

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 ☒ Protocol
Registration date 14/12/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/08/2014	Condition category Circulatory System	☐ Individual participant data

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

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 achievable 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

Study type(s)

Treatment

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(s)

Systolic blood pressure, measured at baseline, 6 months and 12 months

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Primary Care Clinical Sciences

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

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

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	27/08/2014		Yes	No
Protocol article	protocol	23/03/2013		Yes	No