Importance of randomisation—a call to researchers

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Readers of the journal over the past 10 years or so will have noted the improvement both in the quality and quantity of articles published in this journal. While the editorial team can encourage research relevant to hospital pharmacists, at the end of the day, academics and practitioners have to step up to the mark which they have done. These developments are obviously very welcome, but I am aware that in terms of an evidence-based hierarchy,[1] much tends to be at the lower end. In this editorial for the 2025 Congress issue, I want to issue a call to researchers to raise the bar and aim to publish more randomised controlled trials (RCTs).

The journal regularly receives submissions of clinical studies with two groups of participants. However, these studies are rarely randomised, despite the possibility of achieving this with some additional effort. Such effort has the benefit that the publication would have more impact, be cited more often and be of greater interest to the wider healthcare community and decision-makers.

I am sure that most readers can describe randomisation, but a short definition can be found here.[2] The key feature of an RCT is that researchers do not know whether a treatment to be studied is as effective as an existing one (control group) or even a placebo. Researchers may hope it is better, but need evidence to back it up. Such a position is called equipoise.

Randomisation reduces bias and strange though it may seem, nearly all biases in clinical studies make the results look better than they really are. By allocating participants randomly, selection bias is avoided, as researchers cannot manipulate which participants go in to which groups. As a budding clinical pharmacist, I was once told by a junior doctor that he would like a particular patient to go into the treatment group as he felt they would benefit! Not possible!

Randomisation typically is undertaken using computer generated random numbers or random number tables both readily available on the web. Of course, even tossing a coin can be used as long as there is a third party generating the random list.

Once the decision to randomise has been made, several other issues come into play. First allocation must be concealed so that the research team does not know which group a given participant has been assigned to. This should not be confused with blinding, which I will mention further below. Concealing allocation often provides a role for the hospital pharmacist who can manage the allocation but play no other role in the study.

The next issue to consider is blinding of the different treatments, such that in a study of two different medicines they are made to look alike. In this case, the researchers cannot tell which treatment a participant has received. Frequently, participants are also blinded—so-called double blind. This approach reduces performance bias. There are obviously situations where blinding is not possible but, the value of randomisation still stands and in these situations, those assessing the outcomes can be blinded to the allocation of a particular participant.

At the planning stage, the size of the study needs to be considered as small studies also tend to overestimate results.[3] This applies generally as well, and we see quite a few submissions to the journal that have very small numbers of participants and so are rejected. For a fuller description of bias, see Juni *et al*.[4]

Protocols of randomised studies must be submitted to a suitable international trials register,[5] such as the EU clinical trials register. Most journals, including *EJHP*, will decline publication of the study results without evidence of registration. While this may seem a hassle, it has the advantage of stating the outcomes clearly before the trial begins and prevents selective reporting of positive results.

So why bother? RCTs for good reason reconsidered to be of higher quality, though bad RCTs do exist. As a researcher working for many years generating systematic reviews, I would only select RCTs for inclusion. In any hierarchy of evidence, well-conducted systematic reviews are considered the best evidence, followed by good RCTs.

Yes! It is a bit more work, but worth it in the long run.

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