# An evidence base to optimise methods for involving patient and public contributors in clinical trials: a mixed-methods study

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# **Plain English summary**

Involving patient and public contributors in clinical trials

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# **Plain English summary**

The study explored methods and impact of involving patient and public contributors in a sample of clinical trials from a major public funding body. The purpose was to improve future approaches to such involvement by systematically describing and critically evaluating the process, challenges and impact of that involvement from the perspectives of patient and public contributors, chief investigators and clinical trials unit staff. The study included an examination of triallists' plans for patient and public involvement as described within their funding applications; a questionnaire survey of chief investigators' and patient and public involvement contributors' opinions and activities; interviews with chief investigators, patient and public contributors and trial managers; and an examination of the role of clinical trials units in identifying and supporting patient and public contributor needs using a questionnaire survey. The study was informed by a patient and public involvement advisory group.

The study found that if researchers, patient and public contributors, and research funders wish to enhance patient and public involvement in trials they should consider how that involvement can inform or benefit a trial, plan that involvement to suit those goals, involve patient and public contributors at an early stage and work to develop good relationships between those contributors and researchers, with approaches to involvement favouring responsive and managerial roles in preference to oversight committee roles. The training needs of researchers instigating patient and public involvement, and of patient and public contributors, should be considered alongside their roles and experience.

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