

# 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

**Registration date**

10/03/2011

**Overall study status**

Completed

**Last Edited**

23/05/2017

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please contact Dawn Wood, HONEI, University of Hull at d.wood@hull.ac.uk to request a patient information sheet

## 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 measure**

Weight loss at 12 weeks

**Secondary outcome measures**

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)

**Overall study start date**

04/01/2011

**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<sup>2</sup>
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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120 (80 female and 40 males)

**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**

England

United Kingdom

**Study participating centre**

**Michael White Diabetes Centre**

Hull

United Kingdom

HU3 2RW

**Sponsor information****Organisation**

Diet Chef Ltd

**Sponsor details**

c/o Kevin Doran

Rosewell House

2 Harvest Drive

Newbridge

Edinburgh

United Kingdom

EH28 8QJ

**Sponsor type**

Industry

**Website**

<http://www.dietchef.co.uk/>

**Funder(s)****Funder type**

Industry

**Funder Name**

Diet Chef Ltd (UK)

**Funder Name**

Scottish Enterprise (UK)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration