ISRCTN80605705 https://doi.org/10.1186/ISRCTN80605705

A prevention programme for Type 2 Diabetes integrating identification, lifestyle intervention and community services

Submission date
19/08/2010

Recruitment status
No longer recruiting

Registration date
19/08/2010

Overall study status
Completed

Last Edited
26/01/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 Diabetes Mellitus (T2DM) is an increasing chronic disease affecting over 2 million people in England alone. It shortens life and consumes 10% of NHS resources. At diagnosis many have established complications involving damage to the eyes, kidneys, feet and heart. There is a need to focus efforts to prevent this devastating disease. Certain factors such as being overweight, having a family history of diabetes or heart disease, having a previous history of raised blood sugar measurement or diabetes during pregnancy increase the risk of developing diabetes later in life. People who eat a high fat diet or have high blood pressure or smoke are also at high risk. When someones blood glucose levels are higher than normal but NOT high enough for a diagnosis of diabetes, we say they have pre-diabetes (it may also be referred to as Impaired Glucose Tolerance [IGT] or Impaired Fasting Glucose [IFG]), depending on which test was used to detect it. Pre-diabetes is a better way of explaining what it means to have higher than normal blood glucose levels. It means you are more likely to develop diabetes and may already be experiencing some health problems because of it. Just like someone with diabetes, if you have pre-diabetes, you are at higher risk of heart disease and/or stroke. If you are overweight, eating a high fat diet or are not very active, you could be increasing your risks. Some people who have diabetes in their family have an added risk factor. But there are things you can do to help yourself and the Lets Prevent study is about helping us find out which of these are best. The good news is that everyone at risk of diabetes can do things to keep healthy and slow down or even stop the development of this serious disease. Recent studies have shown that lifestyle changes, such as being more active and changing your diet, could be more effective than medicines in helping to stop people developing Type 2 diabetes. But because we dont yet know which of these ways of treating people is best, we need to compare them in a research study.

Who can participate?
Patients with pre-diabetes, aged 40 - 75 if English-speaking European or 25 - 75 if South Asian

What does the study involve?
People who have been identified as at risk will be invited to visit the diabetes research team at a local venue and this visit will take around 3 hours. We will participants to come to this visit

fasting, but this does not obligate the person to take part. After an opportunity to meet the team and to ask any questions, informed consent will be taken. Following this, participants have oral glucose tolerance test (OGTT), blood tests (49ml of blood, this is the same as 10 teaspoons), body measurements, medical history, height/weight and blood pressure recorded. In between the two blood tests participants also complete a questionnaire about health, physical activity, eating habits and overall wellbeing. After this first visit, results will be analysed.
Only those with pre-diabetes enter into the main study and, depending on which GP surgery the participant attends, are randomly allocated to one of our two study groups. Group 1 is what we call the control group - receive the usual excellent care for pre-diabetes provided by their GP practice and some useful leaflets from us. Group 2 is the intensive group and will receive education sessions and continuous support to help the participant address the risks of developing diabetes. Regardless of which group the participant is in, once a year for the next 3 years, participants return for a full health screen, including an OGTT, height/weight and blood pressure readings.

What are the possible benefits and risks of participating?
We hope that all people in the study (who have already been identified as having pre-diabetes) will avoid progressing to diabetes. The information we get from this study may help us to prevent future people with pre-diabetes or at a high risk from developing the diabetes. Participants in this study will not be given any medication. Participants may suffer slight discomfort while the blood samples are being taken from their arm and some people do experience bruising after blood samples have been taken. The participants family doctor will be informed of all the results of the tests taken during the course of the study.

Where is the study run from?
The study is being conducted in Leicester, Leicestershire and Rutland (UK)

When is the study starting and how long is it expected to run for?
July 2009 to July 2014

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Stephanie Goldby
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00677937

Protocol serial number
5854

Study information

Scientific Title
A community based primary prevention programme for Type 2 Diabetes integrating identification, lifestyle intervention and community services for prevention (RCT)

Acronym
DRN 239 LETS PREVENT

Study objectives
Type 2 diabetes mellitus (T2DM) is an increasing chronic disease affecting over 2 million people in England alone, shortens life and consumes 10% of NHS resources. At diagnosis many have established complications involving damage to the eyes, kidneys, feet and heart. There is a need to focus efforts to prevent this devastating disease. One in 7 adults has pre-diabetes (PDM) with 50% developing T2DM over the next 5 - 10 years.

There is clear evidence that treating subjects with PDM with an intensive lifestyle modification programme (LSMP) dramatically reduces T2DM. However, these programmes are costly, involve intensive use of resources and are unproven in the UK. Some minority ethnic groups have a higher risk of T2DM; any LSMP would therefore need to be culturally sensitive to the UK multi-ethnic population. The objective is to test if a low cost but effective LSMP can be developed for the UK. The trialists will develop a training programme to skill healthcare professionals and non-professionals and so called 'lay' educators to deliver the LSMP. Benefits of lay educators are patient involvement in a patient centred service and the contribution to building capacity within the NHS workforce.

The trialists will develop a simple self-assessment tool to identify those at highest risk of T2DM. We will conduct a clinical trial, testing the LSMP in 44 practices and 748 patients. The practices will be randomised to either a control or intervention 'arm'. Control practices will give information to patients at risk in line with current best practice. Participants in the intervention practices will be invited to the LSMP and will receive 6 hours of group education and then followed for 3 years. The LSMP will encourage individuals to scrutinise information, ask questions, and self-manage their condition, using simple, non-technical language and visual aids. This approach has been effective in T2DM and we will use this model along with expertise in physical activity and lifestyle change.

N.B. This is part of a programme grant award which is the same NIHR programme grant as DRN131.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire and Rutland Ethics Committee, 17/11/2008

Study design
Multicentre randomised interventional prevention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2; Disease: Prevention/screening

Interventions
The PREVENTION study is a randomised controlled trial providing a structured intervention for people with pre-diabetes, and is cluster randomised at practice level to negate contamination between individual patients. These practices will be randomly assigned to either the control or intensive arm. The control arm is managed by nationally regarded standard care guidelines for the condition; currently this is reading material and general lifestyle advice provided by the participants General Practitioner or Practice Nurse. Patients in the intensive arm will be given the structured group education and a follow-up support programme.

The structure group education programme will use a modified version of the Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) programme based on published work performed locally for people with pre-diabetes. DESMOND is the only national education programme that is in line with current national guidelines for patient education. Educational sessions will consist of 1 full day (6 hrs) or 2 half days (3 hrs each). In the case of the BME where the English language is not readily spoken the sessions will be 4 x 3 hours delivered by educators and interpreters. Refresher sessions may be available for participants to actively sign up to focusing on helping with action planning and providing awareness of local activities.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Reduction in incidence of diabetes at 3 years

Key secondary outcome(s))
Change in participant's individual characteristics:
1. HBA1c
2. Blood glucose levels fasting and post-glucose load

3. Cardiovascular risk
All patients followed up at 6, 12, 24 and 36 months

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Within specified age range English Speaking European: 40 - 70 years, South Asian: 30 - 70 years
2. Able to attend educational sessions
3. Diagnosed with impaired glucose tolerance (IGT)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Diagnosed with diabetes
2. Unable to attend group education sessions

Date of first enrolment
01/06/2009

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester General Hospital
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 for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) programme

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 results	20/05/2012		Yes	No

Results article		01/01/2013	Yes	No
Results article	results	12/07/2016	Yes	No
Results article	results	01/01/2017	Yes	No
Results article	cost-effectiveness results	09/01/2017	Yes	No