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Low Calorie Diets in Obesity and Type 2 Diabetes – DiRECT, DROPLET and the NHS Pilot Programme

Professor Roy Taylor, Newcastle University

Dr Nerys Astbury, University of Oxford

Dr Chirag Bakhai, NHS England and NHS Improvement

NHS England and NHS Improvement



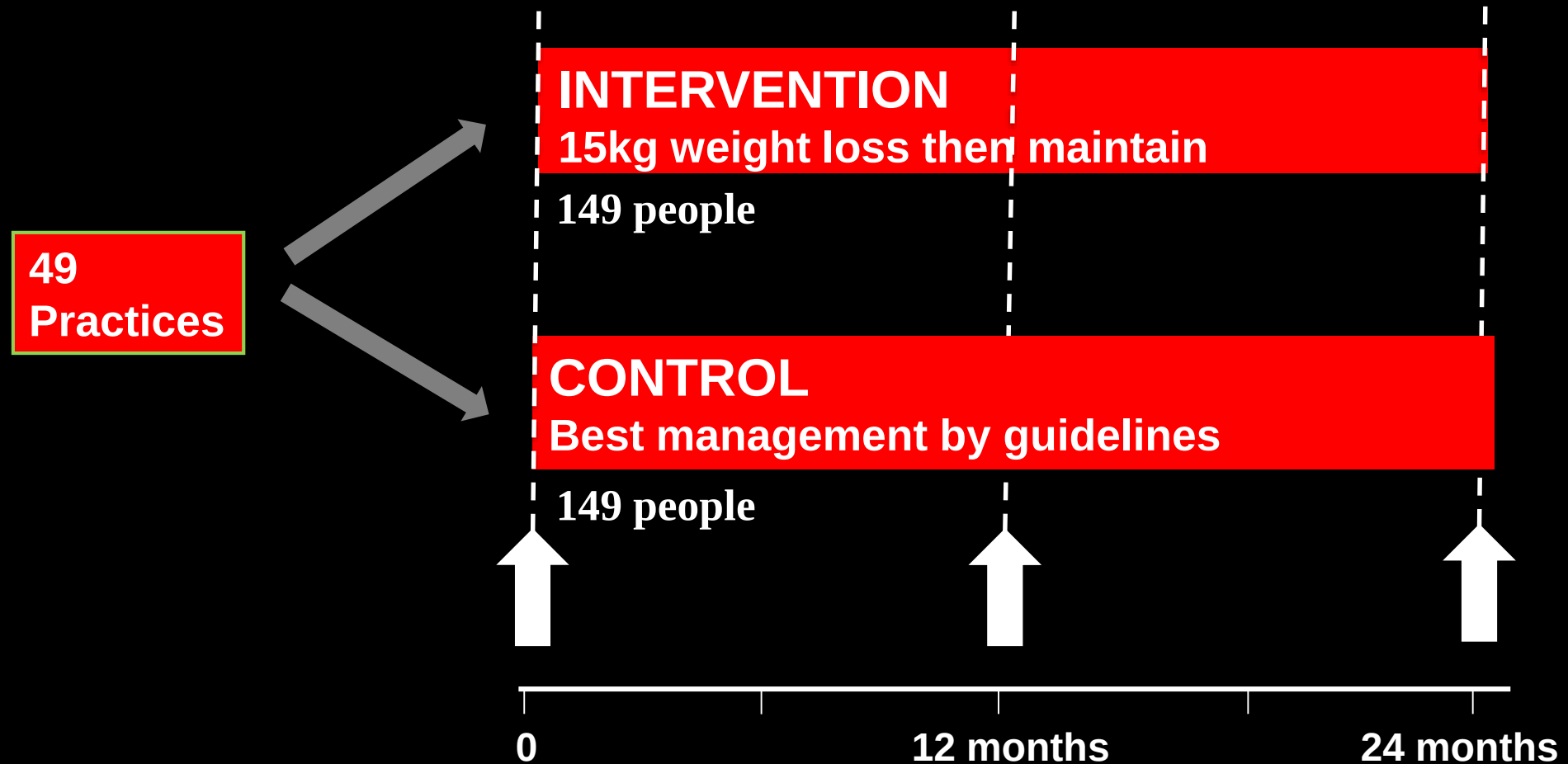
The Randomised Diabetes Remission Clinical Trial - DiRECT

