Participant Information leaflet

TRaining to Improve pArticipant recruitment into randomised controLled trIalS (TRIALISt)

Study title: Developing a training intervention for staff to improve participant recruitment into randomised controlled trials

We invite you to take part in a training course

- Before you decide whether to take part in TRIALISt, it is important you understand why the research is being done and what it will involve.
- You are free to decide whether to take part in this study. You can stop taking part in the study at any time.
- Any information you provide will be treated as confidential and will not be disclosed in an identifiable form outside the research team.
- If you have any questions or would like more information, please contact us.

Important things that you need to know

- We have systematically developed a training course to help staff recruiting participants into trials
- To find out if this course is feasible and acceptable, we want to deliver this training to staff recruiting participants into trials
- Take your time to decide whether you wish to take part.
- You can stop taking part at any time.

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If you have any questions about this study, please contact Dr Adwoa Parker (Research Fellow) at York Trials Unit, University of York, Telephone: 01904 32 1671, Email: adwoa.parker@york.ac.uk.

1 Why are we doing this study?

Many strategies are used by trial teams to improve participant recruitment into randomised controlled trials; however few have been found to be effective. Most recruitment strategies also focus on patients being recruited, rather than the staff who are recruiting. Recruitment has been identified as the number one priority for methodological research; within this the training of staff recruiting patients has been highlighted as the top priority topic for research.

Our overall aim is to develop and pilot test a short training course for staff recruiting participants into trials. To develop the course, we reviewed the literature and identified the training needs of staff involved in recruiting participants to trials, using qualitative methods and an online questionnaire survey. The course has been developed by experienced researchers at York Trials Unit, in conjunction with University of York's Continuing Professional Development department and the NIHR Clinical Research Network.

We are now inviting you to take part in the training course because we want to assess the feasibility and acceptability of the training by delivering it to staff recruiting participants into trials. It is important that we identify the impact, benefit and outcomes of the training course for staff. This will inform a grant application to undertake a full scale evaluation of the training course.

Your participation will help to refine the training course for trialists, and we hope the course will help to improve recruitment of participants for future trials.

2 Why have I been invited to take part?

We are asking you to take part because you are currently or have been involved in recruiting participants into a trial, either as a researcher or a clinician. You are therefore an important stakeholder in this study and we would be very grateful for your help in piloting the training intervention.

Your participation will help us to develop our understanding of what it is like to attend and to deliver the training course. It will help to improve the training course and it will help guide staff in the future when recruiting participants into trials.

3 Who is doing the study?

This study is funded by The Wellcome Trust [ref: 204829] through the Centre for Future Health (CFH) at the University of York.

The Sponsor is The University of York and the work will be undertaken at York Trials Unit at the University of York, who will manage the study and also quality assure study processes.

4 Do I have to take part?

No. Your participation in this study is completely voluntary. If you decide to take part, you will be given this information sheet to keep and be asked to sign a Consent Form. You are still free to withdraw from the study at any time, and do not have to give a reason.

5 What will be involved if I take part in this study?

The training course

The training course will take place over one day, and will be delivered classroom-style in groups of 15-20 people by educational facilitators with experience of delivering trials. The training will be held at The University of York. The training will cover topics identified in the literature and from our qualitative study and survey as important when recruiting trial participants. This will also be based on York Trials Unit's experience of conducting trials in the UK. You will be encouraged to share experiences and ask questions. Course materials may include standardised slides, videos and an information pack.

The online surveys

In order to identify and measure the impact of the training, it is essential that those who attend the training complete two brief online questionnaires. If you decide to take part you will be asked to complete a questionnaire before and immediately after the delivery of the training. This will measure satisfaction with training, change in confidence with recruiting participants, change in knowledge about recruiting participants. Comparison of responses at the end of the research period will help us to measure the effectiveness of the training and refine the course.

The focus group

A focus group will form part of the training day to elicit additional feedback. Topics will include course content, structure and areas for improvement. If you agree for the focus group to be recorded, you can indicate this on the Consent Form. This is so that the researcher can focus on what you are talking about without needing to make handwritten notes. This also makes sure that we don't miss anything relevant and useful that you tell us. What is recorded will be kept confidential.

This will inform refinement of the training and its subsequent full scale evaluation.

6 What are the possible benefits and disadvantages of taking part?

Because we do not know whether the training is effective, we cannot promise a benefit to you. However, it is anticipated that the study will increase knowledge, understanding and confidence in recruiting people into trials. This would be expected to assist you in your day to day work. We hope that you will enjoy contributing to developing an effective and practical training course, which may benefit trials in the future.

The course is free to attend. Lunch and refreshments will be provided. We will also offer to send you a copy of the study results, which we hope you will find interesting.

Attending the training will take up a day of your time. While we do not expect this to happen, you can refuse to answer any questions which you feel uncomfortable with and can opt out of the training and surveys at any time.

7 Can I withdraw from the study at any time?

You are free to withdraw from the study at any time, and do not have to give a reason. However, any data which has been analysed up to that point will be used in the study.

8 Will the information obtained in the study be confidential?

All data will be anonymised, thus nobody taking part will be identifiable in the project report or any other publication. Only members of the research team will have access to the data, which will be kept in locked storage or on password protected computers at the University of York. All information collected during the course of the research will be kept strictly confidential in line with the Data Protection Act. Anonymised data will be securely stored for five years from the end of the study and then destroyed.

9 What will happen to the results of the study?

Once the study has ended and the results have been analysed, reports will be published in medical journals and presented at conferences. The information collected may be used to support other research in the future and may be shared anonymously with other researchers.

You will not be identified in any study reports, publications or presentations. You will be asked at the start of the study whether you would like a summary of our findings.

10 Who has reviewed this study?

This study has been approved by the Health Sciences Research Governance Committee at the University of York.

If you have concerns or a complaint about the study you can contact Prof Patrick Doherty, Chair of the Department of Health Sciences Research Governance Committee Research: patrick.doherty@york.ac.uk.

11 What next?

If you would like to take part, would like more information or have any questions or concerns about the study please contact Dr Adwoa Parker, Research Fellow, York Trials Unit, University of York, Telephone: 01904 32 1671, Email: adwoa.parker@york.ac.uk.

Thank you for taking the time to read this information leaflet.