PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials


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Overview of seminar

- What’s the problem?
- What do we mean by ‘PPI’?
- Impact of PPI on recruitment & retention in clinical trials
- Aims of PIRRIST project
- Methods
- Key findings
- PPI recommendations
- Practical guidance development
- Dissemination plans

Please complete feedback forms. Thank you!
Dissemination & feedback events

- Surgical trial centres: Birmingham, York, Bristol, Aberdeen, Oxford
- Patients and lay contributors: NCRI Consumer Forum, PPI workshop at Library of Birmingham, webinar
What’s the problem?

Recruitment & retention

- Major challenges for clinical trials
- High research priorities in the UK
- Measurable outcomes

PPI

Perceived to be valuable but in need of rigorous evaluation

Improves recruitment & retention (especially in surgical trials)?
Definition of PPI

“PPI contributors”

- Patients
- Carers
- Service users
- Public

Consulted by or working alongside researchers in

Choosing topic
Designing
Planning
Doing
Communicating findings

May be part of e.g.

Grant application
Trial Steering Committee
Trial Management Group
Advisory panel
Consultation exercise

Focus groups
Surveys
Interviews

(Using formal or informal research methods)

NOT researchers recruiting people to be participants in trial, or researchers disseminating information about trial to patients or public
Impact of patient involvement in mental health research: longitudinal study

Liam Ennis and Til Wykes

• **374 studies** in the Mental Health Research Network portfolio

• Greater patient involvement associated with **achievement of recruitment targets** (p<0.05)
Eligibility criteria: Experimental and observational studies quantitatively evaluating impact of a PPI intervention, vs. non-PPI or no intervention

Meta-analyses: Average effect of PPI interventions on enrolment & retention; several exploratory subgroup & sensitivity analyses.
Systematic review: Key findings

• 26 studies included in review (19 eligible for enrolment meta-analysis and 5 for retention meta-analysis)

• Wide variation in PPI characteristics & effect size

• On average, PPI interventions modestly but significantly increased the odds of participant enrolment in our main analysis (OR 1.16 [95% CI and prediction interval 1.01 – 1.34])

• Retention findings inconclusive due to lack of studies (OR 1.20; 95% CI 0.68 – 2.12 for main analysis)

Results by ‘lived experience’ (n=19)

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of participants</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horowitz 2009</td>
<td>277</td>
<td>0.51 (0.21, 1.26)</td>
</tr>
<tr>
<td>Arean 2003</td>
<td>444</td>
<td>0.74 (0.44, 1.24)</td>
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<tr>
<td>MacEntee 2002</td>
<td>887</td>
<td>1.86 (1.42, 2.44)</td>
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<tr>
<td>Wisdom 2002</td>
<td>1177</td>
<td>0.41 (0.23, 0.72)</td>
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<tr>
<td>Man 2015</td>
<td>1364</td>
<td>1.63 (1.00, 2.67)</td>
</tr>
<tr>
<td>Guarino 2006</td>
<td>2793</td>
<td>1.11 (0.96, 1.30)</td>
</tr>
<tr>
<td>Cockayne 2017</td>
<td>3450</td>
<td>1.02 (0.66, 1.57)</td>
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<tr>
<td>Cockayne 2017</td>
<td>3450</td>
<td>1.10 (0.71, 1.69)</td>
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<tr>
<td>Ford 2004</td>
<td>6246</td>
<td>1.38 (1.05, 1.82)</td>
</tr>
<tr>
<td>Subtotal (I-squared = 77.0%, p = 0.000)</td>
<td>1.07 (0.83, 1.37)</td>
<td></td>
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<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>Du 2008</td>
<td>126</td>
<td>1.80 (0.75, 4.36)</td>
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<tr>
<td>Donovan 2002</td>
<td>155</td>
<td>7.26 (3.04, 17.34)</td>
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<tr>
<td>Hutchison 2007</td>
<td>173</td>
<td>0.82 (0.42, 1.62)</td>
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<tr>
<td>Iliiffe 2013</td>
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<td>3.10 (1.04, 9.24)</td>
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<td>Horowitz 2009</td>
<td>277</td>
<td>3.81 (1.79, 8.10)</td>
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<tr>
<td>Vincent 2013</td>
<td>279</td>
<td>13.48 (6.07, 29.95)</td>
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<tr>
<td>Dear 2012</td>
<td>340</td>
<td>0.92 (0.45, 1.89)</td>
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<tr>
<td>Martin 2013</td>
<td>668</td>
<td>3.21 (1.26, 8.14)</td>
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<tr>
<td>Tenorio 2011</td>
<td>21162</td>
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<td>Sanders 2009</td>
<td>21600</td>
<td>2.14 (1.45, 3.17)</td>
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<tr>
<td>Tenorio 2014</td>
<td>53053</td>
<td>6.49 (5.63, 7.48)</td>
</tr>
<tr>
<td>Chlebowski 2010</td>
<td>60800</td>
<td>4.39 (3.09, 6.25)</td>
</tr>
<tr>
<td>Subtotal (I-squared = 92.3%, p = 0.000)</td>
<td>3.14 (2.11, 4.66)</td>
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<tr>
<td>Overall (I-squared = 95.8%, p = 0.000)</td>
<td>1.87 (1.31, 2.68)</td>
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NOTE: Weights are from random effects analysis

p = 0.017
Aim

To develop a PPI intervention aimed at improving recruitment and/or retention in surgical trials

- helping to develop our understanding of whether and how PPI might improve recruitment and retention in clinical trials

- leading to a mixed methods study to implement and evaluate the PPI intervention in UK surgical trials
Surgical trials

✓ Trials of a surgical intervention

✓ Trials in a surgical context, where surgery is involved but is not one of the interventions under evaluation
Methods: Overview

• **3 key stakeholder groups:**
  – Surgical trial staff (trial managers, investigators, administrators, research nurses)
  – Patients & members of the public involved in trials
  – PPI coordinators

• **Mixed methods:**
  – Surveys
  – Focus groups
  – Consensus workshop
Methods

Stage 1: Mapping PPI current practice in UK surgical trials (Online survey)

71 trials

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(6 focus groups + interviews)  
*54 participants*

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Stage 3: Rating importance of recruitment, retention and PPI issues (2 online surveys)
151 & 117 respondents
Methods

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71 trials

Stage 2: Identifying PPI, recruitment & retention challenges; Exploring possible components of intervention  
(6 focus groups + interviews)  
54 participants

Stage 4: Selecting key features of intervention  
(Stakeholder workshop)  
35 participants

Stage 3: Rating importance of recruitment, retention and PPI issues  
(2 online surveys)  
151 & 117 respondents
Key findings

• **92%** surveyed trials reported some kind of PPI, most commonly in **oversight (TSC)** or **advisory** roles.

• **Earlier involvement** enables more pathways to impact on recruitment & retention. PPI in **trial design** (including funding proposal) was considered essential.

• PPI should include patients/carers with **personal experience** of target health condition (although lay people can also help).

• **Two-tier** model of PPI appears effective but is uncommon.
Benefits of having a separate patient advisory group…

We found it's worked really well to have it separate actually, and you can just focus on the things that need talking about with them, rather than I suppose them having to sit through an entire meeting where maybe only certain bits of it might be relevant for them. […] In addition to how it helps the trial, I think patients really value coming along to a meeting of just patients and just all sharing their stories actually.

(PS24, PPI coordinator, focus group 4)
Example of PPI in designing recruitment methods…

They [PPI contributors] had the idea of using social media as a possible avenue to approach patients because of the type of patients in the trial – they were younger and they're more inclined to use Twitter and Facebook… And with their input we started to develop entries for Facebook and to use on Twitter, and our recruitment virtually tripled as a result of using that.

(PS08, trial manager, focus group 2)
Key findings

• Top **recruitment** issue = Patients preferring one treatment over another’ (82%)
• Top **retention** issue = Patients failing to return follow-up questionnaires (81%)
• Top **PPI** issue = Trial staff lacking time to do PPI (50%)
• Trial staff want help **recruiting** suitable PPI contributors
And I think maybe also in order to retain both your PPI members and your participants, you need somebody who is nominated to do that… whose role is to look after them. So, all the nuts and bolts of doing PPI; all the logistical stuff which is what takes up so much time, as well as being able to answer questions.

(PP14, PPI contributor, focus group 6)
PPI recommendations

Trial design & funding proposal

- Minimising burden on participants
- Increasing benefits to participants
- Assessing acceptability of randomisation and placebo
- Planning appropriate & effective recruitment and retention strategies

Trial protocol & patient-facing materials

- Designing attractive/appealing recruitment materials and messages
- Improving informed consent
- Ensuring questionnaires / data collection tools are as easy to use as possible
- Communicating with participants throughout trial to keep them engaged
PPI recommendations

- Trial design & funding proposal → Trial protocol & patient-facing materials
  - Ensure at least some have personal experience of target health condition

- Trial team
  - 3 PPI partners / co-applicants
  - Patient population or target community
  - Budget for wider PPI in grant application

- Identify person responsible for PPI and budget for their time
Guidance: design specifications

• Aimed primarily at Chief Investigators
• Persuasive (why important?)
• Able to be used flexibly or with a ‘pick and mix’ approach
• Succinct (2 A4 sides long)
• Practical (embedded tips & hyperlinks)
• Not re-inventing the wheel but signposting to existing resources, where available
• Structure: chronological steps?
Practical guidance: content

Tips and resources to aid recruitment & retention of suitable PPI partners

Examples of outreach and innovative PPI

Questions to ask PPI contributors

Training resources for trial staff and PPI partners

Resources to help budget for PPI
Dissemination routes

Royal College of Surgeons

NIHR Research Design Service

NIHR INVOLVE

Patient & PPI networks/organisations

NIHR organisations e.g. BRCs, CLAHRCs, CRFs

UK Clinical Trial Units
Messages for funders & institutions

• Short timeframe for grant applications limits quality of PPI

• PPI needs to be well funded, including staff time & training if needed

• Need for more funding to be made available for pre-grant PPI

• Consider funding expert PPI coordinator and database of potential PPI contributors
Thank you

- All participants for their time and generosity
- Collaborators and advisors
- Funders: NIHR Oxford Biomedical Research Centre & Network of MRC Hubs for Trials Methodology Research

Email: pirrist@phc.ox.ac.uk
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5th International Clinical Trials Methodology Conference

Sunday 6th to Wednesday 9th October 2019
Hilton Metropole, Brighton, UK

Key Dates:
Abstract Submission Deadline: Sunday 5th May 23:59 BST
Notification to Authors: Week Commencing 17th June
Early Registration Deadline: Monday 8th July

ictmc@in-conference.org.uk  www.ictmc2019.com