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Home blood pressure monitoring versus standard care in hypertension for stroke/TIA survivors – TASMIN5S/BPTogether

Submission date 12/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/09/2019	**Overall study status** Completed	
Last Edited 30/12/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
This research will develop and test a new system to lower the blood pressure of stroke survivors and those who have had Transient Ischaemic Attacks (TIAs). After a stroke or TIA, people are more likely to have a further stroke. The best way to reduce this risk is to reduce high blood pressure, at present a significant proportion of stroke survivors don't have their high blood pressure properly controlled. The intervention is based around stroke/TIA survivors measuring their blood pressure at home. In studies where most people haven't had a stroke/TIA, measuring your blood pressure at home, with adjustment of blood pressure medication by your GP, leads to better control of blood pressure.

Who can participate?
Patients aged 18 years or above with previous history of stroke and/or TIA and high blood pressure

What does the study involve?
Patients receive an invitation via their GP and if interested, meet a research nurse to explain the study. Those who want to take part have their blood pressure measured and fill in questionnaires. Following consent participants are randomly allocated to one of two groups: (a) self-monitoring or (b) usual GP care. Those who self-monitor send their blood pressure readings monthly to their GP by mobile phone/tablet or computer. Automatic reminders to take blood pressure and to say what action (if any) they should take depending on the level of the blood pressure are sent. GPs receive summaries of patients' blood pressures and work together to control their patients' blood pressure. Participants see a research nurse at the beginning of the study and at 6 and 12 months where blood pressure measurements are taken and questionnaires completed. Interviews are recorded with some participants along with meetings between them and their doctors where they discuss blood pressure. The researchers also talk to people about their experiences of taking part.

What are the possible benefits and risks of participating?
All participants will have more regular monitoring. Participants in the intervention group may

feel they benefit from understanding more about their blood pressure and having it more closely monitored. Possible risk might be that participants using the intervention may be more anxious than those receiving normal care but this was not found to be the case in previous studies of home blood pressure monitoring.

Where is the study run from?
1. NIHR CRN: Thames Valley and South Midlands
2. NIHR CRN: Eastern
3. NIHR CRN: West Midlands
4. NIHR CRN: West of England
5. NHS Lothian

When is the study starting and how long is it expected to run for?
January 2019 to January 2021 (updated 08/12/2020, previously: December 2023)

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Prof. Richard McManus
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Study website
https://www.phc.ox.ac.uk/bptogether

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41703

Study information

Scientific Title
Towards an integrated self-monitoring solution for stroke/TIA: the BP:Together study

Acronym
TASMIN5S (BP Together Study)

Study objectives
After a stroke or transient ischaemic attack (TIA), people are more likely to have a further stroke. The best way to reduce this risk is to reduce high blood pressure, but at present a significant proportion of stroke survivors don't have their high blood pressure properly controlled. This research will develop and test a new system to lower the blood pressure of stroke survivors and those who have had TIAs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/07/2019, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8196; Email: nrescommittee.northwest-gmeast@nhs.net), REC ref: 19/NW/0409

Study design
Randomized; Interventional; Design type: Prevention, Education or Self-Management, Psychological & Behavioural, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Blood pressure monitoring in people who have had a stroke or transient ischaemic attack (TIA)

Interventions
The intervention is based around stroke/TIA survivors measuring their blood pressure at home. In studies where most people haven't had a stroke/TIA, measuring blood pressure at home, with adjustment of blood pressure medication by the GP, leads to better control of blood pressure. Patients will receive an invitation via their GP and if interested, will meet a research nurse to explain the study. Those who want to take part have their blood pressure measured and fill in questionnaires. Following consent, the researchers randomly allocate people to one of two groups (a) self-monitoring or (b) usual GP care. Those who self-monitor send their blood pressure readings monthly to their GP by mobile phone/tablet or computer. Automatic reminders to take blood pressure, and to say what action (if any) they should take depending on the level of the blood pressure are sent. GPs receive summaries of patients' blood pressures and work together to control their patients' blood pressure. Participants will see a research nurse at the beginning of the study and at 6 and 12 months where blood pressure measurements will be taken and questionnaires completed. The researchers will record interviews with some participants and meetings between them and their doctors where they discuss blood pressure. They will also talk to people about their experiences of taking part.

