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Prevention of diabetes using structured education and continuous support programme in those with pre-diabetes in a multi-ethnic population

Submission date
06/06/2008

Recruitment status
No longer recruiting

Registration date
11/07/2008

Overall study status
Completed

Last Edited
23/03/2018

Condition category
Signs and Symptoms

[X] Prospectively registered
[X] 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00677937

Protocol serial number
UHLPRE01

Study information

Scientific Title
Prevention of diabetes using structured education and continuous support programme in those with pre-diabetes in a multi-ethnic population

Acronym
PREVENTION

Study objectives
Structured education and continuous support programme reduce the incidence of diabetes in a multi-ethnic population with pre-diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Parallel controlled cluster randomised trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre-diabetes

Interventions
Intervention arm:
Six hours of education within one month of diagnosis, either as one full day, two half days, or 4 x 2 hours (delivered with interpreters for participants whose first language is not english); follow-up will be for three years with clinical assessments at 6, 12, 24, 23 months. Continuous support will be regular telephone contact, website and additional written material.

Control arm:
Standard care as per national guidelines currently general lifestyle advice and written material follow-up will be for three years with clinical assessments at 6, 12, 24, 23 months.

Intervention Type
Behavioural

Primary outcome(s)
Reduction in the incidence of diabetes at three years

Key secondary outcome(s))

1. Reduction in cardiovascular disease (CVD) risk (assessed using the current Framingham risk equation, standard for CVD risk assessment for General Practice in the UK), measured at baseline and 6, 12, 24, 23 months
2. Reduction in HbA1c, fasting and two-hour glucose, measured at baseline and 6, 12, 24, 23 months

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 40 - 70 years (if White European)
2. Aged 25 - 70 years (if South Asian)
3. Able to attend group education sessions

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unable to give informed consent
2. Diagnosis of diabetes

Date of first enrolment
01/09/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Centre (Broadleaf)
Leicester

United Kingdom
LE5 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 of Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RG-PG-0606-1272)

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	screening results	23/12/2014		Yes	No
Results article	baseline results	23/07/2015		Yes	No
Protocol article	protocol	20/05/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes