

# The European Diabetes Prevention Study

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

## **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 OGTTs

## **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<sup>2</sup>)

**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?
<a href="#">Results article</a>	results	10/07/2008		Yes	No
<a href="#">Results article</a>	results	16/09/2009		Yes	No