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Group coaching for diabetic remission

A report and evaluation of a locally-delivered online group coaching programme for type diabetes and pre-diabetes.

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2. Introduction

Type 2 Diabetes and pre-diabetes (type 2) are predominantly lifestyle-related conditions. It is well established that remission can be achieved and in the long-term even disease 'reversal'. Type 2 Diabetes patients in the UK do not have standardised opportunities to access programmes that aim to support disease remission. There are clear national opportunities in pre-diabetes but this has not been extended to type 2 diabetes. The opportunities here are large which include but are not limited to; direct consequences of improved Hba1c, reducing cost of prescribing, improved energy, weight loss, other associated improved health outcomes including reduced cholesterol, reduced blood pressure, improved mental health and reduced risk of long-term sequelae of type 2 diabetes including eye, nerve and kidney disease, heart attacks and strokes.

Coaching programmes for type 2 diabetes reversal typically focus on a specific area, for example nutrition, which is likely suggestive of being the most important aspect of improving diabetes outcomes, however the importance of how a programme it is delivered, the support and coaching offered, and recognising exercise, wellbeing, sleep and stress as factors of diabetes improvement too are limited. It is difficult to isolate one specific factor and conditions such as type 2 diabetes, it

requires multiple impacts across many different domains to lead to sustained improved outcomes with Hba1c and other positive sequelae.

This report focuses on a holistic, whole health focus looking at Nutrition, Exercise, Wellbeing, Sleep, Stress, coaching methods and support for long-term behaviour change. Nutrition methods focus on recognised methods for improving diabetes remission including low carb, and discuss other evidence-based methods including the Mediterranean diet and plant-based approaches. It has been carefully curated to not exclude individuals based on nutritional culture and also to avoid inadvertently increasing the risks of other conditions, e.g. high cholesterol or suggesting a diet that may be 'pro-inflammatory' or in the long-run increase the risk of other conditions (e.g. gut disorders or cancers).

2.2 Diabetes statistics overview

In 2021 over 500 million people worldwide were estimated to be living with diabetes which is set to rise to 783 million in the next 12 years (2045) with over 90% of diabetes diagnoses being type 2 related (IDF Diabetes Atlas, 2023). In the UK rates of type 2 diabetes continue to rise with an estimated 3.8 million adults in 2016 living with diabetes (8.6% of the population over 16) with South Asian and Ethnic groups experiencing rates of over 15% (Public Health England, 2016) and those living in the highest levels of deprivation. Diabetes disproportionately affects non-Caucasian populations and it is estimated 3 in 4 adults with diabetes are based in low or middle income countries (Diabetes Atlas, 2023).

In financial terms, it is estimated that the cost to the UK 2010/2022 was £23.7bn with an estimation that in 2012 real terms costs will have risen to nearly £40bn in 2035/2036 (Hex, et al., 2012). The prevalence of pre-diabetes in the UK is estimated at 35% of the total population in 2011 (Mainous, et al., 2014). Reducing a Hba1c from DCCT 9.9% (85 mmol/mol IFCC) to 7.7% (61) can lead to an extended life expectancy of 3.4 years in a recent study published in JAMA (Kianmehr, et al., 2022). Valentine et al (2006) noted incremental gains in life expectancy of diabetes patients, although those with poorly controlled had more significant gains in life expectancy (Valentine, et al., 2006).

3. Background

3.1 National Diabetes Agenda

The NHS England has a nationally mandated National Diabetes Prevention Programme (NDPP) which has been developed following studies in the USA on the impact on Hba1c and slowing down and preventing the developing of diabetes incidence in population groups. This is broadly available to individuals who have a Hba1c between 42-47 without a diagnosis of type 2 diabetes and delivered by different providers who are awarded contracts in the UK.

Once a patient is diagnosed with type 2 diabetes in the UK they are not eligible for these programmes. There is a course known as DESMOND which has been present for about 15 years in the UK. This course is a one day programme and subsequent studies following up the impact of the DESMOND show that it is of limited value in the long term.

3.2 Other services for type 2 diabetes remission

Impact of interventions on type 2 diabetes

Currently there are no nationally mandated coaching programmes for type 2 diabetes remission. Reasons for this are complex but are likely to include a lack of studies to confirm the impact across a range of measurable metrics and the ability to standardise a programme. Type 2 diabetes management is more complex than pre-diabetes management in part due to different medications that patients are taking that may increase the risk of hypoglycaemia and a higher chance of multi-morbidity or diabetic complications which can increase the risks of delivering such programmes. Type 2 diabetes is less predictable in its response to dietary and lifestyle interventions, typically the duration that an individual lives with diabetes may dictate the chance of successful interventions with lifestyle methods.

Diabetes health check and management

Type 2 diabetic patients are provided with regular life-long monitoring throughout their life-cycle of diabetes. This includes, but is not limited to, regular medicines reviews, kidney-related checks (UACR), blood tests to monitor Hba1c and other markers including renal, liver and cholesterol and yearly eye screening. This approach helps to pick up deterioration faster before they can lead to more serious complications.

Typically, management is pharmacotherapy focused although there is a consensus that it is expected that during appointments lifestyle advice may be provided. There is some evidence to suggest that this might help across populations, but the impact is limited and many individuals this advice does not turn into actionable advice on changes that are needed, better understanding of how to better improve Hba1c and health through lifestyle intervention and certainly is limited in terms of leading to long-term sustained change.

Primary care incentives

General Practices in the UK have been provided with additional funding through the Additional Roles Reimbursement Scheme (NHS England, 2023) which has enabled practices to take on extra health professionals within budgets ascribed to the practices. Examples of staff include advanced nurse practitioners (ANP), dietitians, health coaches, physician associates (PA) and physiotherapists. In addition, the NHS and government have started to recognise that the approach for prevention of

disease makes sense not just for people's health but from a health economic perspective too. A clear example of this is the NDPP. Health coaches who may have a background in nutrition are included in the funding options, However, they are not utilised through the ARRS funding with the frequency of utilisation of other practitioners including ANPs and PAs.

One of the reasons for this is not understanding the role that these professionals can play in general practice, how they support the business case as well as being able to measure the health impact of employment and intervention with these professionals. How should they be utilised in their role? Providing a disease remission and prevention healthcare service is a relatively new concept gaining traction only in the last 10 years in the NHS, and still very much in its infancy.

A growing concept in medicine is group consultations in physical and mental health. In the NHS, group sessions to help manage mental conditions including post-traumatic stress are increasing in prevalence, and in pre-diabetes, the National Diabetes Prevention Program (NDPP) is a group-based program to help prevent the development of type 2 diabetes. To be able to standardise programmes across exercise, well-being, sleep and stress is another difficult factor. Without programmes being studied by academics and being provided large-scale, the NHS as a national body is not able to fund such programmes nationally without the evidence-based and rigorous standards the NHS expects before rolling out such a program.

Nutrition. National guidance, political and business impact

Nutrition is a complex subject with different scientific objective findings which can contradict each other and is heavily influenced with subjective opinion from individuals, medical bodies, and large industry including the food industry. This makes it particularly difficult to standardise advice across populations.

There is a growing recognition that while there are approaches that can be broadly recommended to individuals, cultural context changes the applicability of the information that can be provided, and there is *some* emerging evidence that individual genetic make-up can impact response between individuals depending on the diet being recommended.

There are economic analyses now identifying the impact of poor nutrition and food industry with some policy in effect, i.e. sugar tax, however there are other areas which are connected to poor health and diabetes that are not subject to regulatory changes to positively impact public health population outcomes.

3.4 Curating the programme

Dr Kiran Sodha

Dr Kiran Sodha MBBS MRCGP MBA PGDipIBLM PGDipClinEd DCH is a GP at Primrose Hill Surgery with a background in developing medical related services in the private sector, and has worked as a GP in the private and NHS sectors in the midlands and London boroughs. His clinical practice is rooted in lifestyle medicine.

He is the obesity and diabetes clinical lead at Primrose Hill Surgery. A mid-career fellowship opportunity allowed Dr Kiran Sodha to develop and deliver a group coaching programme to the practice patients. Dr Sodha has regularly provided a lifestyle approach to supporting diabetes management and remission in patients in his clinics privately and in the NHS.

Overview of program

The project was commissioned for one year, from May 2022 until April 2023. The project required planning, course development and recruitment of patients prior to delivery.

The course was delivered between October 2022 and April 2023 (a 6-month intervention). Further detailed information of this process is outlined in the literature review which identifies the course development, and the course delivery section which outlines the recruitment and delivery process.

Finally, the results and analysis look at the results in Hba1c from a group / cohort population level and also the individual level. We consider the impact not just from a quantitative perspective but also from a qualitative perspective. Data considered includes objective data – Hba1c, cholesterol, blood pressure and weight, and also medicines use and changes. We extrapolate these changes to consider the impact over the practice population and whole populations, and how the NHS could consider alternative ways to improve health outcomes and reduced cost.

The second section of the paper follows the entire process of the program, from evidence and literature review, to program development, recruitment of patients, delivery, qualitative and quantitative results, analysis, discussion and conclusion.

4. Evidence & Literature review

4.1 Introduction

It is generally well known with other programs that type 2 diabetes can achieve remission and pre-diabetes can be managed so Hba1c levels are persistently below the pre-diabetes range (Hba1c <42 mmol/mol). We discuss some programmes in the next section. These projects they often have variations, whether that is a major focus on the nutrition (e.g. low carb program with David Unwin) or

other programmes focused on rapid weight loss (with a focus on low calorie – DiRECT study). There is evidence across the board about the impact of sleep, stress, wellbeing and exercise on diabetes outcomes too. To provide a course which is most effective, applicable to most people and recognise the interplay between different lifestyle medicine factors, evidence needed to be collated before being created into a course.

The following sections outline the development of the course with the evidence that influenced the development, alongside existing qualifications with BSLM, completion of lifestyle medicine courses including Inspired Medics and anecdotal individual patient evidence.

4.2 Summary of major programs and studies

DiRECT – Meal replacements and low calorie

The DiRECT was a formal study to look at a low-calorie approach for type 2 diabetes. This includes as 12-week meal replacement program (825-853 calories) through a liquid formula. All diuretics, antihypertensives and hypoglycaemics were withdrawn at the start. Month 4 and 5 are a food re-introduction phase based on the 'EatWell' guidelines (Public Health England, 2016).

Participants were followed up for up to 104 weeks. Results: At 12 months, 46% patients were in diabetic remission. Just over 33% maintained remission at 2 years. (Lean, et al., 2019). Programmes based on the DiRECT study are available for patients with Type 2 Diabetes (provided they fulfil certain criteria in many parts of the UK, but is not nationwide. A concern with this approach, is that while there are initial great results, the impact diminishes over time, and there is not a clear intervention long-term behaviour change, education and support.

National Diabetes Prevention Program (USA and NHS England)

USA: The National Institute of Health in the USA initiated a randomised clinical trial focusing on diet (calorie restriction) and increasing exercise (150 minutes per week) Studies showed a reduced the incidence of diabetes by 58% and average weight loss of 5-7%. 10 years later follow up studies confirm the chance of developing diabetes was one third lower over 10 years (Center for Disease Control and Prevention, 2022).

Public Health England (PHE) have done a systematic review of international studies which confirm the effectiveness of lifestyle interventions in slowing down the course of developing and/or preventing type 2 diabetes (Public Health England, 2015). The pooled incidence ratio of T2DM was 26% lower in the lifestyle intervention programs compared with usual care. Interventions of 11 RCTs were associated with 1.26kg average weight loss. The impact of weight loss was reduced every year. The average reduction in Hba1c was 1.1 mmol/mol (IFCC) – 0.07% DCCT units.

Data also showed that age or ethnicity were not associated with effectiveness of the programmes. Increased frequency of contact with the programmes (13 or more per year led to 3.15kg more weight loss in intervention arms compared with controls where interventions were up to 7 contacts per year). It was noted the significant variability between these studies. Use of self-monitoring approaches for diabetes did not significantly improve outcomes. Use of an empathy building approach did not significantly reduce incidence of type 2 diabetes however was associated with statistically significant weight loss of 0.8kg compared to when not using this approach.

Person-centred intervention did improve 2-hour glucose levels. Most significant weight loss was achieved when this was delivered in the community. There was no clear evidence whether effectiveness changed depending on who delivered the program. The optimum group size to lead to a significant effect was seen as 10-15. Managing fat intake targets did not impact the rates of type 2 diabetes, or fibre. Notably in this analysis carbohydrate intake was not discussed.

Combined diet and physical activity were more significant for weight loss than PA alone. Recommendations was that interventions should be spread over 9-18 months for maximal impact, and the optimum session time would be between 1-2 hours. 13 sessions should occur over 18 months, with sixteen or more contact hours in the first 18 months. Three or more behaviour change technique implementation was more significant than not implementing. Motivational techniques were associated with greater weight loss.

NHS England made a decision to roll out a national programme in 2015. It was estimated that of the projected 390,000 participants over the next 5 years, 18,000 cases of type 2 diabetes will be prevented (NHS England, 2017).

Results of the NDPP in England

In the first 4 years there were nearly 800,000 referrals since launch (Bakhai, 2021). Rates of update vary with 45% of individuals taking up spaces and 64% registering for the program (Murray, et al., 2019). Average reductions of Hba1c are 1.6 mmol/mol (IFCC) at 6 months and 2.0 mmol/mol at course completion, and 2.1 mmol/mol if completing the final session.

Concerns about program delivery

None of the providers provided a logic model of how the program would lead to changes in behaviour (Miles, et al., 2021) and Goal setting was identified as being underdelivered in the program. Staff training in behaviour techniques was also under delivered and there was concern that these methods were not provided clearly in provider training manuals.

Processes for cultural adaptation and outreach strategies were identified as important to improve (Rodrigues, et al., 2020) and there has been recommendations that community pharmacy could be an appropriate setting for delivery (Katangwe, et al., 2020). There were occasionally problems with having the right setting including large groups, having locations available for delivery, which could potentially improve update in the future (Hawkes & Miles, 2021).

Outcomes were poorer in those who were of older age, female, black ethnicity and low socioeconomic status (Valabhji, et al., 2020). The Odds Ratio (OR) of Asian participants completing a course compared to White groups was 24% lower, although remote delivery was associated with improved retention in these groups. To combat this new provider recruitment has been tailored to manage this.

DESMOND

DESMOND (Diabetes education and self-management for ongoing and newly diagnosed diabetes) is a structured education program to understand more about diabetes which includes 6 hours of self-management group education. One study looked at 207 general practices and 824 patients. The control group had an average reduction of -1.24% compared to the intervention group of -1.49% which was found to not be statically significant. Once there was adjustment for oral hypoglycaemic agents there was no significant difference. There was however a statistically significant impact on weight loss between the control and intervention groups of 1.11kg (Davies, et al., 2008).

3-year outcomes: there was no significant difference in Hba1c outcomes, depression of quality-of-life scores (Khunti, et al., 2012).

Low Carbohydrate Programmes

The Low Carb Programme is a website (‘digital app’) which provides educational videos and nutritional-based content with a focus on low-carb to help improve diabetes outcomes. Results of 45 participants (pre-diabetes and type 2 diabetes) on the programme identified mean Hba1c fall from 58.8 mmol/mol to 54.0 mmol/mol, a mean reduction of 4.78 mmol/mol and an average weight reduction of 3.85kg at 12-month follow-up (Summers, et al., 2021).

Dr Unwin has implemented this approach in general practice in the UK. In one study of 19 patients, patients implementing a low-carb diet led to Hba1c improvements over 8 months from 51 mmol/mol to 40mmol/mol (average Hba1c 11 mmol/mol drop). Benefits were observed with weight (100.2 to 91.0kg), reductions in waist circumference and improvements in systolic and diastolic blood pressures, GGT and total cholesterol reduction (Unwin & Unwin, 2014).

Further detailed discussion of low carb in undertaken in literature review for nutrition.

4.3 Nutrition

Eat Well Guide

Although used in the DiRECT trials the Eat Well Guide (EWG) is not recommended in type 2 diabetes guidance. The EWG has come under significant criticism after being created with food industry involvement. An analysis of the updates of the EWG suggests it would reduce type 2 diabetes diagnoses by 780,000 individuals in 10 years and subsequent reductions in cardiovascular disease (Cobiac, et al., 2016). The EWG does provide advice that is starkly different to other evidence in type 2 diabetes – notably the low carbohydrate approaches that other approaches advocate for in type 2 diabetes, and the NHS does not specifically recommend this guide now for type 2 diabetes.

An analysis of the impact of EWG recommendations on health impact was undertaken, but those who were diabetic are excluded from this study (Scheelbeek, et al., 2020). Notably it was found the impact of reducing saturated fat and improved intake of fish oils had the least impact on mortality on this study. Dr Zoe Harcombe PhD has been clear that the EWG has not been tested as an RCT, despite guidelines recommending low fat, higher carbohydrate diets, there has been a continued increase in obesity and diabetes rates (Harcombe, 2016) although this assumption is made that individuals are following the nationally set recommendations and guidelines.

NICE guidance

The NICE guidance (NICE, 2022) keeps advice broad and generalised for patients.

The broad advice includes “being active, losing weight if you are overweight, getting enough exercise, heaving a healthy diet, not smoking and controlling your alcohol intake if you drink alcohol” It then places the onus on medical professionals to give further specific advice, “your doctor or nurse should give you more information about a healthy lifestyle and what you can do to help keep your type 2 diabetes under control (for example, having a healthy diet, taking more exercise and losing weight)”.

It states “an expert such as a dietitian should give you advice about your diet. This should be designed to suit your lifestyle, culture, beliefs or preferences”. There is a difficulty with this approach as it places the onus on health professionals, and thus makes the assumption that we should know the right methods to help lead to diabetic remission and weight loss, despite the guidance remaining vague.

Other specific advice now includes “eat low-fat dairy products and oily fish, limit the amount of food that you eat that contains saturated fats and trans fatty acids”. It also recommends “there is no need to buy food sold specifically for people with diabetes because this tends to be expensive and is not necessarily any better for you”. This advice is particularly broad.

It gives further recommendations on what questions patients should ask to health professionals including:

- Please explain more about how what I eat and drink affects my diabetes
- What sorts of foods should I eat?
- Do I have to avoid sugary foods?
- Can I eat carbohydrates?
- What are the effects of alcohol on my diabetes?
- How will losing weight help?
- What sorts of exercise are best? Are there any types of exercise I shouldn't do?
- Where can I get advice and support about giving up smoking?
- Are there any support groups in my local area?
- What could happen if I do not change my lifestyle?
- What information and support is available to help me make changes to my lifestyle?

NICE guidance for health professionals

Nice guidance (National Institute for Clinical Excellence, 2022) includes:

1.3.1 - Provide individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition.
1.3.2 - Provide dietary advice in a form sensitive to the person's needs, culture and beliefs, being sensitive to their willingness to change and the effects on their quality of life
1.3.3 - Encourage adults with type 2 diabetes to follow the same healthy eating advice as the general population, which includes: eating high-fibre, low-glycaemic-index sources of carbohydrate, such as fruit, vegetables, wholegrains and pulses
choosing low-fat dairy products eating oily fish controlling their intake of saturated and trans fatty acids
1.3.4 - Integrate dietary advice with a personalised diabetes management plan, including other aspects of lifestyle modification such as increasing physical activity and losing weight
1.3.6 - Individualise recommendations for carbohydrate and alcohol intake, and meal patterns. Make reducing the risk of hypoglycaemia a particular aim for people using insulin or an insulin secretagogue
1.3.7 - Advise adults with type 2 diabetes that they can substitute a limited amount of sucrose-containing foods for other carbohydrate in the meal plan but should take care to avoid excess energy intake
1.3.8 - Discourage adults with type 2 diabetes from using foods marketed specifically for people with diabetes
1.3.9 - When adults with type 2 diabetes are admitted as inpatients to hospital or any other care setting, implement a meal planning system that provides consistency in the carbohydrate content of meals and snacks

Diabetes UK information

Diabetes UK (Diabetes UK, 2022) doesn't specifically recommend a type of diet but does make reference to different approaches including the low carb approach and Mediterranean approach. The information provided does not give absolute clarity on the impact of blood sugar/glucose levels, however they do write about the link between weight and type 2 diabetes. Therefore, the focus is more on weight loss to support diabetes. The healthy food choices do not provide clarity on their direct impact on blood glucose levels.

Diabetes.co.uk information

Diabetes.co.uk is a second charity in the UK. They are affiliated with the low carb program online, which has been developed in conjunction with Dr David Unwin low carb program principles and provide clear information on this program. They also discuss the NHS guidelines and explain some of the controversy about higher carbohydrates and discuss the low calorie DiRECT (Newcastle) study (Diabetes.co.uk, 2022).

American College of Lifestyle Medicine

The ACLM have written a general consensus paper for guidelines for remission of type 2 diabetes (Rosenfeld, et al., 2022). Consensus statements include:

- Diet is the cornerstone for managing T2DM and can be used in combination with medical therapy.
- Intensity of intervention has an impact
- Needs to be acceptable to most patients and accommodate patient preferences
- Diets need to consider a lower risk of CVD too.
- Right diet can also improve cholesterol profile.
- Reduction of calorie intake by: reducing portion size, volume and/or density of energy
- Whole food plant-based diet (WFPB) – whole-grains, vegetable, legumes, fruits, nuts and seeds.
- A very low-carb diet may influence risk of cardiovascular disease so unadvisable for long-term remission.
- Combined with physical activity improves the chance of positive outcomes.
- Intermittent fasting can also help with remission.
- Long-term diets include Mediterranean, dietary approaches to stop hypertension (DASH), and WFPB.
- Nutritional therapy can support.
- Self-management can provide patients with feedback – e.g. blood pressure and blood glucose monitoring.
- The percentage of weight loss is important rather than the absolute number.
- Provider knowledge, experience and ability for supportive communication are essential qualities.
- Lower energy dense foods, water rich foods, fruit and veg, increased fibre and low-fat, whole-grain and legumes.
- Therefore plant-based dietary patterns can be highly effective.
- Other strategies that are successful: very low calorie, fasting-mimicking and intermittent fasting.

- Nutrient dense: Mediterranean, DASH, WFPB, Fibre, anti-oxidants, phytochemicals
- Minimise: ultra-processed / meat / animal products
- Ultra-processed includes cheese, red meat, processed meat – these increase the risk of advice outcomes.
- Very low-fat diets help to reduce liver fat and improve insulin sensitivity
- Ketogenic – not advisable in the long-term. While it improves sugar it didn't deal with some of the underlying issues: i.e. insulin sensitivity in animal studies
- Nutrition knowledge is a key driver of diet quality.

Grains

The EPIC-InterAct study identified greater whole-grain intake is associated with lower risk of type 2 diabetes, cardiovascular disease, and weight gain (InterActConsortium, 2013)

Meat consumption

The EPIC-InterAct Study (InterActConsortium, 2013) identified a higher risk of T2DM among individuals with high meat consumption, specifically red and processed meat. After controlling and managing other risk factors for T2D (e.g. smoking, physical activity, alcohol intake), the association between meat consumption and incidence of T2D still remained statistically significant.

The Hong Kong dietary survey looked at dietary intake and type 2 diabetes in a Chinese population and found the following, a high consumption of fibre, whole grains, fruits and vegetables is associated with a lower risk of T2D which is confirmed in other studies too. (InterActConsortium, 2015; Cooper, et al., 2012; Ye, et al., 2012; Yu, et al., 2011)

Fibre

The EPIC-InterAct study looked at the impact of fibre on type 2 diabetes (InterActConsortium, 2015). "During 10.8 years of follow-up, 11,559 participants with type 2 diabetes were identified and a sub cohort of 15,258 participants was selected for the case-cohort study. Country-specific HRs were estimated using Prentice-weighted Cox proportional hazards models and were pooled using a random effects meta-analysis. Eighteen other cohort studies were identified for the meta-analysis."

"Dietary fibre intake was associated with a lower risk of diabetes (HRQ4 vs Q1 0.82; 95% CI 0.69, 0.97) after adjustment for lifestyle and dietary factors. Similar inverse associations were observed for the intake of cereal fibre and vegetable fibre, but not fruit fibre. The associations were attenuated and no longer statistically significant after adjustment for BMI. In the meta-analysis (19 cohorts), the summary RRs per 10 g/day increase in intake were 0.91 (95% CI 0.87, 0.96) for total fibre, 0.75 (95% CI 0.65, 0.86) for cereal fibre, 0.95 (95% CI 0.87, 1.03) for fruit fibre and 0.93 (95% CI 0.82, 1.05) for vegetable fibre.".

“The overall evidence indicates that the intake of total and cereal fibre is inversely related to the risk of type 2 diabetes. The results of the EPIC-InterAct Study suggest that the association may be partially explained by body weight”.

Intermittent fasting

Intermittent fasting is known to regulate blood glucose and evidence suggests that intermittent fasting can have a beneficial impact on glucose control. A systematic review of intermittent fasting was undertaken (Vitale & Kim, 2020). “The purpose of this study was to evaluate the effects of intermittent fasting on glycaemic control and body composition in adults with obesity and type 2 diabetes. Although intermittent fasting has shown some promise in improving gluco-regulatory indicators and body composition in adults with obesity, there is currently no systematic review evaluating these effects in adults with obesity and type 2 diabetes.”

“Five studies met inclusion criterion. All studies were RCTs in adult subjects (n = 46-137) with T2DM and a BMI of ≥30 kg/m2. Four different intermittent fasting regimens were reviewed. All fasting regimens revealed strong evidence to support intermittent fasting as a feasible diet to improve glycemia and body composition measures within 12–24 weeks. Follow-up 12–18 months *after* intermittent fasting did not show promising results for continued weight loss and improved glycaemic control. Majority of the studies demonstrated insignificant differences between intermittent fasting and continuous energy restriction for measures of Hba1c and body composition. More data on intermittent fasting in adults with obesity and type 2 diabetes was needed to determine its benefits within this patient population.”

“Future research should include consistent fasting regimens and larger sample sizes to improve the reliability and generalizability of the data. Also, consistent follow-up after a fasting intervention may enhance long-term benefits and should be considered in future research.”

This research data on the impact of fasting when continued is backed up by another meta-analysis by Cho et al (2019). “The effectiveness of an IFD was estimated by the weighted mean difference (WMD) for several variables associated with glucometabolic parameters including body mass index (BMI) and fasting glucose.”

“The pooled mean differences of outcomes were calculated using a random effects model. From 2814 studies identified through a literature search, we finally selected 12 articles (545 participants). Compared with a control diet, an IFD was associated with a significant decline in BMI (WMD, −0.75 kg/m2; 95% CI, −1.44 to −0.06), fasting glucose level (WMD, −4.16 mg/dL; 95% CI, −6.92 to −1.40), and homeostatic model assessment of insulin resistance (WMD, −0.54; 95% CI, −1.05 to −0.03). Fat mass (WMD, −0.98 kg; 95% CI, −2.32 to 0.36) tended to decrease in the IFD group with a significant increase in adiponectin (WMD, 1008.9 ng/mL; 95% CI, 140.5 to 1877.3) and a decrease in leptin (WMD, −0.51 ng/mL; 95% CI, −0.77 to −0.24) levels. An IFD may provide a significant metabolic

benefit by improving glycemic control, insulin resistance, and adipokine concentration with a reduction of BMI in adults."

Understanding a low-carbohydrate diet

Feinman et al (2015) provides suggested definitions for different levels of carbohydrate diets which have been adopted by other recent pioneers of the low carbohydrate method including Dr David Unwin (Kelly, et al., 2020). A *very low* carbohydrate diet is defined as <50g of carbs per day (<10% energy from carbs), low carb <130g (<26% energy from carbs), Moderate carb 130-230g and high carb >230g (>45% energy). A low carbohydrate approach for supporting diabetes management is now internationally recognised (Evert, et al., 2019; Davies, et al., 2018)

Glycaemic index, Glycaemic Load and Low Carb

Low-glycaemic index sources of food is now recommended by NICE (NICE, 2022). A meta-analysis of prospective cohort studies understanding impact of glycaemic index and glycaemic load in the risk of type 2 diabetes (Dong, et al., 2011) was undertaken. Thirteen studies of dietary GI or GL related to diabetes risk were included. "The summary RR of type 2 diabetes for the highest category of the GI compared with the lowest was 1.16. For the GL, the summary RR was 1.20" The study came to conclusions that reducing the intake of high GI foods may bring benefits for diabetes prevention,

A second meta-analysis (Brand-Miller, et al., 2003) comprised 14 studies and 356 subjects; 203 with T1DM and 153 with T2DM. The average GI of the high GI diet was 83 and the average GI of the low diet was 65. The mean difference in units was -0.33% (DCCT) and after 12 weeks the average was -0.4% (c.5 mmol/mol). A third meta-analysis observed impact on GI and also identified impact on blood lipids; - total cholesterol average reductions of 6.4mg/dL and LDL 5.5 mg/dL with a dose dependent effect identified. The low GI diets had a statistically significant impact in reducing weight for obese individuals, but not for those of normal weight or overweight category (Zafar, et al., 2019).

Although NICE supports low glycaemic index in its statements for dietary recommendations (NICE, 2022) it explicitly states it does not endorse a *low-carbohydrate diet*. In review of resources that it had previously endorsed from Dr David Unwin and retracting them, it states, "*our diabetes guideline clearly recommends that people should follow a healthy balanced diet that contains, but is not limited to, eating low glycaemic index sources of carbohydrates. We have therefore taken the decision to revoke our endorsement of Dr Unwin's resource and have removed the link to it from NICE's website".*

Dr David Unwin has studied glycaemic-related interventions in NHS General Practice interventions. Average body weight fell by 9kg, waist circumference by 15cm, reduction in hba1c by 10mmol/L (19%) and 5% reduction in total cholesterol and Dr Unwin has estimated a saving of £45,000 of prescribing costs in a single practice (Unwin, et al., 2016).

A meta-analysis of studies by Meng et al (2017) confirms a significant effect of the low carb diet on Hba1c levels and in the short-term; weight loss but not in the long-term. They identified an improvement in cardiovascular risks of lower triglyceride levels, raised HDL, but no overall change in LDL or Total Cholesterol levels (Meng, et al., 2017). The authors wrote the beneficial impacts including on weight could be related to improvements in glucose metabolism and insulin sensitivity. They noted reduced insulin requirements for patients and that the diet might directly improve liver glucose output [via glycogen stores] and also glucose utilisation through production of ketone antibodies and made reference to two papers in-view of this conclusion (Henry, et al., 1990; Muller, et al., 1984).

Position statements as identified by Kelly et al (2020) include: Diabetes UK (2011) – "Diabetes UK support the view that low-carbohydrate diets may be considered an option for weight loss in T2DM when supported by a registered healthcare professional (Dyson, et al., 2011). The Scientific Advisory Committee on Nutrition (2015) recommends that carbohydrate intake should be approximately 50% of dietary energy (SACN, 2015).

SIGN guidelines suggest a low glycaemic index is an option as well as temporarily very low consumption of carbohydrates (<50g) up to 6 months (SIGN, 2017). The American Diabetes Association and European Association for the Study of Diabetes (USA and Europe) have put out consensus reports in 2018 which include low carb, low gi, high protein and DASH approaches, although they identify the Mediterranean diet may be the most effective (Davies, et al., 2018). Consensus reports by the ADA lower carbohydrate diets is a viable approach (Evert, et al., 2019).

Potential negative impacts

Low-carbohydrate diets have been associated with increased all-cause mortality risk including cancer and cardiovascular risk (Noto, et al., 2013; Fung, et al., 2010; Sjogren, et al., 2010). Sjogren et al noticed a reduction in cardiovascular risk with a Mediterranean dietary approach whereas carbohydrate restriction appeared to increase mortality (Sjogren, et al., 2010). Schulze et al identified when carbs were switched to protein, an increased incidence of type 2 diabetes, and when fat was substituted for carbohydrate, no significant change in incidence (Schulze, et al., 2008). Noto identifies the potential changed risk depending on the overall diet (i.e. plant-based inferred a lower risk with lower-carbohydrate method). It is unclear whether it is the replacement with higher protein or other fats from the analyses led to increased risk, or whether it was related directly to limiting carbohydrates.

A key drawback to these studies is the understanding of ultra-processed foods in these studies is limited, and the impact of the level of processing.

Glycaemic diets - Impact on function, blood pressure and cholesterol

The focus of the program is Hba1c improvement for prediabetes and type 2 diabetes patients. The program should not lead to other negative impact on individuals' health do not occur as a result, especially cardiovascular risk. Diabetes management is important largely to do with its cardiovascular implications.

As identified above in meta-analyses and studies there are other benefits that are realised from taking on glycaemic related approaches. This includes positive impacts on cholesterol (Brand-Miller, et al., 2003; Zafar, et al., 2019). Low carbohydrate diets have been associated with improved renal risk factors. Unwin (2021) studied the impact on 143 patients' renal function (those with normal renal function or mild CKD) and noted an improvement of serum creatinine by mean 4.7 micromol/L (Unwin, et al., 2021)

The DASH diet (Dietary Approaches to Stop Hypertension), specifically created for improving hypertension outcomes, is advocated as a diet that can help with diabetes outcomes and recommended by ADA (Davies, et al., 2018). Dr Unwin has studied the impact of a low carb approach on blood pressure. 154 patients studied showed reductions in blood pressure (mean reduction of systolic BP 10.9 and diastolic 6.3, alongside a mean weight reduction of 9.5kg and improved lipid profiles. These readings occurred alongside a 20% reduction in anti-hypertensive medications (Unwin, et al., 2019)

Plant-based and Vegetarian diets

Eleven articles were reviewed in a systematic review (filtered from 1240 articles) by Toumpanakis et al (2018). 433 patients included with mean age 54.8 years. Plant-based diets are associated with significant improvement in emotional well-being, physical well-being, depression, quality of life, general health, HbA1c levels, weight, total cholesterol, and low-density lipoprotein cholesterol (Toumpanakis, et al., 2018).

Compared with several diabetic associations' official guidelines and other comparator diets, plant-based diets can significantly improve psychological health, quality of life, HbA1c levels and weight and therefore the management of diabetes.

Satija et al (2016) reviewed three large prospective cohort studies (nurse's health study, nurse's health study 2 and health professionals follow-up study. Of a total sample of 200,727 participants and concluded that a plant-based diet is associated with significantly lower risk of T2D. Plant-based diets offer high protection against the development of diabetes as it contains antioxidants, fibre, micronutrients and unsaturated fatty acids (Satija, et al., 2016)

The American Association of Clinical Endocrinologists and the American College of Endocrinology have released guidelines in which they suggest that plant-based diet is the optimal nutrition plan for people with diabetes as it promotes the well-being and the better management of diabetes (Garber, et al., 2018)

The BROAD study is a randomised controlled trial using a whole food plant-based diet in the community for obesity, ischaemic heart disease or diabetes (Wright, et al., 2016) Those with a low-fat plant-based diet experienced an average weight drop 11.5kg at 12m, average Hba1c reduction 5.3 mmol/mol TC reduction after a 12-week intervention. The diet enabled reduction in energy density: lower fat, higher water and fibre. An important part of this intervention was not being hungry is important in enabling adherence. It was compared to liquid diets and noted that liquid diets are not intended for long-term use and recognised the importance of 'eating to satisfaction'

A meta-analysis (Yokoyama, 2014) focusing on vegetarian diets (defined as those excluding meat, poultry and fish, but including eggs and dairy) in diabetes revealed a significantly improved glycated haemoglobin (HbA1c) in people who followed a vegetarian diet pattern.

The Adventist Health Study 2 studied disease prevalence of different eating patterns on over 61,000 individuals. The incidence of type 2 diabetes was 2.9% in vegans, and 7.6% in non-vegetarians which was adjusted for BMI. The incidence gradually reduced depending on the amount of meat present in the diet (Tonstad, et al., 2009), and identified that even small increases in meat increased diabetes risk. The Adventist Mortality Study and Adventist Health Study showed a 17-year adherence to a diet with at least weekly meat intake was associated with a 74% increase in odds of developing diabetes compared to long-term adherence of a vegetarian diet (zero meat intake). The association was attenuated but persisted when controlling for weight and weight change (Vang, et al., 2008).

Similar findings have been found in a study of over 4,000 Taiwanese Buddhists; the rate of diabetes was approximately half in vegetarian men compared to omnivores. Satija et al (2016) analysed data from 4.1 million person-years of the Nurses health studies (1 and 2) and the Health Professionals Follow-up study and those most adherent to a healthful plant-based dietary index had 34% lower risk of developing diabetes to those least adherent, which associations independent of BMI and other risk factors (Satija, et al., 2016).

Barnard et al compared an RCT of a plant-based diet compared to the 2003 ADA guidelines (Barnard, et al., 2009) with 99 individuals in the study. The vegan diet was approximately 10% energy from fat, 15% from protein and 75% from carbohydrates. A focus on vegetables, fruit, grains and legumes. They were also advised to move towards low GI foods, e.g. beans and green vegetables.

43% (21 individuals) of the intervention group reduced their medications. 26% (13/50) of ADA group participants reduced their medications. Hba1c fell by 1.23 in vegan group (excluding medications) and 0.38 in ADA group ($p=0.01$). Average weight loss in plant-based group was 6.5kg compared to weight loss 3.1kgin ADA group ($p<0.001$). LDL reductions of >21% in vegan group and >10% in ADA group. ($p=0.02$). Urinary albumin reductions were more significant (15.9mg/24 hr vs 10.9mg/24 hr).

Conversely high meat diets are associated with increased risk of developing diabetes (Satija, et al., 2016; Kim, et al., 2015; van Nielen, et al., 2014; Djousse, et al., 2016). Van Nielen (2014) identified high animal protein consumption was identified as a 22% higher risk of developing compared to lowest quintile of animal protein consumption.

Similarly, the nurse health studies and health professional studies identified a 13% increase in type 2 diabetes between quintiles of animal protein consumption (Malik, et al., 2016). This effect appears more pronounced in older populations with a geriatric study in Greece identifying a 34% increased incidence of type 2 diabetes with a 5% increase in protein intake from meat products despite adjustments for obesity, age, hypertension, obesity, hyperlipidaemia and other dietary behaviours (Pounis, et al., 2010).

