

# **GRANULE: Generating student recruiters for randomised trials**

STARSurg: Student Audit and Research in Surgery Collaborative

## **Authors**

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9-10<sup>th</sup> May 2016, Royal College of Surgeons of England, London

*Supported by a Observational Research Development grant from the Bowel Disease Research Foundation*

## *Scope*

Medical schools currently provide limited clinical research training for students, and as a consequence young doctors are inadequately prepared to approach patients and discuss recruitment and randomisation in surgical studies. Surgical care pathways should facilitate systematic evaluation of new healthcare technologies so that patients receive best care and precious resources are not wasted. Surgical trials are often considered particularly complicated and clinicians report that they struggle to present information clearly to patients. This results in poor recruitment to surgical studies and ultimately a lack of high quality information for patients. The Generating Student Recruiters for Randomised Trials course (GRANULE) aims to create a generation of early career surgeons who are better equipped to recognise equipoise, communicate uncertainty, and recruit patients to clinical trials.

## *STARSurg Collaborative*

GRANULE has developed from the Student Audit and Research in Surgery (STARSurg) collaborative. Since its conception in 2013, 2400 UK medical students have included data from 26,000 general surgical patients in national studies. The first, published in the British Journal of Surgery (BJS), investigated the use of NSAIDs following gastrointestinal resection<sup>1</sup>. The second, also published in the BJS, collected prospective data on body mass index as a risk factor for complications following abdominal surgery<sup>2</sup>. In 2016, a national cohort study of post-operative acute kidney injury, will aim to identify targets for quality improvement.

## *GRANULE Course*

STARSurg collaborated with Birmingham Clinical Trials Unit, the Bristol Medical Research Council ConDuCT-II hub, and the Bowel Disease Research Fund (BDRF) to design and deliver a one-day course focussed on improving communication of equipoise and uncertainty in clinical trials with patients. The course was framed around real examples of trials gastro-intestinal surgery, with a faculty formed of chief investigators and trial recruiters. Twenty delegates, competitively selected from a pool of 3,000 STARSurg members, were invited to the Royal College of Surgeons of England, London on May 9-10<sup>th</sup> 2016. All delegates completed online Good Clinical Practice certification prior to course entry.

There were three key domains to the one-day course:

1. **The Good, The Bad and The Ugly** – A series of interactive lectures details on-going, complex clinical trials in surgery including STAR-TREC (Birmingham), ACCURE-UK (Birmingham) and By-Band-Sleeve trial headed (Bristol). Challenges in communicating equipoise and common hurdles in gaining patient consent were outlined in detail by Professor Jane Blazeby<sup>3</sup> (Professor of Surgery, Bristol), Mr Simon Bach (Consultant Colorectal Surgeon, Birmingham) and Aneel Bhangu (Academic Clinical Fellow, Birmingham).
2. **Best Practice Small Group Discussion** - Quick-fire, small group discussions surrounding common mistakes in trial recruitment, overcoming challenges and strategies to bolster recruitment. Groups presented findings back to the delegation with feedback from the expert panel.
3. **Simulated Patient Recruitment** - Simulated patient interactions using real-life examples. Actors were briefed before 21 Delegates had the opportunity to address questions and concerns from the simulated patients and faculty.

#### **Box 1. GRANULE Course Learning Objectives**

- Appreciated the recruitment challenges faced by randomised trials in surgery.
- Understood the process of obtaining informed consent for recruitment to trials.
- Know how to seek and document valid consent during research recruitment.
- Demonstrated practical experience in recruiting to surgical trials with simulated patients.
- Demonstrated an understanding of ethical principles in trial recruitment.
- Gained Good Clinical Practice (GCP) certification, and demonstrated understanding of this.

#### *Feedback*

#### **Box 2. GRANULE Participant Free-Text Feedback**

- *“The professional feedback from consultants was incredibly useful. I wouldn’t feel comfortable consenting patients without this course!”*
- *“The faculty were fantastic, easy to approach and excellent teachers, which made the course enjoyable as well as useful and informative. I thought the number of delegates was good, as it allowed plenty of collaboration without having too many people present.”*
- *“The role plays were the best. Having hands on practice/experience is the only way to learn the skills. Networking dinner - great idea, allowed everyone just to crack on with business the next day.”*

The interactive style of the course with a high facilitator to student ratio was highly commended by delegates and expert faculty. This allowed mistakes to be made and feedback to be given in a comfortable environment. Following the course all delegates said they would feel confident gaining consent and explaining randomised trials to patients (see box 2). Participants felt more confident in their understanding of clinical equipoise (McNemar's paired chi-squared test,  $P < 0.001$ ), ability to communicate clinical equipoise effectively ( $P < 0.001$ ), communicate risks and benefits ( $P < 0.001$ ) and gain consent for participation in trials ( $P = 0.004$ ).

#### *Lessons learnt from the GRANULE course*

Key lessons were learnt from the first GRANULE course which will enhance future courses. Participant feedback indicated that it would be beneficial to practice the recruitment consultation from start to finish. In the second GRANULE course, full consultations will be built in as formative assessments at the end of the day. This will take students along the full journey from theory to practice of the trial recruitment consultation.

