

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/03/2018	Condition category Signs and Symptoms	<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

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