



Low Calorie Diets- The new Treatment for Type 2 Diabetes



Speakers



Dr. Marlon Morais
Medical Director (Xyla health and wellbeing) & GPwSI Diabetes



William Hadfield
Clinical lead Dietitian

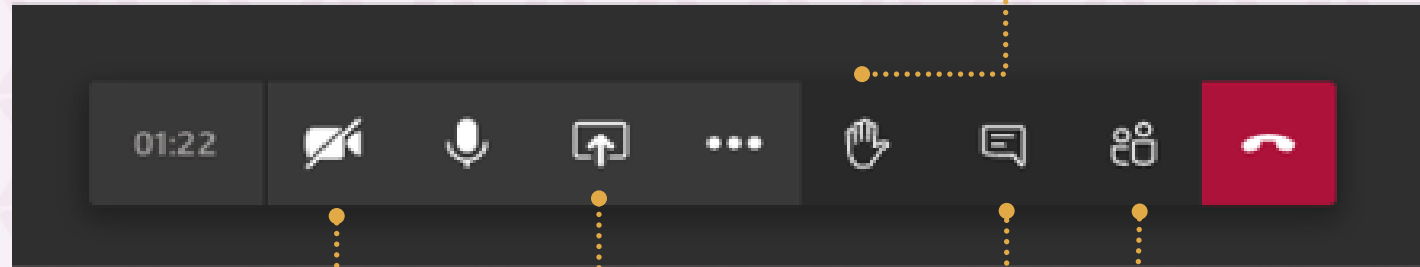


Dr. Shazli Azmi
Consultant in Diabetes



Dr. Tony Willis
GP & Clinical Director for Diabetes for North West London CCG

Desktop browser/ app MS Teams Tool bar:



Raise your hand to **ask a question** - not available on all smart phones

View the **other participants**

View or contribute to the **group chat**

Mute Yourself – If there is a line through the image you are muted

Control your **video** – If there is a line through the image your camera is off

Agenda

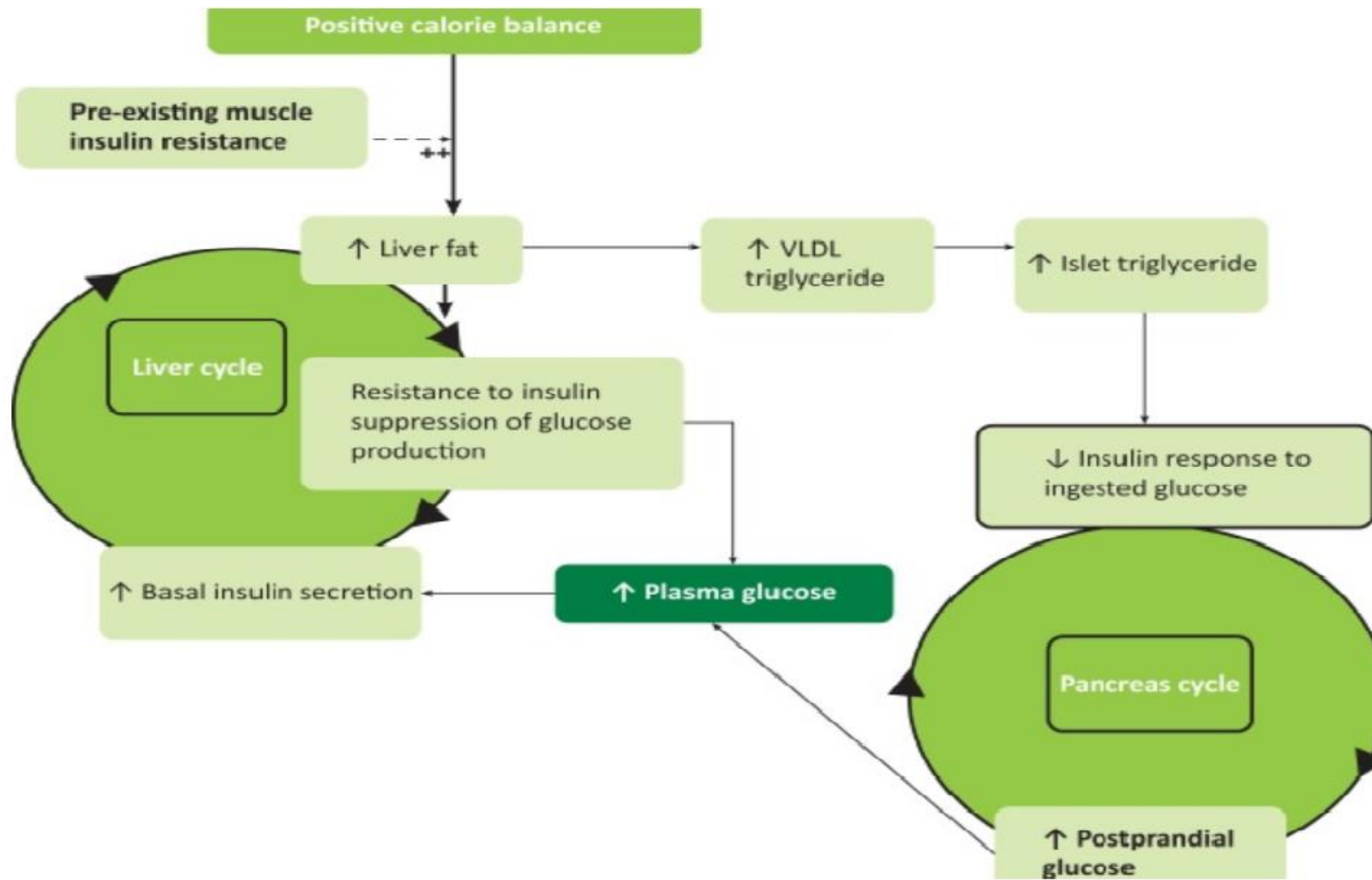
- How do Low Calorie Diets work? – Dr. Azmi
- Background and evidence behind Low Calorie Diets - Dr. Morais
- How do they work in the real world? – Will Hadfield
- What results have they produced? – Will Hadfield
- Round table discussion of pre submitted questions and audience questions
- Referral criteria for programmes – Will Hadfield
- Upcoming events – Will Hadfield

What are low calorie diets?

- This is the latest therapy to treat type 2 diabetes at scale on the NHS
- A non pharmaceutical management option
- Evidence based 800kcal a day diet over 12 weeks
- Then with further food reintroduction plan
- Leading to weight loss, reduction in HBA1c, reduced need for medication, and for some remission of type 2 diabetes

How do they work?

- It is thought type 2 diabetes and obesity can come about through a number of different factors related to chronic excessive carbohydrate intake, nutritional, lifestyle and environmental factor
- Excessive carbohydrates undergo *de novo* lipogenesis leading to excessive fat deposition in liver and islet cells leading to insulin insufficiency
- In obesity reduced insulin sensitivity is seen also



Taylor R. Calorie restriction for long-term remission of type 2 diabetes [published correction appears in Clin Med (Lond). 2019 Mar;19(2):192]. *Clin Med (Lond)*. 2019;19(1):37-42. doi:10.7861/clinmedicine.19-1-37

**Low calorie diet
leads to
lipolysis**

**Leading to
reduction in
liver fat
deposits and
pancreas fat
deposits**

**Study showing
after just 7 days
30% reduction
in liver fat
deposits¹**

**This led to
increased
insulin
sensitivity
within 7 days**

DiRECT

- 49 Primary care centres in Scotland and Tyneside
- Individuals aged 20-65 years
- Type 2 diabetes <6 years
- BMI 27-45 kg/m²
- Not on insulin
- Intervention given calorie controlled diet of 825-853kcal a day for 3-5 months
- Stepped food reintroduction for 2-8 weeks

DiRECT Results (12 months)

- 306 Individuals recruited
- 149 with intention to treat rest as controls
- At 12 months 36 (24% participants) lost > 15kgs weight
- 68 (46%) of the intervention group achieved remission whilst 6 (4%) of the control group achieved remission
- Weight loss appeared to be the key of the full study - 76 individuals gained weight and non of these achieved remission
- 19 of the 56 individuals (34%) that had 5-10kg weight loss achieved remission
- 16 of the 28 (57%) that had 10-15kg weight loss achieved remission
- 31 of the 36 (86%) that had > 15kg weight loss achieved remission
- Mean weight loss was 10kg in intervention group and 1kg in control
- 9 adverse events in 7 in intervention group and 2 in control, with 2 in same individual thought to be related to the intervention
- Around 36% of the intervention group remained in remission at 24 months

Study meta-analysis3

- Looked at 5 VLCD studies
- DIADEM, DiRECT, Counterbalance, Counterpoint, Single arm intervention Study
- Found those with:
 - Shorted disease duration
 - Critical mass and function of Beta cells
 - Those with higher levels of Ghrelin during the liquid phase were more successful in achieving remission
- Unfortunately, no way to screen participants yet
- Modest weight loss of 10-15kg was seen to lead to remission in all studies looked at
- Compared to the LOOK AHEAD trial (intensive lifestyle intervention and 1200-1500KCAL a day diet) DiRECT had a marked improvement in remission at 12 months > 130% more in DiRECT (11.6 vs 46%)
- Large scale analysis of this NHS pilot is hoped to lead to better understanding and for Low Calorie Diets as one of the first true large scale implementations and studies of them



Real-world results



Nutrition

Psychology

Physical activity

**Long-term sustainable
behaviour change**

Group & 121

Digital & F2F

Measurements

App & resources

**39 eLearning
modules**

**Initial
Assessment**

**Stage 1
Total Diet
Replacement**

**Stage 2
Food
Reintroduction**

**Stage 3
Maintenance**

**Final
Assessment**

**13% weight
loss after
TDR**

**12% weight
loss after
food re-
introduction**

**11% weight
loss at one
year**

**11% weight
loss after
TDR**

**12% weight
loss after
food re-
introduction**

**10% weight
loss at one
year**

"I feel great, both mentally and physically. For the first time in what has feels like years I am getting a good night's sleep. In six weeks my weight has reduced from 132.7kgs to 114.3kgs. I feel lighter on my feet and I can see my real personality re-emerging and I feel less like I'm carrying the world on my shoulders. I can see the light at the end of the tunnel and how I can live without medication."

COMMUNITY-BASED PILOT STUDY OF TYPE 2 DIABETES REMISSION THROUGH WEIGHT LOSS ACHIEVED BY TOTAL DIET REPLACEMENT BASED ON DiRECT TRIAL

T Abi-Chahine¹, S Chatterjee¹, C Cooper¹, T Willis², M Morais^{1,3}, W Hadfield¹

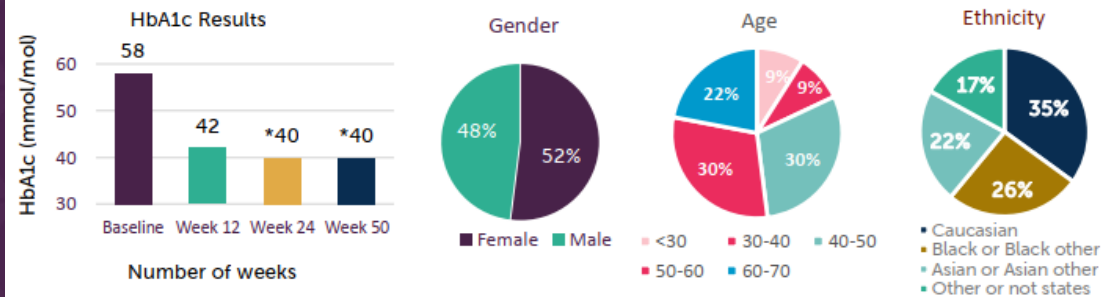
1. Xyla Health & Wellbeing (part of Acacium Group), London, England. 2. Richford Gate Medical Practice, London, England.

Objective

To deliver a person-centred intervention aiming to achieve significant weight loss and potential remission of Type 2 diabetes in a real-world community setting, using a similar model to the DiRECT trial. The programme adapts a holistic multidisciplinary approach with a combination of nutrition, psychology and exercise education support for long-term behaviour change and self-management, as well as enabling system savings.

Methods

23 patients participated in the programme. An initial assessment was carried out followed by 12 weeks of total diet replacement (800 calorie diet), 8 weeks of gradual food re-introduction and 28 weeks of nutrition, exercise and behavioral change support (culturally sensitive where required), to help maintain weight loss in the long term. The intervention included regular phone calls with a Registered Dietitian along with 26 e-learning modules covering behavioural change, nutrition and exercise content.



	Pilot Results	DiRECT Results
Mean Weight Loss after TDR (12 weeks)	13.5 kg	14.5 kg
Mean Weight Gain after FR (24 weeks)	0.8 kg	1 kg
Mean Weight Gain after Maintenance (50 weeks)	0.9 kg	1.9 kg
Final Weight Loss	11.8 kg	11.6 kg

- ▶ Although mean weight loss post TDR is lower for the Pilot in comparison to the DiRECT Trial, weight loss maintenance was more effective in the Pilot.
- ▶ The Pilot had an average weight gain of 1.7 kg from lowest weight compared to 2.9 kg weight gain in the DiRECT Trial, by the end of the programme.
- ▶ Resulting in an overall slightly higher weight loss than the DiRECT trial

Results

Mean weight loss after TDR was 13.5 kg. Mean weight loss at 12 months was 11.8 kg. 83 % of patients at week 24 were not on medication. 74% of the participant cohort on diabetic medication at baseline no longer required any diabetes medication; 13% were prescribed a lower dose and 13% were still on the same dose. 50% of the participant cohort on blood pressure medication at baseline were no longer prescribed any blood pressure medication at week 24 of the programme.

