

The  
**DiRECT**  
diabetes remission intervention  
as presented at IDF 2017



**COUNTERweight**<sup>®</sup>

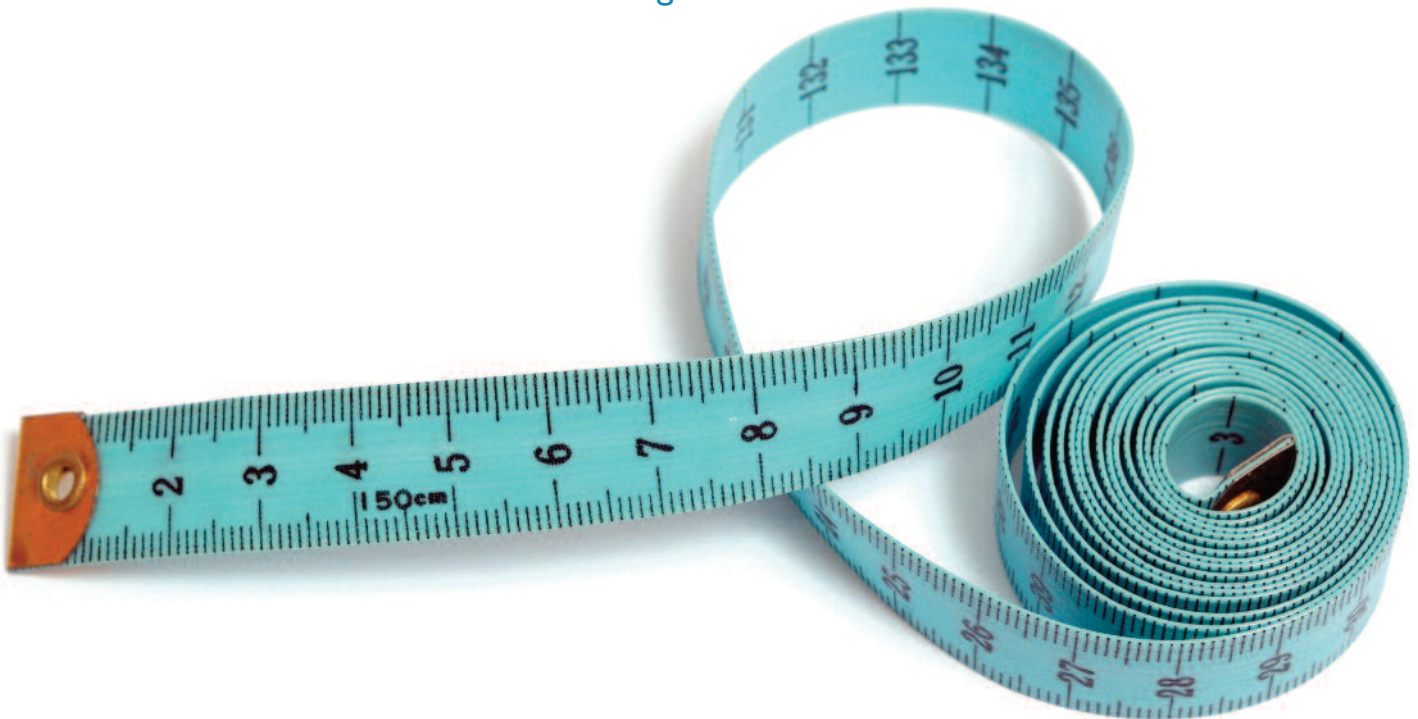
The Leaders in Evidence Based  
Weight Management

# COUNTERweight<sup>®</sup>-PLUS

**A non surgical weight management solution for:**

- People who want to achieve remission of Type 2 Diabetes (T2D)  
AND
- Individuals with greater weight loss needs but cannot or  
will not access bariatric surgery

