# Type 2 Diabetes Remission: the latest evidence

Catherine Washbrook-Davies

Community Dietetics Chronic Conditions Team Lead (Cardiff & Vale UHB)

&

Newly appointed NHS Wales Dietetic Lead for Diabetes (Adults)



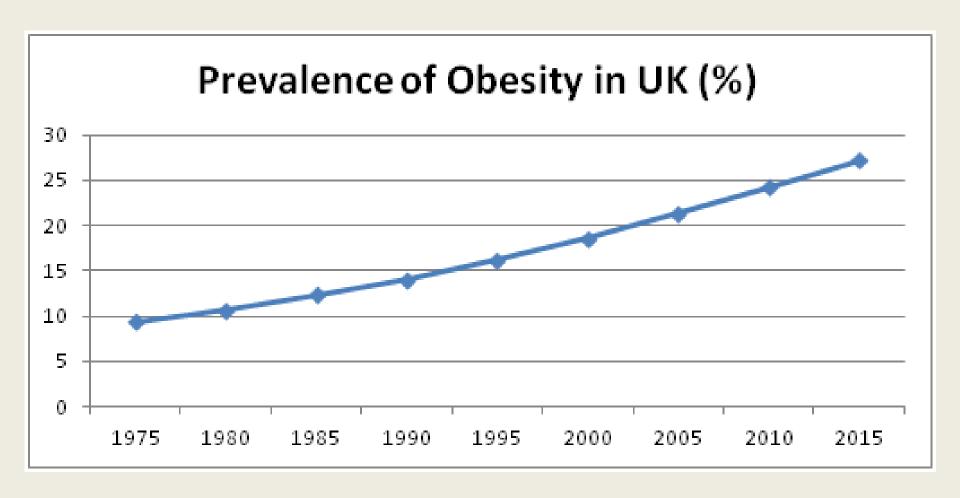


## Questions we might ask ourselves.....

- Do we consider food habits or just drugs?
- Is T2D remission achievable for patients?
  - Is there a non-surgical solution?
- What support do our patients need to be successful?



Study tested the hypothesis:
that negative energy balance alone
reverses T2D by normalising both beta cell
function & insulin sensitivity.



(Ref: Data sourced from Global health Observatory WHO 2017)



1960: 416 kcals 2011: 1400 kcals

2011

120 cal

1960







## Portion Distortion

# Obesity: identification, assessment and management Clinical guideline [CG189]Published date: November 2014

- Offer an expedited assessment for bariatric surgery to people with a BMI of 35 or over who have recent-onset type 2 diabetes as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). [new 2014]
- Healthcare bariatric services could not meet this demand (only reaches 1% of eligible population)
- High cost approx £8,000-£15,000
- Many individuals would not choose/be eligible or be in a position to pay privately
- Potential for complications & long term problems such as micronutrient deficiencies
- Non-reversal/ life changing event

#### Need for an evidence based non-surgical solution.

#### Diabetes Remission in Type 2 Diabetes is defined as:

HbA1c <48mmol/mol and off ALL antidiabetes drug therapy

"...means that your blood sugar levels are healthy without needing to take any diabetes medication."

#### **Diabetes UK**

Normoglycaemia	<41 mmol/mol
Prediabetes	42-47 mmol/mol
Diabetes	>48mmol/mol

## Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial

Michael E J Lean\* Willea C Loulis Alica C Barnes, Naomi Brosnahan, George Thom, Louise McCombie, Carl Peters, Sviatlana Zhyzhneuskaya,

Lucia Rehackova, Ashley J Adamson, Falko F Sniehotta, John C Mathers,

Welsh, Sharon Kean, Ian Ford, Alex McConnachie, Naveed Sattar, Roy Taylor\*

## 9/10 achieved remission if lost >15kg

elong treatment. We aimed to assess whether remission of type 2 diabetes.

imary care practices in Scotland and the uputer-generated list, to provide either a lelines (control), with stratification cipants, carers, and recation was coped with typ

3 kcal/dz g-term wei es, defined a diabetic medica stered with the ISRC

we recruited 306 individuals from 49

Give people the option of: Lifestyle treatment rather than drugs!

