research sites; including LEAP members in reviewing trial documents; completing a practice run-through of trial assessments; inviting LEAP members to sit on the interview panel for recruitment of trial staff.
Findings: LEAP feedback was invaluable in the development of this trial and enabled the research team to make key changes, e.g. avoiding medical jargon within participant facing trial documents, specifically the information sheet, consent form and advertising materials. LEAP members also advised on visit structure, suggested changes to outcome measures, and highlighted the importance of consistency in patient-staff relationships. Following this advice, the treatment period was extended to allow participants more flexibility for attendance. Additionally, LEAP members' inclusion in the interview process ensured that empathetic trial staff were appointed.
Conclusion: By involving patients with lived experience from the outset, several changes were made to the trial design to improve patient experience. The outcome has been promising thus far and we will continue these strategies, involving LEAP members in all dissemination activities. Using this approach throughout the trial has the potential to improve the experience of participants, and therefore has implications for participant retention in future clinical trials into depression.

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Uptake of interventions to communicate results of a phase III randomised controlled trial to participants: early results from the Show RESPECT study (ISRCTN96189403)

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Trials 2019, **20(Suppl 1):**P-89

Introduction: Previous studies show that participants want to be informed of the overall results of trials they have taken part in, but that this often does not happen. Anecdotal reports suggest even when trials do attempt to communicate results to participants, it is often not done well. Show RESPECT tests three approaches, identified and developed through extensive PPI, to communicating trial results to UK participants of ICON8, a phase III ovarian cancer chemotherapy RCT.
Methods: Show RESPECT is a mixed methods cluster randomised factorial Study Within A Trial (SWAT), run within ICON8. Over 40 ICON8 UK centres (hospitals) are being randomised to communicate results to participants using combinations of:
-Link to a basic webpage (text only) vs enhanced webpage (including diagrams, video, links to further support and information, and the option to submit questions)
-Printed summary vs no printed summary
-Invitation to join an email list vs no invitation
The primary outcome measure (OM) of Show RESPECT is participant satisfaction with how the results are communicated. Data are collected from participants, site staff and CTU staff by questionnaires, and qualitative interviews are being carried out with site staff and participants.
Secondary OMs include uptake of the interventions, which is measured using analytic data from customised links (for webpages and email list) and data collected on logs by site staff (printed summaries).
Timing of potential results: The final sites will be randomised in May 2019. We will present data on the PPI process and intervention uptake (available from August). Results from the primary outcome will be presented at a later date.
Potential relevance and impact: These data have the potential to inform future approaches to better communicate overall results to similar participant populations in other trials, helping trialists meet their ethical obligations to offer results to patients in accessible ways.

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MAMMO-50 - Working with the patients to enable multiple types of data collection within a clinical trial

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Introduction: There is a lack of evidence/consensus amongst surgeons on optimum frequency or duration of follow-up including mammography for breast cancer patients aged 50 years and older at diagnosis. Mammo-50 RCT has the opportunity to gather patient reported outcomes and patients' perspectives on follow-up.
Methods: Mammo-50 trial has recruited over 5235 women in a randomised trial assessing duration of mammographic surveillance for women over 50 years old at diagnosis and 3 years post curative surgery. 91% of women agreed to participate in a quality of life substudy (QoL) and 75% of women consented to enter the Qualitative sub-study (QSS). In addition, a national patient-led survey on follow-up was developed by the Independent Cancer Patients' Voice (ICPV) to gather patients' experience of follow-up.
Results: Mammo-50 patient questionnaires indicated that 28% of patients had high levels of distress due to concerns about fatigue, sleep, worry/anxiety, memory/concentration, hot flushes and pain. Mammo-50 focus groups (6 at multiple sites) and individual interviews (32 telephone interviews) indicated that patients in general were satisfied with their care and happy to be in a trial. The interviews reached saturation quickly with patients being concerned about early discharge from hospital follow-up and the fear of recurrence. The ICPV survey indicated that over 2/3rds of respondents said they had some unmet needs during their follow up period; these were varied and included both physical and psychological needs.
Discussion: In summary, focus groups and individual interviews suggest that patients, when followed-up by the trial team, are happy with their care. When given the opportunity to report unmet needs through questionnaires/surveys, patients often report things which could be causing them distress, but which may go unnoticed in routine follow-up. Clinical trials have the opportunity to collect patient reported experiences alongside the standard QoL booklets, providing a rich source of additional data.

