

Investigating the effect of full meal provision on weight loss compared to self-directed dieting behaviour

Submission date 02/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/05/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Investigating the effect of full meal provision on weight loss compared to self-directed dieting behaviour: an open-label randomised parallel study over 12 weeks

Acronym

Diet1

Study objectives

Providing energy controlled meals results in greater weight loss than following self-directed dieting behaviour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Hull, Department of Sports, Health and Exercise Sciences Ethics Committee, 19/10/2010

Study design

Interventional open-label randomised parallel study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Overweight and obesity

Interventions

1. Energy-controlled delivered meals
2. Self-directed delivered meals both of which supported by a dietitian

The trial will aim to provide an energy deficit in each arm of 600 kcal per day in line with consensus recommendations for weight loss. The meal provision arm will be provided by Diet Chef as preprepared meals and snack; the reference or control arm will consist of a freely available diet plan based on healthy eating and a 600 kcal per day energy deficiency. Subjects will be screened at enrollment following giving consent to take part in the study. Subjects will be then randomly allocated to either weight loss strategy with the support of a dietitian.

Both treatments will be for 12 weeks and follow up will be for this period; at the end of the study subjects will be offered advice on continuing weight management by the study dietitian and signposted to other services as necessary.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Weight loss at 12 weeks

Key secondary outcome(s)

Health status:

1. EQ-5D, measured at each visit
2. IWQoL, measured at each visit
3. MTQ, measured at each visit
4. Rotter's Locus of Control, measured at each visit
5. Waist circumference and body volume, measured at the screening visit and end of the study (12 weeks)

Completion date

31/05/2011

Eligibility

Key inclusion criteria

1. Presenting weight of a body mass index (BMI) of between 27 and 35 kg/m²
2. Individuals expressing a wish to try to lose weight
3. Male or female aged between 30 and 70 years
4. No history of diabetes
5. No history of eating disorders
6. Not taking medication likely to lead to weight gain or loss, e.g. steroids, beta blockade, diuretics etc.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Bariatric surgery either in planning or in history
2. Planning or currently pregnant
3. Food allergies
4. Vegetarians and vegans
5. Individuals not willing to commit to trying to lose weight for 3 months/12 weeks

Date of first enrolment

04/01/2011

Date of final enrolment

31/05/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Diet Chef Ltd

Funder(s)

Funder type
Industry

Funder Name
Diet Chef Ltd (UK)

Funder Name
Scottish Enterprise (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration