.

- This may require additional investment initially but this could be offset with additional costs of unnecessary drugs and/or hospital admissions/referrals. This aspect may require statistical modelling given the numbers recruited are likely to be relatively small.
Questions