Intervention Type
Other

Primary outcome measure
Difference in systolic blood pressure (SBP) at 1 year comparing intervention and control groups, using the mean of the 2nd and 3rd readings and adjusted for baseline systolic blood pressure and other covariates

Secondary outcome measures
1.1. Diastolic BP at 1 year: mean of the second and third readings, adjusted for baseline DBP
1.2. Systolic and diastolic BP at 6months: mean of the second and third readings, adjusted for baseline BP
1.3. Multiple SBP and DBP measurements (mean of second – sixth measurements) adjusted for baseline BP at 6 and 12 months
1.4. Proportion controlled below target using mean of 2nd/3rd readings for SBP and DBP at 6

and 12 months adjusted for baseline
2. Quality of life and anxiety levels measured using EQ-5D 5L and STA1:Y-6 item participant-completed questionnaires and healthcare costs during the trial at 12 months adjusted for baseline
3. Healthcare system and social care use/costs plus patient out of pocket expenses during the trial

Tertiary outcome measures:
1. Adverse events, hospital admissions and cardiovascular events between baseline and 12 months, measured using participant-reported events at a 12-month follow-up assessment and review of participant medical notes.
2. Patient enablement or beliefs about medicine measured using patient-completed questionnaires between baseline and 12 months

Process evaluation:
1. How trial recruitment and intervention training is understood by patients, carers and recruiters assessed using thematic and/or conversation analysis of audio recordings of recruitment and consent appointments collected during trial recruitment
2. How the intervention is implemented in daily life and what are the barriers and facilitators for patients/carer assessed using thematic analysis of observations and interviews with patients and carers during the trial
3. What the barriers and facilitators for GPs and other staff are for implementing the intervention assessed using thematic analysis of interviews with professionals during the trial
4. Adherence to antihypertensive medication at 6 and 12 months assessed using participant-completed Medication Adherence Rating Scale Questionnaire at baseline and 12 months
5. Intervention fidelity (if patients randomised to the integrated self-monitoring /management intervention follow the study procedures) assessed using self-monitoring and medication change data between baseline and 12 months
6. How the intervention has been delivered assessed using thematic and/or conversation analysis of direct observations/audio recordings and usage data from the digital intervention obtained during the trial

Overall study start date
01/01/2019

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Previous history of stroke and/or specialist confirmed TIA at least one month before randomisation
4. Baseline systolic blood pressure > 130mmHg (mean of 2nd and 3rd readings)
5. Willing and able to comply with all study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 610; UK Sample Size: 610

Key exclusion criteria
1. Diagnosis of dementia (Clinical Code)
2. Score over 10 on the short orientation memory concentration test
3. Any other significant disease or disorder which, in the opinion of the Investigator, may put the participants at risk because of participation in the trial
4. Pregnancy
5. BP > 180/110mmHg at baseline (to be referred to GP but could be subsequently rescreened if < 180/110mmHg)
6. More than three antihypertensives
7. Unwilling to self-monitor
8. Receiving care for blood pressure by a specialist rather than a primary care physician
9. Stage 4 CKD or worse – i.e.: eGFR less than 30 mL/min/1.73 m2 (as these persons are more likely to be managed by specialists, are more prone to Acute Kidney Injury and/or hyperkalemia and less responsive to certain antihypertensives?)
10. Diagnosed atrial fibrillation
11. Orthostatic hypotension: more than 20mmHg systolic drop after standing for 1 minute. Not relevant if participant unable to stand
12. Participation in other studies that concern hypertension and/or adjustment of antihypertensive medication

Date of first enrolment
01/10/2019

Date of final enrolment
13/03/2020

Locations

Countries of recruitment
England

Ireland

Scotland

United Kingdom

Study participating centre
NIHR CRN: Thames Valley and South Midlands
Oxford
United Kingdom
OX3 9DU

Study participating centre
NIHR CRN: Eastern
Norwich
United Kingdom
NR1 1QQ

Study participating centre
NIHR CRN: West Midlands
Coventry
United Kingdom
CV3 2TX

Study participating centre
NIHR CRN: West of England
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BS1 2NT

Study participating centre
NHS Lothian
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EH1 3EG

Sponsor information

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University of Oxford

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Other

Funder Name
Stroke Association; Grant Codes: TSA BHF 2017/01

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. The study protocol will be published in due course

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Feasibility results	13/01/2023	16/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		27/12/2024	30/12/2024	Yes	No