Aim >15kg / 10% loss



**Information for Professionals**



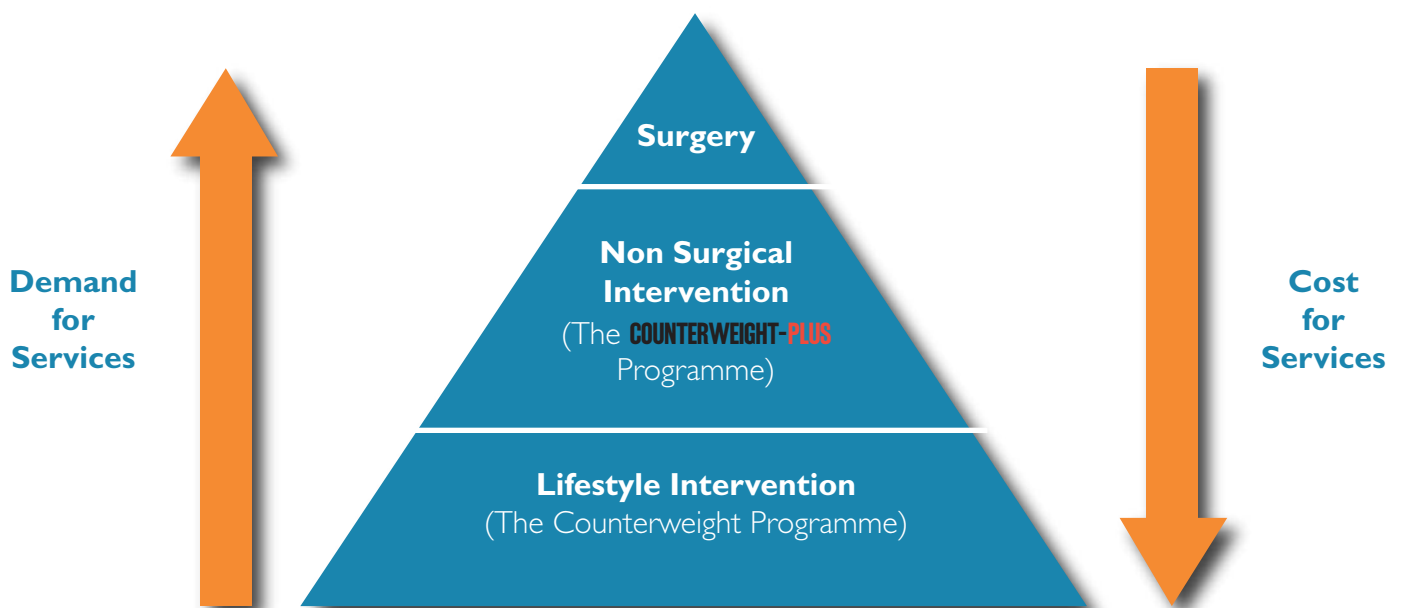
'Although not always obese, virtually everyone with T2D is overweight, as are most people without diabetes. All that drug treatments have ever done is to reduce the blood sugar – this mostly just hides the disease and disabling complications still develop. What drives T2D in susceptible people is the excess weight, and that should be the target for treatment.

The good news is that if you lose a substantial amount of weight (over 10kg and best over 15kg) using an evidence based programme such as **COUNTERWEIGHT-PLUS**, which focusses on maintaining the weight-loss long-term, there is a good chance you will no longer be diabetic.'

**Professor Mike Lean, University of Glasgow**

## Counterweight-Plus: an evidence-based non surgical solution

Guidelines recommend bariatric surgery as the gold standard for individuals with a BMI >40kg/m<sup>2</sup> or 35kg/m<sup>2</sup> to 40kg/m<sup>2</sup> with co-morbidities.<sup>1</sup> However with the increasing number of people qualifying for surgery, the demand cannot be met by public healthcare services. Additionally, many individuals would not choose or be eligible for surgical intervention or be in a position to pay for surgery via private health care. There are requirements for clinically-effective and cost-effective interventions which can achieve weight loss of >15kg in patients with a BMI>30kg/m<sup>2</sup> or BMI>27kg/m<sup>2</sup> with T2D at 12 months. This can be achieved with **COUNTERWEIGHT-PLUS**, which combines a total diet replacement (TDR) with a structured programme of food reintroduction (FR), weight loss maintenance (WLM), behavioural therapy and anti-obesity medication.<sup>2</sup>