Further cardiovascular impact – vegetarian diets

Ischaemic heart disease and mortality is reduced in plant-based diets by between 29% in a large meta-analysis study with also an 18% reduced cancer incidence than non-vegetarians (Huang, et al., 2012). Results reported on the *Esselstyn Program* look at 198 patients of which 89% were adherent to a diet of 'whole-food, plant-based, no meat (including poultry and fish), no dairy, no eggs, or added oils. The CV event rate was 0.6% compared to 62% in the non-adherence group (Esselstyn, et al., 2014).

Plant-based diets combined with low carb diets

Evidence appears to suggest that low-carb diets that are replaced with high amounts of animal products may be associated with higher risk of type 2 diabetes, whereas the opposite may be the case with plant-based approaches to moving towards lower carbohydrates. The Health Professionals follow-up study identified a 37% higher risk of developing type 2 diabetes in low-carb compared to highest-carb intake quintiles, however if the low-carb diet was plant-based it was more protective (de Koning, et al., 2011) with similar results in the Nurses Follow up study looking at low-carb approaches increasing risk of gestational diabetes when low-carb favoured animal-based products (Bao, et al., 2016)

Ultra-processed foods (UPFs)

The Nova definitions are used to define ultra-processed foods (Monteiro, et al., 2019). UPFs might provide a clearer understanding around plant-based, whole-food diets (which may tend to be less processed) and the on-going debate between the different macronutrient contents. Srour et al identified that 1 10% increase in dietary UPFs led to a 15% higher risk of developing Type 2 Diabetes (Srour, et al., 2020). Levy et al have performed a prospective study involving over 21,000 participants in the UK and identify a hazard ratio of 1.44 between the lowest and highest quartiles of UPF consumption (Levy, et al., 2021). 1.1 million individuals were studied in a metanalysis in 2022 which confirm a positive association with a relative risk increase of 12% between zero consumption and moderate consumption of UPFs (Delpino, et al., 2022).

Summary

Dietary approaches based on these studies overall tend to take a '*non-processed'* approach to foods, reducing meat and eating foods that have a lower glycaemic index will lead to significant improved outcomes in Hba1c and also in down-stream impacts of cardiovascular disease, with potentially further reaching impacts including in long-term cancer risk. Low-carbohydrate as an approach is potentially contentious as is going plant-based for individual and communities' lifestyles and culture, however a combined approach appears to be most effective.

UPFs provide another dimension in helping to understand why different studies identify different responses in macronutrient constituents. UPFs are likely to have to foods with a higher GI (Fadet, 2016), and may drive excess energy food intake (Hall, et al., 2019). Srour et al (2020) noted the reduce dietary quality as UPF consumptions increased intake of sodium, sugar, fat, reduced fibre, reduced fruit and veg, increased processed meat and sugar and/or sweetened beverages.

4.7 Exercise

NICE guidance

NICE guidance provides limited advice direct to public (NICE, 2022) and the NHS similarly provides general guidance on being active for a minimum 2.5 hours per week with recommendations for exercise to get 'you out of breath' (NHS UK, 2020). It also directs to further resources in the charity Diabetes UK (Diabetes UK, 2023).

The evidence for improving Hba1c and insulin sensitivity is generally well known.

The American College of Sports Medicine and the American Diabetes Association report on exercise and type 2 diabetes

The American College of Sports Medicine and the American Diabetes Association released a joint report identifying the beneficial impacts exercise with diabetes reviewing academic studies (Colberg, et al., 2010). Key statements are categorised A to E, A being the strongest and E the weakest defined as 'Expert consensus or clinical experience'.

Key statements include:

- PA causes increased glucose update into active muscles balanced by hepatic glucose production, with a greater reliance on carbohydrate to fuel muscular activity as intensity increases (cat A)

- ‘Insulin-stimulated BG uptake into skeletal muscle predominates at rest and is impaired in type 2 diabetes, while muscular contractions stimulate BG transport via a separate additive mechanism not impaired by insulin resistance or type 2 diabetes.’
- Risks of acute hypoglycaemia are minimal without the use of exogenous insulin or insulin secretagogues (cat C)
- Transient hypoglycaemia can follow intense PA (cat C)
- Resistance exercises result in lower fasting BG levels for at least 24 hours post exercise in individuals with IFG (cat C).
- A combination of aerobic and resistance exercise training may be more effective in improving BG control than either alone, however more studies are needed to determine whether total caloric expenditure, exercise duration or exercise mode is responsible (Cat B).
- Milder forms of exercise (e.g. tai chi and yoga) have shown mixed results (cat C).
- PA can result in acute improvements in systemic insulin action lasting from 2 to 72 hours (cat A).
- Aerobic and resistance training improve insulin action, BG control and fat oxidation and storage in muscle (cat B)
- At least 2.5 hours per week of moderate to vigorous PA should be undertaken as part of lifestyle changes to prevent type 2 diabetes onset in high risk adults (cat A).
- Moderate exercise may lower glucose levels in GDM (cat B). Adults with type 2 diabetes should undertake at least 150 minutes of moderate to vigorous activity per week (cat B)

4.8 Mental illness, stress, wellbeing & positive psychology

Mental illness

Depression is three times more common in those with diabetes (Golden, et al., 2008). Anxiety and depression are increased in the presence of lower perceived control over diabetes (Hudson, et al., 2014). They identified poorer emotional health is associated with negative perceptions of diabetes including perceptions about the seriousness and severity of consequences. Those on insulin therapy, longer duration of diabetes or with a Hba1c above 6.5 are more likely to experience suicidal ideation. Depression and diabetes have a bidirectional association. A diagnosis of either predicts the future diagnosis of the other (Tabak, et al., 2014; Goldney & Wittert, 2009).

Prospective data from the Healthy Women Study (n=523) identified those with depression symptoms at baseline, increased symptoms of anger, stress and experiencing very stressful life events had an increased risk of developing metabolic syndrome in 15-year follow up (Raikkonen, et al., 2007).

A meta-analysis of depression and incidence of diabetes found that diabetes incidence was 60% higher in depressed participants compared to non-depressed controls RR 1.60, 95% CI 1.37-1.88 (Mezuk, et al., 2008). The 3DFD model developed for diabetes integrates medical, psychological and social care in diabetes with suboptimal glycaemic control. They identified this approach improved Hba1c, reduced psychological distress and improved social functioning. Interventions included psychological therapy, mental health assessment, medication and social support with patient-led conferences. The aim was to optimise diabetes care. At 12 month follow up there were highly significant reductions in Hba1c – average of 15mmol/mol, improvement in depression scores and patient satisfaction (Doherty, et al., 2016).

Stress

The Whitehall II study looked at over 10,000 civil servants and examined their health related to socio-economic status, with a focus on cardiovascular disease and mortality, with subsequent follow up studies. Over 15-years, work stressors doubled the risk of developing type 2 diabetes with work stress viewed as an independent risk factor. The study controlled for obesity and other unhealthy behaviors controlled for (Heraclides, et al., 2009). The Hoorn study (n=2262) found those who experienced significant life event(s) in the past 5 years increased T2DM risk by 1.6 compared to those not experiencing any life events.

The Hoorn Study (De Vegt, et al., 1999) was analysed to test whether chronic stress was associated with the prevalence of type 2 diabetes by Mooy et al (2000). They found that persons who had experienced significant life events during the past five years had a 1.6-fold increased risk to have type 2 diabetes compared to those who had not experienced life events. This study also controlled for waist-hip ratio, which was only a minor reduction in odds to 1.5, suggesting that increased visceral fact was not the main contributor to developing T2DM related to stress (Mooy, et al., 2000).

Abuse / Adverse childhood experiences

The (USA) National Comorbidity survey was analysed retrospectively to look at childhood neglect and risk of developing T2DM (n=5877). Neglect is associated with a significantly higher risk of T2DM (OR 2.2, 95% CI 1.1-4.4) which a higher risk in women. This risk remained raised when adjusting for race, marital status, income or education; although physical or sexual abuse was not associated with an increase risk (Goodwin & Stein, 2004).

The nurses' study had slightly different findings. It was reviewed from the perspective of abuse and adverse childhood experiences. There is a significant higher risk of developing type 2 diabetes, and it is dependent on the level of abuse. (Rich-Edwards, et al., 2010). The hazards ratio (HR) was 1.03 for mild physical abuse, 1.26 for moderate physical abuse, and 1.54 for severe physical abuse. Compared with women reporting no sexual abuse in childhood or adolescence, the HR was 1.16 for

unwanted sexual touching, 1.34 for one episode of forced sexual activity, and 1.69 for repeated forced sex. Adult BMI accounted for 60% of the association of child and adolescent physical abuse and 64% of the association of sexual abuse with diabetes.

Support from family and friends

There is an association of improved outcomes with support from family and friends but it may depend on the support (Stopford, et al., 2013). Social support – from friends may be better for women on Hba1c outcomes whereas men more likely to have better Hba1c outcomes when getting support from family. Interventions that support family members associated with better control, some interventions may not support family members (Mayberry & Osborn, 2012).

Burn-out

Burn-out is now an officially recognised phenomenon by the WHO and included in the ICD-11 (WHO, 2018) but is classed as an occupational condition instead of a medical condition. In a study of 677 employed individuals, high levels of bsaeline burn-out symptoms was significantly associated with the development of T2DM, OR 1.8, 95% CI 1.2-2.9 (Melamed, et al., 2006).

Pathophysiology

Reviews of the associations of stress and mental illness have been undertaken by and also looked at the potential underlying mechanisms. Kelly summarises this in figure 1 (Kelly & Ismail, 2015). The role of inflammatory markers increases the risk of developing T2DM however this paper does not make clear during discussion the pathophysiological link between inflammation, insulin resistance and rising glucose. A key association is increasing stress itself leading to individuals engaging in adverse-health promoting activities which lead to increasing physiological responses of insulin resistance e.g., quality and quantity of food, smoking, reduced exercise and increased alcohol abuse (Bonnet, et al., 2005; Rod, et al., 2009). Suggested chronic stress explanations by Pouwer et al (2010) include the inflammation pathway (through *pro-immune* activity). The inflammatory cytokines and raised glucocorticoids contribute to neuroendocrine and neurotransmitter changes that are similar to those in physical or psychological stressors (Anisman, 2009). The full cascade of understanding this pathway remains incomplete.

Research looks into this but notes the gap of clarity with these pathways (Lontchi-Yimagou, et al., 2013). White adipose tissue increases activates inflammatory pathways and is implicated with the increased release of a number of markers including TNF-alpha, IL1, IL6, IL10, leptin, adiponectin amongst many others (Shoelson, et al., 2006). Low grade inflammation is associated between adipose tissue and increased risk of developing T2DM (Nikolajczyk, et al., 2011). CRP has been investigated in T2DM and it is possible that it could alter signalling pathways of insulin (Xu, et al., 2007). There is some suggestion this might increase inflammation within the pancreas, where insulin

is produced, and also the liver, hypothalamus and muscle, but evidence remains unclear (Lontchi-Yimagou, et al., 2013).

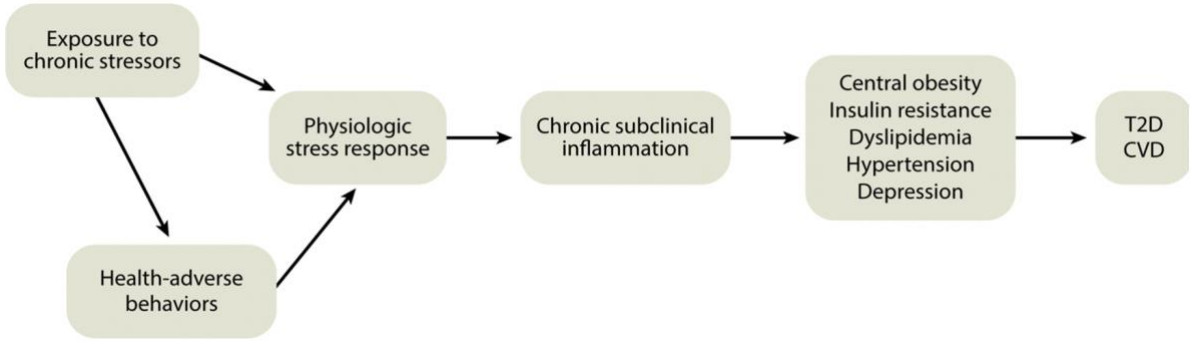

Figure 1 – taken from Kelly & Ismail (2015) - basic pathophysiology of stress leading to T2DM & CVD

Wellbeing & Positive psychology

Positive psychology includes positive emotions, engagement and flow states, positive relationships, social connection, meaning, purpose and achievements. Principles are based on Martin Seligman's work on summarising the core aspects of positive psychology (Seligman, 2002) and understanding the impacts of these specific factors on Hba1c and well-being outcomes. Positive psychology is associated with improved well-being outcomes.

Emotional regulation and emotional intelligence has associations with Hba1c control. As Hba1c rises, emotional intelligence reduces, and the experience of emotions increases (Coccaro, et al., 2016). This finding was held when controlling for depression, income, cholesterol, diabetes literacy and self-care scores.

Papanas et al (2010) identified subject with adequate glycaemic control (Hba1c <7% n=67) had a significantly higher WHO-5 wellbeing score in comparison to those with inadequate glycaemic control (Hba1c >7% n=89) although this data *does not* come to the conclusion that poorer diabetes control leads lower wellbeing, nor suggest a converse or reverse association.

Positive Wellbeing

Insulin use is associated with less positive well-being than oral hypoglycaemic agents (Petterson, et al., 1998). Positive well-being is reduced with diabetes complications (Saatchi, et al., 2010). Positive well-being is reduced in those with neuropathic pain (Saatchi, et al., 2010).

Resilience

The combination of higher resilience and lower distress predicts lower 1-year Hba1c levels (Yi, et al., 2008). Low to moderate resilience was associated with increases in distress and Hba1c levels and

fewer self-care behaviours when experiencing higher distress (Yi, et al., 2008). These relationships are not significant for the higher resilience group.

Emotional health

Literature reviews of positive emotional health is favourable associated with a diverse group of outcomes including reduced mortality, greater participation in self-care activity and lower Hba1c levels (Robertson, et al., 2012)

A high purpose in life is associated with a reduction in mortality among elderly people in the community – HR, -0.6 (Ryff, 2014).

Social Connectedness

Social connectedness is associated with 50% higher reductions in Hba1c, better knowledge of diabetes, better self efficacy and 2.98lb extra weight loss in a study by Shaya et al (2014). Peer coaching has a significant impact on Hba1c control, one hypothesis regarding this impact is due to greater social connection (Thom, et al., 2013).

Positive emotions

Positive emotions are the state of experiencing a 'positive emotion' rather than the general perspective of satisfaction. 341 patients studied on positive emotions as predictors in the management of type 2 diabetes. Results of regression analysis revealed that positive emotions and compliance predicted better diabetes management. The model accounted for 62% of variance explained in the prediction for diabetes management. Inspiration was the most significant predictor of diabetes management. Positive emotions were found to improve diabetes management. (Shamim & Muazzam, 2018). The study also found by enhancing positive emotions this improves diabetes management among patients with Type II diabetes. (Shamim & Muazzam, 2018)

4.9 Sleep

A lack of sleep is associated with similar physiological pathways that may occur with stress, through behavioural changes associated with hormone and energy dysregulation but also through pathophysiological pathways directly leading to the increased risk of T2DM independent of lifestyle-related behaviours. A meta-analysis of ten studies of sleep and diabetes (n=107,756) found short sleep durations (5-6 hours per night) increased T2DM risk (HR 1.3, 95% CI 1.03-1.60) and also increased difficulty in initiating sleep (HR 1.6, 95% CI 1.3-2.0). They also found increased risk at longer durations of sleep (8-9 hours, HR 1.5 95% CI 1.1-2.0). These studies were adjusted to ensure BMI was not a factor (Cappuccio, et al., 2010).

Sleep allows better regulation of insulin, decreased leptin (helps to control appetite), DNA remodelling and repair, increase in GH release, gradual increase in cortisol, fatty acid metabolism, promotion of ATP synthesis, memory encoding and consolidation (Mesarwi, et al., 2013).

Sleep is associated with better emotional regulation (Anderson & Bradley, 2013)
It is associated with better insulin sensitivity, lower glucose levels (Spiegel, et al., 2005). Sleep is associated with lower cortisol.

People with lower leptin levels and higher carbohydrate dense foods – people sleeping 4 hours for 5 nights in a row sought out approximately 300 calories more – especially more from saturated fat during the day. (Spiegel, et al., 2004)

A workplace wellbeing report in 2022 by Nuffield identified;

- Men and women in the UK only got an average 6 hours of sleep per night in the month before the survey, getting slightly less sleep than this time last year at 6.1hrs in 2022 (6.2hrs in 2021)
- Around 37% of men and women got the recommended 7-8 hours of sleep per night in that month, falling slightly from 39% this time last year
- 35–44-year-olds got the least amount of sleep in that month, with almost 50% only getting five to six hours per night, whilst only 33% got the recommended seven to eight hours of sleep per night
- Fewer people (32%) on lower household incomes (£15,000 or less) got the recommended seven to eight hours of sleep per night than people (45%) on the highest incomes (over £75,000)
- 20% more people on lower household incomes (£15,000 or less) said they got lower quality sleep than those on the highest incomes (over £75,000) (82% compared to 62%)
- 71% of 16–24-year-olds have noticed a change in their sleep quantity and quality over the last 12 months, with 59% saying they get less sleep and 61% saying they get lower quality sleep.

4.10 Other External and Environmental Factors

Socio-economic status (SES)

There are three key areas of SES – Income, Education & Occupation. In each of these areas there is an association with reduced risk as the level of income, education and occupation status increases (in more economically developed countries rather than lower to middle income countries). These factors

impact access to housing, transportation, nutritious food and healthcare. It can also impact access to social resource including political power, social engagement and control (Hill-Briggs, et al., 2021) The US National Interview Survey (NHIS – 2011-2014 was analysed and there was continual increasing diabetes prevalence in income levels. The percentage difference from high income to poor was 100.4% and in the US it is noted there are widening disparities in diabetes prevalence compared with income compared to previous studies in 1999-2002 (Beckles & Chou, 2016). The same trends follow in education with higher levels of education associated with lower incidence of T2DM (CDC, 2017).

The reasons for the findings with income are 33-50% associated with modifiable T2DM factors including obesity, diet, physical activity and alcohol intake and other factors be related to other stress related factors including hopelessness, reduced autonomy. Other factors include lack of healthy food access, exercise facilities and health services (Bonilla, et al., 2016; Volaco, et al., 2018).

Understanding the impact of employment is not straightforward. Unemployment increases the risk of prediabetes (OR 1.58, 95% CI 1.07-2.35) and T2DM (OR 1.72, 95% CI 1.14-2.58) results from a meta-analysis (Varanka-Ruuska, et al., 2018). Shift-work rather than normal working times is associated with a higher risk (Gan, et al., 2015). Long work hours of ≥55 hours per week is associated with higher levels of T2DM in low SES but not high SES (Kivimaki, et al., 2015).

Food shopping and habits

The availability of different types of food shops can have an impact on patients ability to improve dietary adherence in diabetes. One study looked at the impact of different food stores availability and shopping locations. If patients were in locations with less access to larger supermarkets and grocery stores (but with more access to ‘convenience’ stores where there is less access to fresh produce) then they were at higher risk of obesity. The inverse association was found in areas with higher levels of supermarkets (Morland, et al., 2006).

Data from the multi-ethnic study of atherosclerosis (n=5124) was studied to look at the impact of neighbourhood exposure to healthy foods and risk of developing type 2 diabetes. As the exposure increased, the risk of developing diabetes reduced, and individuals were followed up for a mean of 8.9 years, HR 0.88, 95% CI, 0.79-0.98 (Christine, et al., 2016).

Holiday/festive seasons can have an impact on patients with diabetes. One study has looked at the effect of Christmas on diabetes control. Prior to Christmas typically Hba1c is much better however between November to January there is a significant rise in Hba1c before it starts to fall again back to pre-November levels in June the following year (Jones, et al., 2014).

Around 21% of adults in England drink more than the recommended guidelines and alcohol intake is associated with obesity, weight gain and more than 200 medical conditions including depression, stroke, mouth, throat, stomach, liver and breast cancers (AlcoholChangeUK, 2020). Excess alcohol is

associated with an increased risk of T2DM (Hodge, et al., 2006) but often studies are conflicting. Low to moderate consumption may be associated with lower risk. and contains carbohydrate, breaking down to glucose, contains glucose and may also contribute to weight gain.

A more recent meta-analysis suggests that alcohol intake is associated with an increased risk of type 2 diabetes (Yuan & Larsson, 2020). Drinking alcohol stimulates appetite in the short-term which is associated with positive energy balance/excess calorie intake (Caton, et al., 2004) which is confirmed in the Nurses Health Studies and Health Professionals Follow up studies. In the long-term excess alcohol intake is associated with rising BMI (Schroder, et al., 2007).

4.11 Behaviour change

SMART

SMART goals are recommended in other NHS-backed programmes (i.e. NDPP). While coaching and behaviour change is seen an important component of improving T2DM outcomes often evidence for the use of tools is lacking compared to other factors that contribute to or improve diabetes outcomes. An intervention with the main focus on SMART goals (n=33) alongside educational information provided by the ADA led to some modest improvement in Hba1c (61.6 to 60.5 mmol/mol – 0.8 points drop). Feedback from participants reported it to be a useful tool, finding it easy to use, and that they would continue to use it (Snyder, 2022).

The main drawback is that there was not a control group, and the only intervention was not SMART, as it involved using SMART within the context of a lifestyle intervention. A second study compared a control group with the SMART intervention group, with the only difference not using SMART as a tool. Over 3 months the SMART goal intervention group (n=50) dropped Hba1c by 1.2% DCCT (13mmol/mol) compared to the control group (n=50) who dropped by 0.85% DCCT (9.3 mmol/mol). In the short-term this programme suggests improved outcomes with SMART goal setting (Cook, et al., 2022).

COM-B model

The NDPP cites the use of the COM-B as one of the models for supporting behaviour change and outcomes in diabetes within its service specification (NHSE, 2022). Google scholar literature review does not identify any studies that are specific for understanding impact of COM-B in diabetes outcomes, rather than part of a whole intervention with COM-B incorporated within for T2DM. In one paper studying lifestyle behaviour in young adults for physical activity (n=582, mean age 22.8) and eating habits (n=455 mean age 24.9) were studied, using COM-B to explain variance in behaviour rather than looking at outcomes. Capability, Opportunity and Motivation were all found to support explanations in behaviour (Willmott, et al., 2021).

The study identified that different areas of the model were statistically significant in the nutrition arm in comparison to the physical activity arm. As the cohort group were of a different age and not related to a specific health outcome it is difficult to apply these results directly for a T2DM model, and was used more to explain and understand why certain behaviours were undertaken rather than to support behaviour change. COM-B itself in the literature is more focused on looking at the reasons why behaviour change did/did not occur, rather than being a core part of the training and delivery and teaching the model as part of an intervention.

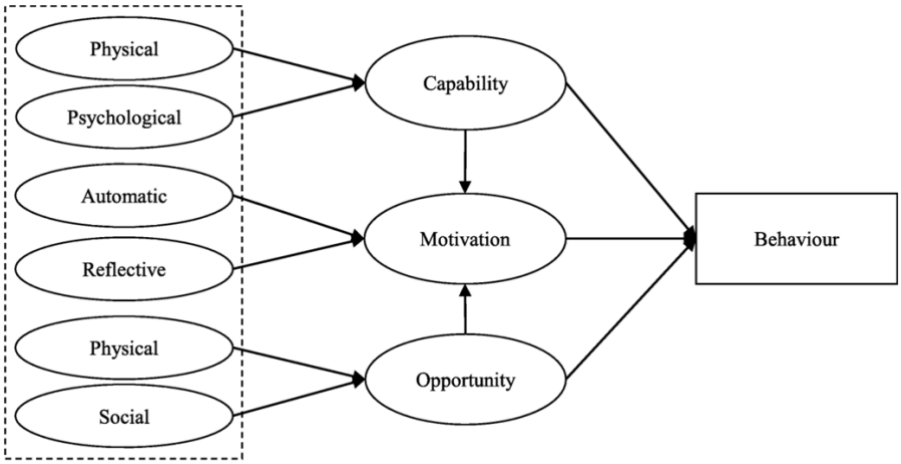

Figure 2 – The COM-B model - (Mitchie, et al., 2014)

Nudge Theory

In 2020 a seminal paper studying nudge theory in type 2 diabetes was published. N=33 studies were used from a search of 11,494 studies. Specific nudge frameworks considered included framing (n=5), reminders (n=10), gamification (n=2), social modelling (n=5) and social influence (n=16). Studies on reminders and gamification were more likely to have a significant outcome including in medication adherence, physical activity, diet, blood glucose monitoring, foot-care, self-efficacy, Hba1c and quality of life (Kwan, et al., 2020).

All five studies using social influence through group meeting sessions were effective in improve Hba1c outcomes. Reminder text messages were found to be ineffective including for glucose monitoring and eating fewer calories (Dobson, et al., 2018; Yoo, et al., 2008). Social influence was ineffective when delivered through a mobile application (Chomutare, et al., 2013), although technology may have improved since this study.

4.12 Medication in T2DM and remission

NICE provides clear guidance on medicines in type 2 diabetes (NICE, 2022) . The courses provided information on medicines and followed the guidance within this document, but was provided in a patient-friendly way.

Taking on a diet and lifestyle dietary approach can create risks of hypoglycaemia for those on insulin or medicines that increase insulin production. The following paper provides guidance on managing medication in a low carb diet. However, the same principles can be applied whichever approach is taken which will lead to rapid improvements in Hba1c using diet, lifestyle and coaching approaches (Murdoch, et al., 2019). The paper by Murdoch et al provides clear guidance on managing medications when embarking on a significant diet and lifestyle treatment intervention.

5. Project Preparation

5.1 Aims & expected outcomes

Aims

To improve control of type 2 diabetes, aim for remission of type 2 diabetes, improved hba1c back to normal level in pre-diabetes, to reduce need for medications and the burden of cost on the health system in the NHS in the long-term.

Expected outcomes

Reduced weight, BMI, Hba1c, BP, lipids and blood pressure. Improved mental health and overall wellbeing. Reduced medication use and long-term cost savings for the practice.

5.1 Research Approval & ethics

This was not considered research to identify if a programme would work to improve type 2 diabete outcomes, as this is will established. The report focuses on the outcomes of this pilot of the programme developed and delivered locally. Patients were not randomised, but invited to join the program. Diet and lifestyle related programs to improve health outcomes, specifically in diabetes are in existence, so does not deviate against current intervention recommendations. Patients joined voluntarily onto the program, and had no change with their routine healthcare access and management.

5.2 Primrose Hill Surgery

Primrose Hill Surgery is in Primrose Hill, a neighbourhood within the borough of Camden, London. It is part of the Primary Care Network Central Hampstead. It has a relatively diverse population due to its location and although in a location typically seen as affluent has a mix of patients from different

socio-economic backgrounds. Primrose Hill Surgery is a smaller than average size NHS practice with 7,142 registered patients. (NHS England average – 9,544). There is one GP partner, multiple part-time salaried GPs and a broad set of healthcare professionals including physician associates, a pharmacist, practice nurse, healthcare assistant and social prescriber.

Average male life expectancy is 83.6 years and female life expectancy 93 years. It is in the 3rd least deprived centile with 78.7% of the population of white, Caucasian ethnicity, 4.8% mixed, 4.5% black, 9.1% Asian and 2.9% other non-white ethnic groups (NHS England, 2023). The UK average is 84.8% white. Primrose Hill Surgery is an outlier within London where the average is 53.8% white (Gov UK, 2023). This information comes with the caveat that there is significant variation in ethnicity demographics throughout London.

Demographic breakdown of Primrose Hill Surgery:

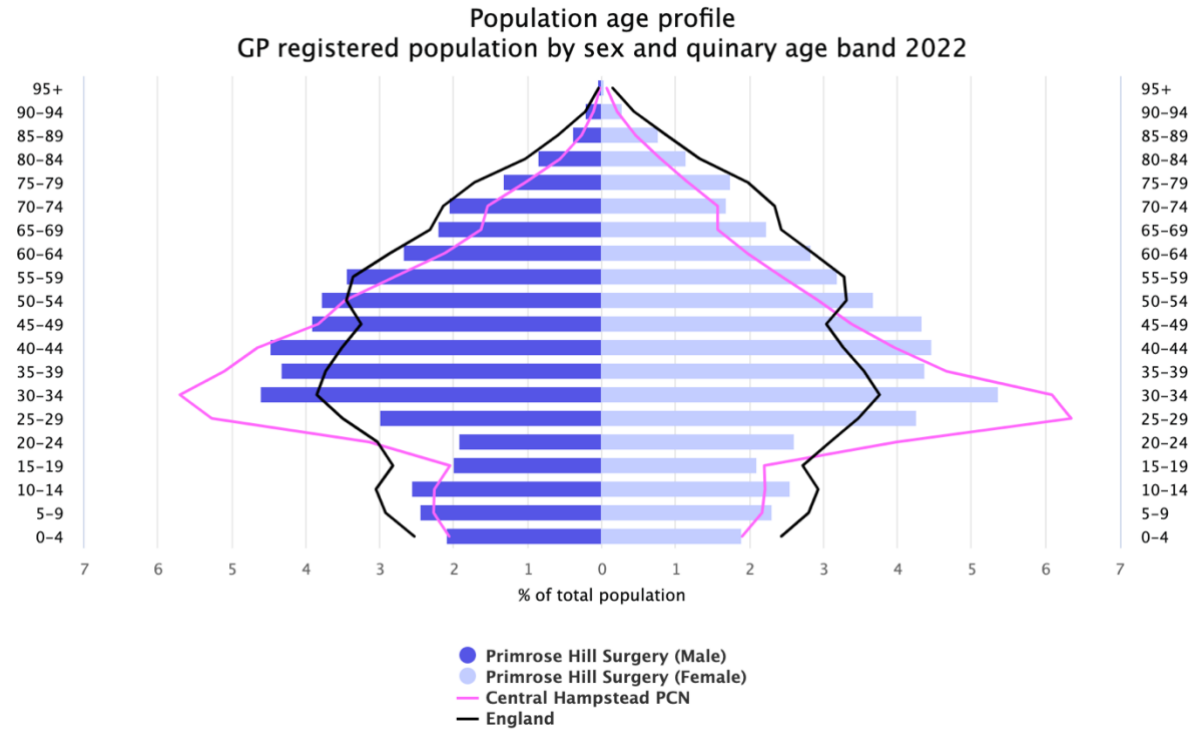

Figure 3 - Primrose Hill Surgery population demographics

5.3 Recruitment

EMIS WEB searches in August 202 identified 427 patients with at least one recorded Hba1c ≥42 in the preceding 24 months. All 427 patients were contacted by text message. 70 patients (16.4%) expressed interest in joining the program. 22 patients joined the program and attended the first session via Zoom, split between 2 sessions.

Criteria for participation

Registered Hba1c ≥42 in the preceding 24 months. Must not be taking insulin. Registered at Primrose Hill Surgery, NW1.

Location

Due to the covid-19 related restrictions still in place, infection-related concerns of groups of individuals together, and a lack of physical space available to deliver the sessions, sessions were delivered by zoom on Thursday afternoons. Two options were provided to patients, 3pm or 6pm to suit the differing needs and lifestyles of patients recruited. Sessions were conducted in English and delivered by Dr Kiran Sodha (GP & Lifestyle Medicine Specialist - 10 sessions) and Ms Laura Fuller (health coach & registered nutritionist - 2 sessions)

6. Project Development & Delivery

The Diabetes program was broken down into 12 modules. The following table shows the module titles, aims and outcomes. The literature review informed content creation, alongside pre-existing programs including the NHS Diabetes Prevention Programme and Low-Carb programmes. The focus was not on nutrition but on a comprehensive and holistic lifestyle intervention encompassing four key factors: Nutrition, Exercise, Wellbeing and Sleep, with coaching to support the delivery.

6.1 Comparison with NDPP & AHEAD programmes

6.2 Programme contents, aims & outcomes schedule

No	Date	Module name	Aims and Outcomes	Follow-up actions
1	13/10/22	Understanding diabetes	What the course can do you for you 12-week course overview Explanation of diabetes Understand measurements Medicine changes required	To do food diaries
2	20/10/22	Nutrition: Low carb, GI and GL	Overview of ‘diets’ in diabetes and weight loss Food diary review Low carbohydrate Glycaemic index and Glycaemic load	3-day check in on mental wellbeing
3	27/10/22	Behaviour change, goal-setting and psychological well-being	Association with mental health and wellbeing Positive psychology Com-B for behaviour change SMART goals and goal planner	Get to know medications and doses
4	3/11/22	Medications, cholesterol & blood pressure	Your medications How medications work	Exercise monitoring, type, frequency and intensity

			Managing sick days Discussion about cholesterol, BP and medications-related Considerations when making lifestyle choices	
5	10/11/22	Exercise	Check in how much exercise people doing Exercise impacts Who benefits most Barriers to exercise	Qs – wins, difficulties, confusions & what hasn't worked. Missing info
6	17/11/22	Nutrition: intermittent fasting, portion management and calories	Calories – what are they and calorie counting Intermittent fating – 16:8 and 5:2 Food labels inc. traffic light system	Qs – monitor sleep and stress diaries Monitor impact on eating habits
7	22/11/22	Sleep & Stress	Sleep – importance, disease risks, recommendations, phases and the sleep-wake cycle Cortisol and Melatonin Light exposure Stress, causes, managing and association with diabetes	n/a
8	5/12/22	Relationships, work & the festive season	Socio-economic and cultural contexts including food deserts Work-related issues Support from family and friends Adverse Childhood Experiences	To look up own area of food deserts and consider food option availability
9	5/1/23	Supermarket shopping & alcohol	Festive season & temptations Alcohol Shopping	n/a
10	12/1/23	Behaviour change & coaching	COM-B and SMART review Coaching Wheels in diabetes – summary of key diabetes principles	Know your numbers/results for the next session (BMI / BP / Hba1c / Cholesterol)
11	19/1/23	Health markers and program summary	Re-cap understanding diabetes Different ways of measuring blood glucose Review behaviour change models and medications Health markers including: Weight, BMI, BP, Hba1c Monitoring tools	Individual consultation prior to final group coaching program
12	16/3/23	Results and moving forward	Results and review Individual successes and review Coaching – through barriers and areas of difficulty	

Table 1 - Programme components

7. Results

7.1 Quantitative data

17 patients attended ≥9 (75%) of 12 sessions delivered between October 2022 and March 2023. Of these patients 12 have been included in results and analysis. Criteria to be included: Hba1c within 6 months of enrolment on program, Hba1c within 3 months of completing program. Of the 17 patients, 3 patients did not have Hba1c 6 months prior to enrolling on program, and 2 patients have not attended for Hba1c check since program completion.

Average age of participants completing the program was 66, with a range of 52-86 years. The gender split was even 6 female (50%) and 6 male (50%). 8 patients were of white/Caucasian descent and 4 patients were of other ethnic groups (33%). 21.3% of the practice population are non-white/non-Caucasian.

The average age was 67 with range 52-86. There was *no* age exclusion for the program. Hba1c average was 56.5 pre intervention and post intervention 47.1 with an average drop of 9.5 mmol/mol. Of note there is one outlier who dropped Hba1c from 122 to 46 during this period. Combined with the lifestyle intervention program she was taking a GLP-1 analogue, dulaglutide once weekly injection. If removed from the analysis the average Hba1c change was 3.45.

Of 7 patients in the type 2 diabetes range (≥48), at the end of the program, 4 patients were in a pre-diabetes range. 4 patients were in the pre-diabetes range, and one patient moved into the non-diabetic range. One patient had a hba1c 41 at the start of the program and at the end his hba1c was 40.

The average weight loss (n=11) was 6.54kg with the largest weight loss of 28.6kg by one individual. There was an average 2.0 mmHg drop in systolic blood pressure (note average blood pressure was within normal range and whether patients are taking medications has not been factored into the blood pressure readings. An analysis of the medicines has been provided. Average diastolic BP fall was 0.7 mmHg. Details of individual results are provided in table 2.

In individual 2, post intervention gliclazide and dulaglutide have been stopped. In individual 5, Ramipril dose has been reduced from 5mg to 2.5mg. Pre intervention systolic BP was 133 and post intervention was 121. Individual 7 had a non-directly related medicine added by hospital specialist teams (apixaban) but of note this patient lost the most significant amount of weight, 28.6kg with a BMI reduction from 36.91 to 28.37 and Hba1c reduction from 59 to 47 (11 points). Patient 11 had spironolactone dose reduced from 100mg to 50mg, but experienced a rise in Hba1c of 8 points and overall systolic reduction was 113 to 110 (3 points pre and post intervention).

Total medicines cost savings of all medicines prescribed for individuals was £267.12 (extrapolated yearly) and total diabetes medicine cost savings are £906.12 per year.

93.3% of patients on the program would recommend the course to another person (n=15).

	Mean	Range	No. of patients
Age	67	52-86	12
Hba1c (mmol/mol)			
Hba1c – pre-intervention	56.5	41-122	12
Hba1c post-intervention	47.1	40-64	12
Hba1c difference	**9.5**	-8 to +76	12
Weight (kg)			
Weight – Pre-intervention	91.77	62.6-123.6	11
Weight – post-intervention	85.23	58-112	11
Weight – difference	**6.54**	-1.5 to 28.6	11
Body Mass Index			
BMI – pre-intervention	30.24	23.94-36.39	11
BMI – post-intervention	28.12	21.8-35.75	11
BMI – difference	**2.11**	-0.55 to 8.54	11
Blood pressure - systolic			
Systolic – pre-intervention	125.6	113-143	10
Systolic – post-intervention	123.6	110-135	10
Systolic – difference	**2.0**	-10 to +13	10
Blood pressure – diastolic			
Diastolic – pre-intervention	76.2	66-88	10
Diastolic – post-intervention	75.5	60-85	10
Diastolic - difference	**0.7**	-10 to +13	10

Table 2 - Average and Range values of outcomes

ID	**Age**	**G***	**E***	**Hba1c**			**H***	**Weight**			**BMI**			**Syst**			**Dias**		
				Pre	**Post**	**Diff**	**(m)**	**Pre**	**Post**	**Diff**	**Pre**	**Post**	**Diff**	**Pre**	**Post**	**Diff**	**Pre**	**Post**	**Diff**
1	76	F	W	44	41	3	1.68	79.83	71.21	8.62	28.4	25.4	3.1	143	120	23	88	75	13
2	52	F	NW	122	46	76	1.8	95	95	0	29.3	29.3	0.0	125	135	-10	73	83	-10
3	68	F	W	52	47	5	1.57							122	117	5	73	69	4
4	54	M	NW	56	52	4	1.77	114	112	2	36.4	35.7	0.6						
5	77	M	W	41	40	1	1.83	91	90	1	27.2	26.9	0.3	133	121	12	68	72	-4
6	70	F	W	54	48	6	1.65	62.6	64.1	-1.5	23.0	23.5	-0.6	114	117	-3	71	68	3
7	54	M	W	59	47	12	1.83	123.6	95	28.6	36.9	28.4	8.5	134	135	-1	81	85	-4
8	72	M	W	45	43	2	1.77	75	71	4	23.9	22.7	1.3	117	124	-7	82	82	0
9	67	M	NW	47	46	1	1.68	88.4	86	2.4	31.3	30.5	0.9						
10	68	M	NW	57	43	14	1.8	108.5	96.2	12.3	33.5	29.7	3.8	130	132	-2	80	82	-2

11	62	F	W	56	64	-8	1.67	107.5	99	8.5	38.5	35.5	3.0	113	110	3	80	79	1
12	86	F	W	46	48	-2	1.63	64	58	6	24.1	21.8	2.3	125	125	0	66	60	6

Table 3 - Individual patient data

*G = Gender
*E = Ethnicity (W, White/Caucasian / NW, Non-white)
*H = Height (m)

Medications

ID	Medications Pre-intervention	Medications Post-intervention	Change
1	Bisoprolol 2.5mg OD Perindopril 2mg OD Pravastatin 20mg OD	Bisoprolol 2.5mg OD Perindopril 2mg OD Pravastatin 20mg OD	n/a
2	Aripiprazole 15 OD Dapagliflozin 10mg OD Metformin 1g BD Dulaglutide 1.5mg inj OW Gliclazide 40mg BD	Aripiprazole 15 OD Dapagliflozin 10mg OD Metformin 1g BD	Stop dulaglutide Stop gliclazide
3	Cetirizine 10mg OD Losartan 100mg OD Pravastatin 20mg OD Ezetimibe 10mg OD	Cetirizine 10mg OD Losartan 100mg OD Pravastatin 20mg OD Ezetimibe 10mg OD	n/a
4	Amlodipine 10mg OD Atorvastatin 20mg OD Fexofenadine 120mg OD Flixonase nasal spray Metformin 500mg OD Ramipril 10mg OD	Amlodipine 10mg OD Atorvastatin 20mg OD Fexofenadine 120mg OD Flixonase nasal spray Metformin 500mg OD Ramipril 10mg OD	n/a
5	Ramipril 5mg OD Codeine 60mg QDS Amlodipine 5mg OD Loperamide 32mg QDS Omeprazole 40mg OD	Rampril 2.5mg OD Codeine 60mg QDS Amlodipine 5mg OD Loperamide 32mg QDS Omeprazole 40mg OD	Ramipril reduced to 2.5mg
6	Colestyramine (SF) 4mg TDS Timolol 1mg/g eye drops OD Amlodipine 5mg OD Atorvastatin 40mg OD Hylo-tear 0.1% eye drop PRN Metformin 500mg TDS	Colestyramine (SF) 4mg TDS Timolol 1mg/g eye drops OD Amlodipine 5mg OD Atorvastatin 40mg OD Hylo-tear 0.1% eye drop PRN Metformin 500mg TDS	n/a

	Ramipril 5mg OD Brinzolamide 10mg/ml BD	Ramipril 5mg OD Brinzolamide 10mg/ml BD	
7	Amlodipine 10mg OD Atorvastatin 40mg OD Metformin 1g BD Spironolactone 25mg OD	Amlodipine 10mg OD Atorvastatin 40mg OD Metformin 1g BD Spironolactone 25mg OD	Apixaban 5mg added
8	Enalapril 10mg OD Simvastatin 20mg OD	Enalapril 10mg OD Simvastatin 20mg OD	n/a
9	Atorvastatin 20mg OD	Atorvastatin 20mg OD	n/a
10	Aspirin 75mg OD Losartan 50mg OD Rosuvastatin 10mg OD Omeprazole 20mg OD	Aspirin 75mg OD Losartan 50mg OD Rosuvastatin 10mg OD Omeprazole 20mg OD	n/a
11	Spironolactone 100mg OD Amlodipine 10mg OD Metformin 500mg BD	Spironolactone 50mg OD Amlodipine 10mg OD Metformin 500mg BD	Spironolactone reduced to 50mg
12	Amlodipine 10mg OD Aspirin 75mg disp Latanoprost 50mcg OD RE Losartan 50mg OD Metformin 1g BD Omeprazole 20mg OD Pravastatin 20mg OD	Amlodipine 10mg OD Aspirin 75mg disp Latanoprost 50mcg OD RE Losartan 50mg OD Metformin 1g BD Omeprazole 20mg OD Pravastatin 20mg OD	n/a

Table 4 - Individual medication changes

Medication cost changes

ID	monthly cost Pre	Yearly cost Pre	Monthly cost Post	Yearly cost Post	Monthly Difference	Yearly Difference
1	0.75	9	0.75	9	0	0
	0.96	11.52	0.96	11.52	0	0
	1.77	21.24	1.77	21.24	0	0
TOTAL	**3.48**	**41.76**	**3.48**	**41.76**	**0**	**0**
2	18.8	225.6	18.8	225.6	0	0
	36.59	439.08	36.59	439.08	0	0
	3.28	**39.36**	**3.28**	**39.36**	0	0
	73.25	879			73.25	879

	2.26	27.12			2.26	27.12
TOTAL	**134.18**	**1610.16**	**58.67**	**704.04**	**75.51**	**906.12**
3	0.82	9.84	0.82	9.84	0	0
	1.22	14.64	1.22	14.64	0	0
	1.77	21.24	1.77	21.24	0	0
	1.84	22.08	1.84	22.08	0	0
TOTAL	**5.65**	**67.8**	**5.65**	**67.8**	**0**	**0**
4	0.76	9.12	0.76	9.12	0	0
	0.92	11.04	0.92	11.04	0	0
	1.49	17.88	1.49	17.88	0	0
	6.53	78.36	6.53	78.36	0	0
	0.82	9.84	0.82	9.84	0	0
	1.22	14.64	1.22	14.64	0	0
TOTAL	**11.74**	**140.88**	**11.74**	**140.88**	**0**	**0**
5	1.13	13.56	1.18	**14.16**	-0.05	-0.6
	8.48	101.76	8.48	**101.76**	0	0
	0.71	8.52	0.71	**8.52**	0	0
	59.52	714.24	59.52	**714.24**	0	0
	3.24	38.88	3.24	**38.88**	0	0
TOTAL	73.08	**876.96**	73.13	**877.56**	**-0.05**	**-0.6**
6	94.66	1135.92	94.66	1135.92	0	0
	7.49	89.88	7.49	89.88	0	0
	0.71	8.52	0.71	8.52	0	0
	1.03	12.36	1.03	12.36	0	0
	8.5	102	8.5	102	0	0
TOTAL	2.46	29.52	2.46	29.52	0	0
	1.13	13.56	1.13	13.56	0	0
	2.19	26.28	2.19	26.28	0	0
TOTAL	118.17	**1418.04**	118.17	**1418.04**	**0**	**0**
7	0.76	9.12	0.76	9.12	0	0
	1.03	12.36	1.03	12.36	0	0
	3.28	39.36	3.28	39.36	0	0
	1.36	16.32	1.36	16.32	0	0
			53.2	638.4	-53.2	-638.4
TOTAL	**6.43**	**77.16**	**59.63**	**715.56**	**-53.2**	**-638.4**
8	1.05	12.6	1.05	12.6	0	0

	0.79	9.48	0.79	9.48	0	0
TOTAL	**1.84**	**22.08**	**1.84**	**22.08**	**0**	**0**
9	1.84	22.08	1.84	22.08	0	0
TOTAL	**1.84**	**22.08**	**1.84**	**22.08**	**0**	**0**
10	0.88	10.56	0.88	10.56	0	0
	1.02	12.24	1.02	12.24	0	0
	1.03	12.36	1.03	12.36	0	0
	1.09	13.08	1.09	13.08	0	0
TOTAL	**4.02**	**48.24**	**4.02**	**48.24**	**0**	**0**
11	1.87	22.44	1.87	22.44	0	0
	0.76	9.12	0.76	9.12	0	0
	1.64	19.68	1.64	19.68	0	0
TOTAL	**4.27**	**51.24**	**4.27**	**51.24**	**0**	**0**
12	0.76	9.12	0.76	9.12	0	0
	0.88	10.56	0.88	10.56	0	0
	1.7	20.4	1.7	20.4	0	0
	1.02	12.24	1.02	12.24	0	0
	3.28	39.36	3.28	39.36	0	0
	1.09	13.08	1.09	13.08	0	0
	1.77	21.24	1.77	21.24	0	0
TOTAL	**10.5**	**126**	**10.5**	**126**	**0**	**0**
	Month Pre	Year Pre	Month post	Year Post	Month diff	Year diff
Total Meds Cost	**375.2**	**4502.4**	**352.94**	**4235.28**	**22.26**	**267.12**

Diabetes Medicines savings - £906.12 / year

Table 5 - Medication cost changes

7.2 Qualitative Data

Qualitative feedback was obtained on the course to get a better understanding of *how* it supported patients, understand any other drawbacks and benefits, and how it could be further improved. This question includes responses from all 18 participants on the program as data was obtained and anonymised prior to exclusion of those who did not fit the analysis criteria. One question asked, *how has the course improved your health?* Responses included, *"The course has helped improve my mental and physical health. I am sleeping better, doing my best to maintain a good exercise programme and eating less carbohydrates".* Another individual stated *"I have found the weekly*

sessions have focused me on being more aware of the food I buy, how much I prepare, the names and terms". There were multiple comments on improved sleep, improved weight and improved mental health and well-being.

A second question was asked, *"what was most useful to you?"*. Comments include, *"Hearing other peoples' experiences", "Taking part in the group itself, as it helps see others improve and feel normal", "Most useful was being in a group, not feeling alone with the problems and hearing other people's situations".* The most frequent answer of what was most useful was being part of a group, and it appears there were significant benefits for many individuals to being part of a group.

A third question was asked. *What was least useful to you?* There were responses that the session on medication was least useful. This could be partly explained by the fact that the medicines may not have been relevant to many people with pre-diabetes and the focus of the program was to reduce medicines. One person stated one of the sessions with a nutritionist was less useful as this was more of an overview. In consideration of this session there was less coaching involved.

"How do you think the programme could be improved?" There was one comment to include the program to anyone that needed to lose weight, and another comment to try and make it even more simple. One person stated face-to-face meetings and including healthy diabetes meals. Increasing competition or having a league table was also suggested and also long-term creating support groups.

8. Discussion

It is well established that diet and lifestyle intervention programmes can have a major positive impact in pre-diabetes and type 2 diabetes with outcomes including reducing
Medication, diabetic remission, improvements in weight, blood pressure and long-term inducing 'reversal' (which has not been discussed in this paper.)

There was considerable variation with this cohort of patients, which included those who had received a diagnosis of pre-diabetes or type 2 diabetes within the last 2 years. One patient with a hba1c 41 had been included following prior discussion with GP leading the program. The positive findings across this variation suggests an intervention for pre-diabetes and type 2 diabetes can be similar, provided that medications are managed. Medications sessions were included and in the first session advice on medicines that could cause hypoglycaemia were discussed, and appropriate safety measures were undertaken including regular monitoring of blood glucose levels and more frequent Hba1c monitoring.

Only one patient was taking a hypoglycaemia inducing agent and that individual had extra access to diabetes specialist nursing team who were managing this patient from a pharmacological perspective. Although qualitative data was not taken prior to initiation of the program there was hesitancy from

some participants for joining a group program, and at least 2 patients had expressed they did not want to join a ‘group-based’ programme.

There was also some feedback during recruitment that patients would not attend an online programme and wanted it in person. There is also concern that a program delivered online would exclude patients that may be at higher risk of diabetes and complications of diabetes as it is a condition that is more likely to affect populations who of lower socioeconomic status who may not have the same level of access or use of devices that require access to the programme. The programme was only available for delivery on a Thursday, although two options were provided, at 3pm and 6pm.

There is significant scope for local delivery of lifestyle intervention programs rather than national delivery. In doing so this could increase access to these programs, reduce barriers to referral and other barriers to accessing interventions, e.g. needing to travel to other locations or online delivery by unfamiliar persons, and also improve follow up of individuals and provide better joined up care within a practice. There are funds available for health coaches who, with the right training, would be able to provide such programs at much lower cost rather than a GP. The advice provided in these programs was not specialist advice but information related to individuals lifestyles including nutrition, exercise, wellbeing and sleep that all have an impact on type 2 diabetes, pre-diabetes, obesity and blood pressure outcomes. Coaching is a core component of these programs as well as groups. It is simply not just about education, or ‘diet and lifestyle’.

