

Randomised control trials (RCT) are considered the gold standard method for evaluating the effectiveness of interventions. It is the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome, where participants are randomly assigned to one of two or more clinical interventions, reducing allocation bias ([#1](#)).

In recent years, many imaging departments have appointed dedicated imaging-based research radiographers, and as part of this role they co-ordinate and oversee RCTs that require imaging as part of the research protocol. In accordance with The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000, a research exposure is defined as 'any exposure required by the research protocol following initial consent from the participant'. This is the case whether the exposure is required as part of standard care or as an additional exposure. Our responsibility in the radiology department is to ensure that these RCTs are conducted in accordance to IR(ME)R regulations, hence to assess the potential increase in ionising radiation to participants as part of the trial, but also to address research governance issues with regards to time and capacity impact on the imaging department. A dedicated research radiographer is responsible for the above issues, whilst working closely with the research nurses to ensure the RCTs are conducted in a rigorous and timely manner. It is therefore evident that close collaboration with the radiology department is essential for the smooth running of RCTs.

The individual with overall responsibility for the design, conduct and reporting of these RCTs is called the 'Chief Investigator' (CI). If however, the study involves multiple sites, a specific site may not have a CI but instead a 'Principle Investigator' (PI). The PI is the person at each site responsible for the day-to-day running of the trial. It is recognised from the millions of RCTs conducted worldwide, that very few have a radiologist or radiographer as CI or PI. Petrou, Foerster and Reich recognised this and suggested that there needs to be a fundamental change in practice, where practitioners use their expertise in imaging to lead research rather than accepting a secondary role in these studies ([#2](#)). Radiology specific journals such as the British Journal of Radiology and Radiography rarely publish RCTs, and when they do they are led by another specialty such as psychology or oncology. A substantial proportion of neuroimaging research is currently performed by neurologists and psychiatrists ([#2](#)). This means that if we don't do it, others will.

A research radiographer as CI and PI

Twelve months ago, I was successful in capturing the College of Radiographers (CoR) novice researcher grant (CoRIPS) to conduct a pilot RCT. My proposal involved randomising first time attending MRI patients into either one of two interventions or a control group, titled 'A pilot single-centre single-blinded randomised controlled trial comparing the use of a short film ([video link](#)) or a telephone conversation with a radiographer versus routine practice (appointment letter and information sheet) to alleviate anxiety in patients prior to MRI'.

Having finished recruiting for this trial, it is important that I share my research experience as a radiology-based CI and PI, to help inform future radiology researchers on the barriers and unforeseen limitations encountered.

When considering the perceived barriers in research, they remain similar across all specialities within healthcare: capacity, capability and funding (#3) (#4) (#5). In other words, there isn't enough time due to clinical workload and staff shortages, there isn't enough training for individuals to become confident in research and there isn't enough money. However, for my particular project these classical barriers were not the issue. The project was funded by the CoR, my research time was protected which made me supernumerary, and I have recently completed a research degree (MPhil). I am progressing towards a PhD by publication and therefore already have substantial research skills and knowledge hence confidence. Although far from a research expert, I had some training hence confidence. Nevertheless, other barriers were encountered, perhaps ones that are not as commonly reported within the literature, and some which are unique to the imaging department.

Barriers encountered

In most circumstances, radiology staffs do not see patients until the day of their investigation. This has major implications on research recruitment. Unlike cancer research nurses, who approach patients during clinic appointments and therefore have the opportunity to recruit and consent face-to-face, radiology departments have to either cold call patients or rely on members of staff from other professions to help identify and recruit patients. In addition, the radiology department receives urgent referrals (investigations needing to be done within a few days) with the urgency of the request allowing for a limited window to recruit and consent eligible patients. This results in a certain cohort of patients missing the opportunity to participate.

Cold calling as mentioned above, was the method of recruitment used for my study. Cold calling is a term derived from 'over the phone' sales known as telemarketing. It is a process whereby unexpected blind phone calls are made to individuals at home in order to sell a product. With this in mind, it is a similar process to that used for this study, whereby phone calls were made to patients' homes at potentially inconvenient times, to ask whether they would participate in a study. A research invitation, including the participant information sheet and consent forms, were already sent out to eligible patients with their appointment letter. This meant that patients should have seen and read the research documents before the call was made. This method has major limitations, as the calls are unexpected and the patients are also forced to trust the unknown individual phoning.

Recruitment problems are common and well documented within RCTs, even within a controlled face-to-face environment. Newington and Metcalfe suggested that patients were more likely to agree to participate in research if they were asked by a medical doctor, especially a known doctor in whom they trust (#6). Patients are usually unfamiliar with staff in the radiology department and therefore the members of staff recruiting from radiology are strangers to them. Trust issues are exacerbated with recruiting over the phone, and this is recognised in the literature where more trust is built on face-to-face interaction, rather than over the phone communication (#7). There needs to be further research into methods of recruiting in radiology, especially surrounding the reasons why some individuals agree to participate whilst others decline.

Alternative methods of recruitment

Although RCTs are considered the gold standard method for conducting a clinical trial, there are other methods that could be used, whereby the recruitment issues discussed above may be resolved. A non-randomised control trial by means of a controlled before and after phase may be an alternative method. This would involve collecting data from eligible patients having routine care (control group) for a certain number of weeks, then for the same subsequent number of weeks, eligible patients would all receive the intervention. This would avoid over the phone randomisation, as patients could be recruited on the day of their investigation if they had completed the relevant paperwork. England et al used a similar method when conducting a patient trial, to determine the effectiveness of increasing distance to reduce patient dose (#8). For my study, sending every eligible patient a video link over a certain time period would have been much easier, rather than having to ring and randomise each patient, and subsequently ensure that they received the video link and password if they were randomised to that group. This caused unnecessary communication and constant contacting of the patients prior to the scan. On the other hand, although this method may increase recruitment rate, it does have limitations. Because participants are not randomly allocated to the intervention groups, they are unlikely to be similar in baseline characteristics. This means that the findings of the trial could be influenced by confounding factors and hence have internal validity issues (#9). Eccles et al emphasised this limitation, by suggesting that before and after studies should be used carefully to evaluate the effects of quality improvement interventions, and that the results of such studies should be analysed and interpreted with caution (#10). The use of randomisation avoids selection bias and protects against accidental bias, whilst producing comparable groups through stratification. It also allows for the use of probability testing, determining the likelihood that an outcome has occurred due to chance (#11).

Another way to overcome the recruitment issues within radiology is the use of a multi-disciplinary research team (#10) (#12). Strong et al emphasises on this and suggests collaboration is required between clinical specialty and research teams for successful recruitment and retention in RCTs. Relying on staff members who are not a part of the research team can be problematic when conducting a study, as experienced for my particular study. Reid and Edwards suggested that there needs to be a balance between research activity being considered a clinical burden or a part of everyday activity (#13). The only problem with using a multi-professional approach to aid in recruitment, is that the research project would need to be specific to a particular speciality, eg the target population would be rheumatoid or orthopaedic patients. For my particular project, using another member of staff from another speciality would be unhelpful as the target population was not specific to speciality; they were referred from a variety of specialities. Raising staff awareness via pre-study presentations may have been the only useful method to aid recruitment, as this may have educated staff and demonstrated the importance of undertaking the research project. With this in mind, there needs to be more encouragement and support for research in practice.

As already mentioned, in radiology we rarely see patients until the day of their scan and then it is uncommon to see them again unless they need another scan at some point. For this study, patients were required to complete a post-scan survey regarding their MRI experience, and either hand them in on the day or send them back via pre-paid postal envelopes. This meant that huge reliance was based upon patients either completing them before they left the department or completing the surveys at home and sending them back. Again, over the phone would be the only method to remind

and encourage patients to complete the required research paperwork. This problem is not as evident in other speciality-based RCTs such as oncology, because research nurses regularly see patients for follow-up appointments, where they can ensure the completion of the required research paperwork. The word blinded RCT has an irony to it within radiology.

Conclusion

RCTs are the gold standard research method within healthcare, however radiology-based studies rarely use this method. From the above experience of a research radiographer, it is evident that specific barriers exist when undertaking RCTs led from the radiology department, especially with regards to recruitment and follow-ups. Certainly, based on the learning points experienced from this project, a multi-professional research team is essential, not only to aid in recruitment where possible, but to give a different perspective based on their speciality and experience. Also, staff support is vital for the smooth running of a trial, and it is important therefore, to educate and involve staff from the preliminary stages of study design, not only to increase their awareness but to emphasise the importance of study outcomes to inform practice.

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How to use this article for CPD

Examine your own work setting:

- What research is being carried out in your department?
- What are the obstacles and barriers you've encountered when undertaking projects?
- Do you undertake research, if yes, why? If no, why?
- Reflect on your own practice and what research projects you could conduct in the near future.

QA Code: 2EE5C600 ([Figure #1](#))

REFERENCES

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This article has been prepared following local guidance relating to the use of patient data and medical images.

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The challenges and barriers encountered whilst undertaking a randomised control trial within a radiology department: A research radiographer's perspective
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