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

Submission date	Recruitment status	Prospectively registered		
16/07/2009	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/09/2009	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/02/2018	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 summaryNot 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