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Cluster randomised trial of a computer based decision support system (CDSS) and decision aid for patients with high blood pressure in the community

Submission date 31/08/2005	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/09/2005	**Overall study status** Stopped	
Last Edited 05/07/2011	**Condition category** Circulatory System	

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
FJH/LETT196/#15542

Study information

Scientific Title

Acronym
The HyDRA trial - Hypertension Decision Reinforcing Aid

Study objectives
High blood pressure (hypertension) is an important public health problem. There is ongoing concern that the benefits demonstrated in randomised trials of antihypertensive drug treatment are not implemented in everyday clinical practice. Community-based studies throughout the world show that blood pressure goals are achieved in only 25-40% of the patients who take antihypertensive drug treatment. A situation that has remained unchanged for the last 30 years. Observational studies have shown that inadequate control of blood pressure is associated with a significant risk of stroke.

This study aims to improve the decision aid tool and develop a web-based CDSS which will facilitate individual care of Tayside/Fife hypertensive patients, enabling health professionals to overcome the pre-specified barriers of poor chronic disease management. These include: treating to therapeutic targets; aiding in the practical complexity of treating to target for different chronic disorders (in this situation blood pressure, cholesterol, cardiovascular risk and for diabetic patients, glycaemic treatment goals); and as an aid to structuring clinical care by facilitating registration, recall and regular review and incorporating prompts for effective clinical care.

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)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
The intervention is a computer based decision support system. It incorporates the dual elements of a health professional decision support system and patient decision aid. The key elements will include: web-based, multifaceted intervention modelled on the successful Tayside regional diabetes network (MEMO/DARTS); a health professional element including prompts/reminders; a facility for registration, recall and review of patients, flexibility so that the functions can be 'tailored' to respond to data entry; feedback (at the individual, practice and regional level). Control: usual care

As of 02/06/2011 this trial has stopped due to a combination of poor recruitment, funding issues and relocation of the Principal Investigator from Scotland to Ireland in 2006.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood pressure control

Secondary outcome measures
1. Adherence to medication
2. Process measures concerning the management of hypertension in primary care
3. Decision conflict

Overall study start date
01/01/2006

Completion date
30/06/2007

Reason abandoned (if study stopped)
Participant recruitment issue/lack of funding

Eligibility

Key inclusion criteria
Patients, if they are aged between 40 to 79 years under treatment for high blood pressure and suffering from uncontrolled high blood pressure in accordance with the British Hypertension Society standard of ≥150/85 mmHg.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3500 (allowing for non response)

Key exclusion criteria
1. Severe hypertension requiring immediate treatment (as determined by the GP)
2. Hypertension associated with pregnancy
3. Inability to understand witten and spoken English
4. Dementia or learning difficulties

Date of first enrolment
01/01/2006

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Tayside Centre for General Practice
Dundee
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Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association, UK (Reference number: TSA 2004/04)

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