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The Diabetes Risk Communication Trial (DRCT)

Submission date 05/04/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2011	**Overall study status** Completed	
Last Edited 01/12/2016	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
11/02/2011

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

Age group

Adult

Sex
Both

Target number of participants
We aim to collect outcome data on approximately 465 participants. Thus, assuming a 20% attrition rate, we will randomise approximately 580 participants in total.

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
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
14th Floor
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Sponsor type
Research council

Website
http://www.mrc.ac.uk/index.htm

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

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?
Protocol article	protocol	18/06/2012		Yes	No
Results article	results	29/11/2016		Yes	No