The number of patients registered on the program was limited to those who were willing to engage online. More than one patient was clear that they would not join the program due to online delivery. Due to limited administration capacity, recruitment was limited to text messaging, and there was a lack of follow-up. This may have reduced the number of patients participating, and text messaging may not have been the preferred method of contact for patients.

Online delivery can potentially be more challenging than face to face delivery. Non-verbal communication, and understanding engagement of the group is limited, and it is harder to group people into doing effective group work. There was diversity in groups with some members of groups having more time than others to give experiences, although generally patients did have opportunity to speak, give opinion, feedback and receive coaching.

These results are preliminary and to see true outcomes one must see the longer lasting benefit, i.e. are these changes borne out in the long-term or are they just temporary. With coaching and changing people’s habits the aim is that a 6-month intervention should lead to longer-lasting benefits. As a follow up, further monitoring should be done at 12-month since beginning intervention (6 month after completion) to see if results are maintained.

8.1 Improving the programme

There are a number of ways this program can be improved. One consideration is whether to deliver from an MDT perspective. There are pros and cons to this. When one person is able to deliver a program then this can help with trust, cohesion and understanding of patient needs and patient communication styles to manage and get best group participation. However, an MDT approach could provide better expertise.

Local delivery in GP surgeries or in communities should continue. This is how a program could be successful and be the right fit for local population needs. The program should ideally be delivered by individuals who understand the patient population well and already work within the local population. Being able to split patient groups into pre-diabetes and diabetes groups may help with keeping some of the sessions more relevant (i.e. medications session).

This programme was delivered with no admin support. Admin support would enable better monitoring and engagement throughout the program and also be able to get pre, during and post-feedback for ongoing improvement. Better measuring and monitoring could potentially improve outcomes and understand value capture. E.g. WHO-wellbeing, PHQ and GAD, nutrition and sleep scores.

Lifestyle intervention programmes such as this exist across the world and across the UK. However, they operate in siloes, without consistent funding. There should be better opportunities for joined up, long-term approaches with the right training to enable the delivery of these programmes.

9. Conclusion

A complete holistic lifestyle-related programme, looking at not just nutrition, but also exercise, wellbeing and sleep with coaching has significant results in improving hba1c, blood pressure and obesity. It is likely that it contributes to improving mental health, and wellbeing. The effects may lead to longer term reduction in risk of many conditions which includes cancer. The cohort size may remain small but it is part of a clear body of evidence showing that unhealthy lifestyles can be improve *and* this leads to improved physical health outcomes in the long-term, *and* there is an alternative approach available to medicines and surgery in modern western medicine.

10. Full qualitative feedback responses

How has the course improved your health?
“The course has helped improve my mental and physical health. I am sleeping better, doing my best to maintain a good exercise programme and eating less carbohydrates”

“I've embarked on a weight loss regime, and it's assisted in encouraging this.”
“I have found the weekly sessions have focused me on being more aware of the food I buy, how much I prepare, the names and terms. I have found that I have lost weight from over 75k to 61.7kg. The sleep session was really helpful this is still a problem. I know this is helped by more exercise.”
This course has taught me to eat more mindfully - to think about what I am eating more. It has made me more aware of my sleep patterns and how that affects my health and well-being - also I found that eating 'properly' induced better sleep. I guess it's made me more aware all-round and that inevitably helps my well-being.”
“It has helped me lose weight and manage a much healthier diet.”
“I have lost a stone and a half and more than two inches from my waist. My blood pressure is lower (120/80 to 120/75) and I may be able to come off one of my medications. My BMI came down from 28.41 to 25.2 I am eating about a third of what I did before and feel fitter and less tired all the time. I can walk faster and further, all of which gives me enormous pleasure. I feel happier, more my real self and more positive.”
“It has helped me to put labels on why and how I behave with my lifestyle”
“Weight down from 75kg to 71kg, blood pressure124/82 down a little/ mental well-being good comfort from group sharing problems/exercise usually good but strained knee presenting problems with knock on for extra food comfort/ stress sleep ok.”
“Yes, it has, I had my 3-month Blood Test and it was good, I am at 51 instead of over 100 and if it goes down to 48 or below, I will be on reduce medication or only Diet controlled. The Diabetes Team has discharged me.”
“The course has for sure helped me to be aware of my weight and losing weight and my blood sugar has been reduced. Also, I learned that stress is one of the factors that causes blood sugar to fluctuate.”
“Improved sleep. Significantly reduced pain and recovered strength in left hand and many other improvements.”

Table 6 - Qualitative feedback - how has the course improved your health?

What was most useful to you?
“Hearing other people's experiences”
“Taking part of the group itself, as it helps to see others improve, and feeling normal. Understanding my medication, looking at calories and the wheel. Hearing other people’s points of view”
“Most useful was being in a group, not feeling alone with problems, and to hear others situations (although I wish more participants had joined in). Also, the facts and figures charts helped - I took screenshots and regularly refer back to them.”
“It gave me a basic understanding of my disease and how to tackle it.”
“I knew I should lose weight but did not have the will power or direction on my own to do this. Being treated as an intelligent adult and given clear medical explanations and easy access to written information and charts helped. Keeping a diary with records not only of food and exercise but sleep and moods etc was a huge bonus. I could analyse my own progress and plan ahead. I shall continue to do this. Being given strategies for improving will power and reaching goals were good. It meant a lot to me that the person running the course was always positive and followed up on everything any participant mentioned. No easy solutions were offered but lots of encouragement given. No assumptions were made that it would be easy. I think the leadership of these courses is key. I learned a lot and felt I could always ask and knew I would get an honest and intelligent answer. Having someone I respected to share the results with made a huge difference and was a key factor. Eating and food can be complex and emotional areas and there is a lot more to it than logic. Hunger goes much deeper than the next mouthful. Knowing I was going to sign in often stopped me from giving in and eating for comfort. Once I started to lose weight that was an incentive too.”
“Seeing other people in the same position as me and identifying similarity in mind set Nutrition advice and linking pre diabetes with total lifestyle”

“Weight and Exercise management”
“The course has helped me to stay on the path of a healthy living and also a good understating of what I should be eating and what food I must avoid
loved how available and sincere Dr Sodha was. I think the community is very important. Just going down a rabbit hole on YouTube. I liked it better when I was in London there was a meet up, it was helpful to have a community. Being online was good because I wasn't in Primrose Hill. I've sometimes found alone a lot better than having nothing. Felt very caring and felt cared for what is doing. remember that is not alone and accepted, and encouraged. Even if I didn't find much substance that revelatory. Was doing best to pay attention too. has been up in the peak district and doing a lot of hikes. Is working on getting daylight in eyes before noon and getting out. found that fasting was great, it was amazing that the hunger didn't get worse. I found better clarity of mind too when fasting. I loved your goodwill and willingness to think it through and share with us.”
“Being selected for the course has given me hope that I can significantly improve my wellbeing with some focussed effort. The technical parts were interesting - but I got lost a few times. It was very useful to be able to replay a video of the session.”

Table 7 - Qualitative feedback - What was most useful to you?

What was least useful to you?
“The session on medication - but only because I am not taking most of the medication discussed.”
“I am not on medication, so it was not something I could relate to, nor am I diabetic.”
“Most useful was being in a group, not feeling alone with problems, and to hear others situations (although I wish more participants had joined in). Also, the facts and figures charts helped - I took screenshots and regularly refer back to them.”
“It was all useful”
“Nothing was least useful - everything had a relevance”
““The content was good and the leadership excellent, it was all useful.”
“Not so good at understanding some of the medications and there effects (more me than the course)”
“Nothing, everything was good”
“The sessions with nutritionist! The sessions were just an over view rather than teaching us a method to evaluate different food and easier way to navigate in food store for right products. not useful: some of the diet recommendations didn't resonate.”
All parts of the course were appreciated and interesting.”

Table 8- Qualitative feedback - what was least useful to you?

How do you think the programme could be improved?
“I think the course was very flexible and we were always being asked for our feedback - so there are no areas that need improvement.”
“To be inclusive of anyone who needs to lose weight.”
“Perhaps make it even more simple. I think face to face group sessions would be preferable I would have liked a booklet - with all the charts and advice.”
“I think a face-to-face meeting(s) Maybe a healthy diabetes meal where everyone brings a healthy dish. (Or everyone is given a simple dish to prepare and bring) I find face to face meetings more impactful. It could even be combined with some simple exercise classes/ lessons.”
“This is exactly what I wanted exactly when I wanted it. For me it was great. I hope that somehow, we will be able to check in again in the future to see how the long-term results are.”
“Depending on what new customers want possibly more inclusive with people sending in their weekly shopping list/other parameters for discussion. Or collecting the weight loss/blood pressure average of whole group to create a competitive league amongst all the groups which will undoubtedly spring up. At commencement of course introducing everyone to each other to create a feel of comradeship and group dynamics going forward.”

“With supervision of a doctor (in our case Dr Sodha) to form groups and exchanging ideas for new recipe, finding healthier ingredients, helping one-another to manage our mental states and arranging outings, etc.”

Table 9- How do you think the programme could improve?

If willing to do so, please can you write a longer testimonial on the impact of the course?
“While I have been on the course I have been going through a lot of stress in my personal life. This course helped me put all aspects of my life in context and showed me how everything is interrelated and how small changes in the Diabetes wheel can have a great impact”.
“It assisted in awareness of where I was, in terms of my health thinking, and where I wanted to be, and now I am on that journey. It is great to be part of a group, and to hear others voice thir opinions and experiences re their health. I do think that, once someone has decided on a goal, weight loss or otherwise, it would be great if the programme could incorporate that, as not everyone can lose weight, for example, at the same speed. Although it has a serious note, it would be good if there was a social media aspect to it, as mentioned previously, something Dr Sodha aimed to try and incorporate by having a forum, yet I do feel that having peer support is so valid, and to access that peer support, through Facebook, or similar, is valuable, as I've found with other b groups. I think it's vital to show that this exercise is not that, but in the long run, really should save money, too, and will prevent illness, or further illness.”
“I would recommend this course to understand diabetes far better it has never been properly described before. The content was perfect for me very good sessions on nutrition, exercise and sleep. Knowing and understanding your figures I.e.: weight, blood pressure and BMI etc was good. Kiran was excellent and I wish him success in expanding this course.”
“The course has helped me get a clearer medical understanding of diabetes. It has given me clear goals and targets for diet and exercise that I understand. I Think this is the most important aspect that the medical facts can be translated into actions. reduction of carbs increased activity and exercise, clear goals that have had a positive impact on me. It is great to see that you can control your disease, take control of your own health with simple and doable actions. The fact that diabetes is reversible has been inspiring and that has given me a clear goal to aim for. The course was very well run, Dr Sodha had put in a lot of hard work and research. He was very understanding and patience, great at explaining and debunking myths and simplifying complex medical issues.”
“Instructors were excellent as was course stacked with info, loved the holistic approach to whole body care. Extremely well put together and a pleasure to attend. This is the way forward for treating pre-diabetes. Was actually fun to attend with other people which I thought might be a problem before I signed up. All in all, a great and worthwhile experience.”
“It was very educational and knowledgeable. I have learnt a lot and hope I could do it again on a ongoing basis as Diabetes is a long-term illness.”
“A very useful course been arranged and created by Dr Sodha with great passion and hard work to help patients with blood sugar issues. It is reasonable to say that he has lift the spirit of participants and to commit themselves to better their own health. It is certainly true about me.”

Table 10 - Qualitative feedback - If willing to do so please write a longer testimonial on the course

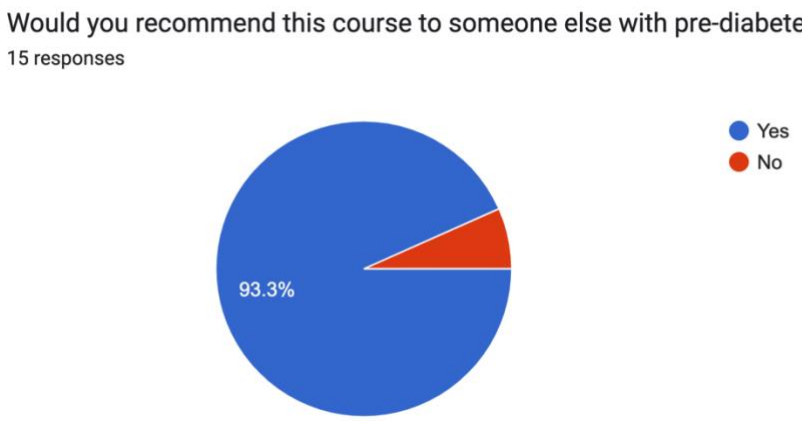

Figure 4 - would you recommend this course to someone else?

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