Educational impact and recommendations from implementation of student-led clinical trial recruitment: a mixed-methods study

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ABSTRACT

Medical students have an essential role in medical research, yet often lack opportunities for involvement within randomised trials. This study aimed to understand the educational impact of clinical trial recruitment for medical students. Tracking wound infection with smartphone technology (TWIST) was a randomised controlled trial that included adult patients undergoing emergency abdominal surgery across two university teaching hospitals. All recruiters underwent prerecruitment training based on ‘Generating Student Recruiters for Randomised Trials’ principles, and completed prerecruitment and postrecruitment surveys. Respondent agreement with statements were assessed using 5-point Likert scales (from 1 (‘strongly disagree’) to 5 (‘strongly agree’)). Quantitative data were analysed using paired t-tests to compare differences pre-involvement and post-involvement. Thematic content analysis was performed on free-text data to generate recommendations for future student research involvement. Of 492 patients recruited to TWIST between 26 July 2016 and 4 March 2020, 86.0% (n=423) were recruited by medical students. Following introduction of student co-investigators (n=31), the overall monthly recruitment rate tripled (4.8–15.7 patients). 96.8% of recruiters (n=30/31) completed both surveys, and all respondents reported significant improvement in clinical and academic competencies. Three higher-level thematic domains emerged from the qualitative analysis: (1) engagement, (2) preparation and (3) ongoing support. Student recruitment in clinical trials is feasible and accelerates recruitment to clinical trials. Students demonstrated novel clinical research competencies and increased their likelihood of future involvement. Adequate training, support and selection of suitable trials are essential for future student involvement in randomised trials.

INTRODUCTION

Evidence-based medicine depends on successful enrolment of patients within research studies and clinical trials. While members of the public value clinical research,1 under-recruitment of patients to clinical trials is common.2,3 While there are multifactorial reasons behind decisions of patients to not enrol, an important aspect is recruiters being unfamiliar with the process itself.4,5 Despite all clinical recruiters in the UK being required to complete Good Clinical Practice (GCP) training, and to be familiar with the informed consent process through their clinical work, successful patient recruitment requires additional, distinct skills.3

Recent large clinical trials such as Randomised Evaluation of COVID-19 Therapy (RECOVERY)6 and other large-scale collaborative studies7-10 have demonstrated the benefit of a research-active workforce. However, despite research and communication skills both being a core aspect of the undergraduate curriculum,11 research skills teaching is heterogeneous across medical schools12 and does not specifically cover recruitment of patients to research studies. The ‘GeneRAtiNg stUdent rEcruiters for randomised trials’ (GRANULE) course13 has been developed to bridge the gap in knowledge and skills obtained in undergraduate studies, provide opportunities for experiential learning14 and ensure the clinical workforce is better prepared for involvement in research.13 However, the involvement of medical students as recruiters within research studies has yet to be evaluated. Therefore, this study aimed to understand the educational effect of involvement in recruitment on medical students, and to derive generalisable recommendations for their involvement in future trials.

METHODS

Research context

Tracking wound infection with smartphone technology (TWIST) was a parallel-arm, individually randomised controlled trial (RCT) across two teaching hospitals in a large health board (NHS Lothian) in the UK15 (ClinicalT rials.gov: NCT02704897). This trial aimed to investigate whether a smartphone-delivered wound assessment tool results in earlier diagnosis of surgical-site infections (SSI) after emergency abdominal surgery. Recruitment in the preplanned internal pilot (80 patients) was initially performed by members of the surgical team (clinicians and surgical nurses) at each site as part of their clinical commitments. Following successful involvement of a student recruiter in the internal pilot, subsequent recruitment was restructured to facilitate broader involvement.16 Medical students from the affiliated medical school (University of Edinburgh) were invited via the university’s
virtual learning environment to participate in recruitment on a voluntary basis. All recruiters were provided a portfolio certificate for participation, with prespecified recruitment target (15 patients) and a minimum of 2 weeks of recruitment for recognition as PubMed-citable collaborators, in accordance with National Research Collaborative guidelines and other clinical trials using a collaborative methodology. Prior to participation, all students completed GCP and underwent a preparatory session, which incorporated trial-specific information required for recruitment and documentation, and core principles for effective recruitment from GRANULE (online supplemental figure 1). The GRANULE course was co-developed between clinical trials units (Birmingham Surgical Trials Consortium, the Bristol Surgical Trials Centre), trial methodologists (members of the Medical Research Council Hub for Trials Methodology Research (ConDuCT-II) and QuinteT research group) and medical student and junior doctor representatives (the Student Audit and Research in Surgery collaborative (STARSurg) Collaborative). Students were supervised by the Primary Investigator at each site, with support from the trial management group.

