

Hub: ConDuCT-II	Host University: University of Bristol
Supervisor: Leila Rooshenas Leila.Rooshenas@bristol.ac.uk	Co-supervisors: Daisy Elliott, Jenny Donovan, Bridget Young
Is the project clinical or non-clinical? Non-clinical	
Title of PhD project: Exploring patient perspectives of recruitment in randomised controlled trials	

Background to the Project

Randomised controlled trials (RCTs) are recognised as the gold standard methodology for evaluating the effectiveness of healthcare interventions. However, recruitment to RCTs is often difficult, particularly in surgical trials. Failure to recruit to target can delay medical progress and carry financial and ethical consequences. The 'QuinteT Recruitment Intervention' (QRI) aims to optimise recruitment and informed consent in challenging RCTs. The intervention has been implemented in 25 RCTs to date, providing opportunities for evidence-based guidance and training for recruiters more generally (i.e. beyond a particular RCT). For instance, ConDuCt-II training workshops have provided support for recruiters in surgical RCTs, offering guidance on how to communicate challenging concepts such as randomisation and equipoise.

The QuinteT research program currently focuses on communication during RCT recruitment consultations, but would be enhanced by exploring how patients interpret the information provided. Linking audio-recorded consultations with interviews has been conducted in paediatric RCTs [1, 2], providing insight into how parents interpret RCT information. There is potential to adopt this methodology across RCTs more generally, with a view to refining the evolving training and guidance that is emerging from the QuinteT research program.

What the Studentship will encompass

The studentship aims to develop QRI methodology to incorporate patient perspectives on observable recruitment interactions. This research will be conducted across a range of RCTs, with a view to informing broadly applicable training materials that can be used by trialists and recruiters more widely (e.g. as a resource publicised on the HTMR website, and disseminated via the HTMR recruitment working group). There will be opportunities for the successful candidate to develop and refine research objectives in collaboration with their supervisors. These objectives may include: a) development of protocols for linking patient and clinician interviews with audio-recorded recruitment discussions (with consideration to the optimal timing and delivery of interviews in relation to consultations); b) implementation of this protocol across a range of RCTs, with a view to exploring how recruiters' explanations of trial concepts are interpreted by patients; c) iterative development of training/guidance materials, based on findings from 'b' and concurrent evaluation.

Details of Supervision

Dr Leila Rooshenas (ConDuCT-II hub, University of Bristol), Dr Daisy Elliott (ConDuCT-II hub, University of Bristol), Professor Bridget Young (North West hub, University of Liverpool) and Professor Jenny Donovan (ConDuCT-II hub, University of Bristol).

Details of planned field work

The project will entail analysis of audio-recorded consultations, linked with interviews with patients and recruiters. It is anticipated that this will be conducted across a range of RCTs that are already implementing the QRI (comparing surgical and mixed-speciality interventions).

References

1. Shilling V, Williamson PR, Hickey H, Sowden E, Beresford MW, et al. (2011) Communication about Children's Clinical Trials as Observed and Experienced: Qualitative Study of Parents and Practitioners. PLoS ONE 6(7): e21604.
2. Woolfall K, Shilling V, Hickey H, Smyth RL, Sowden , et al. (2013) Parents' Agendas in Paediatric Clinical Trial Recruitment Are Different from Researchers' and Often Remain Unvoiced: A Qualitative Study. PLoS ONE 8(7): e67352.

Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy

The proposed project seeks to generate evidence and applied outputs that will be directly relevant to trials methodologists and health care professionals involved in RCT recruitment. This aligns with the Network's prioritisation of projects that generate methods/guidance that are of broad relevance to stakeholders working across and outside the hubs. The focus on generating evidence-based materials to inform recruitment guidance/training directly falls under one of the Network's key areas of focus ('recruitment', as supported through its 'recruitment working group'). It is vital that recruiter training materials are grounded in evidence, and the patient perspective is a cornerstone to this evidence. The proposed project will generate practical outputs that will be applicable to those seeking guidance on the design and conduct of RCTs- especially trialists and clinicians who are experiencing (or expect to experience) recruitment obstacles.

2. Does this project align with the work of a HTMR Working Group; if so, which?

The project aligns with the HTMR Recruitment Working Group (RWG). The project directly maps onto two of the RWG priorities: 'training' (for recruiters), and 'communication' (between recruiters/trialists/patients). The student will therefore become a member of the RWG.

3. Describe how this project aligns with the host Hub strategy

The project aligns with the ConDuCT-II Hub's overall focus on improving the design and conduct of difficult and complex RCTs of invasive procedures, in that there is an intention to focus on RCT recruitment obstacles (and potential solutions) in RCTs involving complex, invasive procedures (particularly surgery). More specifically, this project aligns with two of the four themes of the ConDuCT-II Hub: integrative and dynamic research methods to optimise recruitment to RCTs (Theme 2), and enhancing trial conduct (Theme 3).

4. Detail of any Project specific training offered in the studentship

The successful candidate will have opportunities to receive formal training in qualitative research methodology through the school's extensive short course program, which includes training around fundamental principles of applied qualitative research, and more specialist training in integration of qualitative methodology to optimise the design and conduct of RCTs. Training in novel QuinteT Recruitment Intervention methodology will be provided, including approaches to data collection and analysis (e.g. targeted conversation analysis, Q-Qat methodology).

5. Are there any prerequisite qualifications or experience for this studentship?

Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

For this project: A good first degree will be required (2.1 or above).