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

RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Lean ME, 2019	RCT	149	+	+	?	?

Characteristics of studies

Lean ME, 2019

Population	1. Other exclusion criteria were severe or unstable heart failure, participation in any other trial, substance misuse, known cancer, myocardial infarction within the previous 6 months, learning difficulties, current treatment with anti-obesity drugs, eating disorders or purging behaviours at any time, pregnancy or consideration of pregnancy, hospital admission for depression at any time, and current use of anti psychotic drugs. 2. 13 DiRECT was designed to test an integrated weight- management programme delivered in primary care, with an initial period of effective weight loss (including use of low-calorie formula-based total diet replacement), stepped food reintroduction with emphasis on energy balance, and then structured support for weight loss maintenance with provision for relapse management. 3. Eligible participants were aged 20-65 years, had been diagnosed with type 2 diabetes within the previous 6 years, and had a BMI of 27-45 kg/m¬≤.
Intervention	1. 13 DiRECT was designed to test an integrated weight- management programme delivered in primary care, with an initial period of effective weight loss (including use of low-calorie formula-based total diet replacement), stepped food reintroduction with emphasis on energy balance, and then structured support for weight loss maintenance with provision for relapse management. 2. The intervention programme (Counterweight-Plus), delivered entirely within a routine primary care setting by a trained NHS dietitian or nurse (as available locally), consisted of total diet replacement (825-853 kcal per day formula diet) for 3-5 months (flexible duration to allow for individual goals and circumstances), stepped food reintroduction (6-8 weeks), and then structured support for weight-loss maintenance. 3. Randomisation and masking GP practices that agreed to participate were randomly assigned (1:1) by the Robertson Centre for Biostatistics (University of Glasgow, Glasgow, UK), independently of the clinical research team and via a computer-generated list, to provide either an evidence-based weight manage- ment programme (Counterweight-Plus; intervention) or best-practice care in accordance with

	guidelines (control).
Outcomes	1. Secondary outcomes were quality of life, as measured by visual analogue scale, and general wellbeing by Health Utility Score, both from the three-level EuroQol 5 Dimensions (EQ-5D-3L); serum lipids (triglycerides, HDL cholesterol, and total cholesterol); and physical activity. 2. Other exclusion criteria were severe or unstable heart failure, participation in any other trial, substance misuse, known cancer, myocardial infarction within the previous 6 months, learning difficulties, current treatment with anti-obesity drugs, eating disorders or purging behaviours at any time, pregnancy or consideration of pregnancy, hospital admission for depression at any time, and current use of anti psychotic drugs. 3. The coprimary outcomes assessed at 24 months were a reduction in bodyweight of 15 kg or more, and remission of diabetes, defined as HbA 1c less than 6¬∑5% (<48 mmol/mol) after withdrawal of antidiabetes drugs at baseline (independent of status at 12 months).

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomisation and masking GP practices that agreed to participate were randomly assigned (1:1) by the Robertson Centre for Biostatistics (University of Glasgow, Glasgow, UK), independently of the clinical research team and via a computer-generated list, to provide either an evidence-based weight manage- ment programme (Counterweight-Plus; intervention) or best-practice care in accordance with guidelines (control). 2. Allocation was concealed from the study statisticians; participants, carers, and study research assistants were aware of allocation. 3. Practices were randomly assigned (1:1) via a computer-generated list to provide an integrated structured weight-management programme (intervention) or best-practice care in accordance with guidelines (control), with stratification for study site (Tyneside or Scotland) and practice list size (>5700 or ,â§5700 people).
Allocation concealment	low	1. Allocation was concealed from the study statisticians; participants, carers, and study research assistants were aware of allocation. 2. The study statisticians (AM and C-MM) were masked to treatment allocation for the analysis. 3. Because of the nature of the intervention, participants, carers, and research assistants who collected outcome data were aware of group allocation.
Blinding of participants and personnel	high/unclear	1. Allocation was concealed from the study statisticians; participants, carers, and study research assistants were aware of allocation. 2. The study statisticians (AM and C-MM) were masked to treatment allocation for the analysis. 3. Because of the nature of the intervention, participants, carers, and research assistants who collected outcome data were aware of group allocation.
Blinding of outcome assessment	high/unclear	1. Allocation was concealed from the study statisticians; participants, carers, and study research assistants were aware of allocation. 2. Because of the nature of the intervention, participants, carers, and research assistants who collected outcome data were aware of group allocation. 3. The study statisticians (AM and C-MM) were masked to treatment allocation for the analysis.

References

1. Lean ME et al. 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 2019. 5(6); 344-355 PMID: 24731672