Optimising Treatment for High Blood Pressure in the Elderly

Participant Information Booklet

- We would like to invite you to take part in a research trial.
- Many people take drugs to lower their blood pressure and reduce their risk of stroke and heart attacks.
- After many years of treatment, the benefits of taking these drugs ***may*** become outweighed by the risk of falls and other side effects.
- This trial is looking to assess the safety of reducing the number of drugs prescribed to older people who have blood pressure considered to be in the normal range.
- Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.

OPTiMISE

UNIVERSITY OF OXFORD

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

OPTiMISE Trial: Key Points

1. Why have I been chosen?

(See page 5)

Because you are aged 80 years or older and take more than one medication to reduce your blood pressure. We would like to see if reducing the number of these medications can be done safely.

2. What will I have to do?

(See pages 6-8)

You will have to agree to be put, at random (equivalent to tossing a coin), into one of two groups:

A:

A ***'control'*** group where nothing about your care will change or

B:

An ***'intervention'*** group where you will have one blood pressure medication, chosen by your doctor, removed

There is a 1 in 2 chance you will be in the intervention group. During the study, you will be asked to visit your GP surgery three times over 12 weeks for appointments with your doctor or the research team. During these visits you will be asked to answer some questions about yourself and complete some questionnaires. We will also measure your height, weight and blood pressure. In some cases, your doctor may wish to see you in further appointments. You may also be asked if you would mind if some of these appointments are tape-recorded.

3. What is the intervention being tested?

(See page 9)

If you are allocated to the intervention group, your doctor will choose to stop one of the medications you take to lower your blood pressure.

4. Risks and benefits

(See page 11)

If you are in the control group, there are no risks or benefits to taking part. If you are in the intervention group, your blood pressure could rise, leading to an increased risk of heart attack or stroke. However, your GP will monitor your blood pressure carefully so the likelihood of this happening is very low. Those in the intervention group may be less likely to suffer side effects from medication such as falls.

5. Stopping participation in the trial

(See page 12)

You are free to leave the trial at any point and the decision to do so will not affect the treatment you receive from your GP.

6. What to do if there are problems

(See page 14)

If you have any queries about this trial then please contact the trial co-ordinator on 0800 915 8543 or email optimise@phc.ox.ac.uk.
If you wish to complain about any aspect of the way in which you have been treated during the trial, you should contact the trial co-ordinator, or the University of Oxford Clinical Trials and Research Governance (CTRG) office on ***01865 572224*** or email ***ctrg@admin.ox.ac.uk***.

7. Confidentiality

(See page 13)

All data will be kept securely according to the Data Protection Act 1998. Any identifiable information held and maintained by Department of Health national data centre (NHS digital; ***https://digital.nhs.uk***) may be used to help contact you or provide information about your health status in the future. All trial information collected will be made anonymous at the earliest practical opportunity.

8. What will happen to the results of the trial?

(See page 14)

The results of this research trial will be published in a scientific medical journal and on the study website.

9. Who funded and approved the trial?

(See page 15)

This trial is being funded by the National Institute for Health Research. It has been reviewed and given favourable opinion by South Central Oxford A Research Ethics Committee (ref 16/SC/0628).

Thank you for considering taking part in this trial.

OPTiMISE Trial: Full Details

What is the purpose of the trial?

The population is getting older (over 3 million people in the UK are aged 80 years or older) and the number of people living with multiple illnesses, taking lots of tablets to manage these illnesses is increasing. High blood pressure is one of the most common medical conditions in older people and many take two or more drugs to treat it.

Recent scientific studies suggest that large reductions in blood pressure, and too many drug prescriptions, ***may*** be associated with an increase in falls and death in older patients, particularly in those suffering from lots of medical conditions.

This study aims to assess the safety of reducing the number of drugs prescribed to older people (defined as being aged 80 years or older) who have blood pressure in a normal range and are taking two or more medications.

Why have I been invited to take part?

You have been invited to take part because you have, at least in the past, had high blood pressure and your doctor has given you medications to reduce it. Now that you are older, the benefits of reducing your blood pressure may be outweighed by the side effects of taking these medications (for example, with an increased risk of falling over). We would like to recruit 540 people like you, to see if reducing the number of blood pressure lowering medications you take can be done safely, and potentially improve your quality of life.

Do I have to take part?

No. It is up to you to decide to join the trial and if you do, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you decide you would like to take part you will be invited to attend a consultation with your GP. They will give you some more information, explain what you would have to do and answer any questions you have. ***If you would like to participate you will be asked to sign a consent form.*** If you feel unsure you can ask to have another consultation and longer to think before starting the trial.

Once you have signed the consent form, you will be asked to move to another room where a trained researcher will ask you some basic questions about yourself (e.g. age, ethnicity, whether you smoke, etc.) and your medical history. They will also take some measurements of your height, weight and blood pressure. Finally you will be asked to complete some simple questionnaires about your daily activities and general quality of life.

Some patients may also be asked if these initial visits with the GP and trained researcher may be tape-recorded. This may happen whether you agree to take part in the trial or not. The recordings will help the research team to better understand what happens in these discussions and make sure patients are able to ask all the questions they need when deciding whether to take part in the trial.

Following these consultations you will be randomly allocated by a computer (equivalent to tossing a coin) into one of two groups. Neither you, your GP nor the research

team can choose which group you will be in. This is to make sure both groups are the same to start with, so that we can accurately compare if reducing the number of medications you take is safe and beneficial.

If you are allocated to the 'control' group, you will continue with your current medication, nothing will change. If you are allocated to the 'intervention' group, you will have one medication, chosen by your doctor, removed. If you are in this group, you will be given the opportunity to measure your blood pressure at home, to see if taking less medications causes your blood pressure to change. *There is a 1 in 2 chance you will be in the group taking fewer medications to lower blood pressure.*

Flowchart for Trial Visits

Invitation

Invitation to attend study screening visit

Visit 1
(baseline)

Attend screening visit: Your GP will explain the study to you

If you are willing to participate, you will be asked to give consent in writing

You will then have your height, weight and blood pressure measured, and be asked to complete some questionnaires

Randomisation/allocation to group

Intervention group	Control Group
Visit 2 ***(safety visit)*** Optional blood monitoring at home	
Appointment with GP to discuss safety at 4 weeks (+/- 2 weeks)	
Visit 3 ***(end of study)*** 12 week follow-up: further measurements taken and questionnaires to complete	

What is medication reduction?

If you are allocated to the intervention group, your doctor will choose to stop one of the medications you take to lower your blood pressure. Their decision will be based on whether you have ever experienced any side effects taking the drug, or if there is a possibility that it might react negatively with some of the other drugs you take. If neither is the case, they may choose to remove the drug you were most recently prescribed.

Expenses and Payment

You will not be paid for taking part in this trial. However, we will reimburse you for any travel expenses you incur for visits resulting from your participation in the trial, as by participating in the trial, you will be asked to attend more clinics at your GP surgery. If independent travel is difficult for you and might preclude your participation in the trial, you can contact the trial team directly who will discuss alternative arrangements for travel with you.

What will I have to do?

If you decide you would like to take part, you will attend a consultation at your GP surgery. This is described in the section 'What will happen to me if I take part?' The trial will be conducted over 12 weeks (3 months) and you will need to attend your GP surgery for follow up appointments at week 4 (if you are in the intervention group) and week 12 (***a minimum of 3 visits to the GP surgery***). The doctor may wish to book further appointments in addition to these.

At each follow up visit you attend, you will have your blood pressure measured and depending on the reading, your doctor may adjust your medication again. On your final visit (week 12), you will be asked to complete the questionnaires you did on your first visit again. If you

are allocated to the intervention group, we will also give you the opportunity to check your own blood pressure at home. You will be shown how to do this and provided with the equipment needed.

Throughout this time period you will remain in the same group you are assigned to at the beginning. You will need to continue taking the treatment as indicated unless specifically advised to stop by your GP. You can continue any other medication you normally take.

What are the risks and benefits of taking part in this trial?

Risks of taking part

1. All participants in this trial will receive normal routine care from their GP. If you are in the control group, you will be at no further risk by taking part.

2. Medications which lower your blood pressure also lower your risk of having a heart attack or stroke. Thus, if you are in the intervention group and one is removed, your blood pressure may rise and if this were left unchecked, you could be at risk of suffering a heart attack or stroke (an adverse event).

3. In this trial, you will have the opportunity to monitor your blood pressure at home and see your GP at regular intervals. If blood pressure does increase significantly, your GP will restore your medications, ***rendering the likelihood of you suffering an adverse event very low***.

Benefits of taking part

1. If you are in the control group, there will be no clear additional benefits for you taking part in the trial. However you will have the knowledge that you have contributed to research which helps develop better ways to care for people as they get older.

2. If you are in the intervention group and have your medication reduced, there is the possibility that you will be less likely to fall over, or suffer other side effects which could affect your quality of life. We will not know if this is the case until after the trial is finished.

What if I become unwell during the trial?

If you become unwell, need to attend hospital for any reason or change your normal medication whilst you are in the trial you should inform your GP. We will need to record this in our trial documents.

If you are in the intervention group and become unwell as a result of having your medication reduced, your GP may ask you to start taking that tablet again. You can request to start taking your medication again at any time.

What happens to me when the research trial is finished?

Your active participation in the trial will continue for 12 weeks. After this you may be followed up by your GP or the research team using national health registries but you will not be contacted again. Your blood pressure will continue to be managed by your GP, and this may include continuing/ starting medication reduction where appropriate.

What if relevant new information becomes available during the trial?

Sometimes we get new information about the treatment or strategy being studied. If this happens, your GP will tell you and discuss whether you should continue in the trial. If you decide not to carry on, your GP will make arrangements for your care to continue. If you decide to continue in the trial he/she may ask you to sign an agreement outlining the discussion.

What will happen if I want to stop taking part in the trial?

You are free to leave the trial at any point. Leaving the trial will not affect the treatment you receive from your GP. If you have any concerns once you have left the trial you can contact the research team for help and advice.

Will my participation and personal records be kept confidential?

Yes. All data will be kept securely according to the Data Protection Act 1998 and the research team have a duty of confidentiality to you as a research participant. All data will be stored securely on a password protected computer and only the research team will be able to access the information.

Any identifiable information held and maintained by Department of Health national data centre (NHS digital; *https://digital.nhs.uk*) may be used to help contact you or provide information about your health status in the future. We will not share this information with anyone else.

All trial information collected will be made anonymous at the earliest practical opportunity. The information you provide at the first consultation and subsequent appointments, will be coded with a trial identification number so you cannot be identified from it by anyone other than the research team. Responsible members of the University of Oxford, Cambridge and Southampton, Oxfordshire CCG, Cambridgeshire and Peterborough CCG and Southampton CCG or the regulatory authorities (MHRA) may be given access to anonymous data for monitoring and/or audit of the trial to ensure we are complying with regulations.

If you choose to withdraw from the trial we would still like to collect relevant information about your health, as this will be invaluable to our research. If you have any objection to this please let your doctor know.

What if there are any problems?

If you have any queries about this trial then please contact the Trial Manager (see contact details on page 16).

If you wish to complain about any aspect of the way in which you have been approached or treated during this trial, you should contact the Trial Manager in the first instance, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or email: ***ctrg@admin.ox.ac.uk***. The NHS Patient Advice and Liaison Service (PALS) is available at ***http://www.pals.nhs.uk/***. PALS is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

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. NHS indemnity operates in respect of the clinical treatment with which you are provided.

What will happen to the results of the research trial?

The results of this research trial will be published on the study website (***https://www.phctrials.ox.ac.uk/studies/OPTiMISE***) and in a scientific journal, sometime after the trial has finished. Your individual results will not be identifiable nor would you be identified in any report or publication. Your GP will have access to your personal results, which will be stored in your medical notes, and will address any that are unusual.

Who is organising and funding the research?

This trial is being funded by the National Institute for Health Research (NIHR) Collaborations for Leadership in Applied Research and Care (CLARHC), and the NIHR School for Primary Care Research (SPCR). The trial is being run by Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by South Central Oxford A Research Ethics Committee (ref 16/SC/0628).

Further information and contact details

If you would like any further information about this trial you can call the research team on 0800 915 8543 or e-mail at optimise@phc.ox.ac.uk
For further independent advice you can contact INVOLVE (*www.invo.org.uk*) which is a government funded national advisory group to support people taking part in NHS, public health or social care research.

Thank you for considering taking part in this trial.

Our Contact Details

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

Tel: 08009158543

E-mail: optimise@phc.ox.ac.uk