### Data collection

All recruiters were asked to complete an online prerecruitment survey based on the GRANULE course feedback form, adapted from the QuinteT RCT Recruitment Training evaluation questionnaire (online supplemental appendix 1). Those who started a recruitment period were asked to complete postrecruitment feedback (online supplemental appendix 2).

Feedback forms were disseminated online using secure Research Electronic Data Capture (REDCap) instance. Together these surveys encompassed: previous research experiences, motivations for participation and opinions on the preparation received and authorship criteria. Furthermore, 5-point Likert scales were used in both surveys to evaluate student opinions regarding self-perceived competence in recruitment and clinical-academic careers. Finally, students were also requested to provide free-text responses outlining their experience of recruitment.

### Data analysis

A mixed-methods approach was used, and only responses from students who had started a recruitment period were included. Continuous data were summarised as mean (SD) or median (IQR) based on visual and statistical evaluation for normality. Categorical data were cross-tabulated, and differences tested with appropriate parametric or non-parametric tests performed. Continuous data were summarised as mean (SD) or median (IQR) based on visual and statistical evaluation for normality, with appropriate parametric or non-parametric tests performed. Categorical data were cross-tabulated, and differences tested using chi-square test or Fisher’s exact test. In line with accepted practice regarding Likert scales, the degree of respondent agreement with statements were analysed as numerical data ranging from 1 (‘strongly disagree’) to 5 (‘strongly agree’), and so paired t-tests compared mean differences in agreement prerecruitment and postrecruitment. Paired mean differences were added to means of postrecruitment means to highlight differences from prerecruitment. Resultant CIs outside the 5-point Likert scale were censored at the minimum or maximum. Statistical significance was set a priori at p<0.05 and all statistical analyses were performed in R Studio V.4.1.1 (R Foundation for Statistical Computing, Vienna, Austria).

Qualitative data based on free-text responses were visually inspected and any text which might identify an individual was anonymised prior to analysis. Every effort was made to retain the semantic integrity of the text, and any such amendments were indicated in any direct quotations. A thematic analytic approach was adopted, with transcripts initially read by one author (KAMcL), and a coding frame devised to comprise the initial themes identified. These transcripts were then independently coded by two authors (KAMcL, AMR) according to these themes, and any emergent subthemes.

### RESULTS

#### Student involvement in recruitment

There were 492 patients recruited to this trial between 26 July 2016 and 4 March 2020 (43.3 months). The internal pilot lasted for 17.1 months, with the majority of patients recruited by qualified healthcare staff (72.0%, n=59/82), and 28.0% (n=23/82) by a student (figure 1A). Following restart of patient recruitment postpilot, the remaining 410 patients were recruited over a 26.1-month period with 97.6% recruited by students (n=400/410). Between these two phases, the mean monthly rate of recruitment tripled from 4.8 (pilot) to 15.7 (postpilot) (figure 1B). Based on the pilot, it was estimated that without further change only 50% of the trial target would have been achieved by the time of actual trial completion (figure 1B). Had student recruiters been engaged from the onset, it was predicted that the trial could have been completed over 1 year earlier (within 29.2 months).

Of the 31 students who participated as recruiters within the TWIST trial, 96.8% (n=30/31) completed both the prerecruitment and postrecruitment surveys (table 1). These students were equally represented in terms of gender (45.2% female, n=14) and year of study (36.2% clinical year, n=18). All reported some form of previous engagement with research, although only half (58.1%, n=18) had been involved in clinical data collection or previous recruitment of patients to a research study.

Of all student recruiters, 2/3 (67.7%, n=21) met the prespecified recruitment target of 15 patients (table 1). Just one student did not complete at least a 2-week recruitment period, with 1/3 students (35.5%, n=11) completing 3 or more weeks. The characteristics of recruiters who did or did not meet the prespecified recruitment target were broadly similar (table 1).

A common theme across respondents was that involvement was effective in improving their understanding of clinical trials (‘Great to have students being responsible for every step from patient identification to randomisation. This ensured they could...

