DOCTOR REFERRAL OF OVERWEIGHT PEOPLE TO LOW ENERGY TOTAL DIET REPLACEMENT TREATMENT (DROPLET): PRAGMATIC RANDOMISED CONTROLLED TRIAL

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BACKGROUND AND OBJECTIVE:

Total Diet Replacement (TDR) programmes (diets based on formula food products only and providing up to 810kcal/d) have been shown to lead to about 10kg weight loss in one year (about 10% baseline weight) when used in secondary care or specialist research settings. The DROPLET trial was designed to test whether a similar approach would be effective in primary care, using GP referral to a commercial provider. The intervention was delivered by referring patients to a commercial provider (Cambridge Weight Plan) for behavioural support, with GPs retaining responsibility for medical care and monitoring for patients with co-morbidities.

METHODS/STUDY DESIGN:

Primary Care doctors (GPs) were asked to search their databases for patients with a BMI over 30kg/m^2. Patients were invited to take part - those who agreed and met entry criteria were randomised to either usual care, consisting of a behavioural weight management programme delivered by a practice nurse following the British Heart Foundation booklet 'So you want to lose weight…for good' (British Heart Foundation 2005), or a TDR weight loss and maintenance programme (Jebb SA et al 2017). The Cambridge Weight Plan TDR programme was provided by trained Cambridge Consultants who recommended replacing the entire usual food intake with formula soups, shakes and skimmed milk providing 810kcal/d including all micronutrient, essential fatty acid and protein requirements on a daily basis. The Consultants provided support on a one-to-one basis throughout the 8-week programme with a focus on goal setting, monitoring and feedback, problem-solving, encouragement and reassurance. From week 8-12 conventional food was re-introduced in a step-wise manner with behavioural support and preparation for weight maintenance. Thereafter weight maintenance was encouraged by re-enforcement of behavioural strategies and use of one formula meal replacement product each day (that had been shown in earlier trials to be a successful weight maintenance strategy). In the event of weight-regain participants were encouraged to return to the TDR programme for up to 4 weeks. All product was provided free up to 6 months, any requested use after 6 months was funded by the participant. The participants were followed for one year and standard health measures were recorded (see table opposite).

RESULTS:

Two hundred and seventy-eight participants (average BMI 37.2 kg/m^2, 61% women) were enrolled, 72% of whom were available for measurement at one year when average weight loss in the TDR group was 10.7 kg and in the usual care group was 3.1kg (mean difference 7.2kg). Forty five percent of the TDR group had lost more than 10% of their baseline body weight at one year compared to only 15% in the usual care group. Markers of metabolic and cardiovascular risk improved more in the TDR group than in the usual care group (see table), most notably reductions in HbA1c, a measure of the risk of diabetes. Adverse events (AEs), classified as 'moderate' or as of greater severity, occurred in 1 in 8 participants but were equally common in both groups. The most common AEs (of all severity) that were reported by at least 2% of participants where there was a greater incidence in TDR than UC were constipation, fatigue, and headache. General practitioners successfully managed medication dosage changes throughout the study – see guidelines at – **https://www.phc.ox.ac.uk/research/diet-plans/tdr-medication-adjustment-guide**

CONCLUSION:

GP referral to a commercial provider offering a weight loss and maintenance programme, based on Total Diet Replacement with individual behavioural support, led to an average weight loss of 10.7 kg after 1 year (7.2kg more than usual weight-loss programmes offered in primary care). This was associated with significant reductions in CVD risk. A TDR programme is an acceptable, safe and effective treatment for obesity in primary care.

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Jebb SA, Astbury NM, Tearne S, et al 2017 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 2017;7:e016709. **doi:10.1136/bmjopen-2017-016709**

TOTAL DIET REPLACEMENT PROGRAMMES – RESOURCES FOR HEALTH PROFESSIONALS

Please see: **https://www.phc.ox.ac.uk/research/diet-plans/tdr-resources-for-health-professionals**

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Estimated weight change over 12 months in the intention to treat population

