

Project Title: Developing a Patient and public Involvement intervention to enhance Recruitment and Retention In Surgical Trials (PIRRIST)

Applicants: Mr Richard Bulbulia (CTSUs Hub), Dr Joanna Crocker (University of Oxford), Assoc Prof Jonathan Cook (ConDucT-II Hub), Dr Kerry Woolfall (North West Hub), Dr Sian Rees (Oxford Academic Health Science Network), Prof Shaun Treweek (University of Aberdeen), Miss Nicola Farrar (University of Oxford/Bristol), Mr Alan Chant (Patient Partner).

Specific grant objectives

We sought funding from the MRC Network of Hubs for Trials Methodology Research to carry out stages 2-4 of a four-stage project to develop a patient and public involvement (PPI) intervention which aimed to enhance recruitment and retention in surgical (including surgery-related) trials:

Stage 1: A survey of current PPI practice in UK surgical trials (funded by the NIHR Oxford Biomedical Research Centre)

Stage 2: Focus groups with key stakeholders (surgical trial investigators, administrators, PPI coordinators and involved patients or members of the public) to explore:

- (i) the needs and challenges associated with PPI;
- (ii) perceived barriers to effective recruitment and retention
- (iii) participants' views about PPI impact on recruitment and retention;
- (iv) possible components of a PPI intervention.

Stage 3: A survey of stakeholders' views on the possible components of the PPI intervention and the importance of the identified barriers to recruitment and retention.

Stage 4: A consensus workshop with a purposive sample of stakeholders to determine the most suitable PPI intervention for implementation and evaluation in surgical trials.

What has been achieved?

Stage 1:

- We carried out an online survey of PPI practice in 71 active, UK-led adult surgical trials in Autumn 2015. This sample comprised 55% of eligible trials identified.
- We also used National Research Ethics Service (NRES) data to assess response bias in relation to PPI practice.
- The survey found that 92% of participating trials included some kind of PPI, suggesting that it is much more common in surgical trials now than it was prior to 2010¹. The most common PPI activity was developing participant information materials.
- In order to raise awareness of the PIRRIST project and help recruit participants, we gave seminars at 6 UK academic surgical trial centres and published an article in the Bulletin of the Royal College of Surgeons (see list of outputs below).

Stage 2:

- We carried out six focus groups (four with surgical trial staff and two with PPI contributors) in Oxford, Aberdeen, Bristol and Birmingham in 2016. A total of 54 people took part.
- The focus group findings informed the design of the subsequent surveys and consensus workshop. Key findings regarding the perceived impact of PPI on recruitment and retention were also presented at the 4th International Clinical Trials Methodology Conference / 38th Annual Meeting of the Society for Clinical Trials.

Stage 3:

- The focus groups revealed that there were barriers to meaningful PPI, even when trial staff had a positive attitude towards it. We realised that in order for our PPI intervention to be successful, it would need to address the most important barriers to PPI as well as barriers to recruitment and retention of participants. We therefore decided to carry out two separate surveys: one regarding recruitment and retention issues and one regarding PPI issues identified in the literature and in the preceding focus groups. In order to keep the surveys to a manageable size for participants, we postponed seeking stakeholders' views on the possible components of the PPI intervention until the subsequent consensus workshop.
- We identified 19 distinct possible elements of a PPI intervention from the preceding systematic review and focus groups. These were split into 12 potential core components (addressing barriers to recruitment and retention) and 7 potential supporting resources (addressing barriers to successful PPI), since we felt that both elements would be needed for a successful PPI intervention.
- The surveys were carried out in Autumn 2017. In total, 151 people (UK surgical trial staff) completed the survey regarding recruitment and retention issues in surgical trials, and 117 people (UK surgical trial staff and involved patients/public) completed the survey regarding PPI issues in surgical trials.
- The survey results revealed the frequency of each issue (% of respondents who had experienced it) and the importance of each issue (no/mild/moderate/severe problem, for those who had experienced it). These findings fed into the subsequent consensus workshop.

Stage 4:

- Possible core components and supporting resources, along with evidence for and against their potential effectiveness (gathered from all the preceding stages), were summarised. The PIRRIST study team then shortlisted 5 core components and 5 supporting resources to take forward to the consensus workshop.
- The workshop was held on 10th January 2018 in at the King's Centre in Oxford. Participants worked in small groups to produce a summary of their views on the affordability, practicability, effectiveness, acceptability, side-effects and equity² of each component. Using handheld electronic devices, workshop participants then anonymously rated their level of agreement with the statement 'This component should be included in the final PPI intervention'.
- The core components and supporting resources were then ranked according to the extent to which workshop participants agreed with their inclusion.

The PIRRIST intervention:

- Following the consensus workshop, the PIRRIST team met to decide which components and resources to include in the final PPI intervention for surgical trials.
- Based on the results of the consensus workshop, previous stages and pragmatic considerations, the following features of the intervention were agreed:
 - Core components: PPI in (a) designing surgical trials (including funding proposal and protocol) and (b) developing patient-facing materials (including consent documents, recruitment adverts, verbal recruitment messages, social media communications, data collection tools and participant newsletters).
 - The PPI will be a small number of patient/carer partners with experience of the medical condition under study as members of the Trial Management Group and Trial Steering Committee, linked to a larger patient/public advisory group.
 - Supporting resources: A toolkit for PPI planning and recruitment in surgical trials. This will include a convincing rationale for PPI (including evidence of effectiveness), signposting to or adapting appropriate existing resources (such as Bagley *et al.*'s toolkit for PPI in clinical trials³), some flexibility to allow tailoring to individual trials, and a minimum level of training for trial staff and PPI contributors.

