Quality of consent in a primary care based randomised controlled trial: multi method study of recruitment to the OPTiMISE trial

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Abstract

Introduction

Informed consent is foundational to research participation, and relies on individuals having capacity, being adequately informed, and agreeing to take part voluntarily. OPTiMISE was a randomised controlled trial investigating the feasibility of de-prescribing anti-hypertensive medication in frail older patients aged ≥80 years. This study aimed to explore the quality of consent in OPTiMISE using a multi-methods approach.

Methods

Seventy-eight consent appointments between GPs and eligible patients were audio recorded. Forty-five appointments were purposively sampled for this analysis, based on patient gender, recruiting GP, and timing compared to interventions designed to improve consent. The Participatory and Informed Consent (PIC) instrument was applied to audio recordings to evaluate the quality of consent. Thematic analysis was used to explore how consent discussions played out between GPs and patients.

Results

GPs often presumed consent through patient attendance at the appointment, limiting patients' opportunities for actively participating in the consent process. Some patients expressed an understanding of the trial, while others had little engagement, or deferred to the GP's opinion. The PIC instrument identified that GPs gave little information in areas such as trial processes, risks-benefits, and confidentiality, although this improved following the introduction of a consent checklist within the trial.

Discussion

Analysis will be completed by September 2019. Through combining methods to explore both the content and process of consent appointments, we aim to understand how consent is enacted in a primary care setting between GPs and patients, how this influences the quality of consent and whether simple measures can improve it.

Patient and Public Involvement (PPI)

Patients and public have not been directly involved in this sub-study; however, they were involved in designing the OPTiMISE trial and management of the research.