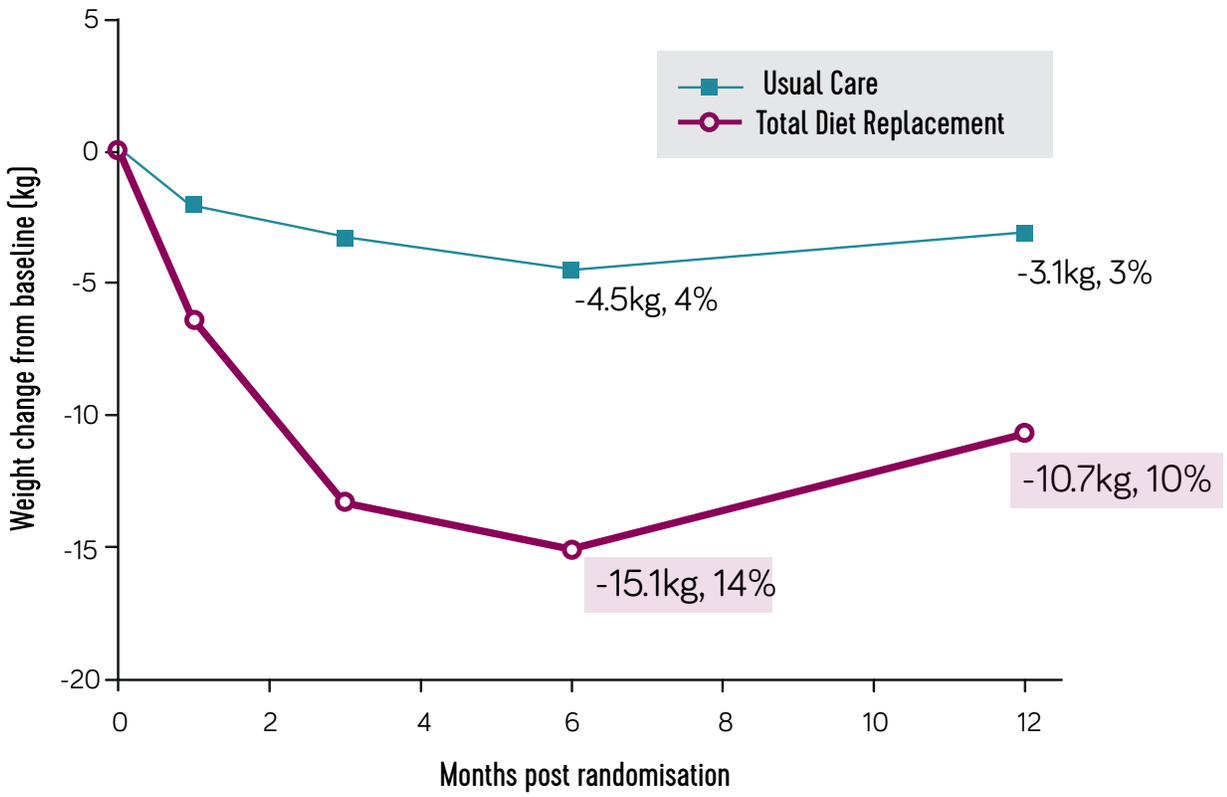

Figure redrawn from Astbury N et al BMJ 2018; 362: k3760 doi: 10.1136/bmjk3760

	Total Diet Replacement	Usual Care	Treatment Difference	Significance p
Body Weight kg	-10.7	-3.1	-7.2 (-9.4, -4.9)	<0.001
Fat Mass kg	-10.4	-4.1	-5.8 (-7.9, -3.7)	<0.001
Waist circumference cm	-10.5	-5.5	-6 (-8.2, -3.7)	<0.001
Diastolic blood pressure mmHg	-4.2	0.3	-3.1 (-5.5, -0.7)	0.01
HbA1c mmol/mol	-3.2	-1.0	-2.2 (-4.4, 0.0)	0.05
Fasting glucose mmol/L	-0.5	0.1	-0.4 (-0.8, -0.1)	0.02
HOMA S %	28.8	-4.6	30.9 (16.4, 45.5)	<0.001
Blood Triglyceride mmol/L	-0.3	0.1	-0.4 (-0.6, -0.1)	0.002
QRISK2 %	-0.9	0	-1 (-1.7, -0.3)	0.01

Changes in mean values from baseline to 12 months. Treatment difference is followed by confidence intervals.
A positive change in HOMA S % indicates an increase in insulin sensitivity See: https://www.dtu.ox.ac.uk/homacalculator/

10% WEIGHT LOSS IN PRE-DIABETES

Average 10% weight loss in 4 out of 5 people with pre-diabetes[1]

- Cambridge Weight Plan is an evidence-based weight loss and maintenance programme with sustained health benefits
- Flexible energy intake and flexible combinations of formula and regular food
- Formula diets for primary and secondary care and community settings
- Average 15% weight loss[2] and 10% maintenance (1 year evidence) in obstructive sleep apnoea with sleep benefit[3]
- In secondary heart disease prevention average 10% weight loss[4] and 7% weight maintenance[5] (1 year evidence with aerobic interval training) and
  - Increased insulin sensitivity[6]
  - Less atherogenic blood lipids[7]
  - Small lean mass losses[5]
  - Improved cardiovascular fitness[5]
- Predictable weight loss before bariatric surgery[8]
- Average 10% weight loss[9] and maintenance[10] (4 year evidence) in osteoarthritis with maintained symptom benefit[11] and improved vitamin D status and maintained bone health[12]
- Weight loss and maintenance (1 year evidence) in psoriasis with maintained skin improvement[13,14]
- Reduced 'pro-inflammatory' and 'pro-insulin resistance' protein panels with weight loss, and one year maintenance of both reduced weight[15] and improved proteomics markers[16]

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