## Remission of T2D: a realistic target

For patients with T2D, the condition is generally perceived as permanent, incurable and progressively destructive, now affects 5-10% of entire populations. However, diabetes management is beginning to focus on reversible underlying disease mechanisms. Substantial weight loss, of 15kg or more, from bariatric surgery or non-surgical methods, restores beta cell function and often a total biochemical remission of T2D without anti-diabetes medication<sup>3,4</sup> In the DiRECT research study, which used **COUNTERWEIGHT-PLUS** as the intervention, almost half of all patients\* achieved (and maintained) remission of diabetes at 12 months.<sup>5</sup>

## Other benefits

There is evidence for the use of total diet replacement programmes in the management of sleep apnoea and osteoarthritis of the knee. Twelve month outcomes demonstrate clinically significant weight loss, improvements in clinical indicators (e.g. mobility tests, apnoea hypopnoea index) and increased vitamin D and vitamin B12 status.<sup>6,7,8</sup> Evidence also demonstrates there is no better weight loss outcomes at 12 months using a very low calorie diet (415-554kcal/day) as opposed to a more liberal low calorie diet (810kcal/day).<sup>7,9,10</sup>

\*Type 2 diabetes diagnosed <6 years, BMI 27-45kg/m<sup>2</sup>, 20-65 years

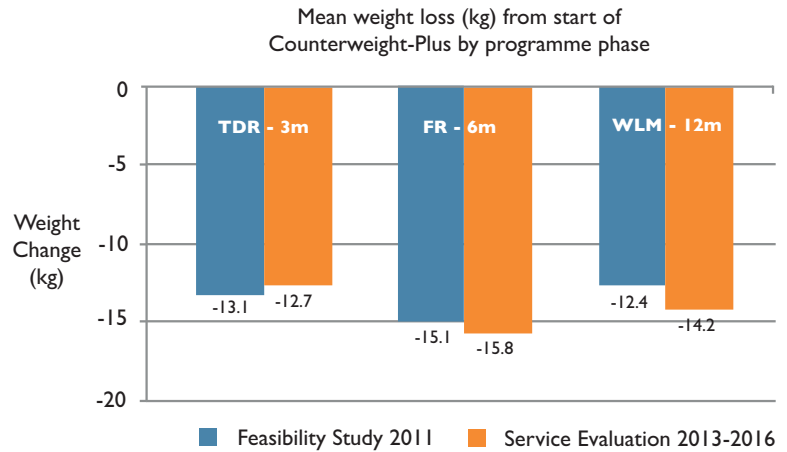
## Counterweight-Plus Evidence

During 2010-2011 the Counterweight Team conducted a feasibility study, in primary care, training nurses and dietitians to deliver the 12 month programme of total diet replacement, food reintroduction and weight loss maintenance.<sup>2</sup>

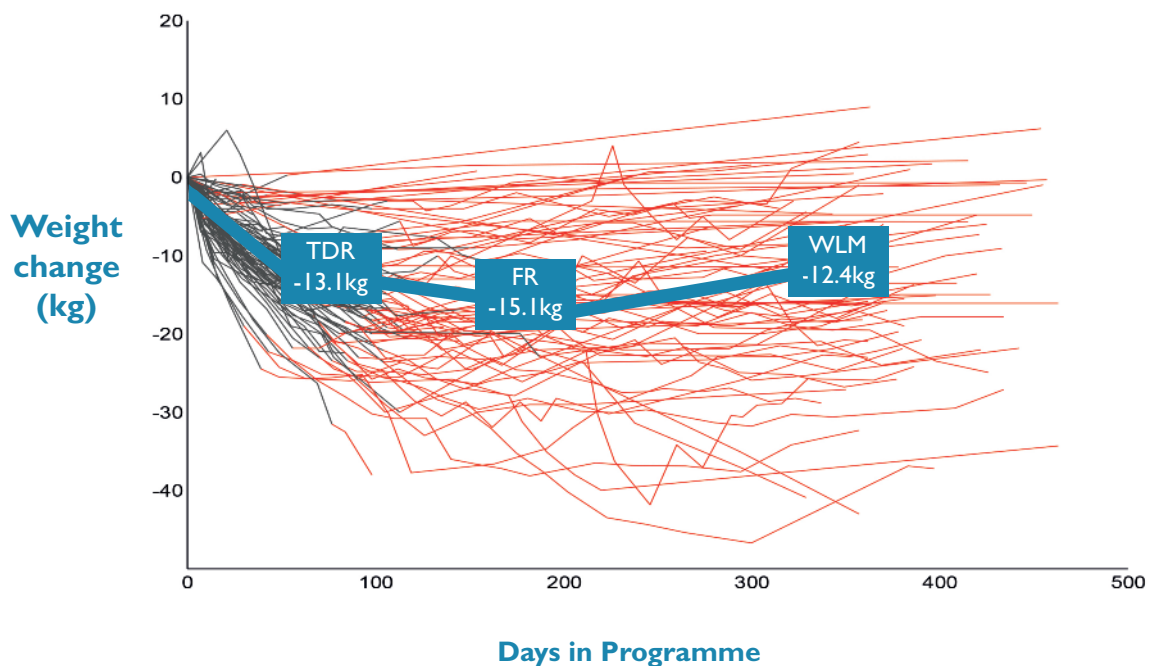
Programme refinements and developments subsequently led to **COUNTERWEIGHT-PLUS** being made available for commissioning. A service evaluation from 2013 to 2016 has been published, with results shown below.<sup>11</sup>