The patient actors fed back positively upon their interactions with the delegates. Future courses will use more defined actor briefs to reduce the focus on the clinical context of the randomised trial whilst increasing interaction with the process of randomisation. The whole delegation, from medical students to consultant facilitators, recognised the importance of conceptualising equipoise and the inherent difficulties in delivering this for both clinician and patient. The course content will be modified to give additional tips and tricks to deepen ability to communicate of uncertainty.

#### *Challenges to GRANULE*

The biggest challenge facing the GRANULE course is translating the course experience to real-world practice. STARSurg are connecting GRANULE participants with trainee-led research collaboratives and principle investigators of trials, to develop pathways for delegates to gain practical experience. The group will work with the Surgical Specialty Leads for the Royal College of Surgeons Surgical Trials Units, to build a database of active trial recruitment opportunities across general surgery.

#### *Plans for the future*

GRANULE has shown that medical students have an appetite for developing skillsets enabling them to recruit patients to randomised trials. The course has created a geographically widespread cohort of future trainees who will champion randomised controlled trials in surgery across the UK. The next GRANULE course will take place in 2017. This will continue the work of STARSurg to integrate research into undergraduate training, with direct benefits to the care of surgical patients.

#### *Acknowledgements*

Kind thanks go to the Bowel Disease Research Foundation and the Royal College of Surgeons of England. Without their support, the GRANULE course would not have been possible.

#### *References*

1. STARSurg Collaborative. Impact of postoperative non-steroidal anti-inflammatory drugs on adverse events after gastrointestinal surgery. *Br J Surg*. 2014 Oct;**101**(11): pages 1413-23.
2. STARSurg Collaborative. Multicentre prospective cohort study of body mass index and postoperative complications following gastrointestinal surgery. *Br J Surg*. 2016 Jun 20.
3. Donovan, JL, Rooshenas, L, Jepson, M, Elliott, D, Wade, J, Avery, KNL, Mills, NJ, Wilson, CH, Paramasivan, S & Blazeby, JM, 2016, 'Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the QuinteT Recruitment Intervention (QRI)'. *Trials*, vol 17.

Figure 1: GRANULE course logo



Figure 2: Pre- and post-course feedback

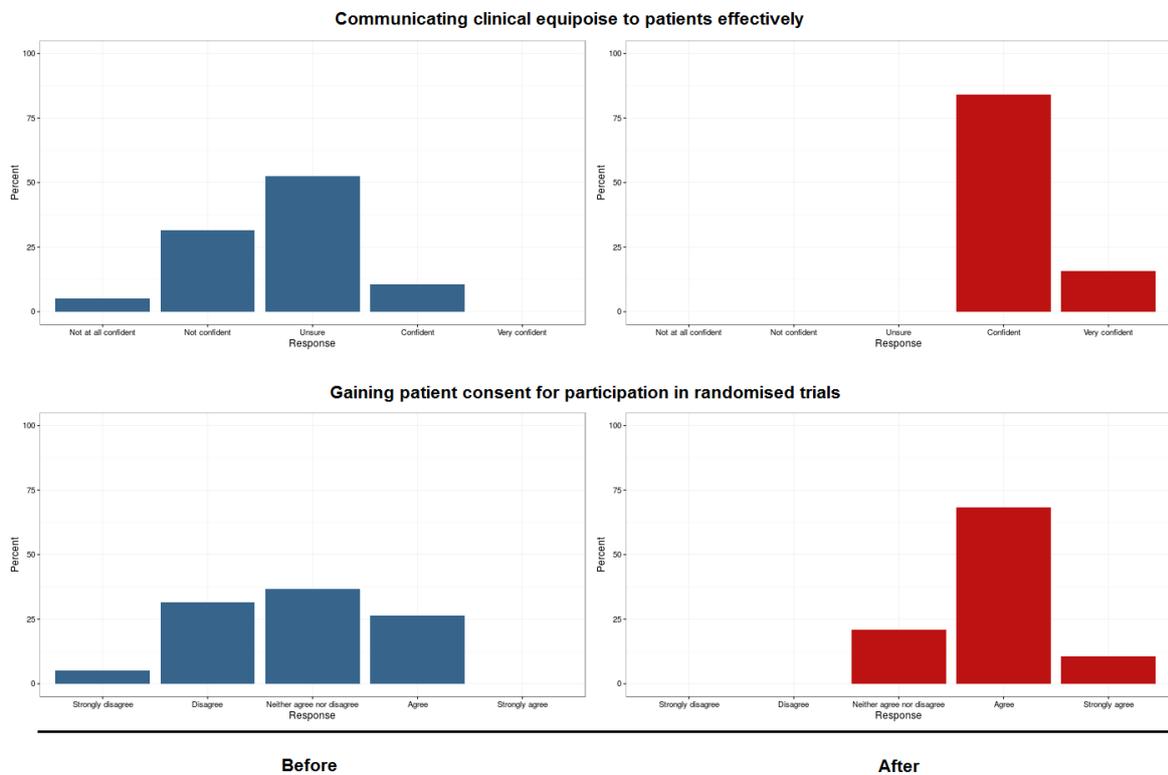


Figure 3: Course participants and faculty

