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Peer support in type two diabetes: a randomised controlled trial in primary care with parallel economic and qualitative analyses

Submission date
12/06/2006

Recruitment status
No longer recruiting

Registration date
26/07/2006

Overall study status
Completed

Last Edited
04/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] 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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Study information

Scientific Title

Peer support in type two diabetes: a randomised controlled trial in primary care with parallel economic and qualitative analyses

Study objectives
Peer support improves the biophysical and psychosocial outcomes in patients with type two diabetes and is cost effective.

Article in Diabetes Voice, a magazine of the International Diabetes Federation: http://www.diabetesvoice.org/issues/2005-12/Can_a_peer-care_model_improve_diabetes_outcomes.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval has been obtained from the Ethics Committee of the Irish College of General Practitioners on the 1st December 2004 (ref: REC0904-11).

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Intervention practices deliver a peer support intervention. This is a complex intervention with the following components:

1. Peer support workers: three peer supporters are identified and are recruited by the general practitioners (GP) and practice nurses in each intervention practice. Eligibility is based the following criteria:
1.1. They have had type two diabetes for at least a duration of one year
1.2. They participate in preventive treatments and generally adhere to treatment and behaviour change regimens, as judged by the practice team
1.3. They have a capacity and commitment to undergo the training required (outlined below)
1.4. They have a full understanding of the importance of patient confidentiality
1.5. They undertake to liaise with the practice nurse and/or GP if unanticipated problems arise during the course of their peer support activity
1.6. Peer support workers will receive a travel and expenses grant each year

2. Peer support training: peer support workers will be trained by the research team. They will attend two sessions delivered locally. The training will prepare them to provide peer support rather than formal diabetes education. During the training, the peer supporters will be

familiarised with the materials designed for the group meetings between peers. They will also be presented with guidance on how to manage groups and how to handle potential problems that arise.

3. Peer support group meetings: the groups meet nine times in the two years of the intervention. Sessions are semi-structured and based on diabetes-related topics. Peer supporters will be provided with a pack outlining the suggested topic and content for each session with materials to be distributed to the group. Each session will conclude with the group identifying questions that they would like addressed. These will be fed back to the research team, who will provide answers to be discussed at the beginning of the next session.

4. Ongoing management of the peer support system: the project manager will make contact with the peer support workers following each session by telephone and they will also be invited to attend an annual meeting to facilitate communication between peer support workers. This will also encourage retention of peer support workers over time.

The control group is not getting a specific intervention but we are introducing a standardised primary diabetes care system across all the practices (intervention and control). This will involve the following:

All participating practices are trained and supported to introduce a standardised primary diabetes care system. This is to avoid the lack of clarity that can result if usual care is used for the control arm of a randomised controlled trial. This diabetes care system includes:
1. Practice based training for GPs and practice nurses
2. Agreement and implementation of evidence-based clinical guidelines
3. Structured registration and recall every four months of patients with type two diabetes to specific diabetes appointments or mini-clinics with practice nurses supported by GPs
4. Provision of treatment algorithms designed to optimise glycaemic control and reduce cardiovascular risk
5. Use of a target card, a patient-held record of results relating to their diabetes
6. Educational resources
7. Annual practice audit

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Blood pressure
2. Total cholesterol
3. Haemoglobin A1c (HbA1c)
4. Wellbeing score

Key secondary outcome(s)
1. Biophysical: body mass index (BMI)
2. Measure of processes of care:
2.1. GP visits
2.2. Practice nurse visits
2.3. Hospital outpatient department (OPD) visits

2.4. Hospital diabetes centre visits
2.5. Hospital admissions
3. Psychosocial measures and level of adherence:
3.1. Diabetes self-care activities
3.2. Self-efficacy
3.3. Measure of medication adherence
3.4. Smoking
4. Medication: e.g., aspirin

Completion date
01/04/2010

Eligibility

Key inclusion criteria
A patient is eligible to participate if they:
1. Are over 18 years of age
2. Have type two diabetes
3. Attend participating practices

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
A patient will be excluded if they have significant mental or physical illness which is likely to impair their capacity to participate in the programme.

Date of first enrolment
01/04/2005

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Ireland

Study participating centre
University of Dublin
Dublin 24
Ireland
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Sponsor information

Organisation
Health Research Board (Ireland)

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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 [Development of a complex intervention to test the effectiveness of peer support in type 2 diabetes.]	31/08/2007		Yes	No
Results article	results [Peer support for patients with type 2 diabetes: cluster randomised controlled trial]	15/02/2011		Yes	No
Protocol article	pilot study and protocol	31/07/2007		Yes	No