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A pilot study involving a randomised controlled trial of an educational intervention designed to improve cholesterol control in patients with type 2 diabetes.

Submission date
30/09/2004

Recruitment status
Stopped

Registration date
30/09/2004

Overall study status
Stopped

Last Edited
29/09/2010

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0171135935

Study information

Scientific Title

Study objectives
Diabetes mellitus is a common condition whose prevalence is increasing. It is estimated that the number of diabetics worldwide will double by the year 2010.
1. This is primarily as a result of the increasing prevalence of type 2 diabetes.
2. The cost of managing diabetes is also high with 5% of the total NHS resources and up to 10% of hospital in-patient resources being used to care for those with this chronic disease.
The focus of care for chronic diseases such as diabetes is now directed towards risk factor management and the prevention of complications. With this shift of emphasis patient education and empowerment has advanced from being an adjunct to medical therapy to an intervention in its own right.
Few educational initiatives aimed at type 2 diabetic patients in a primary care setting have been carried out in the UK.
3. Control of cardiovascular risk factors has been identified as having a key role in the prevention of macro-vascular complications in type 2 diabetes.
4. Evidence exists indicating the importance of lipid lowering therapy and maintaining satisfactory cholesterol levels in diabetic patients.
5. However there is a paucity of evidence on the effectiveness of educational interventions focusing on this risk factor.
This pilot study will examine and compare the effect of a patient education intervention, aimed at the satisfactory control of cholesterol in type 2 diabetic patients with usual care. It will employ a randomised control trial design.
The study hypothesis to be answered is whether an intervention based on adult educational and behavioural principles, aimed at type 2 diabetic patients, will improve patient knowledge of cholesterol control and improve physiological measurement of cholesterol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

Interventions
Please note that as of 29/09/10 this status of this record has been changed to 'Stopped' due to the departure of the Primary Investigator from the trial.

1. Educational intervention plus usual care
2. Usual care

Patients from the same household will be allocated to the same group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Serum lipid profiles
2. Measurement of disease related knowledge with particular reference to cholesterol control

Secondary outcome measures
1. Serum HbAlc
2. Body mass index
3. Blood pressure
4. Number of cholesterol lower medication alterations or initiations

Overall study start date
01/12/2003

Completion date
01/07/2004

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Age range: 18-80
2. Men and/or women: men and women
3. Type 2 diabetic

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
30 (15 per group)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/12/2003

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Primary Care
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Nottingham Primary Care Research Partnership (UK)

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