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**Figure 1** Cumulative patient recruitment in the tracking wound infection with smartphone technology trial.
get a good grasping of how RCTs work\(^8\)). Importantly, pre-involvement a majority (58.2%, n=18/31) felt the undergraduate curriculum had not adequately prepared them to recruit patients to clinical trials (2.47, SD: 0.94), and that there should be more teaching on clinical trials (3.97, SD: 0.81). These opinions remained consistent following involvement (figure 2). There was also recognition that recruitment to research studies and clinical trials are common aspects of future training pathways, and that early engagement would facilitate further involvement. Notably, a significant positive impact was reported by students on their awareness (mean difference: 0.63, 95% CI: 0.21 to 1.05, p=0.005) and interest in clinical academia (mean difference: 0.47, 95% CI: 0.10 to 0.83, p=0.014), as well as their clinical skills around communicating (mean difference: 1.10, 95% CI: 0.70 to 1.50, p<0.001) and documenting discussions regarding consent (mean difference: 1.20, 95% CI: 0.76 to 1.64, p<0.001) (figure 2).

Perspectives on optimisation of student involvement

Engagement of medical students to recruit

In order to engage medical students in any research project, first they need to be aware of the opportunity, and consider it worthwhile and achievable for them as individuals.

Preparation of medical students prior to recruitment

Student recruiters frequently expressed a lack of confidence in their knowledge or capabilities to recruit patients prior to participation (figure 3). However, the preparatory session was positively received with 93.3% (n=28/30) feeling adequately prepared (with the remainder responding neutrally). Furthermore, this session was also felt to serve an important function in establishing rapport between recruiters and research team (“I did feel much more at ease contacting the trial supervisors when I run into any problems during recruitment as a result of having met them face-to-face”).

There was strong support simulation of patient recruitment as effective preparation with students noting “an opportunity to practice the consent process with each other prior to attempting this with a patient was quite useful, particularly as we were given feedback on our performance”. However, several noted an entrustable professional activity (EPA) approach could be adopted, with observation of patient recruitment in practice followed by more direct supervision (“I think it would have been helpful to have somebody to observe with the first patient I recruited to get some feedback, and to make sure I hadn’t missed anything”).

However, it was also noted that there could be a greater emphasis on ‘day-to-day mundane aspects’ of recruitment in the preparatory session, with these reported to present the greatest challenge for student recruiters. In particular, access and

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**Table 1**

| Achievement of prespecified recruitment target | No (n=10) | Yes (n=21) | P value |
|-----------------------------------------------|----------|-----------|---------|
| Gender                                       |          |           |         |
| Male                                         | 4 (40.0) | 13 (61.9) | 0.441   |
| Female                                       | 6 (60.0) | 8 (38.1)  |         |
| Year of study                                |          |           |         |
| Preclinical                                  | 7 (70.0) | 6 (28.6)  | 0.052   |
| Clinical                                     | 3 (30.0) | 15 (71.4) |         |
| Previous experience with clinical research    |          |           |         |
| No                                           | 4 (40.0) | 10 (47.6) | >0.001  |
| Yes                                          | 6 (60.0) | 11 (52.4) |         |
| Total patients recruited                     | Median (IQR) | 6.5 (8.2) | 15.0 (10.0) | <0.001  |
| Duration of involvement                      | Incomplete | 1 (10.0) | 0 (0) | 0.490 |
|                                               | 2 weeks   | 6 (60.0) | 13 (61.9) |         |
|                                               | Over 2 weeks | 3 (30.0) | 8 (38.1) |         |
| Survey completion                            | Prerecruitment only | 0 (0) | 1 (4.8) | >0.000 |
|                                               | Both surveys | 10 (100) | 20 (95.2) |         |

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**Figure 2**  Difference of opinions in respondents (n=30) prerecruitment and postrecruitment (with 95% CI for paired mean difference). Resultant CIs outside the 5-point Likert scale were censored at the minimum or maximum.
navigation of the patient records, orientation to the clinical environment and clinical knowledge to decipher notes.

Support of medical students during recruitment

During the trial, the research team and students shared an online messaging platform to facilitate communication with 40% (n=12/30) specifically identifying this as a positive initiative (“I feel the trial was very well-supported, with help readily available via an [online messaging platform] on the few occasions I run into any difficulty”). Several students also highlighted an appreciation of the physical presence of the research team in proximity to the ward to address more nuanced or patient-specific questions.

Step-by-step guidance materials were provided to support the recruitment process and documentation. These were consistently noted to be useful to refresh knowledge gained from the preparatory sessions. One student also noted that perceived hierarchies may lead medical students to ‘feeling anxious about approaching [the research team]’, and so guidance materials provided an important alternative route to address queries.

DISCUSSION

While the involvement of students as recruiters poses several unique challenges, this study has demonstrated that studies, and students themselves, can substantively benefit from their involvement as recruiters. This can enhance both academic and clinical development of students through experiential learning,14 supplementing potential gaps in their undergraduate education22–25 (figure 2). Through mixed-methods analysis of the first large-scale involvement of medical students within a clinical trial, we derived three themes of recommendations regarding involvement of students based on how to engage, prepare, and support them during recruitment (box 1).

The value of a research-active medical workforce has never been more apparent than during the COVID-19 pandemic, with rapid and large-scale recruitment of patients to research studies essential for evidence-based care.6 However, reflecting previous work nationally,12 respondents did not feel prepared by their undergraduate training to recruit patients to research (figure 2). Increasingly, involvement as patient recruiters are a common part of postgraduate training within the UK, however this can pose challenges to staff unfamiliar and untrained in recruitment.7 This study demonstrates that it is feasible to engage medical students as recruiters, and with appropriate support they can provide invaluable contributions to the success of trials. Earlier training in research skills, equipoise and obtaining consent may enable routine participation of students and junior doctors in research studies with accelerated recruitment (figure 1B), leading to more rapid dissemination of results and practice-changing studies benefiting patients sooner. Furthermore, through experiential learning15 acquired through TWIST, students reported increased confidence in gaining academic competencies, and key clinical competencies around gaining and documenting consent11 (figure 2).

It is essential for patients, methodological quality and medical students themselves that their involvement in patient recruitment recognises the unique differences between students and qualified healthcare professionals. While there is significant literature highlighting the value of student involvement in research,26 these are predominantly framed at students rather than provision of guidance to supervising clinicians. In particular, there are no evidence-based recommendations regarding their involvement in patient recruitment. Aligned with previous work,27 we found that while engagement was predominantly driven by research interest, multiple other motivators were highlighted including an interest in the clinical topic, and personal and career development. However, flexibility of opportunities and recognition of contributions also emerged as key motivating factors behind engagement. One of the key themes identified was that researchers should ensure medical students had sufficient theoretical and clinical knowledge to perform patient recruitment, and that common practical barriers were pre-emptively addressed (such as access to medical records28 or familiarity with the clinical environment).29 Moreover, repeated emphasis was placed on the value of the research team providing an accessible and responsive support system to provide guidance, and address unforeseen questions or issues that arise during recruitment. Conceptualising patient recruitment as a novel EPA30 may serve to facilitate support appropriate to individuals, formalise an assessment process and support greater transition between trials once competence has been achieved.

While medical students have been involved in research studies and clinical trials previously, to our knowledge this is the first RCT to report a majority of recruitment being student-led. There was an inclusive process for selection of student recruiters, with opportunities widely disseminated among the local undergraduate cohort, which was reflected in the range of characteristics and experiences of students involved (table 1). Furthermore, we adopted a mixed-methods approach to provide a nuanced understanding of the impact on those involved, both before and after
1. Engagement of medical students for recruitment:
   - Prior to outreach, researchers should carefully consider whether the clinical trial is appropriate for medical student involvement, and whether sufficient resources and personnel are in place to provide support for students.
   - Researchers can emphasise the potential to gain not just academic experience, but also generalisable skills for future clinical practice.
   - Researchers should ensure involvement of medical students is as unbiased as possible to avoid reinforcing existing disparities in academic opportunities.
   - Researchers should work in collaboration with students to facilitate involvement in the clinical trial around other medical school commitments, and provide flexibility regarding the time period and site of recruitment (wherever possible).
   - Researchers should have a transparent and achievable route for recruiters to gain coauthorship (either PubMed citable ‘author’ or ‘collaborator’ status). This could be based on either a timeframe and/or a patient recruitment target depending on the trial context.

2. Preparation of medical students before recruitment:
   - Researchers should ensure all student recruiters complete mandatory prerecruitment preparatory session(s) (in addition to other required regulatory training, eg, Good Clinical Practice). These preparatory session(s) should encompass demonstration of the full recruitment process the recruiter would be involved in (eg, patient identification to recruitment to documentation). Specific components to ensure are included would be orientation to the clinical environment, essential clinical knowledge and simulated recruitment of a patient according to principles from the Generating Student Recruiters for Randomised Trials course13 (eLearning available for free on the National Institute for Health Research (NIHR) Learn platform (https://learn.nihr.ac.uk/)).
   - Researchers should ensure medical students have access to all clinical areas and electronic health systems required for recruitment in advance. Care should be taken to ensure students have sufficient understanding in navigation of these clinical environments and electronic health systems (particularly if engaging those in preclinical years).
   - Researchers should adopt an entrustable professional activity model to promote progressive and supportive skill development for medical students in recruitment (eg, allowing progression of recruitment from observation only, to proactive supervision, to reactive/on-demand supervision).30
   - Researchers should encourage peer-to-peer knowledge sharing between students through a formal handover session and/or period of shadowing. In some circumstances, a mini-team-based approach (medical students working together, or with research nurses or junior doctors) may also be appropriate to adopt to allow greater flexibility, support and/or supervision of medical students involved.

3. Support of medical students during recruitment:
   - Researchers should ensure there is a responsive support system in place to address unforeseen questions or issues

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**Box 1 Continued**

that arise during recruitment, with a clear route of contact (whether an email, online group or phone number). This should ideally include a physical presence in proximity to the clinical environment.

- Researchers should create step-by-step guidance documents for medical students to refer to during the recruitment process. This should encompass the same topics discussed in the preparatory session(s), and be developed (and adapted as necessary) to reflect the needs and frequently asked questions of a student audience.

These recommendations are aligned with GCP requirements for principal investigators to ensure adequate resources for recruitment (including trained recruiters with adequate facilities).31 Furthermore, while specific to students, these recommendations may also be appropriate for guiding involvement of junior doctors in patient recruitment which is increasingly a feature of research studies and clinical trials within the UK and internationally.5–9 We also used a reproducible educational intervention, with medical students undergoing evidence-based and defined teaching on the recruitment process,3 13 consisting of online modules (GCP and GRANULE; available at learn.nihr.ac.uk) and simulated recruitment of patients prior to involvement based on GRANULE principles.13 Finally, a collaborative research methodology was used based on previous examples of clinical trials adopting this methodology2 10 to ensure appropriate recognition of the contributions of patient recruiters in outputs resulting from TWIST trial data.

There are several limitations in this study. First, students involved in TWIST were associated with a single university, and so there is a need to ensure the educational benefits observed can be reproduced across different undergraduate curricula. Despite the local undergraduate degree containing significant research skills teaching (including an incorporated intercalated degree), participating students did not feel sufficiently prepared to recruit patients. Therefore, the educational benefits may be greater in medical schools with less research focus.12 Second, the TWIST trial itself was considered to be a low-risk and simple design, and did not receive funding for research nurse involvement. Therefore, other ‘higher-risk’ or more complex study designs may have greater barriers to student involvement (including less acceptance from patients and staff, and greater prerequisite knowledge to gain informed consent), and may have less incentive to engage recruiters other than research nurses. Nevertheless, an EPA10 model of student involvement (box 1) would facilitate the safe and supported patient recruitment, irrespective of trial context. Furthermore, it should be noted that while no specific issues were observed or raised, patient opinions and satisfaction with the student-led recruitment was not specifically explored in this study. Third, while the high survey response rates minimised volunteer bias, the self-selective nature of engagement and small sample size means those involved may not be representative of the undergraduate population and increases the risk of type 2 statistical errors. Fourth, the feedback forms were derived from the QuinteT Recruitment Intervention which has been extensively published,19 however it should be noted it has not
been specifically validated for this purpose. Finally, it must be acknowledged that there is the potential for disclosure bias from respondents given the feedback forms were disseminated by the same research team conducting the trial. Respondents were reassured that feedback would have no influence on their involvement or recognition, and that all feedback would be anonymised. Nonetheless, residual concerns regarding the potential for identification may have positively influenced feedback.

Student-led recruitment in clinical trials is feasible and provides a route to developing a research-active workforce. It has potential to accelerate recruitment to research studies, as well as enhancing learning regarding key competencies around informed consent and research. However, adequate training, support and selection of suitable trials are essential for successful student involvement. Reflecting previous work nationally, students involved did not feel prepared by their undergraduate training to recruit patients to research. Particularly as issue is reflected in postgraduates, this should prompt re-evaluation of how both research and communication skills teaching is delivered within the UK. The recommendations outlined will allow inherent challenges to be identified upfront, and provides a roadmap for effective and evidence-based involvement of students.

Key messages

⇒ Involvement of junior doctors in patient recruitment is increasingly a feature of research studies and clinical trials within the UK and internationally; however, the large-scale involvement of medical students as patient recruiters within research studies has yet to be evaluated.

⇒ Medical students were trained and supervised in the tracking wound infection with smartphone technology trial as patient recruiters, leading recruitment of 86.0% of patients (n=423/492).

⇒ Student-led recruitment in clinical trials is feasible and provides a route to developing a research-active workforce; however, adequate training, support and selection of suitable trials are essential for successful student involvement.

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