

The Greater Green Triangle Diabetes Prevention Project

Submission date
15/01/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/01/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/10/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

GGT DPP

Study objectives

That lifestyle intervention carried out in primary health care settings reduces the risk of type two diabetes among high risk individuals [added 07/10/2008] and that the reduction in risk can be continued through telephone support.

Please note that as of 07/10/2008 the initial anticipated end date of this trial was extended from 30/11/2006 to 31/12/2007. Other minor changes to this trial record can be found under the relevant section, with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Flinders Clinical Research Ethics Committee on the 8th March 2004 (ref: 105/034).

Study design

Non-randomised intervention study (intervention group only) [added 07/10/2008] with a randomised controlled trial follow-up

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Type two diabetes

Interventions

During a 12-month period, participants undergo a series of tests at three points (at the start of the study, three months, and 12 months) and a series of six structured group counselling sessions. The first five sessions are carried out in two-week intervals and the final (i.e. sixth) session is carried out eight months from the beginning of the intervention.

Project nurses, dieticians and physiotherapists facilitate all group sessions and the duration of each session is 1.5 hours. The group sessions aim to motivate and support participants to change

their dietary and physical activity habits and to provide them with the skills and social support to set their own goals for lifestyle change.

Added 07/10/2008:

Following the initial intervention, completing participants will be randomised into telephone support (intervention) and self-care only (control). Telephone support will consist of structured phone calls conducted by trained nurses, once a month for 6 months, then every 2 months for 12 months.

Discussions during phone calls will focus on goals for lifestyle change made by participants during the initial intervention and should take approximately 15 minutes each.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Weight
2. Height
3. Waist circumference
4. Fasting plasma glucose and lipids
5. Plasma glucose after two hours oral glucose challenge
6. Blood pressure

Secondary outcome measures

1. Measures of psychological distress and general health outcomes
2. Lifestyle habits

Overall study start date

01/08/2004

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Males and females 40 to 75 years of age
2. Have a high risk of developing type two diabetes

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

345

Key exclusion criteria

1. Cancer
2. Recent myocardial infarction or stroke
3. Cognitive impairment
4. Substance abuse
5. Pregnancy
6. A previous type two diabetes diagnosis

Date of first enrolment

01/08/2004

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Australia

Study participating centre

PO Box 423

Warrnambool

Australia

3280

Sponsor information**Organisation**

The Australian Government Department of Health and Ageing (Australia)

Sponsor details

Diabetes and Evidence Based Strategies

Health Services Improvement Division

MDP 23

GPO Box 9848

Canberra

Australia

2601

+61 (0)262 898 801

DPP@health.gov.au

Sponsor type

Government

Website

<http://www.health.gov.au/>

ROR

<https://ror.org/0314h5y94>

Funder(s)

Funder type

Government

Funder Name

The Australian Government Department of Health and Ageing (Australia)

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?
Interim results article	interim results:	01/06/2007		Yes	No
Results article	final results:	19/09/2007		Yes	No