(n=26) general per group comprised the intention-to-treat p recorded weight loss of 36 (24%) participants in the intervention group a control group (p<0.0001) ssion was achieved in 68 (46%) participants in the inter six (4%) participants in the p (odds ratio 19·7, 95% CI 7·8-49·8; p<0·0001). Remissi tion, with achievement in none of 76 participants who weight loss in the whole s ned 0-5 kg weight loss, 19 (34%) of 56 participants wit six (7%) of 89 participants w loss. 16 (57%) of 28 participants with kg loss, and 31 (86%) of 36 participants who lost 15 kg e. Mean bodyweight fell by 10.0 kg (SD the intervention group and 1.0 kg (3.7) in the control (adjusted difference -8.8 kg, 95% CI -10.3 to 3; p<0.0001). Quality of life, as measured by the Euro( 5 Dimensions ints (SD 21·3) in the intervention group, and decreased b 2·9 points (15·5) visual analogue scale, improved by 7. in the control group (adjusted difference 6.4 points, 95% CI 2.5-10.3; p=0.0012). Nine serious adverse events were reported by seven (4%) of 157 participants in the intervention group and two were reported by two (1%) participants in the control group. Two serious adverse events (biliary colic and abdominal pain), occurring in the same participant,

Interpretation Our findings show that, at 12 months, almost half of participants achieved remission to a non-diabetic state and off antidiabetic drugs. Remission of type 2 diabetes is a practical target for primary care.

were deemed potentially related to the intervention. No serious adverse events led to will depend from the study.

# Primary Outcome Results of DiRECT the Diabetes REmission Clinical Trial

#### Aim:

To assess whether intensive weight management, within routine primary care, would achieve remission of T2DM

#### Design:

Open-label, cluster randomized, clinical trial. Randomized by GP practices, stratified for sex and practice size

#### Intervention:

- Counterweight-Plus Weight management programme: Aim to achieve & maintain at least 15kg weight loss
- Withdraw all anti-diabetes and antihypertensive medication
- Plus best practice care by guidelines

Control: best practice care by guidelines Dietetics Department

### DiRECT: inclusion & exclusion criteria

- Inclusion
- Men and women
- Age 20–65 years
- •BMI 27–45kg/m<sup>2</sup>
- T2DM diagnosed within 6 years
- •HbA1c ≥48 mmol/mol
- (≥43 mmol/mol on anti-diabetes drugs)
- Signed informed consent

#### **Exclusion**

- Insulin treatment, anti-obesity drugs
- Learning difficulties
- Pregnancy or considering pregnancy,
- Weight loss >5kg within 6m, eGFR <30 mls/min, severe or unstable heart failure, known cancer, myocardial infarction within 6m
- Eating disorder/ purging, severe depression, antipsychotic drugs, substance abuse

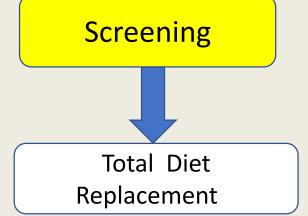
# DiRECT Intervention: Counterweight-Plus Programme

#### **Total Diet Replacement- Counterweight Pro800**

- Nutritionally complete in 4 x shakes/soups
- 825-853kcals: 59% CHO, 13% fat, 26% protein, 2% fibre (approx. 20g protein per shake)
- >2.25l fluid per day
- Follow for 12-20 weeks

#### Maintain PA: ~30mins/day

- STOP all antidiabetes medication
- STOP all antihypertensive medications







## Counterweight-Plus Programme

#### **Stepped Food Reintroduction**

- Add ~400 kcal meal every 2-3 weeks
- Step counters: gradually increase PA

#### **Weight loss Maintenance**

- Food based diet (1200,1400 or 1600kcals)
- 50% CHO, 35% fat, 15% protein
- Encourage upto 15,000 steps/day

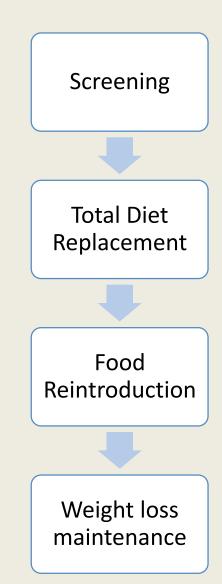
Relapse Management (regain >2kg, relapse of diabetes)

• Tool-kit approach: meal replacement, brief TDR

output

Output

Cardiff & Vale UHB Community Dietetics Department



## Input Required during Intervention

- Patients attended their own primary care practice
- Programme delivered and supervised by Practice nurse or local dietitian

#### Individual appointments:

TDR: 2- weekly

Food reintroduction 2- weekly

Maintenance 4-weekly

(Total of 20 appointments over 1 year)

### Results: weight changes over 12 months

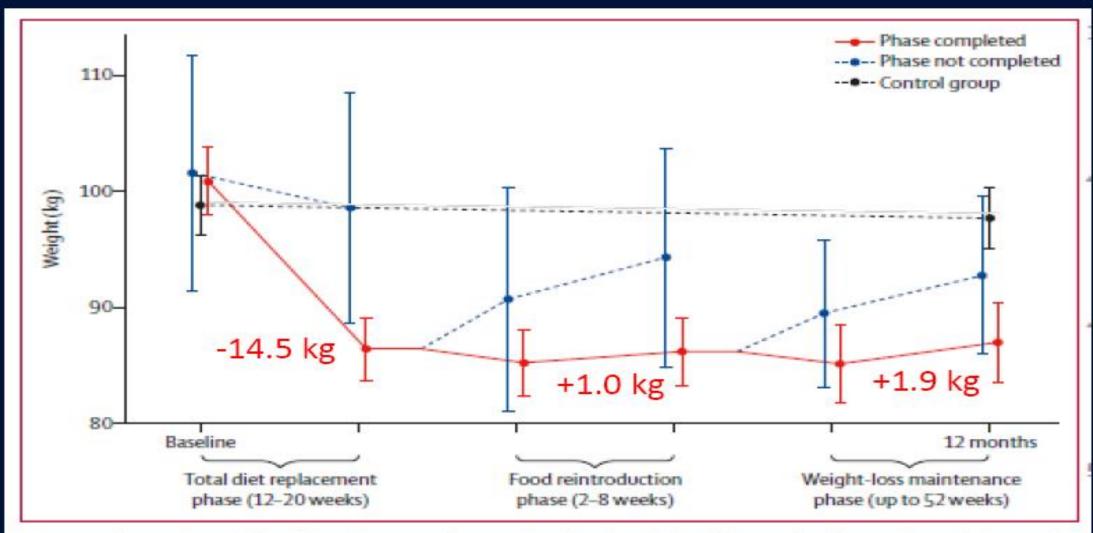


Figure 2: Change in weight of participants who remained in the trial and those who dropped out during each phase of the intervention

Error bars represent 95% Cls.

## Primary outcome Results

A. 1st Co-primary outcome: >15kg weight loss

Intervention 36/149 (24%) (28/149 lost 10-15kg)

■ Control 0/149

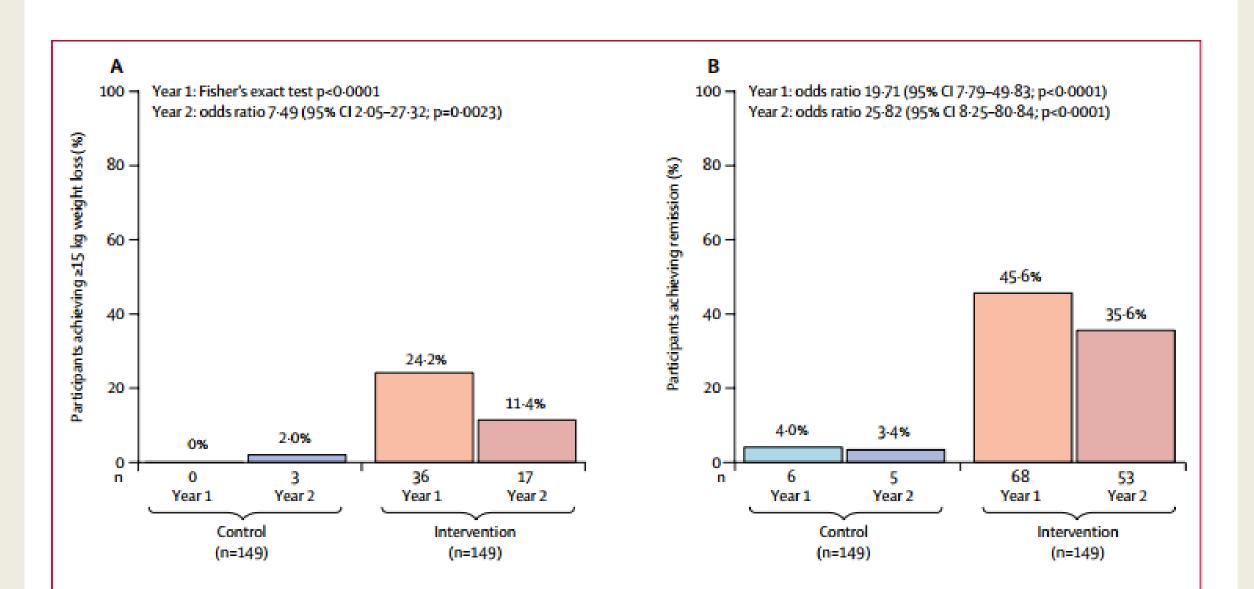
## B. 2nd Co-primary outcome: Remission of diabetes (HbA1c< 48mmol/mol)

Intervention 68/149 (46%) (53/149 at 2 years)

Control 6/149 (4%)

At 12 months **74%** intervention group vs 18% control group were taking no antidiabetic medications

## DiRECT Trial 2 year results



## C. Remission of diabetes in relation to weight loss as 12 months (both groups combined)



#### **DiRECT: Conclusions**

- T2D of upto 6 years duration is not necessarily a permanent lifelong condition.
- T2DM is a complication of weight gain and excess body fat, and it is not necessarily a permanent condition
- Almost half with early T2DM can achieve remission
- Effective long term weight management with <u>a resetting of</u> long term energy consumption is essential.
- Individual flexibility is important to optimize results

## 

Pilot project Jan 2020- March 2021 across 4 UHBs (C&V, BCUHB, ABUHB & Hywel Dda)
Plan to recruit 90 people in total
Following the DiRECT principles......



- 1. 4 key inclusi
  Age 20-65 years
  Diagnosed T2D withir
  HbA1c >48mmol/mol
  BMI 27-45kg/m<sup>2</sup>
- 2. An integrate strategies for lapse Period of TDR providi Supported by Dietitian Supervised food reint Relapse managemen
- 3. Protocols fo
- **4. Prospective** Weight, WC, HbA1c,



## **KEEP** CALM **AND** WATCH THIS SPACE

our change and

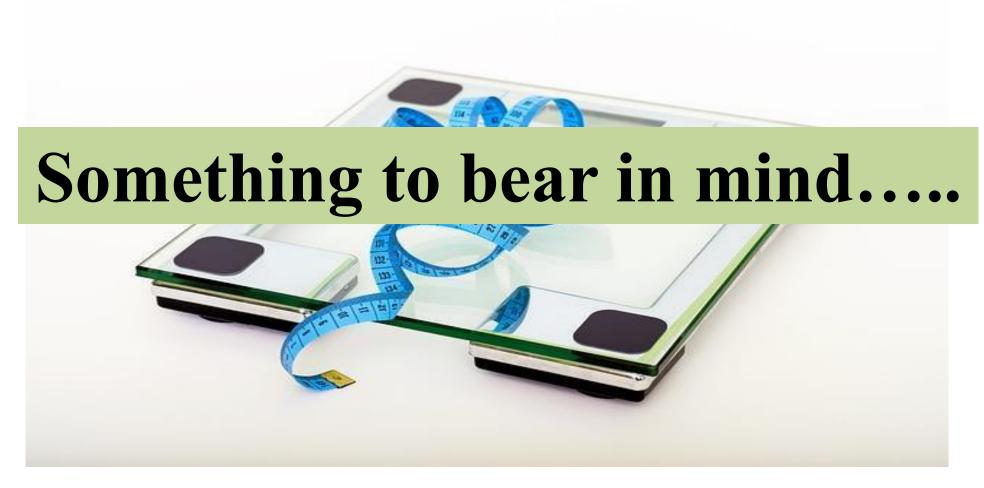
ICP

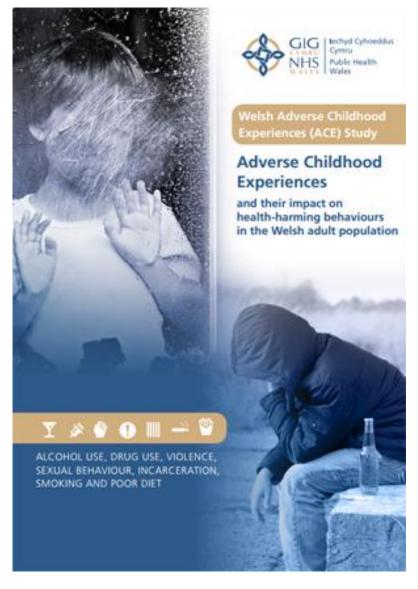
e medication.

me improvement



#### Raising the topic of weight.....





The report found that over a 1 year period those with an ACE of 4+ were:

X **4** times more likely to develop diabetes type 2

X 3 times more likely to develop heart disease

X 3 times more likely to develop respiratory disease









## Key messages:

• Aim for 15kg weight loss (where appropriate) as soon as possible after diagnosis to help achieve remission.

At least 5% weight loss \u00e4

 Recognising remission o patients

 Need to take into consic does NOT which influence health l



isk and glycaemia

ul motivator for

onmental factors





#### **Contact details:**

Community Dietetics dept, Riverside Health centre, Cardiff catherine.washbrook@wales.nhs.uk

029 20668089



#### References

- BDA (2018) Low carbohydrate diets for the management of type 2 diabetes in adults. Available at https://www.bda.uk.com/improvinghealth/healthprofessionals/policy\_statements/policy\_statement\_\_low\_carbohydrate\_diets\_for\_the\_management\_of\_ty pe\_2\_diabetes\_in\_adults.pdf\_ Accessed 09.10.2019
- Diabetes UK. Available at:
   https://www.diabetes.org.uk/guide-to-diabetes/managing-your-diabetes/treating-your-diabetes/type2-diabetes-remission Accessed 09.10.2019
- Diabetes UK (2018) Evidence-based nutrition guidelines for the prevention and management of diabetes. Available at:
   <a href="https://diabetes-resources-production.s3.eu-west-1.amazonaws.com/resources-s3/2018-03/1373\_Nutrition%20guidelines\_0.pdf">https://diabetes-resources-production.s3.eu-west-1.amazonaws.com/resources-s3/2018-03/1373\_Nutrition%20guidelines\_0.pdf</a> Accessed 09.10.19
- Dyson, P. A., D. Twenefour, C. Breen, A. Duncan, E. Elvin, L. Goff, A. Hill, et al. 2018. "Diabetes UK Evidence-Based Nutrition Guidelines for the Prevention and Management of Diabetes." *Diabetic Medicine*. https://doi.org/10.1111/dme.13603
- Dyson PA, et al (2011b). "Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes." Diabet Med, 28(11):1282–8.
- Estruch, Ramon, Miguel Angel Martinez-Gonzalez, Dolores Corella, Jordi Salas-Salvado, Montserrat Fito, Gemma Chiva-Blanch, Miquel Fiol, et al. 2019. "Effect of a High-Fat Mediterranean Diet on Bodyweight and Waist Circumference: A Prespecified Secondary Outcomes Analysis of the PREDIMED Randomised Controlled Trial." *The Lancet Diabetes and Endocrinology*. <a href="https://doi.org/10.1016/">https://doi.org/10.1016/</a> S2213-8587(19)30074-9.
- Feinman RD, et al (2015). "Dietary carbohydrate restriction as the first approach in diabetes management: Critical review and evidence base." Nutrition, 31(1):1–13.
- Hallberg, S. et al (2019). "Reversing Type 2 Diabetes: A narrative review of the evidence" Nutrients 11:766
- Hopkins, MD, Taylor, R & Lean M (2019) "The DiRECT principles: giving Type 2 diabetes remission programmes the best chance of success". DiabeticMedicine. DOI: 10.1111/dme.14126
- Lean, M et al. (2018). "Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster randomised trial." The Lancet, Volume 391, Issue 10120, 541 551.
- Xin, Y, Taylor, R et al (2019). "Within-trial cost and 1 year cost-effectiveness of the DiRECT/Couterweight-Plus weight management porgramme to achieve remission of type 2 diabetes. The Lancet, vol 7 169-172