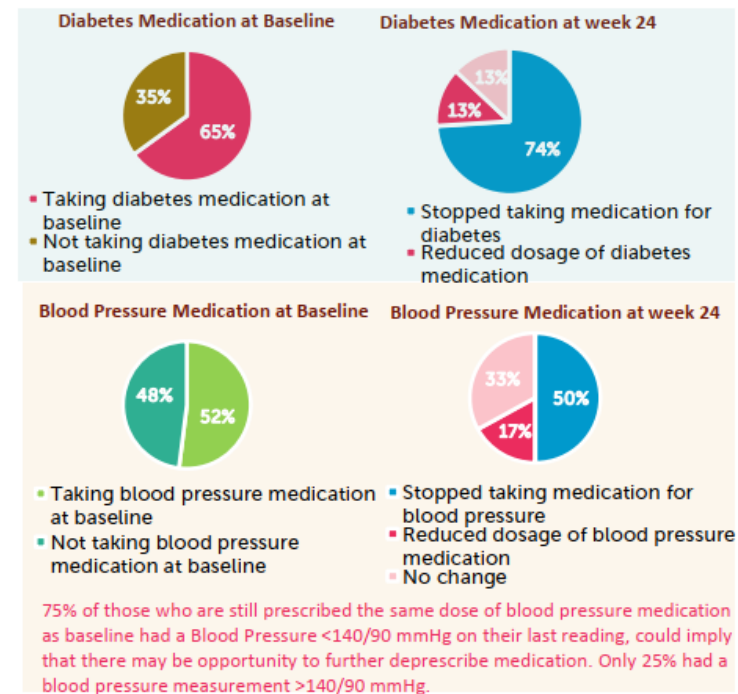
Results	Week	Average	Range
Weight Loss (kg)	Week 12	13.5 (13%)	4-30
	Week 24	12.5 (12.1%)	5-29
	week 50	11.8 (11.3%)	4-27
HbA1c Decrease (mmol/mol)	Week 12	15	32-52
	*Week 24	*14	*33-51
	*Week 50	*20	*34-44

References

- Leslie, Wilma S., et al. "The Diabetes Remission Clinical Trial (DiRECT): protocol for a cluster randomised trial." *BMC Family Practice* 17.1 (2016): 1-10.
- Jebb, Susan A., et al. "Doctor Referral of Overweight People to a Low-Energy Treatment (DROPLET) in primary care using total diet replacement products: a protocol for a randomised controlled trial." *BMJ open* 7.8 (2017).

Acknowledgements

We would like to thank our participants, GP teams and surgeries, admin team and everyone involved in our Pilot



Conclusion

The results of the Pilot programme are in line with the DiRECT trial, with a good self-reported improvement in participants' quality of life. System-wide financial benefit was also achieved through de-prescribing of diabetes and blood pressure medication.



NHS Low Calorie Diet Programme



NHS Low Calorie Diet Programme

For more information on the **NHS Low Calorie Diet Programme** including:

- Patient and GP Information Sheets
- How to refer
- Referrer Information resources
- Case studies

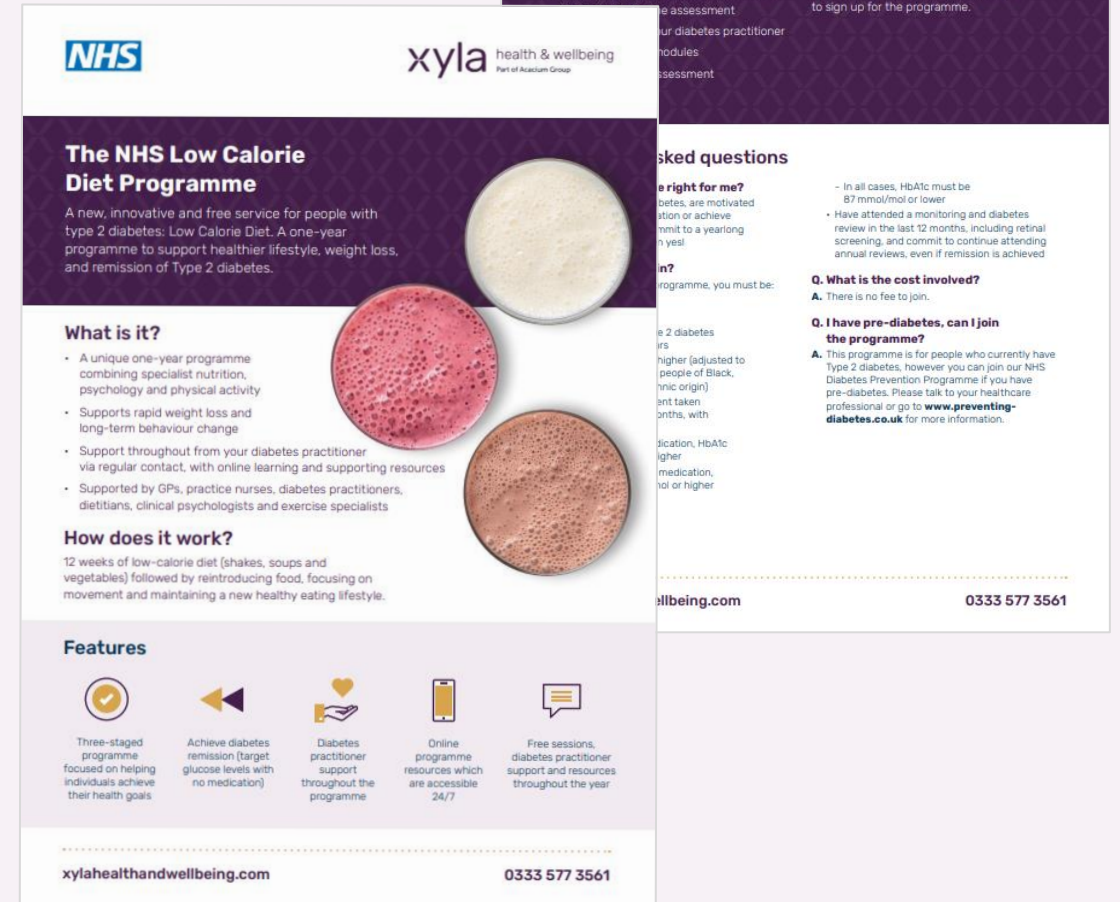
Visit <https://bit.ly/2W7Z43G>

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North East
London

South East of
England
Frimley Health
and Care



The brochure is titled "The NHS Low Calorie Diet Programme" and features the NHS and xyla logos. It includes a section "What is it?" describing a one-year programme combining specialist nutrition, psychology, and physical activity. It also includes a section "How does it work?" detailing a 12-week low-calorie diet followed by reintroducing food. The "Features" section lists: Three-staged programme, Achieve diabetes remission, Diabetes practitioner support, Online programme resources, and Free sessions. The brochure also includes a "Frequently asked questions" section and contact information: xylahealthandwellbeing.com and 0333 577 3561.

The NHS Low Calorie Diet Programme

A new, innovative and free service for people with type 2 diabetes: Low Calorie Diet. A one-year programme to support healthier lifestyle, weight loss, and remission of Type 2 diabetes.

What is it?

- A unique one-year programme combining specialist nutrition, psychology and physical activity
- Supports rapid weight loss and long-term behaviour change
- Support throughout from your diabetes practitioner via regular contact, with online learning and supporting resources
- Supported by GPs, practice nurses, diabetes practitioners, dietitians, clinical psychologists and exercise specialists

How does it work?

12 weeks of low-calorie diet (shakes, soups and vegetables) followed by reintroducing food, focusing on movement and maintaining a new healthy eating lifestyle.

Features

- Three-staged programme focused on helping individuals achieve their health goals
- Achieve diabetes remission (target glucose levels with no medication)
- Diabetes practitioner support throughout the programme
- Online programme resources which are accessible 24/7
- Free sessions, diabetes practitioner support and resources throughout the year

Frequently asked questions

Am I right for me?

- In all cases, HbA1c must be 87 mmol/mol or lower
- Have attended a monitoring and diabetes review in the last 12 months, including retinal screening, and commit to continue attending annual reviews, even if remission is achieved

Q. What is the cost involved?

A. There is no fee to join.

Q. I have pre-diabetes, can I join the programme?

A. This programme is for people who currently have Type 2 diabetes, however you can join our NHS Diabetes Prevention Programme if you have pre-diabetes. Please talk to your healthcare professional or go to www.preventing-diabetes.co.uk for more information.

Contact: xylahealthandwellbeing.com 0333 577 3561

LCD Eligibility Criteria and Referral Pathway

- HbA1c ≥ 43 mmol/mol (if on diabetes medication)
- HbA1c ≥ 48 mmol/mol (if not on diabetes medication)
 - HbA1c must be ≤ 87 mmol/mol in all cases

- T2DM diagnosis within the last 6 years
 - Aged 18-65
- A BMI of $27 + \text{kg/m}^2$ (adjusted to $25 + \text{kg/m}^2$ for ethnicity)
- Attended last monitoring and diabetes review, including retinal screening, and commits to future reviews, even if remission is achieved

Exclusion criteria:

- ✗ Current insulin user
- ✗ Pregnant or planning to be
 - ✗ Breastfeeding
- ✗ Has at least one of the following;
 - Active cancer
 - Heart attack or stroke in last 6 months
- Severe heart failure (grade 3 or 4) Severe renal impairment (recent eGFR less than $30 \text{mls/min/1.73m}^2$)
 - Active liver disease (not including NAFLD)
 - Active substance-use disorder Active eating disorder
 - Porphyria
 - Untreated proliferative retinopathy
- ✗ $>5\%$ body weight-loss in the past 6 months, or is currently on a WMP
- ✗ Had or is awaiting bariatric surgery
- ✗ HCP assessment concludes patient unable to understand or meet the demands of the NHS LCD and/or monitoring requirements (due to physical or psychological conditions or co-morbidities)

Primary Care and other Healthcare Professionals

Opportunistically through direct referral

Referral form embedded in clinical system
(More information here: <https://bit.ly/2W7Z43G>)

Proactive Searches & Letter/Text Invitations

A clinical search will provide a list of possible eligible patients; however, the exclusion criteria of the programme and readiness/motivation must also be considered before making a referral



REWIND Programme



For more information on the REWIND Programme including:

- Patient and GP Information Sheets
- How to refer
- Referrer Information resources
- Case studies

Visit <https://bit.ly/2XNVWub>





health & wellbeing
Part of Mounsey Group

Diabetes REWIND Programme

(Reducing Weight with Intensive Dietary Support)

If you have had Type 2 diabetes for less than 12 years then speak to your healthcare professional about our new one-year programme that supports you to lead a healthier lifestyle, reduce diabetes medicines and even achieve diabetes remission. Referral to the programme is by healthcare professional only.

How does it work?

The unique one year programme combines regular telephone contacts with online learning to support you in achieving your health goals. You will be fully supported by a team that includes GPs, practice nurses, health coaches, specialist dietitians and exercise specialists. Research shows that changing your diet and lifestyle can benefit the management of your Type 2 diabetes, therefore our programme includes education and coaching on nutrition, movement and health behaviour change. After your initial assessment, there are two options:



Total diet replacement

12 weeks of a very low-calorie diet of shakes and soups, followed by 12 weeks of gently reintroducing food into your diet, and then 6-months maintaining your new healthy eating lifestyle. This option is only available to those eligible, and this is explained in the frequently asked questions later in this information sheet.



The low carb choice

If you are ineligible for total diet replacement, you can choose the low carb option. This is 12 weeks of learning a new low carbohydrate diet followed by 12 weeks of incorporating your learnings into your lifestyle and is completed with a 6-month maintenance phase. This option is available to anyone who is eligible for the programme.

Our commitment

You and your health coach will work together over 12 months, and the support you will receive during this time will include:

10

group sessions

10

phone calls with your health coach

26

online support modules

Regular

appointments with your healthcare professional



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Empowering people to live healthier lives for longer

Features

- + Three-stage programme focused on helping you achieve your health goals that may help put your diabetes into remission
- + Support from your health coach throughout the programme
- + Online programme resources which you can access 24/7 to suit your lifestyle (printed handouts available to those who don't have internet access)
- + Free group sessions, coaching support and resources throughout the year

How to join

This unique programme is being exclusively offered to patients in your area. Arrange to talk to your doctor to sign up for the programme.

Frequently asked questions

A. Is this programme right for me?

A. There are two types of Diabetes, are motivated to reduce your medication or achieve remission and can commit to a year long programme of online, group and telephone support... then yes!

A. Am I eligible to join?

A. To be eligible for the programme, you must be aged 18 years and over and have had Type 2 diabetes for less than 12 years.

You are not eligible if you are planning a pregnancy, pregnant or using insulin. If you want to take part in the total diet replacement option, talk to your doctor to ensure it's the right choice for you.

