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Blood pressure control in diabetes in primary care

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/12/2008	Nutritional, Metabolic, Endocrine	

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
RBG 00XX77

Study information

Scientific Title

Study objectives

To assess the effectiveness of a simple treatment algorithm in primary care in attaining the recommended blood pressure in patients with type 2 diabetes compared to usual practice. To assess the cost-effectiveness of the algorithm for improving blood pressure control in these patients.

Assuming 40% of diabetics have a blood pressure of <140/80 an intracluster correlation coefficient (ICC) of 0.02 and an average cluster size of 45 type 2 diabetics per practice. Based on 80% power and 5% two-sided significance level 388 participants would be required in each arm of the study.

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)
Not Specified

Health condition(s) or problem(s) studied
Nutritional, metabolic and endocrine diseases: Diabetes

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Proportion of participants who have achieved good blood pressure control defined as reaching the recommended level of <140/80.

Key secondary outcome(s)
Change in blood pressure from baseline, attendance at hypertension review appointments and patient satisfaction with the care received. Both measures will be assessed at 12 months post recruitment to the trial.

Completion date
28/02/2003

Eligibility

Key inclusion criteria
The study population will comprise all patients with type 2 diabetes on the lists of participating general practitioners who give informed consent to participate in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2001

Date of final enrolment
28/02/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Physician
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

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	01/02/2007		Yes	No