Participant Information
The BP Together Study

We would like to invite you to take part in a research study.

Can you help?

- **Before you decide, it is important for you to understand why the research is being done and what it would involve for you.**
- **Please read the following information carefully and discuss it with others if you wish.**
- **Ask us if there is anything that is not clear.**
- **Take time to decide whether or not you wish to take part.**

PLEASE NOTE:
This information is also available in a video at
www.phc.ox.ac.uk/bptogether

Contents

What is the purpose of the research?

- The BP:Together study is exploring the best ways to manage blood pressure in stroke/TIA patients.
- We will invite half the study group to self-monitor their blood pressure at home, and send their readings to their GP every month via an app/text/web. The other half will receive usual care.
- At the end of 12 months we will compare the blood pressure of both groups.
- This research aims to help reduce blood pressure
- Treating blood pressure can reduce the chance of another stroke occurring in the future.
- Raised blood pressure is common. It causes very few symptoms.
- Many people need some changes to their medicine to control their blood pressure

Why have I been invited?

- You have been invited to take part in this study because you have previously had a stroke or Transient ischaemic attack (TIA)
- Also, a recent blood pressure recorded at your practice was higher than recommended.

What will I have to do?

People taking part in the study will be randomly chosen to be in one of two groups:

- **Group A:** People receiving normal care from their GP

- **Group B:** People will be given a blood pressure monitor to use at home and will send their results to the GP Practice.

  If you are in **Group A**: the way you receive care for your blood pressure will not change.

- You will see your GP at the start to check your medicine
- You will be asked to attend a research clinic at your local GP practice with a nurse to take your blood pressure 6 months and 12 months after you join the study.
- You will also be asked to answer some questions about your blood pressure at all 3 of these appointments.
- Each appointment will last approximately 1 hour.
- People in Group A are also important to the research. By carrying on the same as usual, you help the researchers find out which is the best way to manage blood pressure.

If you are in **Group B**:

- You will see your GP at the start to check your medicine.
- Your GP will make a plan for 3 potential changes to your medication if your BP is raised when self-monitoring at home.
- You will be shown how to use a blood pressure monitor. You will have as much time as you need to feel comfortable with how to use it.
- You will be given a blood pressure monitor to take home for 12 months
- You will get reminders to help you remember to take your blood pressure.
- You will be asked to take 12 readings, over 3 days. Then have 3 weeks off.
- You can choose if you want to send your readings by text message, by app, or by website.
- The programme (called BP:Together) will share your blood pressure readings with your GP after all 12 readings have been received each month.
- BP:Together will also let you know how your blood pressure is each month
- Your GP might change your dose or medicine type. They would make a plan with you at the start about this.
- If your readings remain raised your GP might want to test a small sample of your urine to test how successful your blood pressure tablets are in controlling your blood pressure. Following testing, your urine sample will be destroyed.
- Or your GP might arrange for you to see a blood pressure specialist
- You will be asked to attend a research clinic at your local GP practice with a nurse, to take your blood pressure 6 months and 12 months after you join the study.

- You will also be asked to answer some questions about your blood pressure at the start, and at 6 months and 12 months.
- Each appointment will last approximately 1 hour

Do I have to take part?

- No it is up to you to decide to join the study.
- If you do agree to take part, we will ask you to sign a consent form.
- You are free to withdraw (stop taking part) at any time, without giving a reason.
- This would not affect the care you receive at your GP Practice.

What are the possible advantages and disadvantages of taking part?

- Your GP will continue to decide which medicine is best for you whichever group you are in.
- It is possible that people in Group B may be more anxious than those receiving normal care, although in previous studies we found this was not the case when people took blood pressure readings at home.
- People in Group B may feel they benefit from understanding more about their blood pressure and having it more closely monitored.

What will happen if I don't wish to continue in the study?

- You are free to leave the study whenever you wish without giving a reason.
- You will then receive your usual care for your blood pressure from your GP and nurse as you did before the study.
- If you are in Group B, you may choose not to continue taking your own blood pressure at home but still attend the follow-up clinics after 6 and 12 months.
- We may still need to use the data already collected but would not collect any further information if you did not want us to.
- Although you do not have to give a reason for leaving the study, we may ask if you are willing to discuss your reasons for deciding not to continue as it may help other people taking part in the study.

Will my taking part in the study be kept confidential?

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is "a task in the public interest".
- The University of Oxford, as sponsor, is the data controller and is responsible for looking after your information and using it properly.
- You will be given a unique study number and all information you provide will be recorded against that number, not your name.
- All your information will be treated with the strictest confidentiality.
- Your medical records will be reviewed as part of the research.
- The only people from this study with direct access to your information will be the research team from the Nuffield Department of Primary Care Health Sciences at the University of Oxford, and research teams from Universities of Southampton, Cambridge and Edinburgh.
- All the study data is owned by the University of Oxford. It will be kept locked away or on secure computer servers in locked rooms with restricted access.
- Responsible members of the University of Oxford and the relevant GP practice may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.
- We will share identifiable data (for instance name, date of birth, NHS number) in a secure manner (including encryption during data transfer) with the Department of Health national data centre (NHS digital; https://digital.nhs.uk). This may be used to help contact you (for instance if you move house) and to provide information about future health events.
- We will keep identifiable information about you for three months after the study has finished, unless you consent to being contacted for future research in which case we keep your details for up to 20 years, stored separately from the study date on a secure university computer in the Department of Primary Care, Oxford University.
- We will store the de-identified research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for up to 20 years after the end of the study. De-identified data may be shared with other researchers for research purposes.

What will happen to the results of the study?

- The research will be published in medical journals.
- A summary of the findings of the study will be offered to everyone who has taken part.
- It will not be possible for you to be identified in any report or publication.

Who is organising and funding the research?

- The study is organised by a team of researchers led by Professor Richard McManus from the Nuffield Department of Primary Care Health Sciences at the University of Oxford.
- It is funded by the Stroke Association and the British Heart Foundation.

What happens when the research study stops?

- You will go back to having your blood pressure looked after in the same way as before the study.
- If you wish to be more involved in your blood pressure care, for example by measuring your blood pressure at home, you will need to discuss this with your GP.
- People in Group B will need to return the equipment they have on loan from the study.

Who has approved the research?

- All research in the NHS is looked at by an independent group of people called a Research Ethics Committee.
- This study has been reviewed and been given a favourable opinion by North West - Greater Manchester East Research Ethics Committee.

What if there is a problem?

- Any complaint about the way you have been dealt with during the study will be addressed.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Professor Richard McManus on Freephone 0808 196 1530. Alternatively, email bptogether@phc.ox.ac.uk or contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

Will I be reimbursed for taking part?

- We can reimburse reasonable travel expenses for any visits additional to normal care on production of receipts, or a mileage allowance can be provided as appropriate.

What do I do now?

- If you are interested in taking part, please phone 0808 196 1530 or return your reply slip in the enclosed envelope with your contact details.
- If you do not want to take part, please return the opt-out reply slip to the research team in the freepost addressed envelope.
- If you do not contact your GP Practice or return the opt-out reply slip, your practice may contact you by telephone to see if you would like to take part.

Further information:

- The research team are available on the following number if you have any questions.

  BP:Together Research Helpline: **0 8 0 8 1 9 6 1 5 3 0**

- The Oxford University Data Protection team can be contacted via:

  http://compliance.admin.ox.ac.uk/individual-rights

Contact details and collaborating organisations:

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Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
Oxford OX2 6GG

Email: bptogether@phc.ox.ac.uk

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