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Abstract omitted

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PIRRIST: Patient and public involvement (PPI) to enhance recruitment and retention in surgical trials

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Trials 2019, **20(Suppl 1):**P-92

Introduction: Poor recruitment and retention are common challenges to the successful delivery of surgical trials. Patient and public involvement (PPI) has the potential to improve both but there have been few attempts to formally investigate this. We aimed to develop an evidence-based PPI Intervention to enhance Recruitment and Retention In Surgical Trials ('PIRRIST').
Methods: Four stages: (1) Online survey to identify current PPI practice in UK surgical trials; (2) Stakeholder focus groups and interviews to explore PPI needs and challenges, issues with participant recruitment and retention, and how PPI might address these; (3) Two online surveys to estimate the frequency and importance of the identified issues with recruitment, retention and PPI in surgical trials; (4) Stakeholder workshop to determine key features of the final PPI intervention.
Results: 393 individuals took part across four stages of data collection. Based on the findings, we made recommendations for PPI in surgical trial design including: use a two-tier model of PPI (ongoing partnership with individuals plus consultation with the wider patient population); involve patients/carers with personal experience of the target health condition; budget for staff time on PPI. We held eight events with surgical trial staff and patient/public contributors across the UK to review these recommendations and plan next steps. From this we developed succinct, practical guidance to aid Chief Investigators (CIs) in planning PPI in surgical trials. We involved a professional graphic designer, user-tested the guidance with CIs and consulted many stakeholders including PPI contributors and trial managers.
Discussion: Our evidence-based guidance will help CIs to plan PPI that should boost participant recruitment and retention (evaluation needed). Although based on evidence gathered from surgical trials, the guidance could be applied to other clinical trials within the UK. The guidance will be available online from June 2019 via www.phc.ox.ac.uk/pirrist

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Patient and Public Involvement & Engagement in UKCRC Registered Clinical Trials Units – A Scoping Exercise

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Trials 2019, **20(Suppl 1):**P-93

Introduction: The UK National Institute for Health Research 'Breaking Boundaries' review of patient and public involvement (PPI) in research highlighted the need for a more strategic approach to PPI, recommending that PPI leads should have opportunities to network and share best practice. Furthermore, there is increasing emphasis on public engagement within clinical trials, including public dialogue about the need for and design of trials.
The UK Clinical Research Collaborative (UKCRC) Registered Clinical Trials Unit (CTU) Network established a Patient and Public Involvement and Engagement (PPI&E) Task and Finish Group to conduct a scoping exercise to:
•Identify different approaches for delivering PPI&E within CTUs
•Map existing PPI&E resources during the course of clinical trials
•Develop more effective collaborative PPI&E working across registered CTUs.
Methods: We conducted an e-survey with registered CTUs to investigate the current PPI&E landscape and challenges. Responses were discussed at a workshop with targeted activities to explore PPI&E practices. 4 public contributors also attended the workshop, sharing their perspectives on how CTUs should involve and engage patients and the public.
Results:
•46/51 registered CTUs completed the survey, 39 attended the workshop. Findings included:
•15/46 CTUs reported one person with overall PPI &E responsibility
•11 CTUs had PPI guidance for trial staff, 2 CTUs had PE guidance. 6 CTUs used PPI standard operating procedures
•No CTUs stated they would be unwilling to collaborate in PPI&E activity.
Discussion: This scoping exercise illustrated that PPI&E is evolving, with involvement currently more advanced than engagement. Resources to support PPI&E varied amongst CTUs. There is duplication of activities, suggesting a need for a formal sharing mechanism across the Network. The UKCRC PPI&E group will be developing a national communication strategy and central repository for resources and training for PPI&E to address the findings of this scoping exercise.

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Research nurse and patients perspective on innovative early phase trial designs

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Trials 2019, **20(Suppl 1):**P-94

Introduction: In recent years there has been a significant increase in the use of novel trial designs increasing statistical efficiency, particularly in the early phase setting. Little work has been done to assess how these designs impact patients and research nurses. We set out to develop an understanding of their views on novel early phase designs including Continual Reassessment Method, exploring if trial designs can be more patient-centred.
Methods: We conducted a joint interview with two research nurses working in early phase oncology trials (RN) and held a group discussion with nine representatives from a Patient and Public Involvement group (PPIgroup) to identify the aspects of trial design that mattered most. An interactive session was held at the NIHR Statistics - Early phase trials meeting, February 2019 (EPmeeting).
Results: 78% (7/9) in the PPIgroup and 48% (20/42) of EPmeeting felt that increased trial design complexity would have no impact on patient recruitment. Members of PPIgroup felt that an increase in logistical complexity would discourage trial recruitment but that trial design complexity would not. 39/44 delegates at the EPmeeting felt that patients would feel less secure joining a first –in-man trial however RN reported no concerns with recruiting to these trials; 1 member of the PPIgroup commented "We were clutching at straws and would have done anything". When asked about dose selection in a dose-finding trial, EPmeeting gave mixed responses across dose ranges however; the PPIgroup felt that patients would be reluctant to receive the highest dose due to potential toxicities.
Discussion: Trialists understanding of patients' needs may not necessary be in line with patients'. In order to ensure that innovative designs achieve benefits that matter most to patients, they need to be designed with patients as co-developers. Further work is required to identify how to encourage a more patient-centred approach.