Roy Taylor

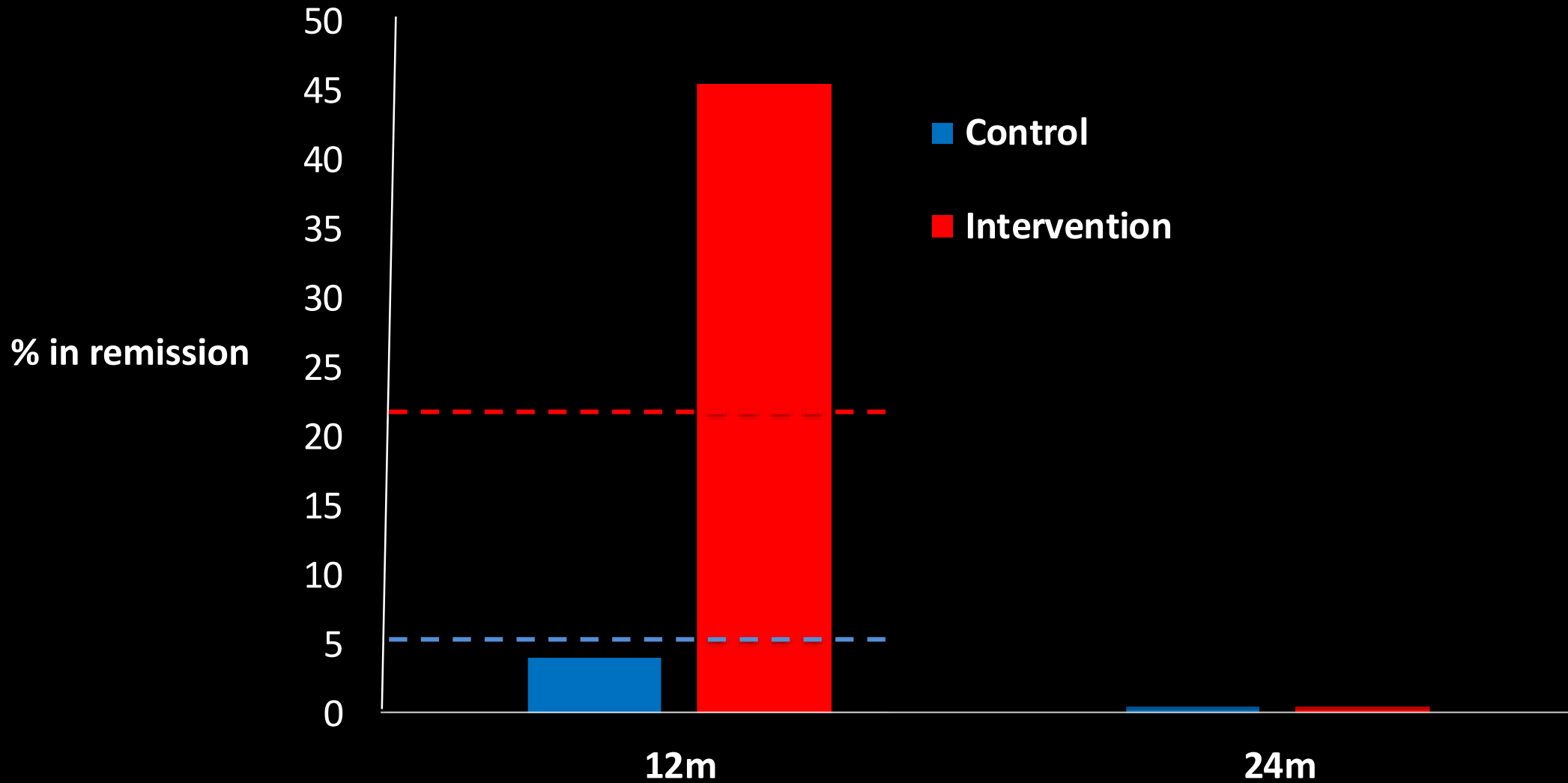
Professor of Medicine and Metabolism, Newcastle University

DiRECT – a study in routine NHS General Practice

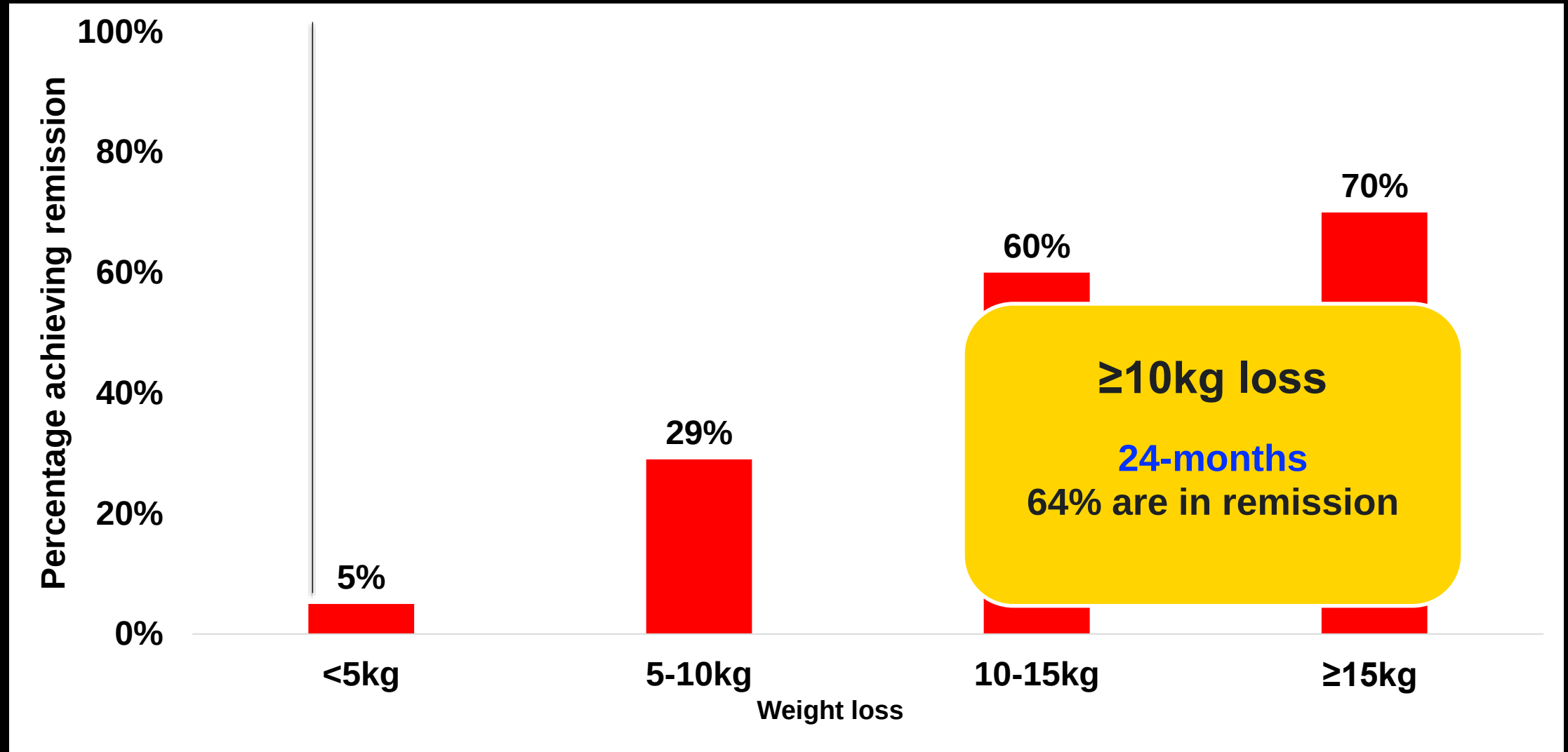
Duration of T2DM less than 6 years; on oral agents and/or diet



Remissions at 12 and 24 months



Remissions by 24-month weight loss: entire study population



“Diet” for weight loss

Simple

Practical

Spouse/partner on board

Duration limited and planned

**Compensatory eating
renders exercise counterproductive
during weight loss**

DiRECT Intervention: Rescue Plans



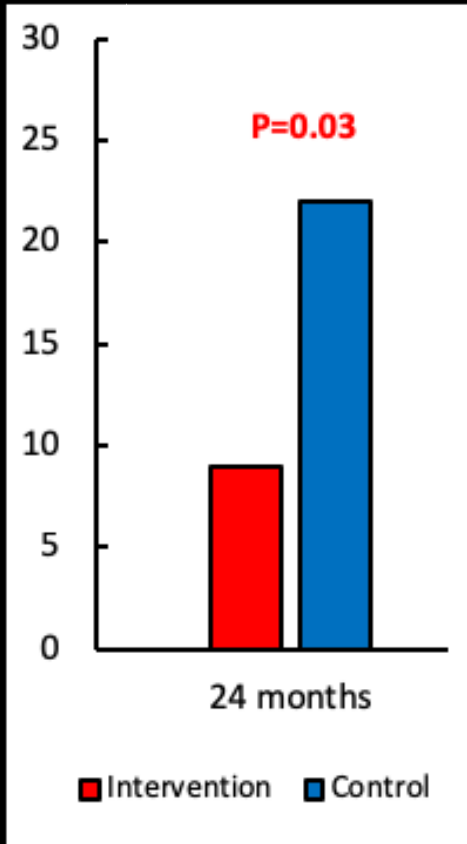
Rescue Plans for Relapse Management

1: Regain >2kg - 1 meal/day replaced with TDR

2: Regain >4kg - TDR offered

Effects of achieving HbA1c <48mmol/l over 2 years

Serious adverse events



Major events

HbA1c <48

1 non-fatal MI

No cancers

HbA1c >48

1 Fatal MI

2 CVA

1 atrial fibrillation

1 aortic aneurysm

1 toe amputation

5 cancers (2 colon, bladder, kidney, prostate)

Summary at 24-Months

- One third with early T2D achieve remission
- Two thirds achieve remission if ≥ 10 kg loss
- Achieving and maintaining weight loss are critical for success
- Weight loss at 24-months remains greater than most lifestyle interventions, despite modest regain

Essential components of future T2DM management

Information

**Personal planning
with family & friends**

**15kg wt loss
in 3 months**

**Long term support
via Primary Care**



Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET): a randomised controlled trial

Dr Nerys Astbury

Nuffield Department of Primary Care Health Sciences
University of Oxford

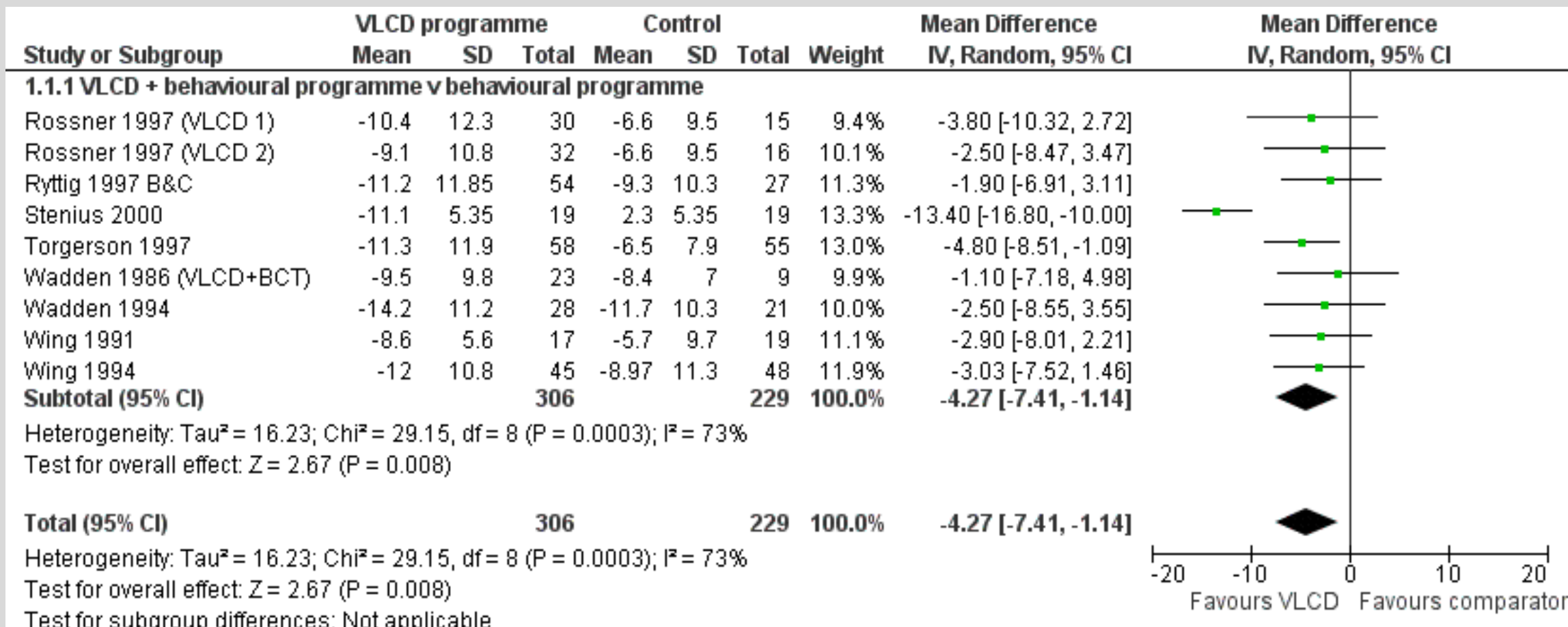
What is a total diet replacement programme?

- A period of Total Diet Replacement (TDR) using low-energy formula diet products

ALL foods are replaced with specially formulated low-energy food replacement products, such as soups, shakes and bars, which provide 800kcal– 1200kcal/day and all essential nutrients, vitamins and minerals.

- **Regular behavioural support**
Used alternative model of delivery to DiRECT

Evidence before the DROPLET trial



VLCD vs BWMP: -4.27 kg
(95% CI: -7.41, -1.14); $p < 0.00003$

Participants: n = 278;

BMI > 30

Excluded patients on insulin or with contraindications to TDR

Intervention: Total Diet Replacement (810 kcal/d) for 8 weeks, food reintroduction over 4 weeks, plus 12 weeks weight-loss maintenance plan

Comparator: Nurse-led behavioural weight management programme (usual care)

Primary outcome: weight loss at 1 y

Secondary outcomes: BP, lipids, HbA1c, QoL

Clinical Oversight

Practice nurses conducted initial onboarding & review at 4 weeks

GPs adjusted medication for hypertension and diabetes at the start of the programme and as needed thereafter

Clinicians were supplied with guidelines for this

Medication changes

Guidance on making adjustments to your patients' medications



This guidance aims to help you make these medication adjustments, but please use your clinical judgement or contact the lead physician for this study.

TYPE 2 DIABETES

Patient currently takes:

Recommendation

Metformin

HALF daily dose

Sulphonylurea

STOP

Glitazone

STOP

Glinide

STOP

DPP IV inhibitor

STOP

Acarbose

STOP

At the end of the weight loss phase, re-assess patients requirements for oral diabetic therapies using HbA1c measurements or a finger prick blood glucose measurement.

HYPERTENSION

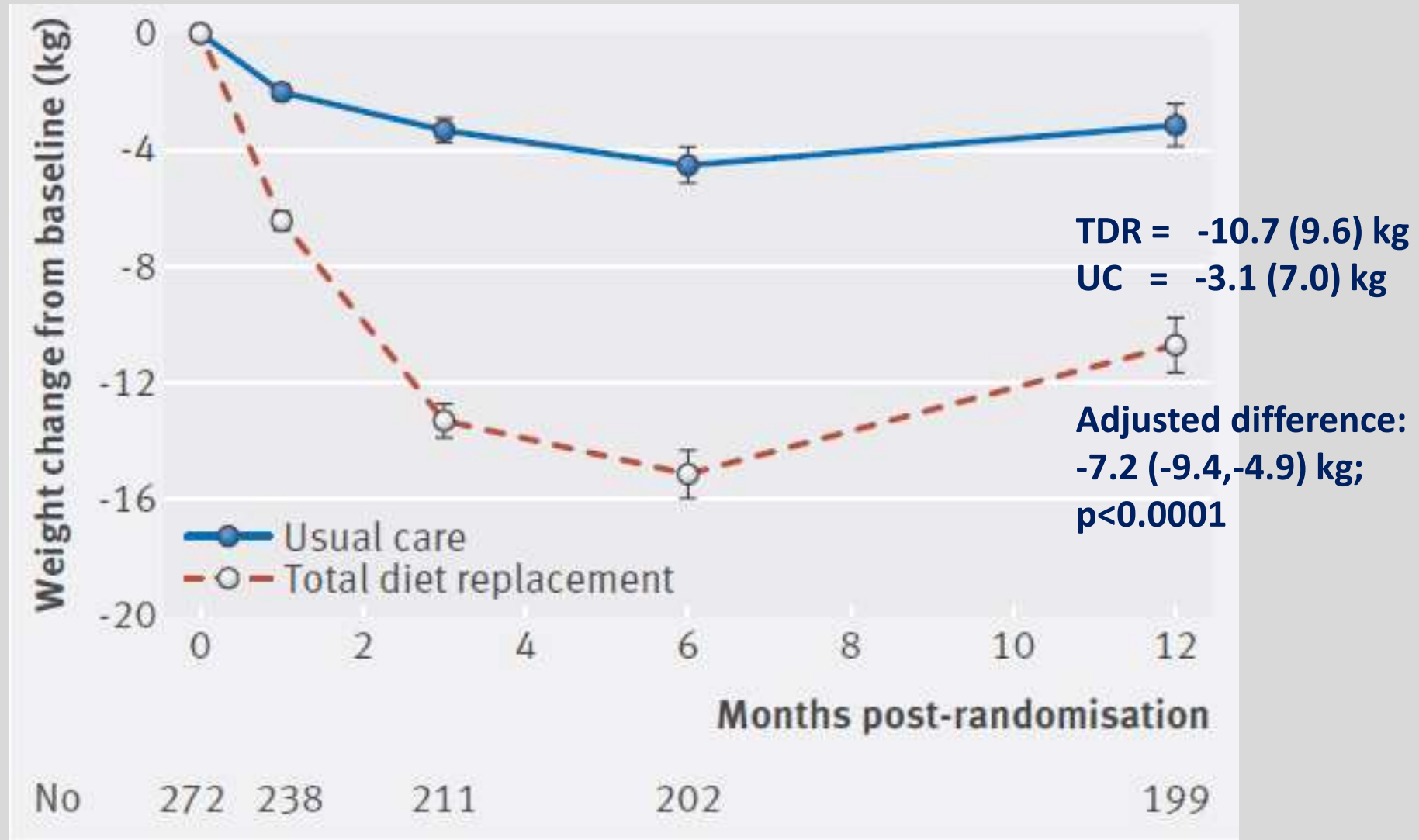
Patient currently takes:

Current dose

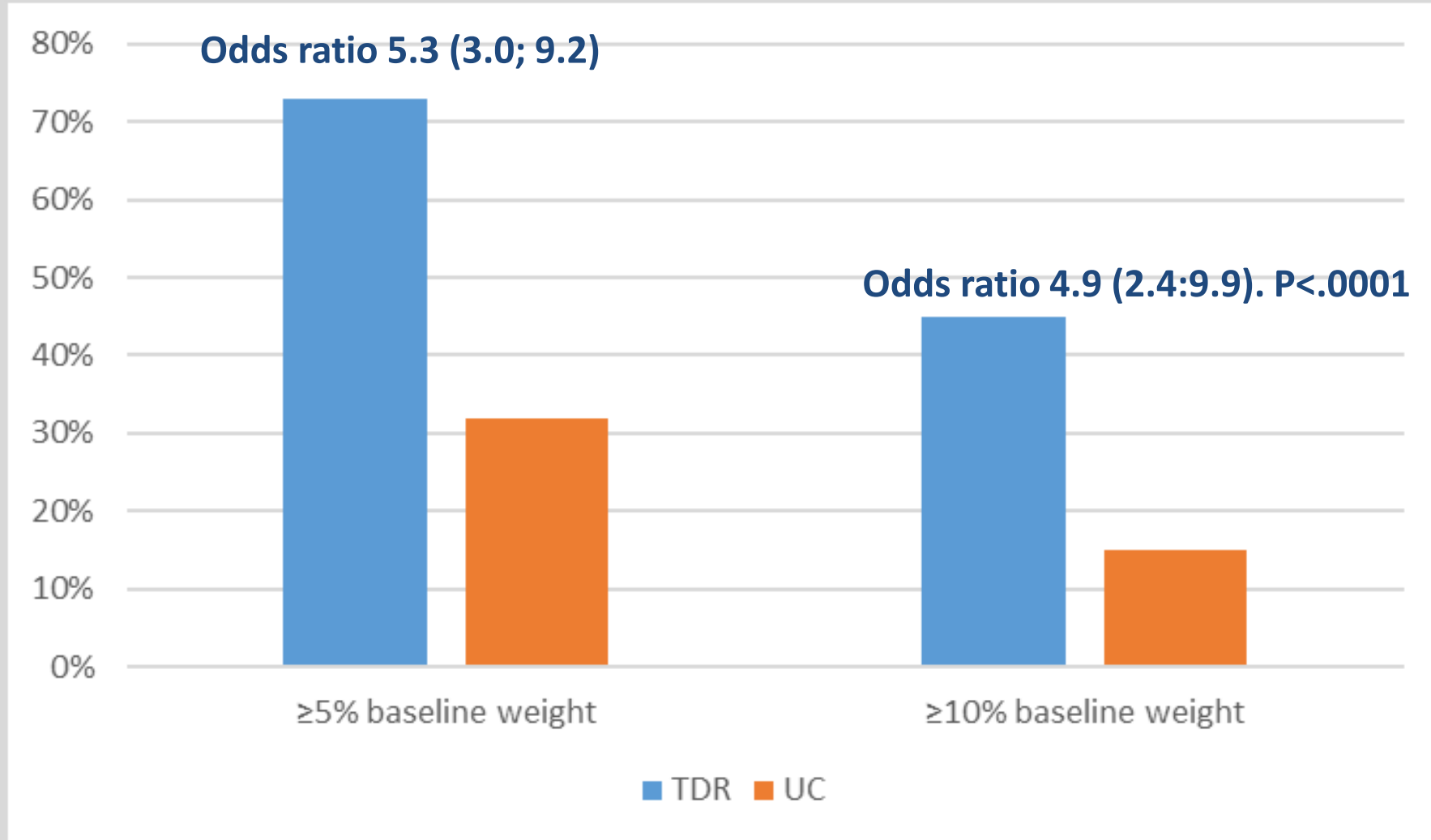
Recommendation

Loop Diuretic:

Weight Loss over 1 year



Percentage achieving $\geq 5\%$ and $\geq 10\%$ baseline weight loss



12 month outcomes by group

	Usual Care	Total Diet Replacement	Treatment Difference	P value
Systolic blood pressure (mmHg)	2.9 ± 15.2	-1.6 ± 16.4	-2.9 (-6.4; 0.6)	0.1072
Diastolic blood pressure (mmHg)	0.3 ± 9.3	-4.2 ± 11.1	-3.1 (-5.5; -0.7)	0.0117
HbA1c (mmol/mol)	-1.0 ± 7.7	-3.2 ± 8.8	-2.2 (-4.4; 0.0)	0.0511
LDL Cholesterol (mmol/L)	-0.1 ± 0.7	-0.1 ± 0.6	0.0 (-0.2; 0.2)	0.8184
QRISK (%)	0.0 ± 2.1	-0.9 ± 2.6	-1.0 (-1.7; -0.3)	0.0061
EQ-5D (VAS)	9.2 ± 17.0	13.0 ± 18.7	n/a	n/a

Adverse events

AEs recorded during the first three months of the programme and at six months for gallstone-related events only, to allow for diagnostic delay.

Any AEs reported in 52% and 30% of TDR and UC groups (a treatment excess of 1 in 5 cases)

Most common AEs with an excess in TDR groups were:

- Constipation;

- Fatigue;

- Headache;

- Dizziness;

AEs classed as moderate or greater occurred in 11% and 12% of participants in TDR and UC

One SAE which occurred after randomisation but before treatment initiated

Participants experiences



Changed me, changed my life.

Summary

- Referral to a commercial total diet replacement programme was a feasible, acceptable, safe, clinically and cost effective treatment for obesity in routine primary care.
- Weight losses average 10kg at 1 y, 45% patients losing >10% baseline weight
- Significant improvements in biomarkers of cardiovascular disease and diabetes
- Highly cost effective when offered as a referral to a commercial provider
- Positive experiences of participants and healthcare practitioners
- NHS pilot will provide opportunity to explore whether trial results can be translated into routine care



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Low Calorie Diets in Type 2 Diabetes – the NHS Pilot Programme

Dr Chirag Bakhai

GP and Vice-Chair of Luton CCG

Primary Care Lead, East of England Diabetes Clinical Network

Primary Care Advisor to the NHS Diabetes Programme

NHS England and NHS Improvement



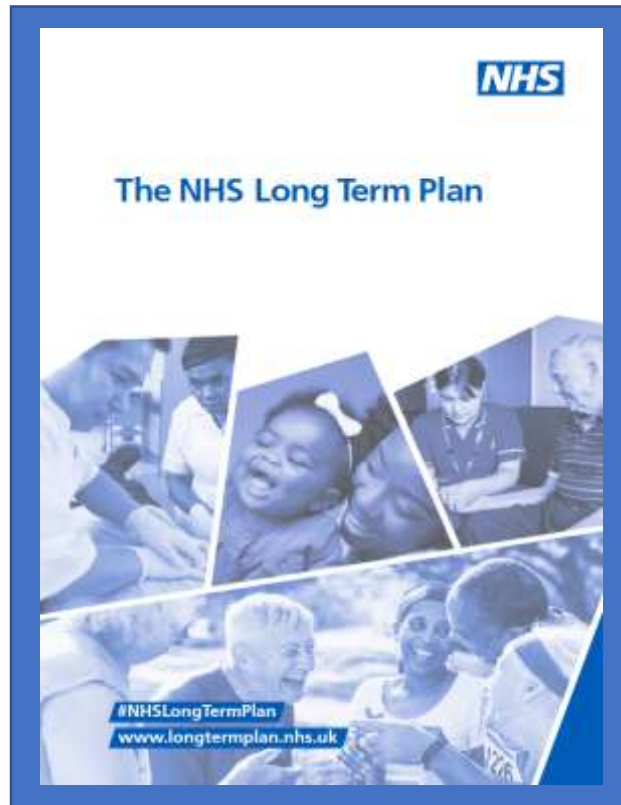


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DiABETES UK
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The NHS Long Term Plan commitment



Medical research has shown that some people with Type 2 diabetes can achieve remission through adoption of a low calorie diet. This allowed nearly half of patients to stop taking anti-diabetic drugs and still achieve non-diabetic range glucose levels. We will therefore test an NHS programme supporting low calorie diets (LCD) for obese people with Type 2 diabetes.

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Purpose of the NHS LCD Pilot Programme

- Launch real-world pilots of Total Diet Replacement in people recently diagnosed with Type 2 Diabetes (within 6 years of diagnosis with BMI ≥ 27 kg/m² [ethnicity adjusted])
- Weight loss and achievement of remission
- Reduce glycaemia and improve cardiometabolic risk factors
- Further build the evidence base for clinical and cost-effectiveness in the real world
- Evaluate the effectiveness of TDR in more diverse population groups
- Explore and evaluate alternative delivery approaches for the behavioural support

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Moving from the RCT to the ‘real world’

- Guided by an Expert Advisory Group
- Seeking to implement TDR, similar to DiRECT and DROPLET, at scale in real-world settings
- Eligibility criteria aligned to the evidence-base but adapted pragmatically for real-world
- Aiming for optimal feasibility in Primary Care – three elements:
 - TDR and behavioural support
 - monitoring response to intervention and checking for adverse events
 - medication adjustments and responding to clinical needs
- Commercial process to select a provider for each pilot site

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Programme overview

- TDR products in line with European regulations
- No direct cost to participants
- Referral to the programme by primary care
- Three phases to the intervention:
 - Total Diet Replacement: 12 weeks
 - Food re-introduction: 4-6 weeks
 - Weight maintenance: Until 12 months
- Relapse protocol if participant regains weight after TDR phase

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Testing three delivery approaches

- 1:1 Face to Face support
 - Group Face to Face support
 - Digital / remote support
-
- Which approaches are most feasible to implement at scale?
 - How effective are they at achieving remission / weight loss?
 - How does cost-effectiveness compare?

