PIRRIST Project

Developing a Patient and Public Involvement (PPI) intervention to enhance Recruitment and Retention In Surgical Trials

We invite you to take part in a workshop

- Before you decide whether to take part, please read the following information carefully.
- It is entirely your choice whether or not to take part. If you have any questions please contact us.
- If you agree to take part, you may withdraw yourself and your information from the study without penalty at any time, and without giving a reason.
- Any information you provide will be treated as confidential and will not be disclosed in an identifiable form outside the research team.

Summary

- The aim of this project is to develop a robust, evidence-based PPI intervention aimed at improving recruitment and/or retention in surgical trials.
- We're inviting you to take part in the final stage of a four-stage project. This is a **consensus workshop** to decide on the PPI intervention we will take forward into practice and evaluation.
- The consensus workshop will take place in **Oxford** for half a day, with breaks for lunch and refreshments.
- To thank you for your time, we will offer you a **£50 high street shopping voucher**. We will also cover reasonable travel and out of pocket expenses related to your participation.
- If you have read this information sheet and would like to take part, please contact us (see right) to reserve your place.

Contents

How to contact us

If you have any questions about this project, please contact Joanna Crocker (Postdoctoral Research Fellow) at

Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.

Email: **pirrist@phc.ox.ac.uk**

Tel: **01865 617837**

Or Mr Richard Bulbulia (Consultant Vascular Surgeon) at

Email: **richard.bulbulia@ctsu.ox.ac.uk**

Tel: **01865 743891**

1 Background and aims of the project

Slow **recruitment** and poor **retention** are common challenges to the successful delivery of clinical trials. **Patient and public involvement (PPI)** is when researchers work with members of the public, patients, service users and/or carers in all or any part(s) of the research process. PPI could potentially enhance recruitment and retention in clinical trials; however, the evidence for this is weak at best, with few attempts to evaluate it quantitatively.

The aim of this project is to develop a robust, evidence-based **PPI intervention** aimed at improving recruitment and/or retention in surgical trials, and then to test its effectiveness. The intervention development phase consists of four stages outlined on page 4. We're inviting you to take part in the final stage.

The project is a collaboration between researchers, trial administrators, patient and lay partners and PPI coordinators associated with the Universities of Oxford, Aberdeen and Liverpool. It is supported by the NIHR Oxford Biomedical Research Centre and the MRC Network of Hubs for Trials Methodology Research.

2 Why have I been invited to take part?

We're inviting a small, diverse group of expert stakeholders to work with us to choose and refine a PPI intervention. We hope this will maximise the effectiveness and usefulness of the intervention in practice.

We have chosen you because we think you'll bring a unique and valuable perspective to discussions.

3 Do I have to take part?

It is entirely your choice whether or not to take part in the workshop, and we encourage you to contact us with any questions you may have (see section 11).

If you agree to take part, you may withdraw yourself and your data from the study without penalty at any time, and without giving a reason, by letting us know.

4 What will happen in this study?

Using the results of earlier stages of the project and a systematic review, we have developed some ideas of possible PPI interventions, or features of interventions, that we think might work well in practice. We now need your help to decide which one(s) to try out in real surgical trials. We are therefore inviting you to take part in a **consensus workshop** with other key stakeholders.

The workshop will take place on **Wednesday 10th January 2018 at the King's Centre, Osney Mead, Oxford, OX2 0ES**. We anticipate that 20-40 people will take part, and it will last half a day (starting no earlier than 10:30 and finishing no later than 15:30), including breaks for lunch and refreshments.

We will cover the cost of any reasonable travel, accommodation (if needed) and other expenses related to your participation. Where possible we can directly book/purchase these for you in advance.

5 What are the benefits of taking part?

We hope that you will enjoy contributing to developing an effective and practical PPI intervention, which may benefit surgical trials in the future.

To thank you for your time, we will offer you a **£50 high street shopping voucher**.

We will also offer you a copy of the study results, which we hope you will find interesting.

6 Are there any potential risks?

We do not think there are any risks to you in taking part. Any information you provide will be treated as **confidential** within the workshop and will not be disclosed in an identifiable form outside the research team (see section 7).