Q. Are there any additional procedures involved that I should be aware of?

A. As part of the programme you will have your blood tested regularly to track your progress. This will happen at your GP practice at the beginning before you start, followed by 3, 6, and 12-month tests.

Q. What is the cost involved?

A. There is no fee to join, however there is cost linked with the 'total diet replacement' option. This is approximately £2 per day, and replaces all your food, so may make your shopping bill lower!

Q. I have pre-diabetes, can I join the programme?

A. This programme is for people who currently have Type 2 diabetes, however you can join our NHS Diabetes Prevention Programme if you have pre-diabetes. Please talk to your healthcare professional or go to www.preventing-diabetes.co.uk for more information.

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0333 577 3561

REWIND Eligibility Criteria and Referral Pathway

- Diabetes duration <12 years (in phase 1)
- A HbA1c measurement taken within the last 12 months, with values as follows;
- HbA1c 43-87mmol/mol with diabetes medication
- HbA1c 48-87mmol/mol without diabetes medication
 - Latest HbA1c 88-108mmol/mol if:
 - Patient is within 6 months of diagnosis OR
- Retinal screening within past 6-12 with no evidence of untreated proliferative or pre-proliferative retinopathy and potential impact discussed with service user. Retinal screening 6m after programme start if HbA1c improves >25mmol/mol

- Aged 18 or over and registered with NWL GP

Exclusion for both pathways:

- ✗ Not attended diabetes review in last 12 months
 - ✗ HbA1c > 108mmol/mol;
 - ✗ Current insulin use (at least in phase 1);
- ✗ Pregnant or planning to become pregnant within the next 6 months. Defer those breastfeeding until lactation ceases;
- ✗ Severe renal impairment (eGFR <30);
- ✗ Health professional assessment that the person is unlikely to understand or meet the demands of the treatment programme and/or monitoring requirements (e.g. active psychotic illness or severe depression requiring psychiatric review);
- ✗ Unwilling to provide blood samples;
- ✗ Unwilling to allow sharing of clinical information with WSIC

Specific Exclusions for TDR:

- ✗ BMI of under 27kg/m² (adjusted to 25kg/m² in people of South Asian and Chinese origin);
 - ✗ Significant physical co-morbidities:
 - Active cancer other than skin cancer treated with curative intent by local treatment only
 - People taking hormonal or other long term secondary prevention
- Heart attack or stroke in last 6 months (defined as New York Heart Association grade 3 or 4)
 - Severe heart failure
 - Active liver disease (not including NAFLD);
 - Active substance use disorder/eating disorder
 - Porphyria
- Known untreated proliferative or pre-proliferative retinopathy if HbA1c 88-108mmol/mol
- ✗ Current treatment with anti-obesity drugs (would need to stop);
- ✗ Recent weight loss > 5% body weight / on current weight management programme / had or awaiting bariatric surgery (unless willing to come off waiting list)

Specific Exclusions for Low Carb Diet (<130g/day):

- ✗ Concurrent SGLT2 inhibitor usage (SGLT-2 inhibitors will need to be stopped in view of potential risk of ketoacidosis whilst on intensive carb reduction programme);

Primary Care and other Healthcare Professionals

Opportunistically through direct referral

Referral form embedded in clinical system
(More information here: <https://bit.ly/2XNVWub>)

Proactive Searches & Letter/Text Invitations

A clinical search will provide a list of possible eligible patients; however, the exclusion criteria of the programme and readiness/motivation must also be considered before making a referral

Upcoming events

As the largest and proud provider of the NHS Healthier You: Diabetes Prevention Programme (NDPP), we want to invite you to a free event.

It will be an opportunity for you to meet the clinical team, learn more about our latest updates and gain an insight into the NDPP and our outcomes.

The webinar will take place on **15th November 2021 at 12pm** and will be 1-hour long.

There will be an opportunity to register your interest in attending this event in the communications sent after today's event.





NHS Healthier You Diabetes Prevention Programme

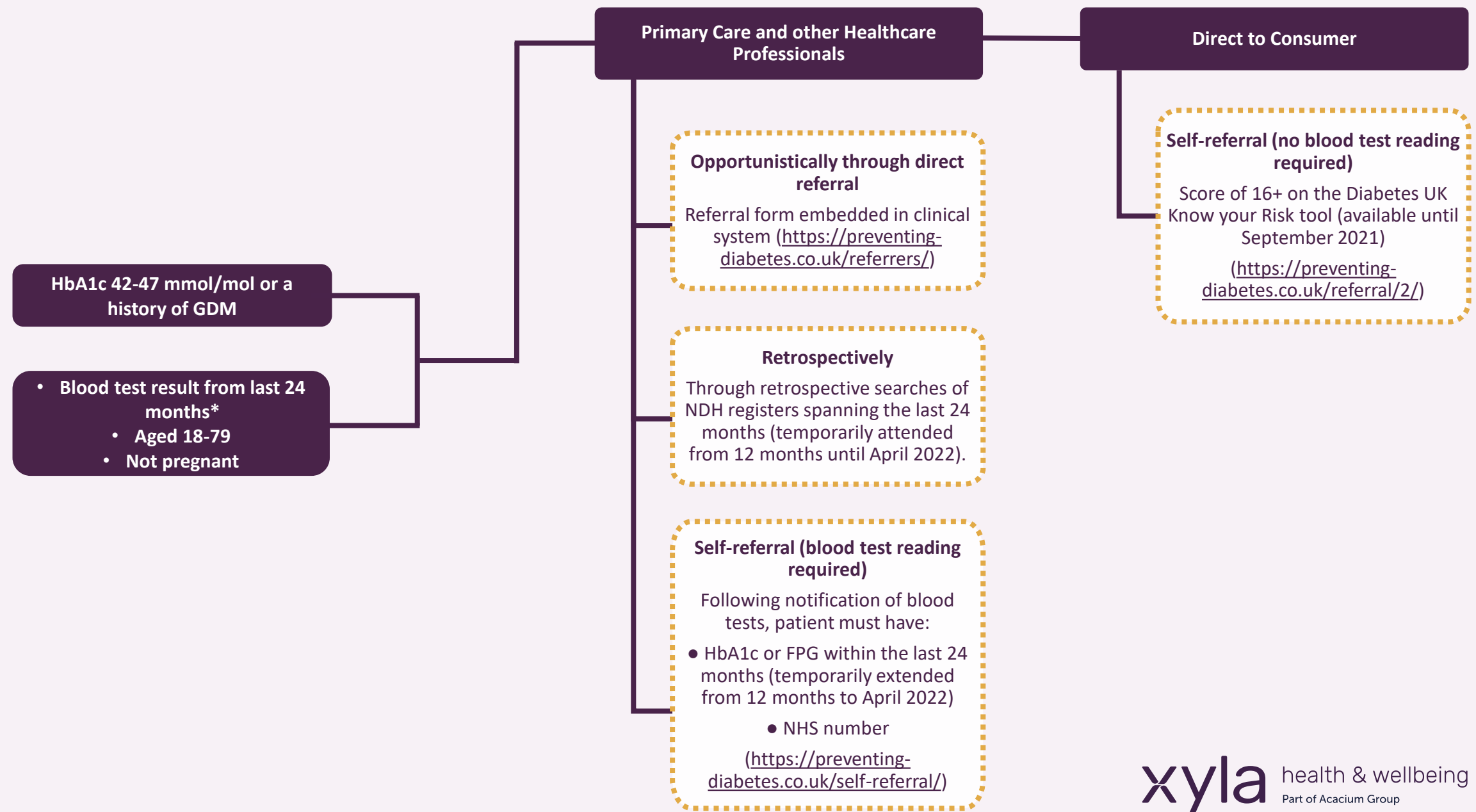


NHS Diabetes Prevention Programme



North West Greater Manchester	North East & Yorkshire Humber, Coast Vale,	Midlands Lincolnshire, Leicester, Leicestershire & Rutland	London North Central London North East London North West London South East London South West London	East of England Bedford, Luton & Milton Keynes Hertfordshire & West Essex Suffolk & North East Essex	South West of England Gloucestershire Bath, North East Swindon & Wiltshire Somerset	South East of England Buckinghamshire, Oxfordshire & Berkshire West, Surrey Heartlands & East Surrey Sussex Kent & Medway
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NDPP Eligibility Criteria and Referral Pathway



References

1. Taylor R. Calorie restriction for long-term remission of type 2 diabetes [published correction appears in Clin Med (Lond). 2019 Mar;19(2):192]. *Clin Med (Lond)*. 2019;19(1):37-42. doi:10.7861/clinmedicine.19-1-37
2. Lean et al, DiRECT : [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)33102-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)33102-1/fulltext)
3. Juray, S.; Axen, K.V.; Trasino, S.E. Remission of Type 2 Diabetes with Very Low-Calorie Diets—A Narrative Review. *Nutrients* 2021, 13, 2086. <https://doi.org/10.3390/nu13062086>

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