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Requirements of Primary Care

- Identify possible patients who could benefit
- Clinically screen for suitability
- Explain programme and obtain informed consent to refer
- Discuss and agree medication adjustments to take place on Day 1
- Make further medication adjustments as required
- Respond appropriately to concurrent / adverse events
- Check bloods at 6 months and 12 months

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Pilot sites

- Expressions of interest were submitted by sites in September
- Sites selected by NHS Regional Teams
- 7-10 STPs – one delivery model in each
- 5000-8000 places in total
- Pilots will run over 3 years
- Sites will be publically announced in next few weeks

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Evaluation

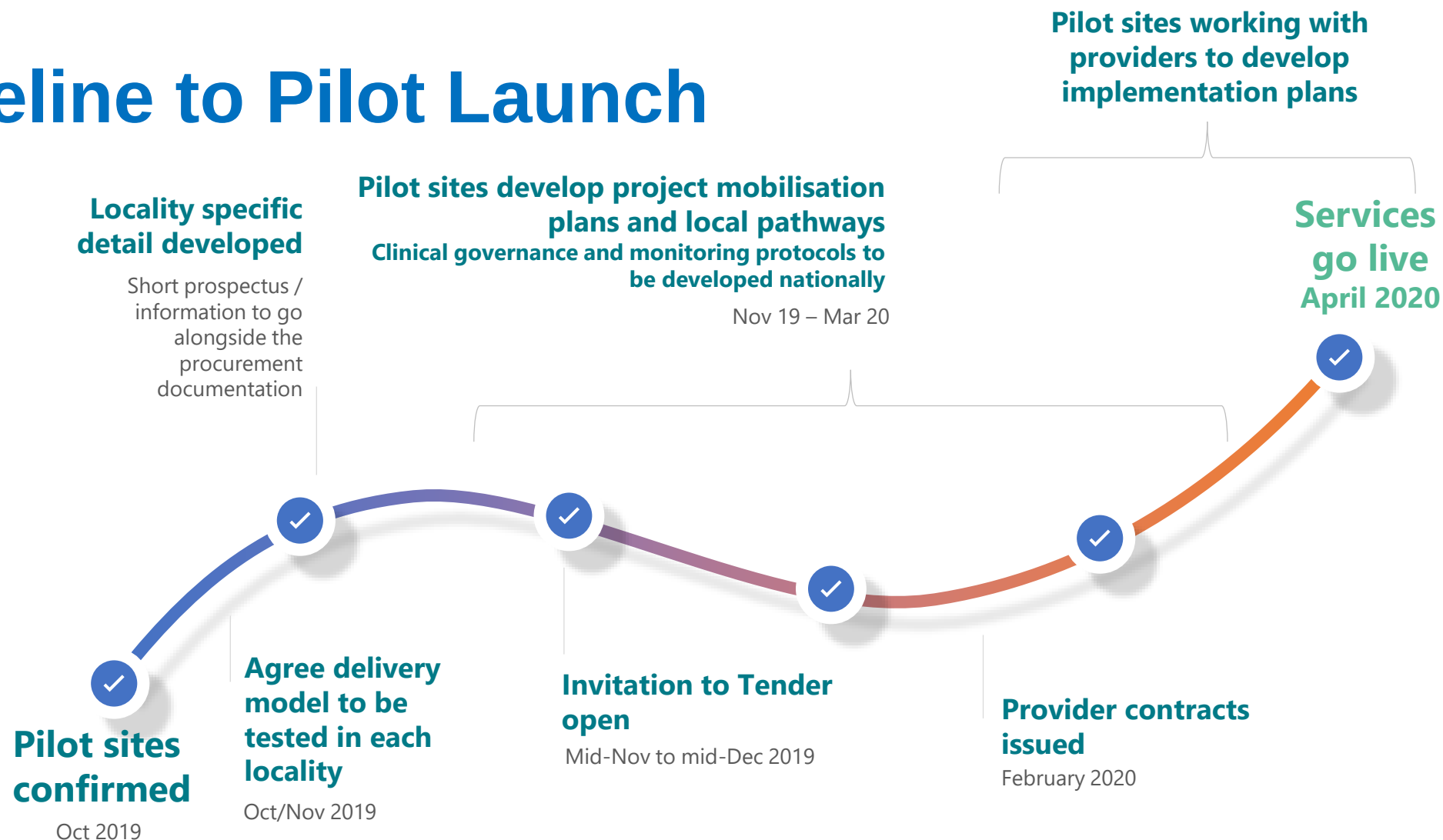
- Given proposed scale, likely to expand international evidence base
- Evaluation specification has been developed
- Process with Department of Health and Social Care and National Institute of Health Research to identify programme evaluator

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Timeline to Pilot Launch





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Questions?

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