Understanding the quality of a quantitative paper (2): randomised controlled trials

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- Critical appraisal,
- Methodology
- Randomised controlled trials (RCT)
- Research quality
- Quantitative

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In the last paper in this series we started to consider the reasons why health and social care professionals might need to be able to critically appraise quantitative research (Ellis, 2021). We identified that there is a need to understand the quality of such research before considering its adoption in practice. We also identified how it is important that professionals consider how applicable, and generalisable the findings are to the specialism within which they work and the sorts of people they work with.

We identified how quantitative research has its own rules that govern the quality of the research and how these rules will vary in their application between the various methodologies that constitute quantitative research. We identified how it is good practice to use a critiquing framework when appraising research from whatever paradigm and that it is always a good idea to use a research methodology textbook to help define and understand terminology and methodological issues.

In the last paper in this miniseries, we considered how it is important that the researchers are clear about how they came to asking the questions, or posing the hypothesis, aims and objectives for their research. We saw that the research question must follow logically from the introduction and literature review to the paper and that this forms the start of what needs to be a logical sequence of decision making around how the research is undertaken — its methodology. We saw how the research methodology chosen to answer a particular question must itself fit the question, with some methodologies being fit to explore associations and correlations while others might be used to answer questions relating to cause and effect.

In this paper we will continue to consider the main elements of critiquing quantitative methodology focussing on elements of randomised controlled trials (RCTs), including sampling and randomisation methods. Some of the detail of this discussion will continue in subsequent papers in this series.

RANDOMISED CONTROLLED TRIALS

Thought by many to be the gold standard methodology for use in healthcare research, randomised controlled trials (RCT) are a very specific experimental approach used to examine cause and effect relationships (Polit and Beck, 2017) in clinical care. In essence, RCTs manipulate one factor, an exposure or independent variable, e.g. a wound dressing type, to see what effect this has on an outcome, dependent variable, e.g. wound healing (Ellis, 2022). While this might seem like a straightforward thing to do, there are elements of the methodology that need to be considered when undertaking a critique, some of which will be considered here.

SAMPLE

For RCTs, as with most quantitative research, the way in which the sample is selected in critical to the quality of the study. When a health or social care professional is reading a paper, one of the things they need to consider is whether the people involved in the study are generally similar to the people for whom they provide care (Ellis, 2019). It is important therefore that samples, and the characteristics of the people within them, are fully explained alongside any characteristic under study, e.g. the wound type, grade, site, etc. so the reader can make their own assessment as to how applicable the study might be to their practice.

The initial thing to consider is the way in which the sample for the study was handled. In RCTs this means considering the whole process from the selection of people for the study from a general population of individuals through to how people are accounted for at the end of the study (Critical Appraisal Skills Programme [CASP], 2020) as well as considering the size of the sample. People need to be selected for any RCT because they fit the criteria of the study, and they have the characteristics that are being studied, e.g. not just a wound but a specific type of wound perhaps in a specific place, such as, a venous leg ulcer. It is important that everyone is broadly similar at the start of the study

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otherwise the effect of the intervention may not be truly seen later (more on this in later in the series).

Once the sample population has been chosen, a good study will be clear about how they are then placed in the groups — in the case of a RCT this is normally done by a form of randomisation (Cathala and Moorley, 2018). In the basic form, this will mean that the sample is split into the cases (or intervention group) and the controls (very often these days people receiving the current 'gold standard' treatment) for the purposes of the study (more on this later in the series). When writing up the work the best papers will be clear about how this happened, for example, did they use randomisation tables or perhaps a computer programme (Ellis, 2022). Some studies will use different approaches that may be dependent on the type of intervention and the population available to them for the study (Parahoo, 2014), whatever the case, it is important that the researchers justify their approach in the when writing up there work.

It is then important that the researchers are clear about what happened, numerically, to the people in the sample as the study progressed. That is to say the best studies will show in their data how everyone placed in the two study groups, cases and controls, progresses through the study and that they are accounted for in the final analysis — even if they did not stay in the study right to the end (CASP, 2020). This is called an intention to treat analysis (ITT), rather than just an analysis of people who made it to the end of the study, and is important in reflecting what might happen in the real world if the particular intervention is applied (Polit and Beck, 2017), e.g. if the new versus an established wound dressing, is used.

Randomisation of the sample should lead to an even spread of both the known and unknown variables and characteristics within the two study groups. The better studies tend to present the patient characteristics in a table so the reader can compare things like the gender, age and ethnicity split between the test and the control groups (CASP, 2020). They will also report inferential statistics that should demonstrate the two groups are broadly similar at the start of the study. Again, this is important if the study wants to demonstrate the impact of an intervention rather than there being the nagging suggestion that any differences in the outcomes between the two groups is down to differences between them at the start.

All RCTs should also report how they determined the size of the sample they would use for the study, as well as how this number would be split into the cases and controls. A sample size calculation will invariably report the expected effect to be seen, e.g. how much quicker the wound might heal (perhaps as a percentage), what statistical level of significance the study accepts (usually by convention in medical studies 5%, p=0.05) and the power of the study (that is the ability of the study to detect a difference between the groups; Grove and Cipher, 2016).

CONCLUSIONS

Here we have examined some of the elements that go towards determining the quality of a RCT. We have considered the need for characteristics of the sample to be well described to enable the reader to make comparisons with the sort of people to whom they provide care. Furthermore, the best papers identify the way that the sample is allocated, usually randomised, into the test subjects and controls so the reader can judge if this was reasonable. We have also identified how the characteristics of the randomised groups should be explained to the reader to demonstrate that they are broadly similar at the start of the study.

The paper should account for all participants at the end of the study in order to achieve a real world, ITT analysis of the data and how such an approach helps satisfy the reader that the study demonstrates what would happen if they adopted the intervention in their practice. We have also seen how the researchers need to report how they decided on the size of the sample to be used in their research.

In the next paper in this series we will how practitioners might critically appraise the quality of RCTs looking at issues like blinding and the levels of care provided to each study group WUK