

The European Diabetes Prevention Study

Submission date 14/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/02/2016	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

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). One 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 Tyne (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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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 note 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

Study type(s)

Treatment

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

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Intervention Type

Behavioural

Primary outcome(s)

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 OGTTs

Key secondary outcome(s)

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

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/m²)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes