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Telescot Stroke Study

Submission date 15/12/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/02/2012	**Overall study status** Completed	
Last Edited 01/03/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious, life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. A transient ischaemic attack (TIA) or 'mini stroke' is caused by a temporary disruption in the blood supply to part of the brain. We know that if people who have previously suffered a stroke or TIA keep good control of their blood pressure (BP), they will be much less likely to have problems in the future. Using modern mobile technology, people can now easily take these measurements at home using a new kind of meter and send them to a secure website so that only they and their doctor or nurse can see the results. Their doctor or nurse can then make changes to their treatment if needed. Monthly printed summaries of blood glucose and blood pressure results can be sent to patients. If patients use the internet they can also see their record on the website and receive automatic feedback by email. We aim to find out whether using these new kind of meters really helps people to control their blood pressure, or if using it is too much trouble.

Who can participate?
Patients aged 18 or over registered on the TIA/stroke register of general practices in the selected study areas.

What does the study involve?
Participants will be split into two groups. We will give one group the new meters and the other group are looked after in the usual way. After 6 months we will measure blood pressure in both groups to see if people using the new meters have better control of their blood pressure. We will also interview a proportion of participants to explore their experience of self-monitoring, the sources of support they used and any unintended consequences of self-monitoring.

What are the possible benefits and risks of participating?
Lowering blood pressure is the most important factor in preventing first or recurrent stroke and this technology has the potential to help patients achieve this.

Where is the study run from?
Edinburgh Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
October 2011 to January 2012

Who is funding the study?
Chief Scientist Office, Department of Health, Scottish Executive (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11417

Study information

Scientific Title
The impact of a telemetric blood pressure monitoring service in people who have had stroke: a randomised controlled feasibility study

Study objectives
As the population ages, more people are living with long-term conditions. Current methods of management, relying on clinicians to monitor patients, are becoming unsustainable. There is potential for people to monitor their own condition with appropriate supervision and support, but so far there is little good evidence that this helps them achieve better control.
Systems referred to as telemetry, are now available which allow patients with high blood pressure to monitor their own illnesses and automatically send the information to a secure website, which they and their clinicians can view. The system can provide reminders to take measurements and medication, and alert patients and clinicians if additional treatment is required.

In patients who have had stroke/Transient Ischemic Attack (TIA), we want to find out if it is feasible to:

1. Implement telemetrically supported blood pressure monitoring
2. Conduct a randomised controlled trial comparing telemetrically supported blood pressure control compared with normal care

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, 24/08/2011, ref: ARPG/07/03

Study design
Randomised interventional phase II study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
A randomised controlled feasibility trial on 56 patients will be run in which stroke/TIA patients whose blood pressure is poorly controlled are randomised to one of two groups:

1. The group who get the telemetry (the intervention group)
Patients in the intervention group will be given blood pressure monitors which use Bluetooth to transmit readings via a (supplied) mobile phone to a remote server. Their GP and practice nurse will also be able to access this record via the Internet. Users will also receive regular automated text or email feedback (or both if they wish) based on the reading they just sent and their rolling average blood pressure over the past 10 readings. The system can be set to provide reminders to check blood

2. Group who continue to receive their usual care (the control group)

We will collect data at the start and at the end of the study to see if those in the intervention group are better able to control and manage their blood pressure with the supported self monitoring which telemetry provides.

Intervention Type
Device

Phase
Phase II

Primary outcome(s)
The participation rate in the pilot trial

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/01/2012

Eligibility

Key inclusion criteria
Patients registered with general practices in the selected areas who:
1. Are on the TIA/stroke register of the practice
2. Are aged 18 years or over
3. Have a last recorded blood pressure of > 130/80mmHg
4. Have an average daytime ambulatory blood pressure measurement of >130/80mmHg
5. Have given informed consent
6. Have a mobile telephone signal available from home
7. Consider themselves able to use the equipment, appear to be able to use the equipment when assessed by the researcher

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Have secondary hypertension
2. Have hypertension which is managed in secondary care
3. Have atrial fibrilation
4. Have terminal illness or major concurrent illness where treatment is likely to affect the ability to self monitor
5. Have had a stroke in the last 3 months
6. Have major surgery in the last 3 months
7. Are unable to consent
8. Are unable to use self monitoring equipment alone with no easy access to help
9. Pregnant

Date of first enrolment
01/10/2011

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
The Queens Medical Research Institute
Edinburgh
United Kingdom
EH16 4TJ

Sponsor information

Organisation
NHS Lothian (UK)

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, ref: ARPG/07/03

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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	25/03/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes