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Targets and self management for the control of blood pressure in stroke and other at-risk groups (TASMIN-SR): a randomised controlled trial

Submission date 14/12/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/12/2010	**Overall study status** Completed	
Last Edited 27/08/2014	**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
9361

Study information

Scientific Title

Acronym
TASMIN-SR

Study objectives
TASMIN-SR is a primary-care based, unblinded, randomised controlled trial of self-management of blood pressure consisting of self-monitoring with self-titration of anti-hypertensive medication in people with stroke and other at-risk conditions.

Recruitment will be through the Primary Care Research Network, with patients invited to participate if they have a diagnosis of stroke/transient ischaemic attack (TIA), diabetes, chronic kidney disease (CKD3), coronary artery bypass graft (CABG), myocardial infarction (MI) or angina, and their blood pressure is above 130/80 mmHg. Patients will be randomised to either self-management of blood pressure or usual care.

The main research questions are:
1. Does self-management of blood pressure (BP) result in better control of BP in people with Stroke and other at-risk conditions compared to usual care?
2. Is self-management of BP in people with Stroke and other at-risk conditions acheivable in routine practice and is it acceptable to patients?
3. What is the relationship between self-management of BP, self-efficacy, lifestyle behaviours, patient attitudes to health and health care and use of other self-care strategies in people with Stroke and other at-risk conditions?
4. Is self-management of BP in people with Stroke and other at-risk conditions cost effective?

Please note that as of 04/02/2013, the anticipated end date for this study was updated from 31 /08/2011 to 31/07/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, 30/09/2010, ref: 10/H1013/60

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Cardiovascular; Subtopic: Not Assigned, Cardiovascular (all Subtopics); Disease: Cardiovascular, All Diseases

Interventions
Self management of BP:
Patients will monitor their own blood pressure at home each month, and follow a pre-determined titration plan if their BP is above target over two consecutive months.

Follow-up length: 12 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Systolic blood pressure, measured at baseline, 6 months and 12 months

Secondary outcome measures
1. Adverse events, measured at baseline, 6 months and 12 months
2. Anxiety, measured at baseline, 6 months and 12 months
3. Attitudes to health and health care, measured at baseline, 6 months and 12 months
4. Blood pressure measurement preference, measured at baseline, 6 months and 12 months
5. Diastolic Blood pressure, measured at baseline, 6 months and 12 months
6. Health related quality of life, measured at baseline, 6 months and 12 months
7. Lifestyle behaviours, measured monthly
8. Pulse rate, measured at baseline, 6 months and 12 months
9. Reasons for non-participation, measured at invitation/baseline
10. Self-care strategies, measured at baseline, 6 months and 12 months
11. Self-management self-efficacy, measured monthly
12. Time at target blood pressure, measured at baseline, 6 months and 12 months

Overall study start date
01/12/2010

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Aged above 35 years, either sex
2. Have had a diagnosis of stroke/TIA, diabetes, CKD3, MI, angina, or CABG
3. Systolic blood pressure greater than 130/80 mmHg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 540; UK sample size: 540

Key exclusion criteria
1. Inability to self-monitor such as dementia or score over 10 on the short orientation memory concentration test (and with no carer support)
2. Postural hypotension (fall in SBP greater than 20 mmHg after 1 minute standing)
3. Taking more than three anti-hypertensive medications
4. Taking part in a current blood pressure study or previously taken part in TASMINH2
5. Terminal disease
5. Pregnant
6. Blood pressure not managed by the GP and acute cardiovascular event in the last 3 months

Date of first enrolment
01/12/2010

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Clinical Sciences
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0606-1153)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/03/2013		Yes	No
Results article	results	27/08/2014		Yes	No