

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	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Stopped	☐ Protocol
Last Edited 29/09/2010	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

1. Serum HbA1c
2. Body mass index
3. Blood pressure
4. Number of cholesterol lower medication alterations or initiations

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

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

United Kingdom

England

Study participating centre**Division of Primary Care**

Nottingham

United Kingdom

NG7 2RD

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Nottingham Primary Care Research Partnership (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration