

# The role of trainees and the NIHR Associate PI scheme to support screening and recruitment to a multicentre RCT: an example from the Sunflower Study

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**Background** Recruitment to RCTs requires a teamworking approach (1), with many studies benefitting from the contribution of surgical trainees as recruiters. On the large-scale multi-site Sunflower study (2), an embedded QuinteT Recruitment Intervention (QRI) (3) reported the benefits of trainee involvement, and engagement with the NIHR Associate PI (API) scheme to both the study and to trainees (4). A goal of the API scheme is to develop trainees to become future research leaders.

**Aim** To explore the ongoing involvement of trainees in the Sunflower RCT incorporating the inclusion of Radiology APIs, and the piloting of a scheme to maintain engagement from trainees once they complete their 6 months on the API scheme.

**Methods** Using a range of data sources we examined the role of trainees working on the Sunflower RCT with a particular focus on their engagement in the NIHR associate PI scheme. We interviewed trainee doctors and consultants to explore how they viewed their contributions to the study. We examined screening and recruitment data to record the different roles trainees undertook. We approached former trainee leads to see whether their work on Sunflower had led to career developments and/or further involvement in research.

**Results** 124 trainees have applied to the API scheme via the Sunflower study, 31 have attained their certificate of completion and 25 are actively taking part in the scheme. 38 withdrew from, or did not complete the scheme.

Participation in the Sunflower RCT and the API scheme was viewed as a valuable tool to demonstrate research capacity on trainee's CVs and thus to support their career development.

Consultant PIs viewed trainees as an integral part of the local site research teams providing support to them and research nurses.

At a study level, trainees made a substantial contribution to patient identification and recruitment. – to date, approximately 16% of patients have been screened or recruited to the study by trainees. Some trainees did not complete the API scheme, typically because of the requirement to be at one site for a full six months.

To enhance ongoing engagement from trainees post-API scheme, we have now appointed 2 lead trainees to attend study management group meetings, and are in the process of appointing regional liaison leads.

## Key findings

- Trainees can play a valuable role in supporting recruitment and other activities on large scale RCTs
- Working on a large-scale RCT led to further research roles for many trainees
- The NIHR Associate PI scheme provides a framework for trainees to engage with RCTs

## Promotion and Progression

11 former Sunflower trainees have consultant posts  
3 former Sunflower trainees are now site PIs

## Ongoing research activities:

- On delegation log for other UGI RCTs
- Lead roles in national and/or local audits
- Data collection and analysis on observational studies
- Undertaking Academic Clinical Fellowships
- Developing own research projects with trainee research collaboratives

## Sunflower Recruitment activity

1437 patients screened for Sunflower by trainees

16% of all Sunflower patients were consented by trainees (representing c700 patients in total)

**Conclusions** The NIHR API scheme provides a framework for supporting trainees to develop into future research leaders. The results from the large scale Sunflower study will be useful to RCT CIs and trials units in understanding the challenges of engaging with the scheme to support recruitment and other RCT activity.

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For information about how the Associate PI scheme was applied and managed on the Sunflower Study contact: [jane.collingwood@bristol.ac.uk](mailto:jane.collingwood@bristol.ac.uk)

1. Strong S, Paramasivan S, et al 'The trial is owned by the team, not by an individual': a qualitative study exploring the role of teamwork in recruitment to randomised controlled trials in surgical oncology. *Trials*. 2016;17(1):212.

2. Clout M, Blazey J, et al. Randomised controlled trial to establish the clinical and cost-effectiveness of expectant management versus preoperative imaging with magnetic resonance cholangiopancreatography in patients with symptomatic gallbladder disease undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones (The Sunflower Study): a study protocol. *BMJ Open*. 2021;11

3. Donovan JL, Rooshenas L, Jepson M et al. Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the QuinteT Recruitment Intervention (QRI). *Trials*. 2016;17(1):283.

4. Jepson M, Lazaroo M, et al. Making large-scale surgical trials possible: collaboration and the role of surgical trainees. *Trials*. 2021;22(1):567.