

Actively Involving Patients/Public with Trials Methodology Research (TMR)

Report of Workshop

held on 13th November 2019
at University of Manchester

This meeting was supported and funded through the [Hubs for Trials Methodology Research \(HTMR\)](#) and supported by [MRC-NIHR Trials Methodology Research Partnership \(TMRP\)](#).

Actively Involving Patients/Public with Trials Methodology Research (TMR)

An exploratory workshop held on Wednesday 13th Nov 2019 at University of Manchester

Facilitated by Derek C Stewart, Pete Bower, Kerry Woolfall & Katie Gillies

Purpose

The aim of the workshop was to initiate a dialogue with key stakeholders to gather examples and develop guidance for effective Patient, Public Involvement & Engagement (PPIE) in the context of Trial Methodology Research. This report is a record of the workshop and is intended for the Trials Methodological Partnership Executive and Working Groups. It will form part of a much more broader set of resources.

Definitions

Trials Methodology Research

Research into the methods used in the design, conduct, analysis and reporting of clinical trials is essential to ensure that effective methods are available and that clinical decisions made using results from trials are based on the best available evidence, which is reliable and robust.

[Catrin Tudor Smith, et al](#)

Patient and Public Involvement (PPI) in research

Research being carried out 'with' or 'by' patients and the public rather than 'to', 'about' or 'for' them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials and undertaking interviews with research participants

[NIHR INVOLVE \(2012\) Briefing notes for researchers](#)

Patient, Public Involvement in Trials Methodology Research (TMR)

As with intervention research, Patient, Public Involvement is also important for methodological research since this will help to increase both the value, integrity and quality of research.

[Alice M. Biggane, Maria Olsen and Paula R. Williamson](#)

Appendix

The programme for the workshop along with a list of attendees are provided

SUMMARY

It seems clear that patients, carers and the public are increasingly being actively involved with Trials Methodology Research (TMR). This involvement is across different aspects of trial methods and throughout the lifespan of a trial as well as research on the methods. There is an increasing amount of anecdotal evidence of this involvement illustrated by the examples given at the workshop and from social media [#PPI TrialMethods](#).

Patient and Public Involvement (PPI) does not appear to be any different in this context so many of the comments are more about good practice than specific to TMR.

However, the complexity of TMR requires a sharp learning curve for those who get actively involved. The term itself can be an issue. As a field of research it perhaps requires more explanation of what it is and isn't to enable people to get involved meaningfully. TMR is seen as having the potential to engage the wider population as it does not necessarily depend on particular personal or family experience of a specific diagnosis or condition.

Researchers need to be encouraged to keep an open mind and a willingness to explore the ways in which patients and public can be involved – by opening it up and helping people learn about the value of the research into trial methods and democratising the process.

Thought needs to be given to more tailored approaches for who we involve depending on type of study – the difference between involving those with previous PPI experience versus a wider groups with different sets of knowledge and skills. Individual projects may include a range of involvement.

Additional planning and preparation for PPI would be of benefit, including clarification of roles and tasks with research teams.

The **Trials Methodology Research Partnership** might like to consider gathering further examples of practice, developing resources and sharing ideas to enable the involvement of patients/public and researchers with this work:

- Develop focussed webinars about Patient, Public Involvement in trials methodology research
- Generate and showcase case studies of good practice –
 - Preparing for involvement
 - Adapting existing resources – E.G. The POPPIE working group and the PRIORITY study
- Survey TMRP PhD students re: plans for PPI in their project
- Gather further examples...
 - Researchers/Patient Contributors doing methodological research collaboratively – maybe consider video clips
 - Animations – with embedded examples of relevant stakeholders (as real persons)
 - Explanations of this type of research – for PPI contributors, research teams, funders, ethics, other stakeholders

- Articles and reports of impact of involvement on trials methodology research (things you did differently or changed or how you approached something)
- Illustrations of involvement in different trials methodology projects e.g. direct patient impact (e.g. recruitment and retention) versus less direct (e.g. stats analysis)
- Learning from PPI contributors and research team about what worked well/could be done better

Top Questions for designing and conducting Trials Methodology Research

The group identified a number of top tips for patient & public involvement. The suggestion was made by Mike Robling that these be translated into questions that researchers could ask of themselves. We present below for comment

- What is the aim and **purpose** of actively involving patients and the public with your Methodology Research?
- What is **distinct** about this involvement with Methodology Research or methodologies and how will it ultimately **benefit** patients?
- How do we best explain the **complexity** of this research?
- What planning are you doing to define specific **roles, expectations, perceptions** and **assumptions** people might have in this context?
- What **examples** and **case studies** of similar work can we draw upon?
- What **questions** would we like to explore together with patient contributors?
- Do we have the **community capacity** to carry this out?
- How are we **communicating** the task (language and style)?
- What **planning** and **resources** are required and how will the impact be measured??
- How might we identify and overcome any **challenges** and leave **preconceptions** aside?
- How might we tell others and **disseminate** the way we have involved patients & the public to different audiences?

Thank you to everyone who attended, provided notes and gave of their time.

Report of the Workshop

The meeting brought together a number of individuals experienced with Patient & Public Involvement (PPI) within the [Hubs for Trials Methodology Research \(HTMR\)](#) and [MRC-NIHR Trials Methodology Research Partnership \(TMRP\)](#). Attendance was by invitation of people known to the planning team.

The workshop was in the format of a structured conversation (see full programme Appendix A). It began with an opening session providing the purpose of the meeting and some definitions. Discussions were informed by a series of presentations and subsequent questions and related experiences of the attendees. 17 people attended 3 patient partners, 10 triallists and the 4 facilitators (see Appendix B).

Presentations

Nine participants were invited to talk/present some information about their work and the learning that had resulted. The following spoke and a number provided slides.

Kerry Woolfall - [Methodical Study](#)

To identify the priorities of UK PPI stakeholders for methodological research to help resolve uncertainties about PPI in clinical trials. The study team included three patient partners who were involved in all aspects of study design and conduct, including development of protocol, pilot topics and accompanying text, survey recruitment, interpretation of study findings and review of the published manuscript.

<https://www.youtube.com/watch?v=osVytFzXg8o>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5689224/pdf/HEX-20-1401.pdf>

Laura Flight – [Medical Statistics](#)

The aim of this work was to look at how adaptive designs and health economics can be used together to increase the efficiency of health technology assessments without compromising accuracy. This research is supported by the Health Economic Evaluation and Adaptive Designs (HEEAD) advisory panel. The panel is comprised of seven members of the public who provide regular input, guidance and a lay perspective to the on-going research.

<https://www.sheffield.ac.uk/scharr/sections/dts/statistics/msg-research/lfnihrdf>

Sandra Galvin – [START](#), [The People's Trial](#) and [PRIORITY 1](#)

In Ireland, the Health Research Board – Trials Methodology Research Network, START initiative invites primary school children to create their own fun randomised control trial in their classrooms. *The People's Trial* is a new and exciting way to participate in scientific research, where you decide all the major steps of a randomised trial.

The PRioRiTy I study identified research priorities for how to improve the process of how people are recruited to randomised control trials (RCT).

<https://www.hrb-tmrn.ie/public-engagement/start-competition/>

<https://thepeoplestrial.ie/>

<https://priorityresearch.ie/>

Katie Gillies – [PRIORITY II](#)

Priority II looked at retention in randomised clinical trials. Both PRIORITY studies used a James Lind Alliance approach and had extensive patient involvement within the advisory group.

<https://priorityresearch.ie/>

Bridget Young & Heather Bagley – [COMET](#) and [Core Outcome Sets animation](#)

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as '[core outcome sets](#)' (COS).

COMET established a People and Patient Participation, Involvement and Engagement (PoPPiE) working group with its own remit and resources. The team have produced numerous resources to support patient involvement and engagement in work to develop core outcome sets, including an animation to introduce patients and the public to this area :

<http://www.comet-initiative.org/Patients>

Sophie Staniszewska – [GRIPP2](#)

GRIPP2 (short form and long form) is the first international guidance for reporting of patient and public involvement in health and social care research. This paper describes the development of the GRIPP2 reporting checklists, which aim to improve the quality, transparency, and consistency of the international patient and public involvement (PPI) evidence base, to ensure that PPI practice is based on the best evidence.

<https://www.bmj.com/content/358/bmj.j3453>

Claire Planner & Ailsa Donnelly - [PACT](#)

Patient-Centred Trials (PACT) aims to design, deliver, implement and evaluate patient-centred trials. The objectives of PACT include to define what we mean by a 'patient-centred trial' and explore how we measure a 'patient-centred trial'. They have a number of PPI collaborators linked with this study. <http://research.bmh.manchester.ac.uk/patientcentredtrials/>

Other studies mentioned by participants during workshop discussions:

[The EPIC Study](#) - from plans to actions in patient and public involvement: a qualitative study of documented plans and the accounts of researchers and patients sampled from [a cohort of clinical trials](#)
<https://www.ncbi.nlm.nih.gov/books/NBK316049/>

[The RAPPORT study](#) to determine the types of PPI in funded research, describe key processes, analyse the contextual and temporal dynamics of PPI and explore the experience of PPI in research for all those involved.

<https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr03380#/abstract>

[PPI in Research: Reflections from Early Stage Researchers](#) states that by providing early stage researchers with appropriate educational, interactive and real-world training, this will introduce the various merits and challenges associated with PPI in early-stage research.

Two other studies - looking at the processes of involvement in surgical trials were also mentioned

<https://www.journalslibrary.nihr.ac.uk/hta/hta15150#/abstract> and

<https://abdn.pure.elsevier.com/en/publications/patient-and-public-involvement-ppi-in-uk-surgical-trials-a-survey>

COMMON THEMES

The presentations led to a variety of conversations captured separately by Katie, Kerry, Pete and Derek. The subsequent notes provide an overview of the common themes and issues discussed.

Trials Methodology Research

Need to make this more understandable

- HRB TMRN is developing an animation on trials methodology research to assist public understanding
- Need to explore what resources on research-on-research exist already and avoid duplication of resources
- Need to address language: research on research rather than methodology? Language creates a closed environment of what is an open invitation to get involved
- How to we advertise opportunities to get involved in trial methodology projects to the totally members (i.e. those with no previous PPI experience) such that they understand what we are doing and why?

Who to involve?

- Is this dictated by duration (and possibly funding) e.g. when you have short duration you need people who can hit the ground running?
- Often we bring people because of their clinical condition – should we be asking what skills we need and applying that approach?
- Who are the other public contributors in this space? E.g. service providers, HVPS, policy makers, etc
- Blurring of roles – sometimes when Patient partners are also asked to act as a research participants (e.g. in METHODICAL or COS Delphi)
- People may have multiple PPI roles and wear ‘different PPI hats’

Finding PPI contributors/partners

This is often perceived as a challenge but the following was found to be successful:

- Recruiting PPI partners via social media
- Holding an information session to initially explain the project to assist engagement
- Approaching existing PPI groups may assist recruitment and engagement (experienced)
- Involving a key stakeholder representative on the study team may help with engagement (e.g. involving a teacher on the team helped with access to schools)

Resources:

- Resources need to be carefully considered to help ensure that patient partners can be actively involved more frequently
- Plan ahead as time and resource heavy - need to ensure PPI partners are paid for their time (as the researchers are)
- Use different resources and processes to make it interesting and accessible to facilitate PPI.
- POPPIE study examples were made available - possible tip-share resources or knowledge about what works in engaging PPI partners in methodological research (e.g. description of COS from POPPIE shared with NIHR and now given to PPI reviewers on grant panels.

- Collaborate with funders to show them why this is important. We need to provide evidence to funders as to why this is important e.g. well conducted research is of benefit to patients (group discussion). Perhaps there is a need for this group to work with chairs of funding panels to raise awareness of the importance and benefits of 'research on research'

Time and planning:

- Lots of preparation time needed to explain methodology angle, consider jargon and any training needed (for researchers and PP partners), as well as explain the research to patients (both verbal explanations and written materials) for PPI partners
- Co-produced PPI plan assisted the PACT study (as shown by EPIC study, if you plan PPI it is more likely to happen)
- Researchers may need support in how to involve PPI in methodological research
- May need different models of PPI (experienced v not experienced) depending on timeframe of the study and ability for researchers. A mix of people may be beneficial (comments from patient contributor in group discussion)
- Good to explain to PPI partners that we are doing this methodological research because we don't know the answers, this could be a leveller
- Relationships between researcher and PPI partners are important and take time to develop

