MRC Network of Hubs for Trials Methodology Research

Advancing training for health professionals and trialists to optimise RCT recruitment and informed consent

Final Report

Original project (R53): Developing, delivering and evaluating training courses for recruiters to randomised trials

Aim of impact project: To refine and advance existing RCT recruitment training making it more sustainable, accessible and suitable for a wider audience (impact grant - original project R53).

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Project dates: 1/09/2018 – 30/6/19 (10 months)

Expenditure: £10,000

Background, aims and objectives

The original HTMR Network award was to develop, deliver and evaluate RCT recruiter training workshops to enhance recruitment and informed consent. This project highlighted the need for such training and the challenges and discomfort that recruiters have with responding to patients' treatment preferences and conveying equipoise as part of this. In the current project we aimed to increase the dissemination and impact of our original project by: (1) further refining and advancing the training material by reviewing recent literature and audio-recordings of recruiter-patient discussions to identify effective practice in managing the challenging aspects of RCT recruitment discussions, in particular patient treatment preferences; (2) disseminating the refined training material more widely by tailoring it to different audiences (expanding it to those who design and conduct trials in addition to frontline recruiters); and (3) developing a sustainable and regular training course to optimise RCT recruitment and informed consent.

Summary of achievements

Objective 1: To refine and advance the original training material, recent literature was reviewed and audio-recordings of recruiter-patient discussions scrutinised across a range of RCTs to identify effective practice in responding to expressed treatment preferences. Since the original project, no advances in the literature have been made outside the University of Bristol's QuinteT research group in terms of effective ways of engaging with preferences. The QuinteT group recently showed that health professionals can be trained to engage with patients' preferences, utilising extracts from audio-recordings of recruitment discussions to raise awareness and demonstrate how recruiter's responses to a voiced preference can hinder or facilitate recruitment. This led to increased confidence and perceived positive impact on recruitment practice.[1] In the present study we drew a new sample of audio-recording extracts to further develop techniques to enable trained recruiters to engage with preferences to facilitate decision-making. Three RCTs that had post-training recruiter-patient consultation audio-recordings held within the QuinteT's group data repository were purposefully selected for their diversity in clinical contexts and challenges with treatment preferences. Audio-recordings were analysed using qualitative content and thematic analysis methods,[2] drawing out strategies by recruiters to address voiced preferences with evidence of enhanced informed patient decision-making ('good practice').[3] Findings were translated into training material and are currently

being written up as a paper on good practice for engaging with patient treatment preferences during RCT recruitment discussions.

Objective 2: In the original grant, we developed and delivered workshops to surgeons and research nurses who were 'frontline' RCT recruiters, with training focused primarily on the recruitment to trial discussion. We recognise that recruitment is a team activity involving other clinicians, academics, trial designers and co-ordinators who are all involved with the recruitment process. We therefore expanded the focus of training, making content relevant to those beyond frontline recruiters. The current course covered topics prior to the trial discussion, including organisational and practical challenges of recruitment, eligibility assessment and the design and implementation of screening logs as a tool to identify recruitment bottlenecks – in addition to the communication-related challenges of presenting trials to potential participants. This opened the course to a wider audience making it relevant to researchers/academics with an interest in designing, leading and conducting RCTs as well as frontline clinicians, research nurses and allied health professionals.

Objective 3: The training material was synthesised to create a revised and extended version of the existing HTMR Network-funded training workshops, with updated and advanced material and more use of the novel and well received audio-extracts of real recruitment discussions to support a variety of learning techniques. A 1-day course was held on 5th March 2019 as part of the University of Bristol's Medical School short course programme, delivered initially as an internal pilot course restricted to 20 attendees. The course reached capacity, attracting academics, trial designers and co-ordinators, post-graduate students, chief investigators and aspiring chief investigators.

The course was a mix of didactic lectures, and whole group/small group discussion, sharing the experience of participants alongside evidence-based strategies to optimise recruitment and informed consent. It aimed to raise awareness of the hidden challenges of recruitment, from identifying patients to discussing the trial with them, with techniques offered to overcome them. Mean feedback scores relating to the structure, content, quality of teaching and amount learned ranged from 8.2-9.0 (with 10 being excellent), on a par with established School courses. Free text comments on what worked well related to the material being thought provoking, engaging, well explained and the usefulness of group interaction to discuss issues raised. Expanding the setting of trials beyond secondary care or making the course clearer that this was the focus, was the predominant point to improve on. Given the positive feedback overall, the course has now been embedded formally in the School's short course programme and will be open to a wider number of external participants. The next course is set for 29/11/19 with intention to run it annually thereafter. This means the network investment has led to a sustainable training resource.

Outputs completed

- Development of a 1-day training course as part of the University of Bristol's Medical School short course programme targeting recruiters and trialists to optimise RCT recruitment and informed consent (delivered March 2019 as a non-paying pilot course to 20 (capped) academics, trialists, trial co-ordinators, health professionals)
- Sustainable adoption of the newly created course in the School's annual short course programme following positive feedback
- Spin-off recruiter training opportunities that drew on material from the training course:
    - 2 recruiter training workshops for a bariatric RCT (Stockholm and Gothenburg, Sweden, March 2019 – 27 clinicians, research nurses, allied health professionals, trialists attended – before and after training data are currently being collected to evaluate its effectiveness)
    - Invitation to speak at the Association of Breast Surgery NW Breast Clinical Trials Roadshow on patient treatment preferences, conveying equipoise and recruitment to RCTs (Manchester, May 2019 - ~25 academics, trialists, health professionals attended)

- Optimising recruitment into surgical RCTs - 1-day workshop for nurses, allied health professionals and research practitioners as part of a feasibility SWAT (study within a trial) evaluation led by University of York (Birmingham, May 2019 – 11 attendees)
- 90-minute in-conference tutorial - Strategies for optimising recruitment to difficult clinical trials, Society for Clinical Trials (New Orleans, USA, May 2019 - ~45 academics, trialists, health professionals attended)

Outputs in progress

- A pre-conference half-day workshop has been accepted at the International Clinical Trials Methodology Conference in Brighton (October 2019)
- A paper is currently in preparation on good practice in relation to dealing with patient treatment preferences at trial recruitment from a range of RCTs [Target journal: Journal of Clinical Epidemiology or Trials]

Future plans

- Steps are in progress to undertake randomised and non-randomised evaluations of the effectiveness of training workshops
- Training will continue to be refined, adapted and advanced for use in a wider range of RCT contexts and to fit with an increasingly diverse and international audience
- Training reach, accessibility and impact will be further expanded by, for example, delivering components online

References

[1] Mills N, Gaunt D, Blazeby JM, Elliott D, Husbands S, Holding P *et al.* Training health professionals to recruit into challenging randomized controlled trials improved confidence: the development of the QuinteT RCT Recruitment Training Intervention. *J Clin Epi* 2018; 95: 34-44

[2] Miles MB, Huberman AM, Saldana J. *Qualitative data analysis: a methods sourcebook and the coding manual for qualitative researchers.* California: Sage Publications, 2014.

[3] Wade J, Elliott D, Avery KNL, Gaunt D, Grace J *et al.* Informed consent in randomised controlled trials: development and preliminary evaluation of a measure of Participatory and Informed Consent (PIC). *Trials* 2017; 18: 327.