

Pilot randomised controlled trial to assess the use of food diaries and pedometers on the glycaemic control and weight in people with type 2 diabetes requiring insulin that are obese

Submission date 17/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/10/2011	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Using food diaries and pedometers as tools for empowering people to make lifestyle changes that will encourage a reduction in their weight and improve their glycaemic control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Barnsley Research Ethics Committee. Date of approval: 06/12/2006 (ref: 06/Q2304/44)

Study design

Pilot, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes mellitus - type 2

Interventions

Intervention schedule:

Week 1: All participants kept a food and pedometer diary

Week 2 to 13: Participants were in randomised groups (see below for details)

Week 14: All participants kept a food and pedometer diary

Participants were randomly assigned to the following four groups:

Group 1: Pedometer. Participants were asked to use a pedometer and record the daily number of steps, and at the end of the week, to review what they had completed, and maybe to try to increase it

Group 2: Food Diary. Participants were asked to complete a food diary on a daily basis, and at the end of the week, to review it and see if they could make dietary changes

Group 3: Food Diary and pedometer. Participants were asked to complete a food and pedometer diary on a daily basis, and at the end of the week, to review it and see if they could make changes
Group 4: Control. Participants did not keep a food diary or pedometer diary

A dietitian undertaking the research instructed the participants on the use of food diaries and pedometers. Participants met the trial staff at the initial meeting and then every 4 weeks.

Total duration of follow-up: 14 weeks

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Recruitment and retention rates

Secondary outcome measures

The following were assessed at baseline and week 14:

1. HbA1c
2. Serum lipids
3. Blood pressure
4. Weight
5. BMI
6. Waist circumference
7. Percentage body fat

Overall study start date

01/01/2007

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Both male and female patients, no age limits
1. Diabetes mellitus - type 2
2. Requiring insulin treatment
3. Obese (Body Mass Index [BMI] greater than 30)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

32

Key exclusion criteria

1. Hypothyroid
2. Anyone using anti-obesity medication

Date of first enrolment

01/01/2007

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Dietetics & Nutrition

Barnsley

United Kingdom

S75 2EP

Sponsor information

Organisation

University of York (UK)

Sponsor details

York Trials Unit

Heslington

York

England

United Kingdom

YO10 5DD

+44 (0)1904 321340

djt6@york.ac.uk

Sponsor type

University/education

Website

<http://www.york.ac.uk>

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (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