Working Instructions

OPTiMISE Eligibility and Informed Consent

Eligibility

1) Trained practice staff will search practice-based registers to identify potentially eligible patients using the following criteria:
   i) Over the age 79 years,
   ii) on two or more antihypertensive medications,
   iii) with a last recorded systolic blood pressure of <150 mmHg,
   iv) no history of stroke or myocardial infarction in the preceding 12 months AND
   v) no conditions which preclude the ability to give informed consent

2) GP will assess the search list and use the additional eligibility criteria as described in 'Reference Guide 01 - Eligibility Criteria OPTiMISE' to shortlist the patients who will be invited to take part in the trial.

3) Those deemed eligible will be sent letters of invitation from their GP.

GP review of patient's current medication

Prior the patient's appointment, participating GPs will review the patient's current antihypertensive medication regime and decide which medication should be removed if the participant is randomised to the intervention arm of the trial (10 mins allocated).

1) The choice of medication to be reduced, and reasons why, will be documented in the 'GP medication reduction CRF'.

   The patient will not be informed of the choice of medication.

2) This information will be passed to the Research Facilitator who will conduct the Screening and Baseline visit immediately after.

Patient Appointment and Informed Consent

Informed consent will be taken at the initial visit by the GP who will have received training in Good Clinical Practice. They will be authorised to take consent by the Chief Investigator, delegated through the Principal Investigators where applicable.

Twenty minutes has been allocated for the patient appointment and taking informed consent.

1) Patient Appointment, prior to consent

- During the patient appointment, the GP will show the study video infographic and go through the full PIS explaining the exact nature of the trial; what it will involve for the participant; the implications and constraints of the protocol and any risks involved in taking part.
- Having had a chance to ask questions, those individuals willing to participate will be asked by the GP to give informed consent adhering to the relevant PC CTU Standard Operating Procedure (SOP).
- If a patient requires more time to make a decision on participation then a further consultation should be arranged.

2) Completing the Consent Form

- Individual points on the consent form must be **initialled, NOT ticked.**
- The consent form will be signed and dated by **both**
  - Participant
  - GP
- Patients will be asked to consent to being contacted by the research team to discuss participation in a separate interview study related to this trial.
- Consent will be requested to allow relevant sections of patient medical notes and data collected during the study to be looked at by responsible individuals from the research team, regulatory authorities (including the MHRA) and the NHS trust, where this is relevant to taking part in the trial.

3) Sending the Consent Form

- **What to do with the original (top signed copy) consent form and attached copies:**
  - Original (white copy) will be given to the onsite research facilitator who will send it back to **PC-CTU Oxford.**
  - Yellow copy to be given to the participant
  - Blue copy to remain in the patient's trial records at the GP practice

Eligibility Assessment

- After informed consent has been obtained patients will move to another room in the practice where a trained member of the research team (PCRN/research/practice staff) will complete the screening procedures, which include:

  - Confirmation of the patient's age
  - Past medical history (e.g. history of stroke or heart attack in the past 12 months)
  - Current cardiovascular medication
  - Blood pressure measurement

- Once eligibility is confirmed baseline data will be collected.

Withdrawal from the trial

Participants are free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give a reason for withdrawal.