General thoughts

- Is 'trials methodology' the right term? Is it 'Research on Research'? 'Improving Research'? How do we better communicate to patients and the academic community? How can we link this into wider issues (such as the NIHR drive on 'research following patient need')?
- What is the role of patients in raising the profile of methodology research with funders? Is there an assumption among funders that patients want 'patient benefit' and improvements to research are too far removed?
- How can patient contributors/partners be better identified and what expertise/experiences (and the range of) do they need for trials methodology research?
- Is the role of patients in assessing the 'acceptability' of methods development? Or is that too restrictive, and is there a role for more fundamental questioning (e.g. 'democratising' methods, and the role of methodology versus methods)
- How do we communicate our TMR to involve people with the project (making it interesting); to engage people in the project (to make the issues understandable)
- Should we be selective with involvement (e.g. to people with experience) or not? If yes, how do you balance that selection with the need to promote diversity?
- How do we influence Early Career Researchers in trials methods research in order to influence cultural change? Who do we mean by trialists or researchers?
- Do we want to influence all of those professional groups or are we thinking of targeting individuals – do we want to have other resources for different groups
- Need to think about reporting mechanism to all on involvement in methodological research that is a one size fits all – in other words target at level of patients so as not to make extra effort
- Patients often understand a lot more than researchers give them credit for (group discussion and theme throughout). Is there a need for methodological research to be more patient driven than researcher driven?
- Health Care Research Wales will fund PPI in the work up to research projects as do Research Design Service in England – We could perhaps test out with methodological research
- What culture do we want in research? What do we want to change? we need to influence researchers early on in their career about PPI, what it is and what it means. It's not just about changing views in CTUs. It's about reinforcing that this important because it's about

relationships and the importance of collaboration and working together well. Do we need to extend this culture (or value of it) to the funders. See RAPPOR study and RECRUIT study for examples of how if PPI is woven in it makes a difference. NIHR need to be encouraged to monitor how PPI plans are being enacted as PPI perspectives can often provide solutions to recruitment issues but if they are not actively engaged in the team then this is a missed opportunity.

- Are there markers of culture in order to monitor it? or should it be just 'what is going well? UNICEF have minimum quality standards for community engagement which is to be considered by NIHR
- Can we look at considered a model for research that happens in Labs (with no patient facing aspects) – and then think about how PPI can be relevant in those areas.

Broader Issues

- Addressing the challenges of gaining funding in general for Trials Methodology Research as this subsequently affects support for Patient & Public Involvement? Also makes point that although the work is 'unfunded' someone is picking up that cost and so maybe worth having conversations with department heads about supporting the linked PPI activities
- Requesting funders to include PPI in this work (PPI contributors can't be added as partners on some forms) Co-produce statements for funding forms - collate information from various successful funding bodies about how this research has direct patient benefit and share within the community (RfPB/MRC/ESRC/HCRW/CSO) and for IRAS forms – about why this research is important
- Encouraging Funding Panel Chairs to support public contributors at these meetings and of those we know (Chairs and existing public contributors) could we encourage them to support others with regard to methodological research
- Showing Research Excellence Framework (REF) returnable methodology papers (and how involvement of patients in these projects) has the potential to amplify patient voice and REF Impact case studies

Appendix A - PROGRAMME

Actively Involving Patients/Public with Trials Methodology Research (TMR)

An exploratory workshop facilitated by Derek C Stewart, Pete Bower, Kerry Woolfall & Katie Gillies

Wednesday 13th Nov 2019

Ellen Wilkinson Building room B2.4, University of Manchester

1030 Welcome and introductions

1040 Background and Purpose including Objectives and Outputs

1050 What do we mean by Involvement in Trials Methodology Research? Definitions and assumptions

1100 What has been happening already? (5 minute slots from attendees willing to describe and highlight key points from work they have done)

- Kerry Woolfall - [Methodical Study](#)
- Laura Flight – [Medical Statistics](#)
- Sandra Galvin – [START](#), [The People’s Trial](#) and [PRIORITY 1](#)
- Bridget Young & Heather Bagley – [COMET](#) and [Core Outcome Sets animation](#)
- Sophie Staniszewska – [GRIPP2](#)
- Claire Planner & Ailsa Donnelly - [PACT](#)
- Mike Robling – [Children’s research](#)

1200 What has been learned? (About Involvement in TMR; by Trial Methodologists; and by Patients who have got involved)

1215 Are there any common themes?

1230 lunch

1315 Reflections on the morning session - Is there anything we haven't mentioned? What specific challenges are there within Trial Methodologies?

1345 What information and advice would be most useful to research / researchers and the patients?

1355 Planning and preparing some Top Tips - small groups

1430 Feedback from groups and further work

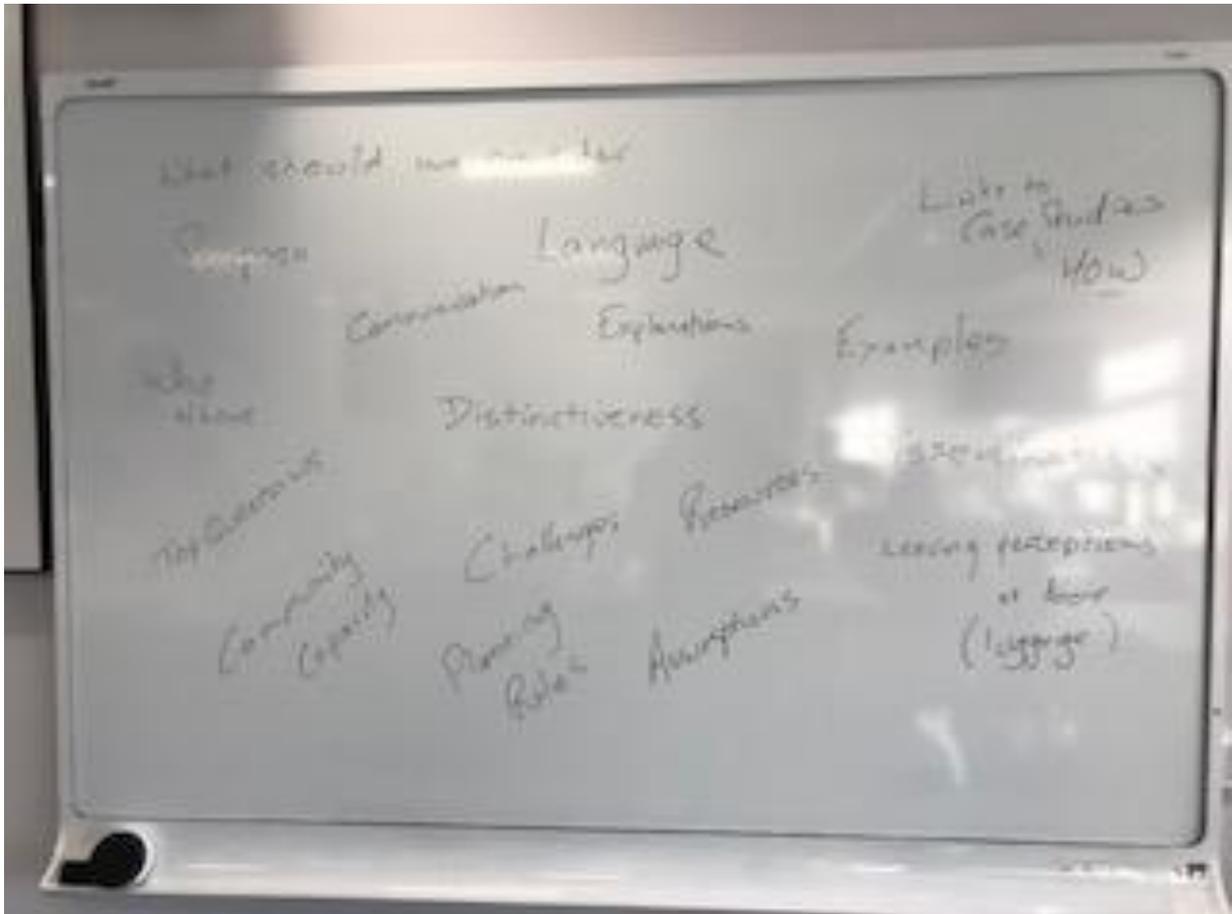
1455 Next steps

1500 Close of workshop

Appendix B

LIST OF ATTENDEES

Name		Linked project	Notes
Derek Stewart	Lead for Patient, Public Involvement	Trials Methodology Research Partnership	Workshop Facilitator
Peter Bower	Methodologist	Trials Methodology Research Partnership	Workshop Facilitator
Katie Gillies	Methodologist	Trials Methodology Research Partnership	Workshop Facilitator
Kerry Woolfall	Methodologist	Trials Methodology Research Partnership	Workshop Facilitator
Ailsa Donnelly	Patient partner	PACT	
Lynsey Brown	Patient partner	PACT	
Heather Bagley	Patient partner	Methodical and COMET	
Declan Devane	Methodologist	PRIORITY I and II	
Sandra Galvin	Methodologist	PRIORITY I and II	
Mike Robling	Methodologist		
Bridget Young	Methodologist	EPIC/methodical	
Claire Planner	PPI expertise trials	Methodical/PACT	PACT
Sophie Staniszewska	PPI expertise general	PPI	GRIPP 2
Laura Flight (Sheffield)	PPI in Statistical Analysis		Public involvement in the development of statistical methods
Nicola Harman	Methodologist		
Isobel and Carla – on behalf of Delia Muir	PPI expertise – trials	Methodical	



Snapshot of the marker board showing the key points for our questions.