OPtimising Treatment for MIld Systolic hypertension in the Elderly (OPTiMISE): primary results from a randomised controlled non-inferiority trial

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Abstract

Introduction: Previous trials show that prescribing antihypertensives in some patients aged ≥80 years is effective but conflicting observational data suggest it may carry overall harm in older multi-morbid patients. This study examined whether antihypertensive medication reduction is safe in older patients without significant changes in blood pressure control.

Design: Open label, randomised controlled trial. Patients were randomised to medication reduction (one antihypertensive stopped) or usual care (medication continuation). The primary outcome was the difference in the proportion of participants with controlled blood pressure (<150mmHg) at 12-week follow-up. Secondary outcomes included the proportion of patients maintaining medication reduction and the difference in blood pressure, quality of life (EQ-5D), side effects and adverse events at follow-up.

Setting: 69 practices across UK primary care.

Participants: Aged ≥80 years, with systolic blood pressure <150mmHg and receiving ≥2 antihypertensive medications. Participants had to be considered to potentially benefit from medication reduction by their GP, due to polypharmacy, co-morbidity or frailty.

Results: 569 patients (mean age 85±3 years, 49% male) were randomised with a baseline blood pressure of 130/69±13/9mmHg. Participants were multi-morbid (79% had 2 or more morbidities) with minimal cognitive impairment (MoCA score 24.4±3.8) and disability (MRS 1.4±3.8) and mild frailty (eFI 0.16±0.06). Primary outcome data were available in 534 participants (93.9%). A total of 459 adverse events occurred during follow-up, of which 23 were classified as serious. Full results will be presented in November.

Discussion: This trial provides evidence to inform clinical guidelines recommending deprescribing in older patients with multi-morbidity.

Patient and Public Involvement (PPI)

Patients and the public have been involved throughout the trial, from the original grant and protocol development, through to dissemination of the results. We have one PPI member on our trial management group and three members sitting on our trial steering committee. PPI was instrumental

in developing the novel recruitment literature used in the study which included a video infographic to explain the study and a two-part patient information sheet which was re-designed in partnership with a graphic designer.