### Baseline characteristics for all patients starting COUNTERWEIGHT-PLUS

Baseline	Feasibility Study 2011 Mean	Service Evaluation 2013-2016 Mean
n	91	288
Age, years	46	47.5
Male, n(%)	17 (19)	76 (26)
Weight, kg	131	128
BMI, kg/m <sup>2</sup>	48	46
Diabetes, n(%)	3 (3)	99 (34)



## Trajectories of weight changes of all patients who started Counterweight-Plus (feasibility study)



Black lines = TDR phase  
 Red lines = FR and WLM  
 Blue boxes = mean loss by programme phase

- Target loss of 15kg at 12 months achieved by 40% of those still on the programme (~1/4 on ITT)
- Commissioners may wish to operate an 'early stop' process, where those not achieving weight loss of at least 4kg in first month discontinue the intervention as early weight change influences programme retention (see below).

3 month loss (kg)	0-<5	5-<10	10-<15	>15
12 month retention (%)	14	35	51	71

## DiRECT: Key Outcomes<sup>5</sup>

- A quarter achieved target of >15kg loss after 1 year and a half maintained over 10kg loss
- Greater weight loss more likely to result in remission of diabetes

Weight Loss	<5kg	5-10kg	10-15kg	>15
% remission	4%	34%	57%	86%

- Only 26% of intervention patients still required anti-diabetic medications at 12m compared with 82% of patients in the control arm
- Mean HbA1c fell by 9.6mmol/mol (from baseline of 60) with the intervention, despite stopping anti-diabetes drugs, versus an *increase* of 1.4mmol/mol (from baseline of 58), and *increased* drugs, in controls

## Which individuals are eligible for Counterweight-Plus?

Those who

- are aged 18-75 years

**AND**

- Body Mass Index (BMI): Caucasian: BMI  $\geq 30 \text{ kg/m}^2$  or  $\geq 27 \text{ kg/m}^2$  with T2D  
Asian: BMI  $\geq 28 \text{ kg/m}^2$  or  $\geq 26 \text{ kg/m}^2$  with T2D

**AND**

- are assessed as 'Ready to Change' by the Counterweight Practitioner

**AND**

- have no medical condition that contraindicates taking a Total Diet Replacement (see page 8 for further details on exclusions)

## How does Counterweight-Plus compare to bariatric surgery?

Bariatric surgery has the most published evidence for treatment of severe and complicated obesity. However non surgical interventions are also required to address this increasing problem. An initial cost analysis has been conducted to compare the use of bariatric surgery and **COUNTERWEIGHT-PLUS**.<sup>2</sup> This demonstrates that for £1 million of health service resource, >15kg weight loss can be achieved in around 110 people using bariatric surgery\* compared to 383 people using **COUNTERWEIGHT-PLUS**. Therefore, for the same level of resource, three times as many people are likely to achieve >15kg weight loss using **COUNTERWEIGHT-PLUS**, in comparison to bariatric surgery. The availability of **COUNTERWEIGHT-PLUS** means more people will be able to access a weight management solution for the treatment of severe and complicated obesity. \*Bariatric surgery is based on a laparoscopic procedure with an estimated cost of £7,500.

**COUNTERWEIGHT-PLUS** is generally being used as a treatment option in the treatment category between lifestyle intervention and bariatric surgery, or as an alternative to surgery, but it is also being used in some areas for individuals being considered for or waiting for surgery.

## The Counterweight-Plus Programme Structure

COUNTERWEIGHT-PLUS offers a 12 month structured programme (up to 20 appointments), as follows:

### SCREENING

One appointment, to check entry criteria

### TOTAL DIET REPLACEMENT

(12 Weeks)

Total Diet Replacement (shakes and soups)  
810+ calories per day (Counterweight PRO800)  
Seven appointments (weekly or two weekly)  
\*if weight target not reached practitioners can offer shakes/soups for up to 20 weeks

### FOOD REINTRODUCTION

(12 Weeks)

Gradual introduction of portion-controlled balanced meals  
Total Diet Replacement reduced as meals are introduced  
Option to take weight loss medication  
Six appointments (two weekly)

### WEIGHT LOSS MAINTENANCE

(6 months)\*

All nutrition from food and drink  
Focus on maintaining lifestyle changes and preventing regain  
Option to take weight loss medication  
Six - eighteen appointments (monthly)\*

\* Depending on local services, monthly appointments are recommended for ongoing support for Year 2 of the programme. However, this is optional.

**The programme can be delivered one to one or in groups and using a mixture of face to face and remote support.**

## Advice for GPs on the Medical Management for Counterweight-Plus

### Aims:

1. Weight loss >15kg (individualising the target), using Total Diet Replacement (TDR) providing ~810kcal/day, usually for 8 – 12 weeks (some people may require up to 20 weeks)
2. Weight loss maintained for at least 12 months using structured behavioural change, with protocols for Food Reintroduction (FR) and Weight Loss Maintenance (WLM)

Before a patient can commence Counterweight-Plus their GP/Consultant needs to check the following:

### STEP 1: Eligibility

- Age 18 – 75 years
- Body Mass Index (BMI):      Caucasian:      BMI >30kg/m<sup>2</sup> or >27 kg/m<sup>2</sup> with T2D  
  Asian:            BMI >28kg/m<sup>2</sup> or >26 kg/m<sup>2</sup> with T2D
- The patient is assessed as 'Ready to Change' by the Counterweight Practitioner

### STEP 2: Exclusions

- Active mental illness: severe depression, bipolar disorder, schizophrenia or other psychotic disorders
- Myocardial infarction or stroke within the previous 3 months
- Severe or unstable Heart Failure e.g. New York Heart Association grade IV
- Porphyria
- Pregnant until >4 months post-partum; breastfeeding
- Substance abuse e.g. drugs, alcohol
- Eating disorder accompanied by purging (through laxative abuse or induced vomiting)

Medical Management Guidelines are provided to support GPs and Counterweight Practitioners in managing patients while on

**COUNTERWEIGHT-PLUS.**



### **STEP 3: Monitoring and medication adjustment**

It is not essential, from a safety perspective, to do any medical screening or assessment, except for:

#### **Diabetes and hypertension requiring medications:**

Protocols are provided for medication management for these clinical conditions.

#### **Heart Failure potentially affected by major weight loss:**

A stepped energy restriction approach might be preferred.

#### **Gallstones:**

Patients should be advised of an increased risk of developing symptoms from gallstones during any effective weight loss programme. To reduce that risk, the diet contains some fat (needed to allow normal gall-bladder function), a stepped energy restriction is recommended, and ursodeoxycholic acid may be considered as a preventative measure.

#### **Gout:**

Weight loss can precipitate gout in susceptible people. Continue or initiate uric acid lowering therapy where appropriate.

#### **Drug therapies:**

Might need dose adjustments with major weight loss.

#### **Warfarin:**

Measure INR weekly after weight change and adjust warfarin dose. Continue until weight and INR have stabilized.

#### **Contraception:**

Fertility may increase and there may be alterations in fertility, menstruation and effect of contraceptive devices with weight loss.

#### **Drugs for Arthritis:**

Some patients may be able to reduce or stop some medications.

#### **Corticosteroids:**

The effect of weight loss, suppressing pro-inflammatory signals may allow dose reduction.

#### **Anticonvulsants:**

Weight loss may reduce requirements: blood levels can be measured and clinical response assessed by seizure diary.

All other measurements and follow up will be provided by the Counterweight Practitioner delivering the weight management intervention (generally registered dietitians) with appropriate reporting to the patient's General Practitioner.



## Implementing Counterweight-Plus

A Counterweight Specialist (dietitian) provides a structured competency based training and mentoring programme to Counterweight Practitioners. This includes data collection systems and evaluation.



**Training:** A two-day\* interactive training course is delivered. This includes the presentation of evidence, practical activities and real life case studies.

\* 4 x half days if delivered online

**Mentoring:** A structured mentoring process is delivered by Counterweight Specialists using a mix of face to face, telephone or online sessions

**Data Collection and Evaluation:** Guidance on data collection and evaluation is provided

## Weight Regain Prevention

Preventing weight regain following a Total Diet Replacement requires effective weight management strategies. **COUNTERWEIGHT-PLUS** endeavours to equip individuals with the skills and tools to manage their weight for life. **COUNTERWEIGHT-PLUS** supports long term weight loss maintenance which is treated proactively using Rescue Plans and/or ongoing use of 1 sachet of Counterweight PRO800 per day. There is an optional year 2 programme.

## Cost to access Counterweight-Plus

The upfront cost is dependent on the number of people undertaking training and mentoring, and anticipated numbers of patients going through **COUNTERWEIGHT-PLUS**.

### Recurring Costs

The cost of this intervention is based on the total 12 month **COUNTERWEIGHT-PLUS** package, which includes an annual licence, Total Diet Replacement products and educational materials. In addition, the annual licence includes ongoing guidance and support from the Counterweight Team.

### Payment Options

There are a number of ways to access **COUNTERWEIGHT-PLUS**:

- Organisation pays for training for practitioners, annual programme licence and full cost for individuals to undertake **COUNTERWEIGHT-PLUS**
- Individuals pay the full/part cost (where organisation pays part cost) to undertake **COUNTERWEIGHT-PLUS**
- Organisations may refer individuals who are interested in **COUNTERWEIGHT-PLUS** direct to the Counterweight Team, who will direct them to trained Counterweight Practitioners (private practice)

'COUNTERWEIGHT-PLUS is excellent. It is a welcomed part of our dietetics department weight management toolkit. I saw some brilliant results and it was fantastic to see the participants' confidence rise throughout COUNTERWEIGHT-PLUS especially when they maintained their weight loss as this was something they hadn't achieved before'

*Lindsay Kolthammer, Dietetic Team Lead, NHS Orkney*

**For more information contact:**

Anna Bell-Higgs BSc Hons RD

Counterweight Specialist

Counterweight Ltd.

Visiting Senior Research Fellow, RGU

**Mobile:** +44 (0)7701 281653

**Email:** [anna.bell-higgs@counterweight.org](mailto:anna.bell-higgs@counterweight.org)

**Web:** [www.counterweight.org](http://www.counterweight.org)



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'Being obese involves becoming trapped with a pattern of eating and activities which maintain the obese state. Life-long changes are needed, to be a thinner person. **COUNTERWEIGHT-PLUS**, and similar programmes offer a total break from usual eating habits, complete with all necessary nutrients, to achieve rapid weight loss, and then a structured programme to reintroduce the types and amounts of foods needed to stay at a lower, healthier, weight. People who stick to programmes like **COUNTERWEIGHT-PLUS**, will lose over 15kg, and keep it off for at least a year, and most will no longer be diabetic.

**Professor Mike Lean, University of Glasgow**



[www.counterweight.org](http://www.counterweight.org)