You may withdraw from the workshop at any time without giving a reason. You will receive a list of the proposed workshop participants in advance, and can opt out at this stage if you wish. This means that other proposed participants will also see that you are intending to take part.

7 What will happen to the data I provide?

A member of the research team will take notes during the workshop, and parts of the workshop may be audio -recorded to help capture key issues discussed. You will not be identifiable in the notes.

Workshop participants will also have the opportunity to submit additional written comments/reflections after the workshop if they wish.

How will the data be stored?

The notes, written comments and any audio files will be stored securely at the University of Oxford and in accordance with the UK Data Protection Act. These will be stored separately from your personal identifying information (name and contact details). Only the research team will be able to access all of these datasets. All of the identifying information will be securely destroyed within 10 years of publication of the results. You will not be identifiable in any publications or presentations.

Will the data be shared with anyone else?

The University of Oxford is committed to sharing its research for the benefit of society and the economy. We would like to archive the workshop notes and written comments at the University of Oxford, so that other professional researchers in the UK can access it free of charge on request. All identifying data will be removed so that no one will be able to trace it back to you. If you would like to opt out of this now, or view the notes before they are archived, please let us know.

8 What will happen to the results of this project?

We plan to **publish** the results of this study in an international, peer-reviewed, open-access academic journal article, a conference paper and an online lay summary. These may include some anonymous quotes from workshop participants.

These publications will be promoted as widely as possible. We also intend to apply for further funding to implement the resulting PPI intervention in a number of different surgical trials, and evaluate its effectiveness.

9 Who has reviewed this project?

This project has been reviewed by, and received ethics clearance through the University of Oxford Central University Research Ethics Committee (reference number: MS-IDREC-C1-2015-163).

10 Who do I contact if I have a concern about the project?

If you have a concern about any aspect of this project, please speak to one of the lead researchers (Joanna Crocker or Richard Bulbulia - see contact details on page 1). They should acknowledge your concern within 10 working days and indicate how they intend to deal with it.

If you remain unhappy or wish to make a formal complaint, please contact the chair of the Medical Sciences Inter-Divisional Research Ethics Committee - Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD.

11 What next?

If you have read this information sheet and would like to take part in the workshop, please **contact us** (page 1) to reserve your place. We will ask about your travel, accommodation and dietary requirements, as well as any special needs for participating. We will send you a workshop agenda, directions and a list of the proposed participants a minimum of 4 weeks in advance. If you are still happy to take part, you will need to complete a consent form when you attend the workshop. A copy of the consent form can be viewed on the following webpage: www.phc.ox.ac.uk/files/research/pirrist-stage-4-consent-form.pdf

If you would prefer **not** to take part and/or do **not** wish to receive further information about this project, please let us know so that we do not send you reminders (see contact details on page 1).

If you are not sure and have questions, please contact us (page 1) and we will do our best to help.

Thank you taking the time to read this information.

PIRRIST Project Overview

Stage 1
(Sep – Dec 2015)

Aim:
Identify current PPI practices in UK surgical trials

Methods:
(1) Online survey of active UK surgical trials
(2) Analysis of existing National Research Ethics Service data

Stage 2
(Jan – Jul 2016)

Aims:
(1) Identify challenges & needs associated with PPI in surgical trials
(2) Identify possible components of a PPI intervention
(3) Identify perceived barriers to effective recruitment & retention *not* already identified from literature
(4) Explore stakeholders' views of PPI impact on recruitment & retention in surgical trials, including possible mechanisms of impact.

Method:
Focus groups with surgical trial staff, PPI contributors and PPI coordinators across the UK

Stage 3
(Jul – Nov 2017)

Aims:
Determine how the barriers to recruitment, retention and PPI identified from the literature and stage 2 are rated by stakeholders in terms of size/severity.

Method:
Two surveys:
(a) Barriers to recruitment and retention (aimed at surgical trial staff and methodologists across the UK)
(b) Barriers to successful PPI (aimed at surgical trial staff, PPI contributors and PPI coordinators across the UK)

Stage 4
(Jan – Feb 2018)

Aim:
Develop a suitable PPI intervention based on the findings of stages 1-3 and research literature.

Method:
Collaborative workshop with 20-40 key stakeholders (including surgical staff, PPI contributors, PPI coordinators, methodologists and others)