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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
Michael White Diabetes Centre
220-232 Anlaby Road
Hull
United Kingdom
HU3 2RW

Additional identifiers

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

Primary study design
Interventional

Study design
Interventional open-label randomised parallel study

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/m^2
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