PRACTICE INFORMATION SHEET

The OPTiMISE Trial

Optimising Treatment for Mild Hypertension in the Elderly: (OPTiMISE) Long Term Follow-up

Background

Your practice recruited participants to the OPTiMISE trial which ran between April 2017 and January 2019. The initial trial results showed that in two thirds of older people, it is possible to reduce the number of blood pressure lowering medications people take with limited impact on their blood pressure control or quality of life.

The trial was conducted in 69 GP surgeries across the Midlands and South of England. A total of 569 participants aged 80 years or older with well-controlled blood pressure taking two or more antihypertensive medications were included in the study. The trial showed over a period of 12 weeks that blood pressure remained well controlled (150 mm Hg or less) regardless of whether or not an antihypertensive was deprescribed. There were no differences in side effects, adverse events or quality of life between groups (see infographic below).

Although the initial period of active follow-up was limited to 12 weeks, the study consent included permission for the research team to access participants medical records for longer term follow-up. We are pleased to tell you that this long term follow-up has now started.

Aims:

The long term follow-up aims to examine whether there were any differences between treatment groups in hospital admissions and general health after medication reduction. The study plans to:

- Conduct a long term follow-up study of participants enrolled in the original OPTiMISE trial
- Use electronic health records to determine study outcomes
- Collect data remotely (via ORCHID and NHS Digital) and via manual notes reviews

Research questions:

1. Is medication reduction associated with an increased risk of serious adverse events (death or hospitalisation for any cause)?
2. What are the long-term benefits or harms of medication reduction in terms of adverse events, risk of death, cardiovascular disease, hospitalisations?
3. What effect does deprescribing an antihypertensive have on blood pressure and blood pressure control up to three years after randomisation?
4. Is medication reduction maintained for up to three years after randomisation?
5. Are differences in outcomes modified by baseline characteristics of participants including frailty and multi-morbidity?

OPTiMISE Participant involvement

We will contact each participant to remind them of the long term follow-up and of their right to opt-out if they wish to do so. No further Consent will be required and there will be no direct involvement from participants.

Practice Involvement

Your active participation in this follow-up will be minimal. We will however contact you to check that the details we currently hold for the trial participants are still correct and whether or not it is appropriate for us to make contact. Following that we will then ask you to provide electronic health record access to a member of the NIHR Clinical Research Network (CRN) who will undertake a medical notes review of your study patients who gave consent to take part in the main OPTiMISE trial.

We will reimburse each practice £100 plus an additional £15 per participant for supporting this follow-up study. NIHR CRN teams will also receive service support costs for extracting data from the electronic health records.

Oxford-Royal College of GPs (RCGP, Research and Surveillance Centre (RSC).

In addition, and with your agreement, we would also like to obtain this longer term follow-up data via ORCHID. This automated system run in collaboration with RCGP allows data to be extracted from clinical records with minimal practice input and state of the art security. A dedicated practice liaison officer will contact you to help facilitate this set up which would include agreeing and signing the ORCHID Agreement.

Will the study data be kept confidential?

All study procedures and data processing will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018.

What will happen to the results of this study?

Information collected during the study will be fed back to practices and commissioners of care by means of the summaries of the results. The research team will publish the findings in scientific journals and present them at conferences. Both traditional and social media will be utilised to support dissemination of the study findings.

Who is organising and funding the study?

The OPTiMISE longer term follow-up is funded by the British Heart Foundation and is being organised by Professor James Sheppard and Professor Richard McManus at the University of Oxford, Primary Health Care Clinical Trials Unit in Oxford.

Further information and contact details:

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Is it safe to deprescribe blood pressure lowering medications in older adults?

OPTiMISE
Optimising Treatment for Mild Systolic Hypertension in the Elderly

Results from the OPTiMISE trial

Summary This trial suggests that antihypertensive medication reduction can be achieved without substantial change in blood pressure control in some older, multi-morbid patients with hypertension.

Population Patients aged 80+, taking 2 or more antihypertensives with well controlled systolic blood pressure (150mmHg or less).

569	48.5%	51.5%	98.4%	85	4
Participants	Female	Male	Multimorbidity	Years old	Medications prescribed

Randomisation

Comparison

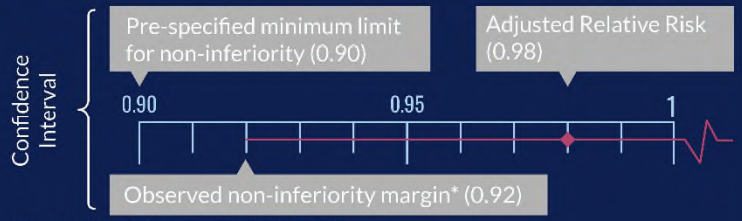
- Continue all medication (Control) — 287
- Medication reduction (Intervention) — 282

Follow for 12 weeks

Findings

Primary outcome Is medication reduction similar to usual care with regard to short-term systolic blood pressure control (<150 mmHg)?

	Control	Intervention
% with controlled systolic blood pressure	87.7%	86.4%

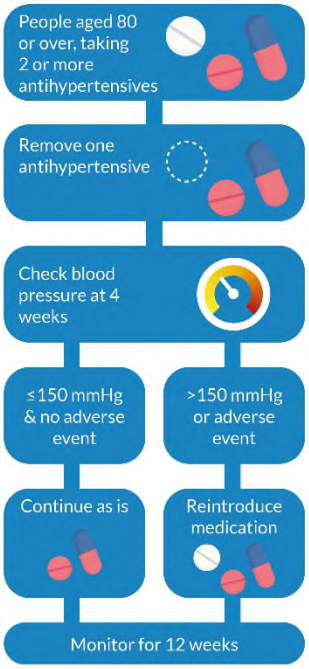


*Adjusted RR 0.98, (97.5%, 1-sided CI 0.92 to ∞)

Result: Yes – primary outcome met.

	Control	Intervention
Systolic blood pressure (mmHg)	130.8	133.7
Number of anti-hypertensives	2.6	1.8

OPTiMISE Deprescribing algorithm



Caveat:
The long-term impacts of medication reduction remain unknown, and were not examined by this study.

Healthcare professionals should exercise caution when considering whether or not to deprescribe blood pressure medication.

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Reference:
Sheppard JP, Burt J, Lown M, et al. Effect of antihypertensive medication reduction vs usual care on short-term blood pressure control in patients with hypertension aged 80 years and older: the OPTIMISE randomized clinical trial. *JAMA*. 2020; 323(20):1-13. doi:10.1001/jama.2020.4871