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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/07/2006	**Overall study status** Completed	
Last Edited 06/01/2014	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.peach.unimelb.edu.au

Contact information

Type(s)
Scientific

Contact name
Prof Doris Young

Contact details
200 Berkeley Street
Carlton
Australia
3053

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)

Treatment

Participant information sheet

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 measure
The change in HbA1c level from baseline to 12 and 18 months post-randomisation in the intervention group compared with the control group

Secondary outcome measures
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

Overall study start date
01/08/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
336 patients from 56 practices

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)

Sponsor details
MDP 33
GPO Box 9848
Canberra
Australia
2601

Sponsor type
Research council

Website
http://www.nhmrc.gov.au

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

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	11/04/2007		Yes	No
Results article	results	18/09/2013		Yes	No