Outputs:

The following outputs have been achieved to date (in chronological order):

- Crocker JC, Rees S, Locock L, Petit-Zeman S, Chant A, Treweek S, Cook JA, Farrar N, Woolfall K, Bulbulia R. Developing a patient and public involvement intervention to enhance recruitment and retention in surgical trials (PIRRIST): study protocol. Poster presentation at 3rd International Clinical Trials Methodology Conference (ICTMC), Glasgow, 2015. Published in *Trials* 2015; 16: P89.
- Crocker J, Bostock J, Bulbulia R. PPI: calling all surgical researchers... *Bulletin of the Royal College of Surgeons* 2016; 98(1): 30-33.
- Crocker JC, Rees S, Locock L, Petit-Zeman S, Chant A, Treweek S, Cook JA, Farrar N, Woolfall K, Bostock J, Bowman L, Bulbulia R. Developing a patient and public involvement intervention to enhance recruitment and retention in UK surgical trials (PIRRIST). Poster presentation at IDEAL Collaboration Conference, Oxford, 2016. Published in *International Journal of Surgery* 2016; 36, Supplement 2: S140-S1.
- Crocker JC, Rees S, Locock L, Petit-Zeman S, Chant A, Treweek S, Cook JA, Farrar N, Woolfall K, Bostock J, Bowman L, Bulbulia R. Developing a Patient and public Involvement intervention to enhance Recruitment and Retention In UK Surgical Trials (PIRRIST). Oral presentation at 37th Annual Meeting of the Society for Clinical Trials, Montreal, 2016.
- Crocker JC, Pratt-Boyden K, Hislop J, Rees S, Locock L, Petit-Zeman S, Chant A, Treweek S, Cook JA, Farrar N, Woolfall K, Bostock J, Bowman L, Bulbulia R. How might patient and public involvement (PPI) improve recruitment and retention in surgical trials? A qualitative study exploring the views of trial staff and PPI contributors. Oral presentation at 4th International Clinical Trials Methodology Conference (ICTMC) and 38th Annual Meeting of the Society for Clinical Trials, Liverpool, 2017. Published in *Trials* 2017; 18(Suppl 1): 200.

The following articles are in preparation for submission to open-access, international, peer-reviewed journals in 2018:

- Crocker JC, Pratt-Boyden K, Hislop J, Rees S, Locock L, Petit-Zeman S, Chant A, Treweek S, Cook JA, Woolfall K, Farrar N, Bostock J, Bulbulia R. How are patients and members of the public involved in the design and conduct of UK surgical trials, and how should they be involved? A survey and focus groups with stakeholders.
- Crocker JC, *et al.* Barriers to recruitment and retention of participants in UK surgical trials: a survey of their frequency and importance.
- Crocker JC, *et al.* Patient and public involvement (PPI) in UK surgical trials: why is it so hard?
- Crocker JC, *et al.* A patient and public involvement intervention aimed at enhancing recruitment and retention in surgical trials (PIRRIST).

All reports and conference presentations are publically accessible via the PIRRIST study website,⁴ and we will publish a lay summary alongside each academic journal article.

Key recommendations for PPI in surgical trials

Based on the evidence gathered during this project, we have the following key recommendations for PPI surgical trials:

1. Involve PPI contributors as early as possible in any surgical trial. Aim to involve at least three patient/lay partners in developing your funding proposal, who would then continue as members of the trial team. Budget for more extensive PPI in your grant application (for example, a separate patient advisory group or community outreach) in addition to these ongoing partnerships.

2. When developing the trial funding proposal, identify someone on the trial team who will be responsible for PPI throughout the trial. Include a sufficient budget for their time on PPI, as well as PPI contributors' time.
3. Ensure that the PPI includes some people with personal experience of the health condition requiring surgery in the trial.
4. In the early stages of trial design, ask patients from the target population (those awaiting or considering the surgery being studied) about the acceptability of randomisation in this context. For example, would they be willing to be randomised to receive the proposed surgery, treatments or care? Would they have strong preferences for one treatment over another, and how might you overcome or accommodate this? How would they feel about a surgical placebo (if applicable)? Plan how you will explain jargon such as 'randomisation' and 'placebo' in lay terms.
5. Seek as much PPI input as possible into the design and planned delivery of follow-up questionnaires. How can you make them as appealing and easy to complete as possible? What strategies or incentives could be used to encourage participants to complete and return them?

The PIRRIST intervention will provide tools to help surgical trial teams implement these recommendations.

Next steps

- In addition to the planned publications listed above, in 2018 we will hold at least four dissemination events at surgical trial centres across the UK and at least one public dissemination event. As well as raising awareness of the findings, these events will help to refine the intervention and may result in new collaborations for feasibility testing and evaluation.
- We will continue working to refine the intervention in 2018, and plan to apply for funding for a feasibility study in 2019. We hope this will lead to a subsequent full-scale, mixed methods evaluation of the intervention.

¹ Gamble C, Dudley L, Allam A, et al. Patient and public involvement in the early stages of clinical trial development: a systematic cohort investigation. *BMJ Open*. 2014;4(7):e005234.

² Adapted from 'The APEASE criteria for designing and evaluating interventions' in 'The Behaviour Change Wheel: A Guide to Designing Interventions' by Susan Michie, Lou Atkins and Robert West (2014, Silverback Publishing).

³ Bagley HJ, Short H, Harman NL, et al. A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials – a work in progress. *Research Involvement and Engagement*. 2016;2(1):1-14.

⁴ 'Developing a Patient and public involvement Intervention to enhance Recruitment and Retention in Surgical Trials (PIRRIST)' URL: www.phc.ox.ac.uk/pirrist