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Patient Engagement And Coaching for Health: an intensive treatment intervention for patients with type 2 diabetes in communities

Submission date
19/06/2006

Recruitment status
No longer recruiting

Registration date
14/07/2006

Overall study status
Completed

Last Edited
06/01/2014

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
359355

Study information

Scientific Title
Patient Engagement And Coaching for Health: an intensive treatment intervention for patients with poorly controlled type 2 diabetes - a cluster randomised controlled trial

Acronym

PEACH

Study objectives
1. Are health outcome measures for patients with type 2 diabetes (T2D) from a community improved through access to a patient-focused method for intensive disease self-management (the COACH Program) in the general practice setting, in comparison with usual general practitioner (GP) care only?
2. What is the cost of this intervention and is it likely to be cost-effective in reducing morbidity and mortality?
3. What are the barriers and facilitators of this intensive treatment intervention in general practice in a community?

Please note that extensive amendments have been made to this trial record as of 06/02/2009. They include the following:
1. Scientific title has been added
2. The anticipated end date of this trial has been updated from 31/10/2008 to 31/03/2009
3. The target number of participants has been updated from "608 patients from 32 general practices" to "336 patients from 56 practices"
All other changes are recorded in the relevant fields.

2008 results of a focus group study (phase 1 of the PEACH Study) undertaken prior to the randomised controlled trial (phase 2) can be found at http://www.ncbi.nlm.nih.gov/pubmed/18928555

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Melbourne Ethics Committee, approved on 09/05/2006 (ref: 060123)

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes with HbA1C >7.5% in the last 12 months

Interventions
Intervention group: will receive telephone coaching sessions from existing practice nurses over an 18-month period. The telephone coaching session is a patient-centred program for disease self-management (COACH program), tailored to achieve intensive, multifactorial diabetes treatment. Monitoring rates and process of care, as well as clinical and laboratory indicators will be measured at baseline,12, and 18 months.

Control group: will only receive usual care from their GPs.

The telephone coaching session is a patient-centred program for disease self-management (COACH Program), tailored to achieve intensive, nultifactorial diabetes treatment. Monitoring rates and process of care, as well as clinical and laboratory indicators will be measured at baseline, at 12 and 18 months

As of 06/02/2009: Recruitment completed. Currently completing 12 and 18 months follow up.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The change in HbA1c level from baseline to 12 and 18 months post-randomisation in the intervention group compared with the control group

Key secondary outcome(s)
Comparative change from baseline to follow-up of:
1. Process of GP care measures
2. Diabetes therapy
3. Antihypertensive therapy
4. Statin therapy
5. Aspirin therapy
6. Total cholesterol, triglyceride, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol levels, urinary albumin, blood pressure, body mass index, quality of life, diabetes self-efficacy, depression, and cost-effectiveness

Added as of 06/02/2009: Follow-up assessments will be carried out at 12 and 18 months post-baseline assessments

Completion date
31/03/2009

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/02/2009:
1. General practices will be included in the study if practices are computerised
2. >50% of Practice GPs agree to participate and to be randomised to intervention or control group
3. GPs are willing to search their medical records and pathology database with assistance from research team and be willing to recruit patients with T2D from their practices in accordance with privacy and ethical guidelines
4. Patients with T2D will be invited to participate if they are >18 years with haemoglobin HbA1c (HbA1c) >7.5% and receiving care from general practices in the northern or northwest region of Melbourne that employ a practice nurse.

Previous inclusion criteria:
1. General practices will be included in the study if practices are computerised
2. >50% of Practice GPs agree to participate and to be randomised to intervention or control

group
3. GPs are willing to search their medical records database with assistance from research team and be willing to recruit patients with T2D from their practices in accordance with privacy and ethical guidelines
4. Patients with T2D will be invited to participate if they are >18 years with haemoglobin HbA1c (HbA1c) >7.5% and receiving care from general practices in the northern or northwest region of Melbourne that employ a practice nurse.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients will be excluded if they are not contactable by telephone
2. Patients having a complex debilitating coexisting medical condition e.g. mental illness, end-stage cancer
3. Patients who do not provide signed consent

Date of first enrolment
01/08/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Australia

Study participating centre
200 Berkeley Street
Carlton
Australia
3053

Sponsor information

Organisation
National Health and Medical Research Council (Australia)

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (Australia) - GP Clinical Research Grant (ref: 359355)

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	18/09/2013		Yes	No
Protocol article	protocol	11/04/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes