

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	☐ Prospectively registered
Registration date 10/07/2008	Overall study status Completed	☐ Protocol
Last Edited 13/10/2011	Condition category Nutritional, Metabolic, Endocrine	☐ 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

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Additional identifiers

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)

Primary study design

Interventional

Study design

Pilot, randomised controlled trial

Study type(s)

Not Specified

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(s)

Recruitment and retention rates

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre
Department of Dietetics & Nutrition
Barnsley
United Kingdom
S75 2EP

Sponsor information

Organisation
University of York (UK)

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

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration