# The Diabetes Risk Communication Trial (DRCT)

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
05/04/2011		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/06/2011	Completed	[X] Results		
<b>Last Edited</b> 01/12/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	[] Individual participant data		
01/12/2010	radi idollat, Metabolic, Elidoci ille			

### Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Simon Griffin

#### Contact details

Institute of Metabolic Science
Box 285
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)122 333 0315
simon.griffin@mrc-epid.cam.ac.uk

# Additional identifiers

## Protocol serial number

R100621/136

# Study information

#### Scientific Title

Effect of communicating genetic and phenotypic risk for type 2 diabetes in combination with lifestyle advice on objectively measured physical activity: a randomised controlled trial

#### Acronym

**DRCT** 

#### **Study objectives**

The primary objective of the DRCT is to assess the effects of providing:

- 1. A genetic risk estimate for type 2 diabetes in combination with standard lifestyle advice and
- 2. A phenotypic risk estimate for type 2 diabetes in combination with standard lifestyle advice on objectively measured physical activity

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee, 21/10/2010, ref: 10/H0304/78

#### Study design

Parallel-group randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Prevention

#### Health condition(s) or problem(s) studied

Type 2 diabetes/physical activity/risk communication

#### **Interventions**

Participants are randomly allocated to one of three groups:

Intervention Group A: Participants receive a genetic risk estimate for type 2 diabetes based on 23 single nucleotide polymorphisms

Intervention Group B: Participants receive a phenotypic risk estimate based on age, sex, body mass index, family history of diabetes, smoking status, and prescription of steroid or antihypertensive medication

Control Group: Participants do not receive either of the risk estimates until after they have completed follow-up

Each group will receive standard lifestyle advice, which includes general information about type 2 diabetes as well as information about how to reduce the risk of developing the disease.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Objectively measured physical activity energy expenditure over 1 week (8 weeks post-intervention), assessed using an Actiheart®

#### Key secondary outcome(s))

- 1. Self-reported diet
- 2. Self-reported weight
- 3. Intentions to be physically active and to engage in a healthy diet
- 4. Anxiety
- 5. Diabetes-related worry
- 6. Self-rated health
- 7. Self-reported sedentary behaviour
- 8. Cognitive and emotional theory-based antecedents to health behaviour change

### Completion date

11/02/2012

# Eligibility

### Key inclusion criteria

Residents of Cambridgeshire, in the east of England, born between 1950 and 1975, are potentially eligible to participate in the Fenland Study. Participants of the Fenland Study are invited to take part in the DRCT if they:

- 1. Agreed to be contacted regarding potential involvement in future studies
- 2. Provided sufficient data to calculate genetic and phenotypic risk estimates for type 2 diabetes
- 3. Wore an Actiheart® for 3 or more full days without experiencing a severe rash
- 4. Returned an Actiheart® that recorded 36 or more hours of total data

### Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

#### Key exclusion criteria

Residents of Cambridgeshire are excluded from the Fenland Study by their GP if they:

- 1. Have diagnosed diabetes
- 2. Have a medical condition with a prognosis of less than 1 year
- 3. Suffer from psychotic illness
- 4. Are pregnant or lactating
- 5. Are unable to walk unaided

After participating in the Fenland Study, participants are excluded from the DRCT if they:

- 1. Have diagnosed diabetes
- 2. Are actively participating in another study

### Date of first enrolment

11/02/2011

#### Date of final enrolment

11/02/2012

## Locations

### Countries of recruitment

**United Kingdom** 

England

Study participating centre Addenbrooke's Hospital

Cambridge United Kingdom CB2 0QQ

# Sponsor information

## Organisation

Medical Research Council (UK)

#### **ROR**

https://ror.org/03x94j517

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

Medical Research Council (UK) Ref. R100621/136

#### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## 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	29/11/2016	Yes	No
<u>Protocol article</u>	protocol	18/06/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes