Study contacts:

Study Co-ordinator: Eleanor Temple **Tel:** 0800 915 8543 **E-mail:** optimise@phc.ox.ac.uk	**Primary Care Research Facilitator:** **Mobile:** **Email:**

Research Information Sheet for Practices

OPTiMISE

Optimising Treatment for Mild Systolic Hypertension in the Elderly

CSP number:
UKCRN Study ID: 212465
Chief Investigators: Dr James Sheppard and Professor Richard McManus
Host Institution: University of Oxford, Nuffield Department of Primary Care Health Sciences
Funded By: NIHR Oxford Collaborations for Leadership in Applied Research and Care (CLARHC) and the NIHR School for Primary Care Research (SPCR).

The Study

Study Title: OPtimising Treatment for MIld Systolic hypertension in the Elderly: a randomised controlled trial.

Type of study: Primary Care based, open label, phase IV randomised controlled trial.

Aim of study: To determine whether antihypertensive medication reduction in elderly patients with controlled systolic hypertension (≤150mmHg) is possible without significant changes in blood pressure control.

Summary:
Approximately half of individuals with hypertension aged 80 years or above are prescribed two or more antihypertensive medications. Current evidence equivocal as to whether reducing the number of antihypertensive drugs prescribed to older patients is beneficial. This multi-centre non-inferiority trial will investigate the safety of antihypertensive medication reduction in 540 older patients (≥80 years) with controlled systolic blood pressure (<150mmHg). The trial will compare the proportion of patients with controlled blood pressure at 12 week follow-up in those randomised to a strategy of medication reduction (with optional self-monitoring of blood pressure) versus usual care (continued treatment). The proportion of patients having their medication reintroduced due to unsafe change in blood pressure and any changes in quality of life, functional independence, frailty or adverse events will be monitored as secondary outcomes.

Recruitment Target: 15*
Number of patients per practice screened: 150
Number of patients per practice invited: 75
Number of patients per practice recruited: 15 (20%)
Study recruitment period: 20 months recruitment (including 6-9 month feasibility phase), 12 weeks follow-up
***based on list size of 7,500. Less patients expected if list size is smaller.**

Inclusion/Exclusion Criteria (Summary)

Inclusion Criteria (summary):

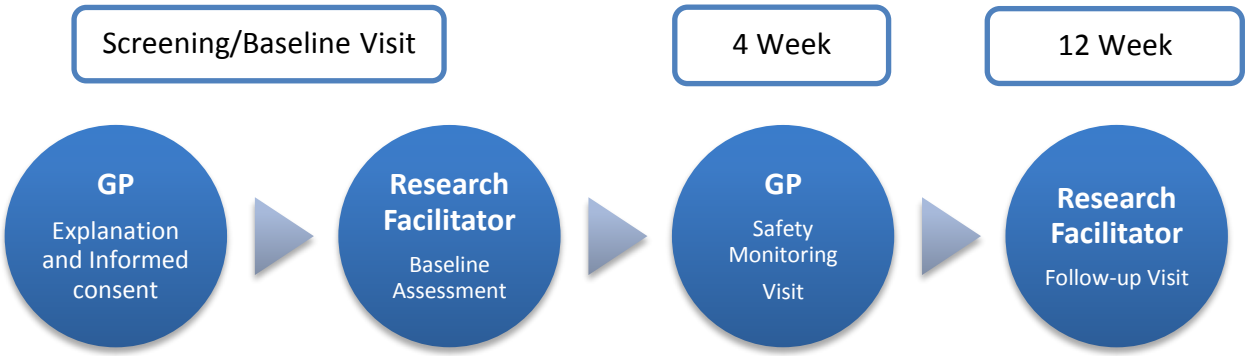
- Male or Female, aged 80 years or above.
- Taking antihypertensive medication to lower BP.
- Clinic systolic blood pressure <150 mmHg at baseline.
- Prescribed 2 or more antihypertensive medication for at least 12 months prior to trial entry.
- Could potentially benefit from medication reduction due to existing polypharmacy, co-morbidity, non-adherence or dislike of medicines and/or frailty.
- Able and willing to comply with all trial requirements.

Exclusion Criteria (summary):

- Heart failure due to left ventricular systolic dysfunction (LVSD) and is on only ACE inhibitors/ARBs and/or beta-blockers and/or spironolactone.
- Heart failure but not had an echocardiogram since onset.
- Compelling indication for medication continuation.
- Suffered a myocardial infarction or stroke within the past 12 months.
- Blood pressure managed outside of primary care.
- Secondary hypertension.
- Previous accelerated or malignant hypertension.
- Unable to provide consent due to incapacity.
- Any other significant disease or disorder which may put the participants at risk, influence the result of the trial, or the participant's ability to participate in the trial.
- Participated in another antihypertensive medication trial in the past 4 weeks.

  * Search file will be provided by the CRN.

Involvement in the Study – Summary



By Clinicians / Practice:

- Admin to search electronic clinical records (eCRs) for potential participants, GP to review list to confirm eligibility.
- Admin/Nurse to send invitation letters with Patient Information Sheet (replies sent to the PC-CTU), reminder letters and/or Nurse to follow-up with phone call.
- GPs may also opportunistically approach potentially eligible patients.
- GPs will review each participant's prescribed antihypertensive medication and decide which drug should be withdrawn (with medication withdrawal algorithm provided by the research team).
- GP will be responsible for taking informed consent at the baseline visit.
- GP/nurse will be required to conduct at least one safety monitoring appointment for patients in the intervention group (at 4 weeks follow-up) to review clinic/self-monitored blood pressure readings and re-introduce medication if necessary.

