

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	<input type="checkbox"/> Prospectively registered
Registration date 23/09/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/02/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Interventional cluster-randomised single centre controlled trial

Study type(s)

Prevention

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(s)

Change in ambulatory activity (walking); measured at 0, 12, 24 and 36 months using:

1. A uniaxial accelerometer
2. International Physical Activity Questionnaire (IPAQ)

Key secondary outcome(s)

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-challenge 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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

Leicester General Hospital

Leicester

United Kingdom

LE1 4PW

Sponsor information**Organisation**

University Hospitals of Leicester NHS Trust (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

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