ISRCTN31392913 https://doi.org/10.1186/ISRCTN31392913

Walking away from diabetes: structured education versus written information for individuals with high risk of developing type 2 diabetes

Submission date
16/07/2009

Recruitment status
No longer recruiting

Registration date
23/09/2009

Overall study status
Completed

Last Edited
21/02/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Melanie Davies

Contact details
Leicester Diabetes Centre (Broadleaf)
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE1 4PW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LNR CLRN 10343

Study information

Scientific Title
Walking away from type 2 diabetes: a cluster-randomised controlled trial to investigate the effect of structured education on walking activity in those with a high risk of developing type 2 diabetes

Study objectives
A pragmatic structured education programme aimed at promoting walking activity initiates long-term increases in physical activity in individuals identified through a risk score as having an increased risk of developing type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 02/03/2009, ref: 09/H0408/32. A substantial amendment (1.0) was approved on the 21/05/2009 and a second amendment (2.0) is pending as of 17/07/2009

Study design
Interventional cluster-randomised single centre controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions
Experimental arm (lifestyle counselling):
The lifestyle counselling (a group-based structured educational programme to promote physical activity) in the experimental arm is 3.5 - 4 hours at baseline. All individuals will be invited to attend annual group-based sessions (of the education programme) during the trial period. These follow-up programmes will be designed to help participants interpret and analyse their annual

biochemical and anthropometric follow-up data, review progress and goals and respond to issues, queries and barriers; the main objectives of the programme will also be reinforced. Each follow-up programme will last two hours and will be conducted after the participant's annual clinical measurement session. All participants will also receive telephone contact at 6 months after the initial educational programme and at 6 months after each annual follow-up session where motivational interviewing techniques will be employed to review progress.

Control arm:
Written information (booklet) on risk factors for type 2 diabetes and cardiovascular disease (CVD) and how physical activity can be used to prevent these conditions.

Follow-up measurement sessions will be conducted at 12, 24 and 36 months (for both intervention arms).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in ambulatory activity (walking); measured at 0, 12, 24 and 36 months using:
1. A uniaxial accelerometer
2. International Physical Activity Questionnaire (IPAQ)

Secondary outcome measures
Measured at 0, 12, 24 and 36 months:
1. Light-, moderate- and vigorous-intensity physical activity, measured using a uniaxial accelerometer
2. Time spent in sedentary activities assessed by International Physical Activity Questionnaire (IPAQ)
3. Fasting and 2-hour post-challenge plasma glucose, measured by venous sampling
4. Glycosylated haemoglobin (HbA1c), measured by venous sampling
5. Advanced glycation end products, measured by a dermal spectroscopic measurement technique (SAGE, VeraLight, USA)
6. Fasting and 2-hour post-challange plasma insulin, measured by venous sampling
7. Adipokines (leptin, interleukin 6 and tumour necrosis factor alpha), measured by venous sampling
8. C-reactive protein, measured by venous sampling
9. Standard anthropometric variables (including weight, body mass index [BMI], body fat %, waist circumference)
10. Visceral adiposity (sub-set of participants), measured by single section abdominal magnetic resonance imaging (MRI) scan
11. Muscle mass (sub-set of participants), measured by whole body dual energy X-ray absorptiometry (DEXA) scan
12. Illness perceptions and efficacy beliefs, measured using the Brief Illness Perceptions Questionnaire and 100% Confidence Rating scale (exercise self-efficacy)
13. Health related quality of life, measured using the EQ-5D
14. Depression, measured using the Hospital Anxiety and Depression Scale (HADS)

Overall study start date

01/09/2009

Completion date
30/05/2014

Eligibility

Key inclusion criteria
1. Aged 18 years and older, either sex
2. High risk of developing type 2 diabetes as identified through a risk score

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
804

Key exclusion criteria
1. Diagnosed diabetes
2. Taking steroid medication
3. Serious chronic illness preventing participation in trial
4. Unable to speak English

Date of first enrolment
01/09/2009

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester General Hospital
Leicester

United Kingdom
LE1 4PW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Collaborations for Leadership in Applied Health Research and Care (CLAHRC)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013		Yes	No
Results article	results	23/07/2015		Yes	No
Results article	results	13/01/2017		Yes	No