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Research: Educational and Psychological Issues

Acceptability of a very-low-energy diet in Type 2


diabetes: patient experiences and behaviour regulation

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Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomised controlled trials

 OPEN ACCESS

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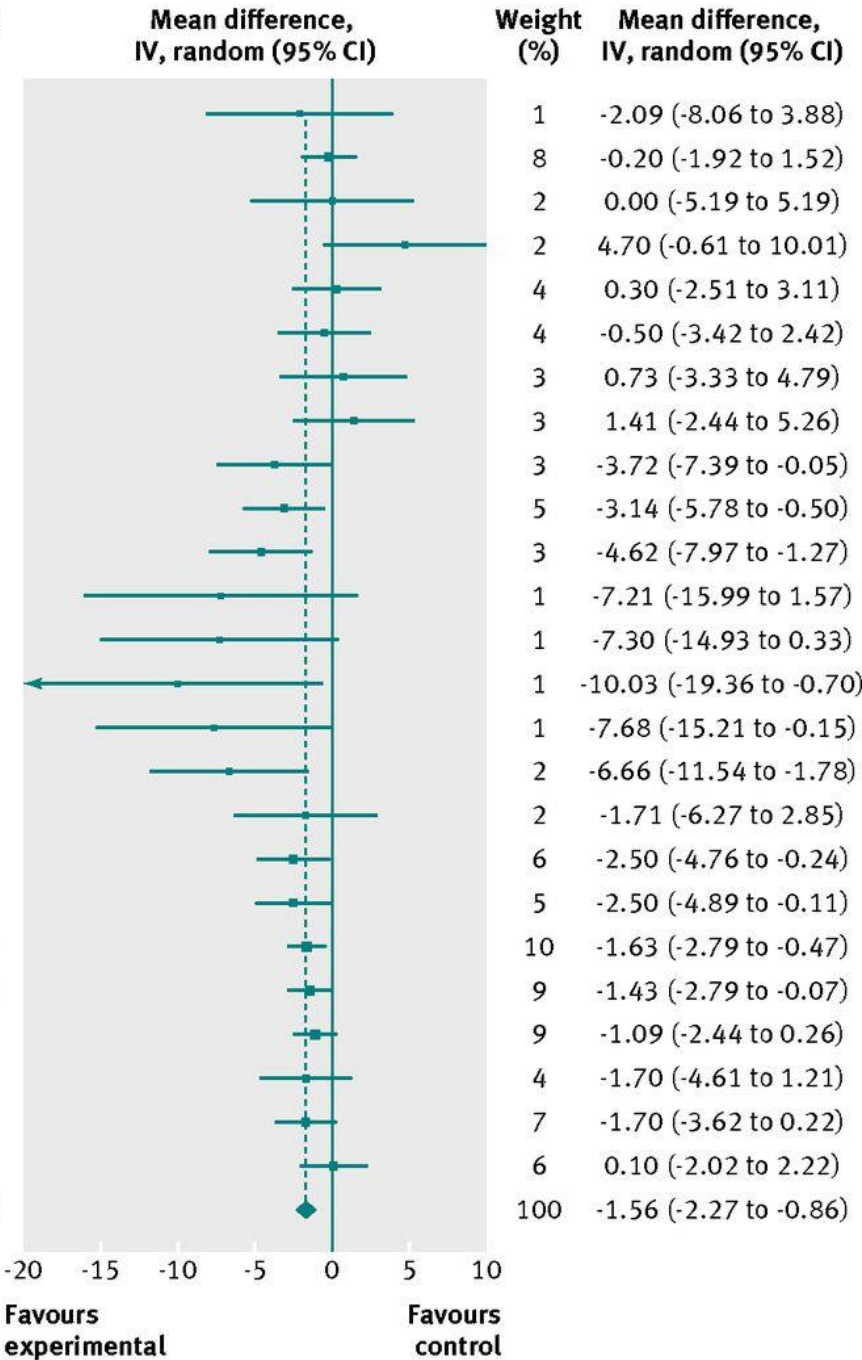
- 45 trials, N = 7788
- Obese adults with $\geq 5\%$ weight loss within 24 months
- Interventions: behavioural, nutritional & pharmacological
- Outcome = weight change from baseline
- RCTs

Interventions to support weight loss maintenance

Dombrowski, S. U., Knittle, K., Avenell, A., Araújo-Soares, V., & Sniehotta, F. F. (2014). Long term maintenance of weight loss with non-surgical interventions in obese adults: Systematic review and meta-analyses of randomised controlled trials. *BMJ*, 348.

Study or subgroup	Experimental		Control	
	Mean (SD)	Total	Mean (SD)	Total
Baum 1991	-3.63 (9.84)	15	-1.54 (6.49)	15
Cussler 2008	0.40 (5.00)	52	0.60 (4.00)	55
Harvey-Berino 2002 - FIPS	-10.40 (6.30)	32	-10.40 (9.30)	14
Harvey-Berino 2002 - Int	-5.70 (5.90)	30	-10.40 (9.30)	14
Harvey-Berino 2004 - FIPS	-3.90 (5.90)	77	-4.20 (7.90)	39
Harvey-Berino 2004 - Int	-4.70 (6.90)	77	-4.20 (7.90)	39
Kramer 1986 - WF	5.40 (5.81)	28	4.67 (6.58)	14
Kramer 1986 - SF	6.08 (4.72)	29	4.67 (6.57)	14
Perri 1984a	-5.81 (7.26)	26	-2.09 (5.03)	17
Perri 1984b	-7.50 (7.85)	48	-4.38 (5.23)	52
Perri 1986	1.54 (6.26)	35	6.16 (7.61)	32
Perri 1988 - BC	-12.88 (12.44)	19	-5.67 (6.90)	4
Perri 1988 - BCA	-12.97 (7.63)	18	-5.67 (6.90)	4
Perri 1988 - BCAS	-15.70 (14.29)	19	-5.67 (6.90)	4
Perri 1988 - BCS	-13.35 (7.37)	19	-5.67 (6.90)	4
Perri 2001 - PST	-10.80 (8.65)	23	-4.14 (4.86)	8
Perri 2001 - RPT	-5.85 (6.39)	20	-4.14 (4.86)	7
Perri 2008 - F2F	1.20 (5.47)	83	3.70 (6.22)	40
Perri 2008 - Phone	1.20 (5.94)	72	3.70 (6.22)	39
Sherwood 2013	0.77 (5.99)	210	2.40 (6.17)	209
Svetkey 2008 - F2F	-6.16 (7.66)	341	-4.73 (7.25)	170
Svetkey 2008 - Int	-5.82 (7.56)	347	-4.73 (7.25)	171
Wing 1996	3.90 (5.28)	23	5.60 (5.22)	27
Wing 2006 - F2F	1.30 (6.00)	105	3.00 (5.70)	53
Wing 2006 - Int	3.10 (7.50)	104	3.00 (5.70)	52
Total (95% CI)		1852		1097

Test for heterogeneity: $\tau^2=0.94$, $\chi^2=37.39$, $df=24$, $P=0.04$, $I^2=36\%$
Test for overall effect: $z=4.33$, $P<0.001$





- open-label, cluster-randomised trial at 49 primary care practices in Scotland and England
- N=306 participants were aged < 66 years diagnosed with type 2 diabetes within the previous 6 years, and had a BMI of 27–45 kg/m².
- 1:1 randomisation stratified to maintain balance for practice list size (>5700 or ≤5700) across intervention groups within each study region.
- Diabetes UK funded

Lean MEJ, Leslie WS, Barnes AC, Brosnahan N, Thom G, McCombie L, Peters C, Zhyzhneuskaya S, Al-Mrabeh A, Hollingsworth KG, Rodrigues AM, Rehackova L, Adamson AJ, Sniehotta FF, Mathers JC, Ross HM, McIlvenna Y, Stefanetti R, Trenell MI, Welsh P, Kean S, Ford I, McConnachie A, Sattar N & Taylor R. (2018). Primary care weight-management for type 2 diabetes: the cluster-randomised Diabetes Remission Clinical Trial (DiRECT). *The Lancet*, 391, p541–551.



Intervention

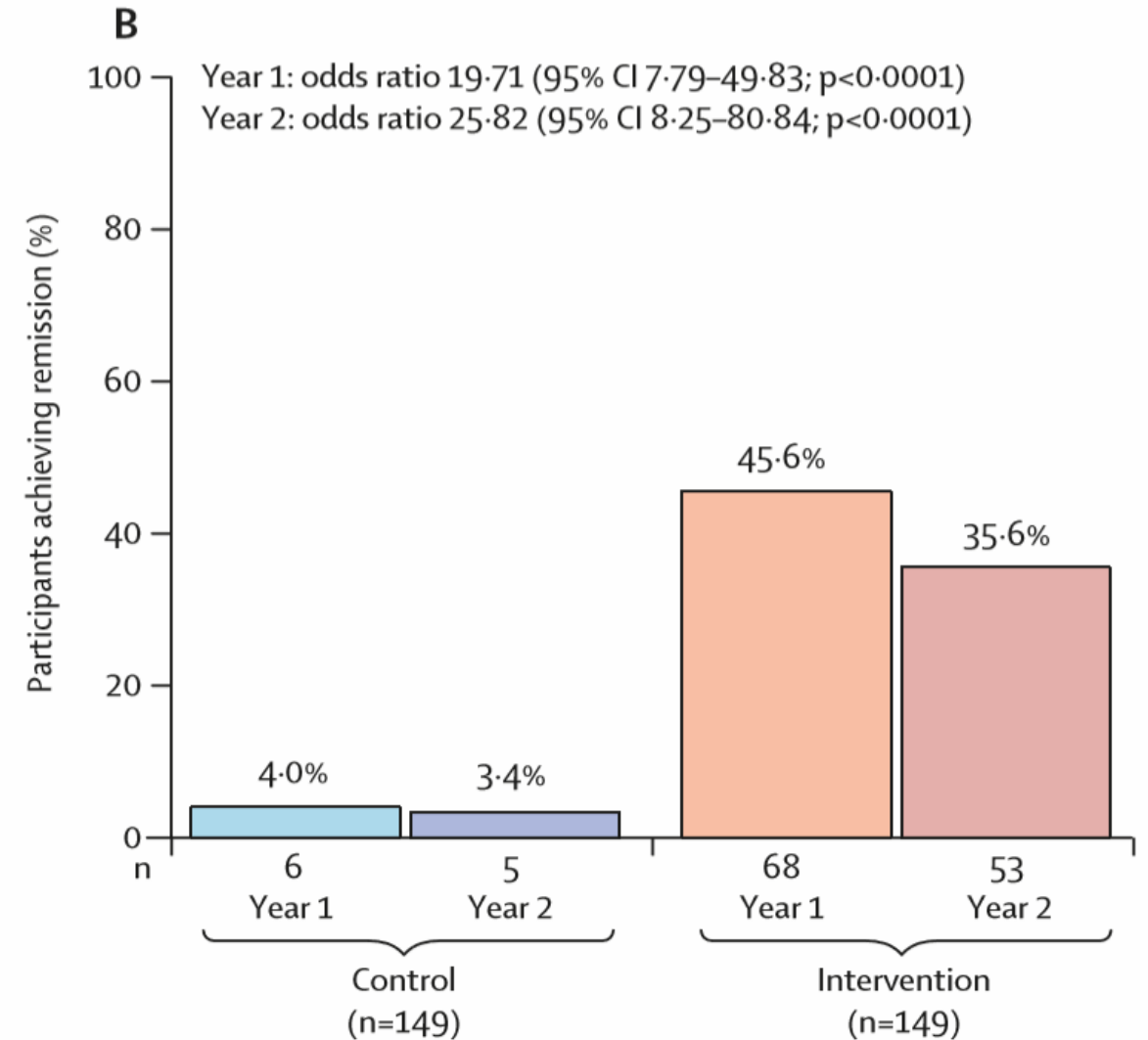
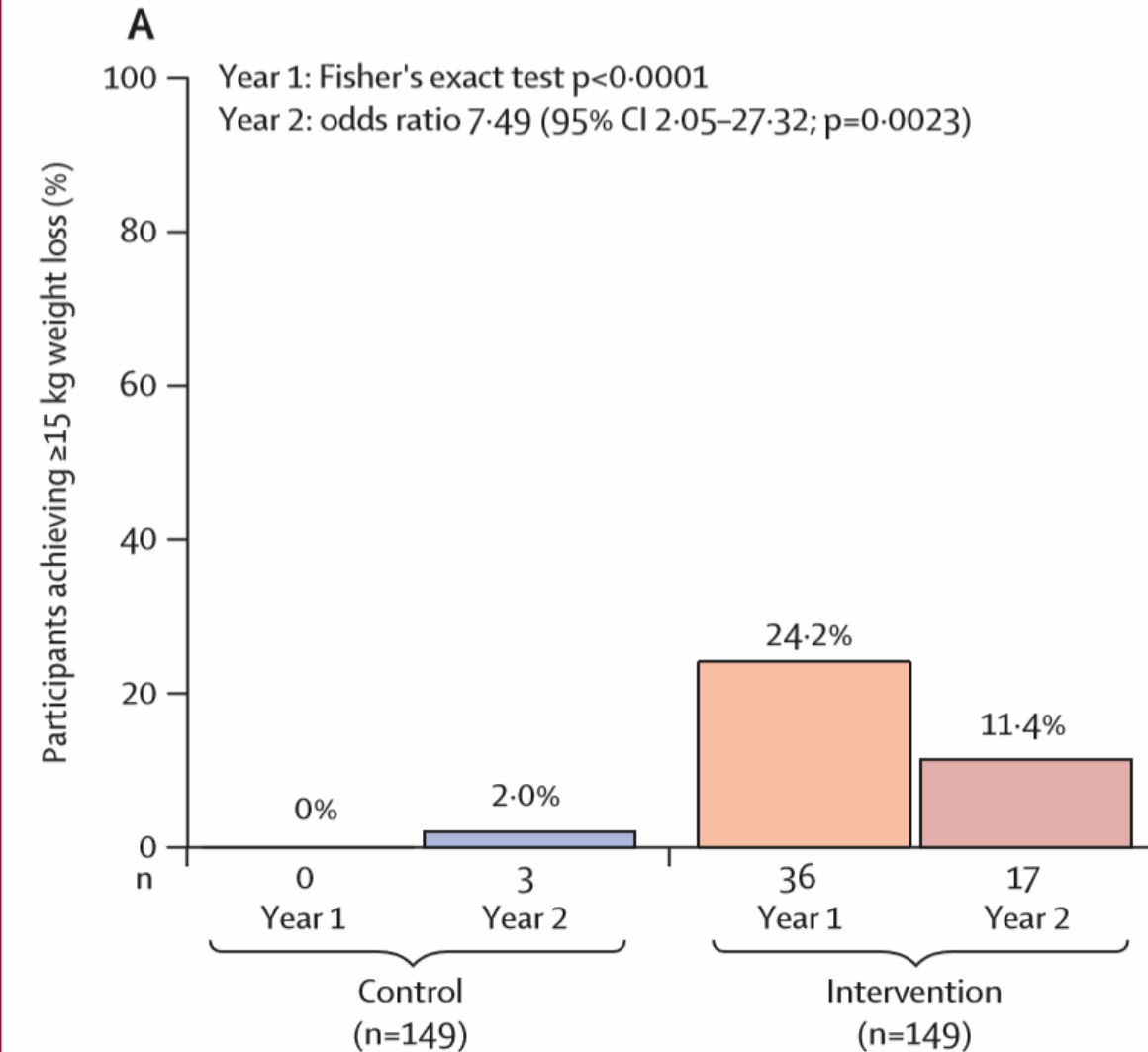


- Counterweight-Plus - aim of achieving & maintaining at least 15 kg weight loss
- **Total diet replacement** - low energy formula diet (825–853 kcal/day) for 3M (extendable up to 5M), **followed by structured food reintroduction** of 2–8 weeks +ongoing structured support with **monthly visits**.
- **All oral antidiabetic & antihypertensive drugs discontinued on day 1 .**
- **Participants encouraged to maintain usual physical activities during total diet replacement.**
- Step counters provided at the start of food reintroduction, **physical activity strategies introduced**, to help participants in the intervention group to **reach and maintain their sustainable maximum—up to 15 000 steps/day**.



- Evidence based
- Flexible
- Reduces points of choice for participants
- DiRECT provides additional reinforcements (e.g., Diabetes remission and discontinuation of drugs; rapid visible effects)
- Supports structured food reintroduction of 2–8 weeks
- Ongoing structured programme with monthly visits for long-term weight loss maintenance.
- Uses evidence based behaviour change techniques

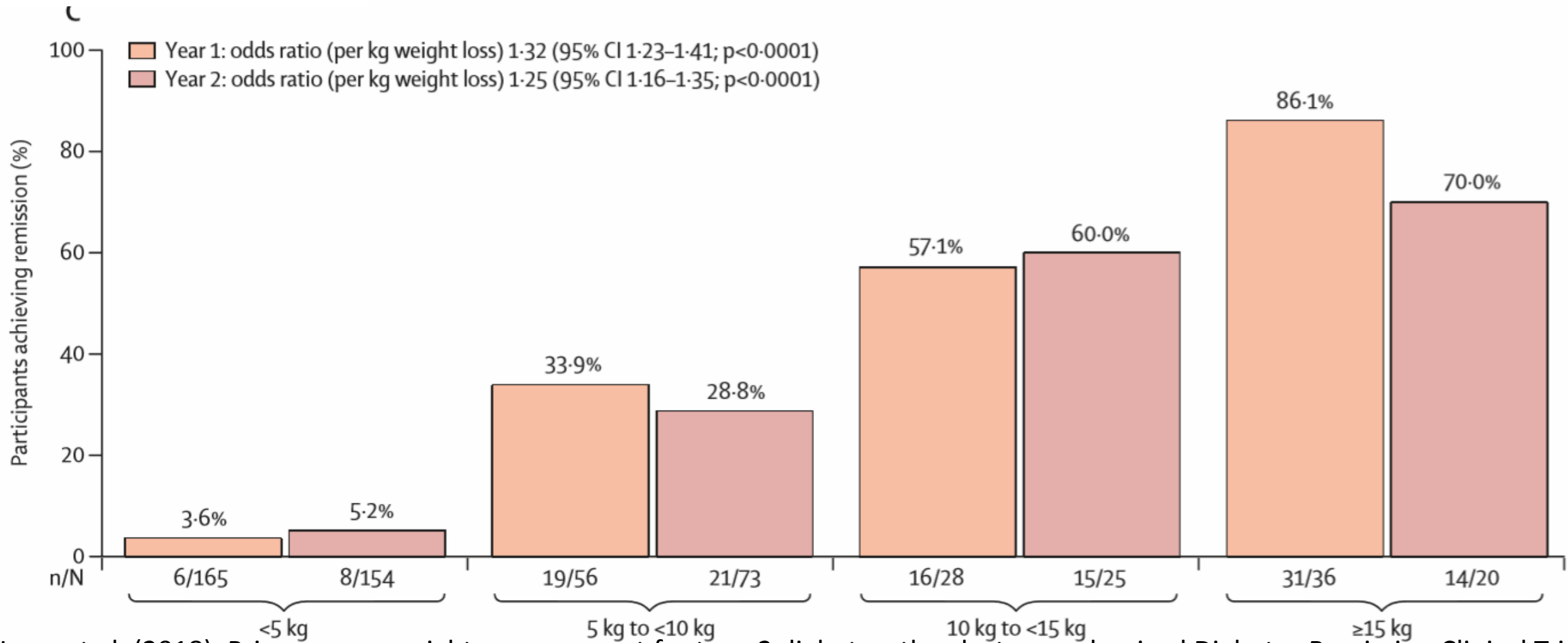
Outcomes at 12M and 24M



Lean et al. (2018). Primary care weight-management for type 2 diabetes: the cluster-randomised Diabetes Remission Clinical Trial (DiRECT). *The Lancet*.

Lean et al., (2019) Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *Lancet Diabetes Endocrinol*

Weight loss and remission



Lean et al. (2018). Primary care weight-management for type 2 diabetes: the cluster-randomised Diabetes Remission Clinical Trial (DiRECT). *The Lancet*.

Lean et al., (2019) Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *Lancet Diabetes Endocrinol*

Delivering DiRECT: Implementation context

I was scared, I'll be quite honest. You know, you're talking about taking these patients off their medication erm and then replacing their diet with soups and shakes to the tune of 800 calories a day and you're thinking my god, is this going to work, are we going to get a lot of people who are unwell. But, you know, we bit the bullet and we went with it and it's been good. It's been good, but yeah, it was a bit scary and I don't mind admitting that. I've been a practice nurse for 35 years and the thought of removing somebody off their diabetic medication was scary stuff.

HCP 3 Tyneside, 4 participants



Thinking about the intervention delivery, how did you find the following:

Stopping all oral anti-diabetic/oral-hypertensive medications at the start of the weight loss period?

(1 = Not challenging at all - 5 = Extremely challenging)

N	MED	Min	Max
10	2	1	3

Participant perspective

- Motivation
 - Diabetes Remission
 - Weight loss
 - Live without drugs
 - Focus on positive outcome
- Satisfaction with Outcomes
 - Quick visible success (rather than uncertain long term health outcomes)
 - Normalisation of glycaemic control
- Confidence
 - Experience of regaining control as powerful motivator
 - Positive effect on emotions and wellbeing
- Acceptability
 - Positive response to total diet replacement and formula diet
- Maintenance
 - Supported structured food re-introduction
 - Evidence based maintenance support

GPs to prescribe very low calorie diets in hope of reversing diabetes

NHS prevention programme in England to invite 5,000 people with type 2 to take part in trial

Sarah Boseley Health editor

Fri 30 Nov 2018 06.01 GMT



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▲ The NHS announcement followed a smaller trial of a VLCD that proved to be more successful than expected.
Photograph: Peter Byrne/PA

Thousands of people are to be offered a very low calorie diet (VLCD) by their GPs in the hope of reversing their type 2 diabetes, [NHS](#) England has announced.

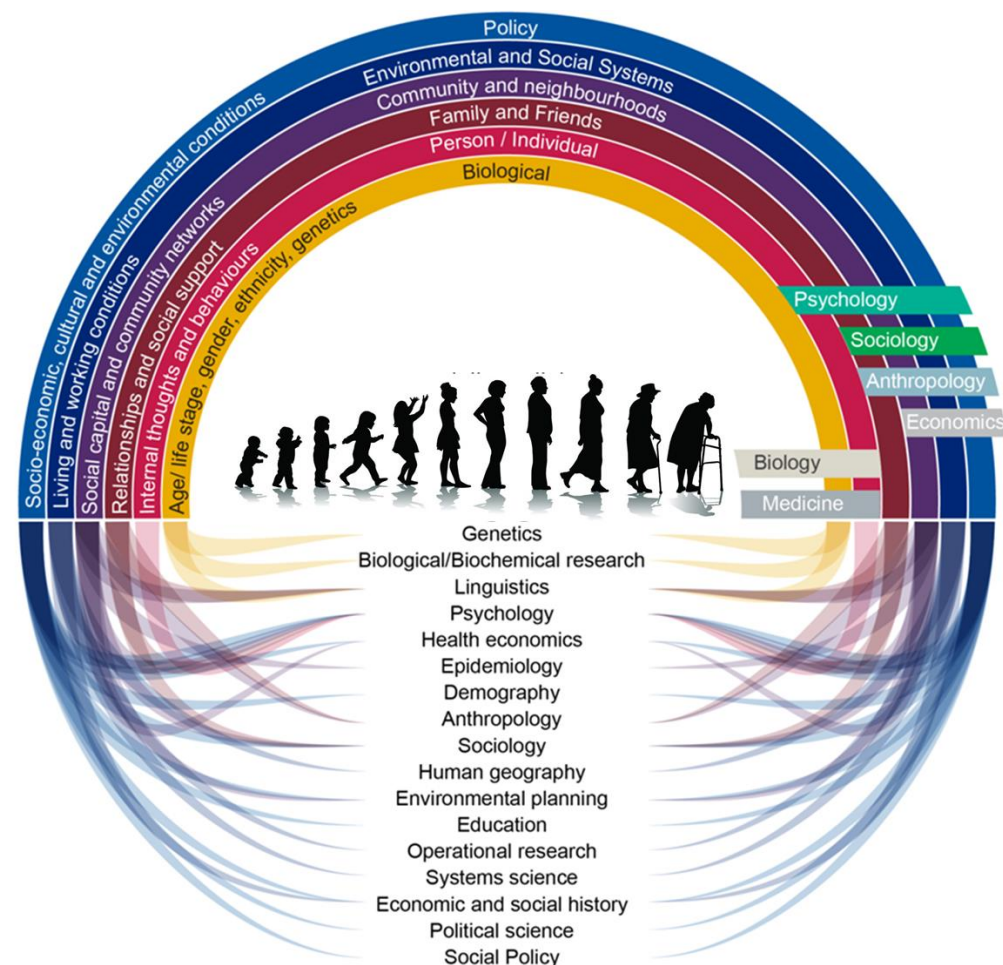
The 800-calories-a-day regimen, made up of soups and shakes, has been shown to help people lose excess weight that has caused fat to build up around their internal organs including the pancreas, leading to type 2 diabetes. About 10% of the NHS budget is spent on treating diabetes, which can have serious complications including blindness and the need for

theguardian



3 generalising beyond the DiRECT experience

Behavioural Science Strategy



Public Health England (2018) Improving Lives: Applying behavioural and social sciences to improve population health and wellbeing in England. Sniehotta FF, Araújo-Soares V, Brown J, Kelly MP, Michie S & West R (2017). Complex systems and individual-level approaches to population health: a false dichotomy? The Lancet Public Health, 2 (9): e396–e397.

Reflections for Cancer Prevention

- The importance of thorough intervention development
- Negative associations with both weight management and cancer might lead to disengagement
- Offering a positive evidence based approach to regain control over weight and health might be welcome
- Implementation features in DiRECT
 - Strong embedding in primary care services
 - Integrated evidenced based intervention package
 - Food reintroduction, weight loss maintenance support
- The option of refreshers