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Prevention of diabetes in South Asians with impaired glucose levels: a family based clinical trial using physical activity and dietary modification

Submission date 29/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2007	**Overall study status** Completed	
Last Edited 18/03/2014	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
http://www.podosa.org/faq.html

Study website
http://www.podosa.org/index.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0501310

Study information

Scientific Title

Acronym
PODOSA

Study objectives
Current information as of 26/04/10:
Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians with impaired glucose tolerance and/or impaired fasting glucose, result in a clinically meaningful weight loss in the intervention group compared to the control group?

Initial information at time of registration:
To evaluate whether a 3-year family based programme combining weight loss and physical activity can reduce the incidence of type 2 diabetes in South Asians with impaired glucose tolerance.

Please note that as of 26/04/10, this record has been updated. All updates may be found in the relevant field with the above update date. Please also note that the anticipated end date of this trial has been extended from 31/07/11 to 31/01/13.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 27/04/10:
Scotland A Research Ethics Committee approved on the 15th of March 2007 (ref: 07/MRE10/2). Substantial amendment to protocol to change primary outcome and sample size was approved on the 29th of June 2009

Study design
Controlled cluster randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Patient information can be found in http://www.podosa.org/faq.html

Health condition(s) or problem(s) studied
Nutritional, Metabolic and Endocrine Diseases: type 2 Diabetes

Interventions
Intervention group will receive 15 contacts with trained dieticians over 3 years with the goal of reducing weight and increasing physical activity.
Control group will receive 4 contacts over 3 years to provide health information.

Current information as of 26/04/10:
Intervention and control group - 85 recruits in each group plus family volunteers.

Initial information at time of registration:
Intervention and control group - 300 recruits in each group plus family volunteers.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Current information as of 26/04/10:
Weight change at 3 years.

Initial information at time of registration:
To evaluate whether a 3-year family based programme combining weight loss and physical activity can reduce the incidence of type 2 diabetes in South Asians with impaired glucose tolerance.

Secondary outcome measures
Added 26/04/10:
1. Changes in fasting and 2-hour glucose
2. Progression to type 2 diabetes
3. Body Mass Index (BMI)
4. Waist circumference and hip circumference
5. Cost effectiveness

Overall study start date
01/08/2006

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Self-assigned ethnic group using Census 2001 categories as Indian or Pakistani
2. Normal place of residence is in Greater Glasgow & Clyde or Lothian Health board areas
3. Given informed consent
4. Impaired glucose tolerance (IGT) on oral glucose tolerance test (OGTT) at least once
5. An age of 35 or more
6. A waist size of > 90 cm (men) or > 80 cm (women)
7. No confirmed medical history of diabetes (other than gestational diabetes)

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Updated 26/04/10: 170 (At time of registration: 600 recruits with IGT [approx 300 families])

Key exclusion criteria
1. The main cook for the potential participant with IGT is unwilling to give consent to cooperate
2. A diagnosis of diabetes made on the OGTT during the screening phase of the study
3. Other disease where adherence to the intervention is contraindicated or improbable e.g. terminal illness or psychological or physical illnesses; alcohol dependency; planned or actual pregnancy; use of prescribed drugs that affect the primary outcome
4. An expectation, reported by participants or the GP, that the person will be emigrating or dying before the conclusion of the trial
5. Failure to make a commitment to stay in the study until, at least, the three year follow-up examination

Date of first enrolment
01/08/2006

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Public Health Sciences
Edinburgh

United Kingdom
EH8 9AG

Sponsor information

Organisation
The Queens Medical Research Institute (United Kingdom)

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Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
MRC National Prevention Research Initiative (UK)

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?
Results article	results	06/10/2011		Yes	No
Results article	results	22/02/2013		Yes	No
Results article	results	01/03/2014		Yes	No
Results article	results	01/12/2014		Yes	No