

The Diabetes Risk Communication Trial (DRCT)

Submission date 05/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/06/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 01/12/2016	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
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 anti-hypertensive 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, Medical Research Committee and Advisory 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
Protocol article	protocol	18/06/2012		Yes	No