ISRCTN15670600 https://doi.org/10.1186/ISRCTN15670600

The European Diabetes Prevention Study

Submission date
14/10/2005

Recruitment status
No longer recruiting

Registration date
14/10/2005

Overall study status
Completed

Last Edited
05/02/2016

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 a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Once of the main reasons why people develop T2DM is because they are overweight or obese. The increase in obesity in recent years has led to an increase in type 2 diabetes and it increasingly affects younger people as well. Many people who are overweight suffer from impaired glucose tolerance (IGT), a condition where blood sugar is raised but not enough for it to be classified as diabetes. People with IGT have a much greater risk of developing T2DM and so it is important to find an effective way of preventing this. Many studies have shown that losing weight, exercising more and eating a healthy, balanced diet all help to treat IGT and prevent it from developing into T2DM. The aim of this study is to find out whether a diet and exercise programme can help to prevent or delay the onset of T2M in people suffering from IGT.

Who can participate?
Overweight adults aged between 40 and 74 who have high blood sugar (IGT).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group take part in an intensive programme designed to change their behaviour regarding diet and exercise. This involves attending a number of sessions with a trained dietician and a physiotherapist, in order to encourage calorie restriction, healthier eating and 30 minutes of moderate aerobic exercise (cardio) every day. Participants in the second group are given written standard health promotion advice about healthy eating and physical activity. At the start of the study and then again after 12 weeks, participants in both groups have their blood sugar levels, weight and diet and exercise habits measured in order to see if there have been any changes.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Institute of Health and Society, Newcastle upon Type (UK)

When is the study starting and how long is it expected to run for?
July 2000 December 2007

Who is funding the study?
Wellcome Trust (grant reference: 057146) (UK)

Who is the main contact?
Professor Martin White
Martin.White@ncl.ac.uk

Study website
http://www.newcastle-hospitals.org.uk/hospitals/royal-victoria-infirmary.aspx

Contact information

Type(s)
Scientific

Contact name
Prof Martin White

Contact details
Institute of Health and Society
Baddiley-Clark building
Richardson Road
Newcastle upon Tyne
United Kingdom
NE2 4AX
+44 191 222 6275
Martin.White@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
057146, N0565163209

Study information

Scientific Title
Reducing the burden of non-insulin dependent diabetes mellitus: a randomised controlled trial of behavioural interventions to modify diet and physical activity in people with impaired glucose tolerance
Also from June 2011: A follow-up at 10 years of participants in the Newcastle Arm of the European Diabetes Prevention Study who remain free of type 2 diabetes at 10 years from

baseline, based of diagnoses from within the trial or subsequent General Practitioner diagnoses: to assess the difference in incidence of type 2 diabetes between the intervention and control arms of the original study

Acronym
EDIPS

Study objectives
Reducing the burden of type two diabetes. To assess the effectiveness of a diet and exercise intervention programme to prevent or delay the onset of type two diabetes in people with Impaired Glucose Tolerance (IGT).

The null hypothesis is that there will be no difference in the proportions of intervention or control group subjects progressing to develop diabetes within five years.

Please note that due to continuing follow-up the end date of this trial has been extended to 31 /07/2007. The previous anticipated end date of this trial was 31/12/2006.

Please note that as of 26/01/2009 this record was updated; due to further continuing follow-up the end date of this trial was extended to 31/12/2007. The initial anticipated end date of this trial was 31/12/2006.

Please not that from June 2011 the original EDIPS-Newcastle participants, who remained free from type 2 diabetes,have been invited to return for a follow-up assessment at ten years from their original recruitment date.

Participants for EDIPS-Newcastle were recruited from the UK. EDIPS-Newcastle is part of a European collaboration, participants in Finland have been recruited to the Finnish Diabetes Prevention study and participants in The Netherlands have been recruited to the SLIM study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Newcastle and North Tyneside NHS Joint Ethics Committee (Local Research Ethics Committee 1), 17/08/1999, ref: 99/186
2. Ethics approval for the follow-up study (EDIPS2) NRES Committee North East Newcastle and North Tyneside, 16/03/2011, ref: 11/NE/0036

Study design
Multicentre parallel design randomised controlled study. Also from June 2011 a follow-up study at 10 years.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
The study is a parallel design, randomised controlled study with one intervention arm and one control arm. Individuals with IGT are randomly allocated to receive either intensive behavioural intervention to promote dietary modification and increased physical activity or a control group which will receive minimal intervention consisting of widely available information on healthy lifestyle.

Sponsor for the follow-up study:
Newcastle upon Tyne Hospitals NHS Foundation Trust
Joint Research Office
Level 6, Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

Tel: 0191 282 5959
Fax: 0191 282 4524
e-mail: amanda.tortice@ncl.ac.uk

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 26/01/2009:
Incidence of diabetes confirmed by two OGTTs (between one and 12 weeks apart).

Previous primary outcome measure:
Changes in new diabetes confirmed on two OGGTs

Secondary outcome measures
Current secondary outcome measures as of 26/01/2009:
Changes in:
1. Weight
2. Physical activity
3. Dietary fibre intake
4. Carbohydrate intake as a percentage of total dietary energy
5. Fat intake as a percentage of total dietary energy

Previous secondary outcome measures:
1. The proportion of energy consumed from fat, protein, carbohydrates and saturated,

monounsaturated, polyunsaturated fatty acids, fibre and cholesterol
2. Physical activity
3. Glucose tolerance
4. Insulin sensitivity
5. Cardiovascular risk factors
6. Cardiovascular morbidity and mortality
7. Quality of life

Overall study start date
20/07/2000

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Have IGT, defined as a mean two-hour plasma glucose value more than 7.8 and less than 11.1 mmol/l from two Oral Glucose Tolerance Tests (OGTTs), the second conducted one to 12 weeks after the first
2. Be aged 40 to 74 years on their last birthday, either sex
3. Be overweight (Body Mass Index [BMI] more than 25 kg/m^2)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
104 recruited as of 09/09/2003

Key exclusion criteria
1. Previous diagnosis of diabetes according to World Health Organisation (WHO) 1999 criteria
2. Previous intensive treatment for IGT
3. Previous participation in a programme of vigorous physical activity

Date of first enrolment
20/07/2000

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Health and Society
Baddiley-Clark Bldg
Newcastle upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
Newcastle Primary Care Trust

Sponsor details
Benfield Road 00A
Newcastle upon Tyne
England
United Kingdom
NE6 4PF
+44 191 219 6000
alison.emslie@newacstle-pct.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.newcastlepct.nhs.uk

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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 summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2008		Yes	No
Results article	results	16/09/2009		Yes	No