By Participants:

- Participants will be randomised to one of the two trial arms: i) usual care ii) medication withdrawal.
- All Participants will attend a Baseline and 12 week follow-up visit. Participants assigned to the intervention group will also attend a 4 week safety visit.
- During visits participants will complete questionnaires and answer questions about their medical history.
- Those in the intervention group will be required to monitor their BP at home for a week at the end of each 4-week period.

By Researchers:

- Research Facilitators will conduct baseline and follow-up visits.
- Collection of primary and secondary endpoint data.
- Review of questionnaires at end of participants' period in the study.
- Provide home BP equipment and training to participants.

Reimbursement

Reimbursements have been agreed for the following activities. When the practice is initiated into the study, researchers will discuss the process for claiming these costs.

Costs	Invoice Study Team	Invoice CRN	Indicative costs*
One-off Costs:			
Study set up and site initiation visit	£123.92		£123.92
Preparation and database search		£43.92	£43.92
Per Patient Costs:			
GP oversight of trial activities (15 patients)	£13.33		£199.95
Eligibility review (150 patients)		£0.67	£100.50
Mail out and postage (75 patients)	£1.16		£87.00
Approaching patient opportunistically (not including replies to mail out)	£1.83		£1.83
Notes review and medication withdrawal plan (15 patients)		£13.33†	199.95
Take informed consent (15 patients)		£26.66	£399.90
Research use of a room at the Practice (15 patients)	£22.50		£337.50
Patient safety monitoring visit (15 patients)		£13.33	£199.95
Serious Adverse Event reporting (per event)	£13.33		£13.33
Total costs*	**£735.92**	**£944.22**	**£1,692.59**

*Total costs based on screening 150 patients, inviting 75 and consenting 15. (Using mail out method with no opportunistic recruitment and assuming no Serious Adverse Event reporting).

†If the patient is randomised to the intervention group please invoice the CRN. If the patient is randomised to the control group please invoice the study team.

Invoice to study team: OPTiMISE Team, Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.

Invoice to CRN: Tracey Allen, Oxford University Hospitals NHS Trust, NIHR Clinical Research Network Block 8, Nuffield Orthopaedic Centre, Windmill Road, Headington, Oxford OX3 7HE

Potential Benefits for the Practice

- Opportunity for patients and practice to engage in a study investigating a potential new treatment strategy for elderly patients with hypertension.
- Reimbursement of all clinical / admin time. GCP training available.
- Opportunity for developing research at your practice and to raise practice profile.
- Professional development for staff involved.

Advice on using DOCMAIL

Docmail is provided by CFH Docmail Ltd a secure print and mailing company who provide print and mailing services for Local Government, GP's, Dentists, Opticians, Medical Practices, Schools, Exam Boards and Banks etc. throughout the UK. The system can be found online at

www.docmail.co.uk and requires a user name and password for businesses to send secure mailings via the website, print driver or API.

Docmail currently has over 50 health research studies and 3000 medical practices registered and using Docmail to send out their mailings. Docmail, this is approved by the following:

- GP System of Choice – Lot 2 supporting services
- Crown Commercial Service for Hybrid Mail, which allows all government organisations to use Docmail.
- Health Trust Europe and London Procurement Programme for Outgoing Mail Solutions
- Caldicott Guardians across a number areas have approved the use of Docmail
- Ethics Committees have approved the use of Docmail by surgeries for use in medical studies.
- EMIS Partner Programme
- Connecting For Health - achieved a 100% rating when completing the Dept. of Health's Information Governance Toolkit Assessment for 2014-2015 and meets the terms and conditions of the DH Information Governance Assurance Statement. The assessments are available at:
  https://www.igt.connectingforhealth.nhs.uk/reportsnew.aspx?tk=401634495202720&cb=10%3a49%3a25&lnv=6&clnav=YES

For further information on the Docmail system please visit FAQs page at http://www.cfhdocmail.com/faqs.html. If you do not wish to use Docmail, contact the study co-ordinator for alternatives.

Patient Confidentiality

Participant data will only be accessed upon notification of consent being obtained. Data collected will be securely stored in compliance with all national and local regulations. All Staff adhere to the principles of Good Clinical Practice (GCP) and the Data Protection Act, 1998. All study documents will be anonymised and patients will only be identified by unique Participant ID. Any documents holding Patient Identifiable Data (PID) are held securely with restricted access either electronically or in paper format and kept securely, and will be used only for patient follow-up, e.g. if a member of the research team needs to make a follow up phone call to a patient or recall them for a follow-up visit. In the event that the study team require access to PID as part of an agreed protocol, explanation of this will take place at the point of consent.

If you wish to take part in the study, what happens next?

Please e-mail your research facilitator or Tracey Allen with the following details:
Email to: tracey.allen@oxfordhealth.nhs.uk
Email subject heading: Expression of Interest – *OPTIMISE*
GP name:
Practice manager/Research admin:
Practice Address:
Telephone Number:
Email address:

Thank you for your interest in this study. Please call the Study Co-ordinator if you would like to discuss this study further.