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

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

Plain English summary of protocol

http://www.podosa.org/faq.html

Contact information

Type(s)

Scientific

Contact name

Prof Raj Bhopal

Contact details

Public Health Sciences
University of Edinburgh
Teviot Place
Edinburgh
United Kingdom
EH8 9AG
+44 (0)131 650 3216
Raj.bhopal@ed.ac.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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 recruitmentUnited Kingdom

Scotland

Study participating centre
Public Health Sciences
Edinburgh
United Kingdom
EH8 9AG

Sponsor information

Organisation

The Queens Medical Research Institute (United Kingdom)

ROR

https://ror.org/01nrxwf90

Funder(s)

Funder type

Government

Funder Name

MRC National Prevention Research Initiative (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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Output type	Details	Date created Date adde	d 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes
Study website	Study website	11/11/2025 11/11/202	.5 No	Yes