

## EDITORIAL

### Randomised controlled trials in critical care nursing: essential to move practice forward

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There is a growing need to generate empirical evidence to support clinical nursing practice. This is of particular importance in the critical care environment where practice is constantly evolving, new treatments and interventions are emerging, and historical practices sometimes need challenging<sup>1</sup>. This has become even more evident in the response to the COVID-19 pandemic, which has required practices and interventions to change rapidly.<sup>2</sup> For this reason, research is needed to compare treatments and interventions to ensure patients receive the best possible care that can be delivered. To achieve this, nurses must be at the forefront of generating evidence and answering important research questions as they arise.

Randomised controlled trials (RCTs) are considered the gold standard research design to reduce bias and ensure practice is evidence based<sup>1</sup>; yet they are frequently underutilised in nursing research compared to other research methods<sup>3</sup>. Although not the sole methodological answer to all research questions, they can produce an objective and, if adequately powered and well conducted, definitive answer to a clinical nursing question around effectiveness or safety of interventions. Many clinical nursing questions (or problems) exist in critical care that can only be answered adequately by an RCT. Some examples of these are:

*What is the most clinically and cost-effective wound dressing for sternal wounds after cardiac surgery?*

*What method (rapid changeover or double pumping) of inotrope infusion changeover is the least likely to result in haemodynamics instability in neonates and children?*

*What method of endotracheal suction (open or closed) causes least respiratory compromise and more rapid recovery in patients with acute respiratory failure and ARDs?*

*Is not routinely measuring gastric residual volume (GRV) to guide enteral feeding safe (no increased in VAP) and does it result in better nutritional achievement?*

This is not an exhaustive list, but illustrates the types of research questions that are best answered through an RCT. All these interventions are performed primarily by nurses and are within the decision-making remit of critical care nurses. If nurses do not study the things they do, then either others (often physicians) will, or the evidence base for these aspects of our nursing care will be lacking. We all like to believe our practice is 'evidence based' and indeed this is embedded in the UK Nursing & Midwifery Council's (NMC) code as a fundamental criteria for practicing as a nurse<sup>4</sup> but how can we practice evidence-based nursing when no or only poor-quality evidence exists? Nurses have an important role to play in both conducting research to generate evidence, and in translating this into clinical practice<sup>5</sup>. While this is widely recognised, and the numbers of RCTs in nursing has increased over the past two decades<sup>6</sup>, relatively few nurses are actively involved in conducting RCTs (in critical care) in comparison to other healthcare disciplines.

So where does the lack of understanding and drive to conduct RCTs in nursing arise, and how can we address this issue? We believe the problem often starts in undergraduate nursing education, where some suggest qualitative research methods are emphasised and preferred over quantitative methods<sup>7,8</sup>. This may lead to students perceiving RCTs as outside of the scope of nursing practice, and/or that the statistics are too complex to understand<sup>9</sup>. This does not mean qualitative methods

do not have a place, but that an equal balance must be placed on both methods. This situation may be perpetuated by a nursing faculty somewhat biased toward qualitative research. Indeed, due to the high vacancy rate in many UK universities, many nursing academics are recruited without PhDs and sometimes even without a master's degree<sup>10</sup>. This has implications for the teaching of research methods, as postgraduate study is where the mastery of research methods occurs. Although there is variation between universities, this remains a concerning issue within the UK<sup>10</sup>. Furthermore, qualified nurses who trained prior to 1992 in the UK (when nurse education moved into higher education) may have had very little exposure to or education around basic statistics and quantitative research methods. This is problematic as many of these nurses are very experienced clinically, and therefore well placed to identify clinical issues or questions that need to be answered to ensure ongoing commitment to evidence based nursing care. However, they often do not have the support (education, time and mentorship) they need to undertake research, particularly, RCTs, which are perceived to be more difficult to conduct.

If our assumptions are correct and the problem relates to how undergraduate education surrounding research methodology is delivered, then it could be argued that there is work to do to change the culture surrounding this issue, and to challenge the belief that RCTs are not useful for nursing and should be left to other disciplines. It could also be argued that to address the limited exposure to quantitative research methodology at undergraduate level, emphasis should be placed on educating qualified nurses, on how to read and interpret a quantitative paper in the first instance. Nurses should also be educated around how RCTs should be reported, using the CONSORT guidelines to enable them to read, understand and critically appraise papers, which can only improve the implementation into practice<sup>11,12</sup>. Furthermore, research mentorship through clinical academic nursing posts embedded in practice may help to address this knowledge and skills gap in the current nursing workforce<sup>13,14</sup>. Clinical academic roles for nurses remain rare in the UK, and even rarer in critical care, but there is a drive to develop these roles to enhance nursing-based research capacity and capability<sup>15</sup>.

Whilst clinical nurses are often engaged in, or committed to, quality improvement (QI), many clinical nurses do not participate in or conduct any research. However, it must be recognised that QI and RCTs are not mutually exclusive and should complement each other to ensure improvements in how care is delivered to patients in ICU<sup>16</sup>. Therefore, nurses should be supported to conduct well designed QI studies which may involve an RCT or quasi-experimental methodology. An example of a large multicentre RCT is the recent Sedation and Weaning in Children (SANDWICH) trial of a 'best practice' team-based intervention to target weaning of sedation and ventilation in children<sup>17</sup>. This trial was led by a critical care nurse and is an important step forward, showing that a team-based intervention (involving much greater bedside nursing involvement) can reduce invasive ventilation times in children<sup>17</sup>.

RCTs are an important research methodology but must be conducted well (as should all research) and this involves an understanding of basic statistics, randomisation, sample size calculations, and choosing the right outcomes. This knowledge can be acquired through postgraduate education including, but not limited to, MSc or PhD studies. Many nurses (at all levels in critical care practice, as well as academia) still seem scared of statistics and shy away from researching important questions using RCTs<sup>3,8</sup>, the answers to which may benefit patients/families and the health service. There are increasing examples of critical care nurses leading large multicentre trials<sup>17,18</sup>, and even running their own clinical nursing research laboratory<sup>19</sup>, who have contributed to the evidence base and successfully changed practice. However, these numbers need to increase substantially to keep up with the increasingly diverse and dynamic environment that is ICU.

In terms of challenging the perception that RCTs are only for others rather than nurses, it must be appreciated that nurses are core members of the interdisciplinary team and can produce high quality RCT results, as evidenced by a recent paper examining the reporting quality of paediatric RCT articles in nursing and medical journals.<sup>20</sup> A review found trials led by nurses have the same level of scientific credibility and rigor as medically led studies.<sup>21</sup> A further issue recognised in the literature is

that many nurse-led RCTs are not registered on a trials database, and that there is a disparity between the proportion of nurse-led trials that are registered, compared to those conducted by physicians<sup>22</sup>. Nurses must register RCTs in a timely manner (at the beginning, as they cannot be registered in retrospect) by supervisors, mentors or colleagues; otherwise, many journals will refuse to publish them. This is because trial registration is essential to ensure alterations to the analysis and study outcomes are not made after data collection to camouflage a poorly conducted trial<sup>23</sup>.

Another significant barrier for nurses (or any researcher) wishing to conduct an RCT is that they are costly to set up and run, as well as being resource intensive<sup>23</sup>. For this reason, many researchers, including nurses, do not undertake RCTs despite having a clear research question and a robust proposal. There is a clear need to increase the number of research-active clinical academic nurses in critical care so that nurse-led research programmes can be developed and sustained<sup>13</sup>.

While the critical care environment is rapidly changing, RCTs in critical care are also evolving. For example, methodological features of RCTs are changing to answer complex research questions. Adaptive and platform trials are increasingly being employed in critical care over conventional RCTs, particularly during the COVID-19 pandemic as new therapies emerged<sup>24</sup>. Nurses have an important role to play in the clinical research arena and should be engaged in conducting RCTs of this nature to answer complex questions that directly relate to nursing practices.

In summary, we believe that RCTs led by nurses are essential to critical care nursing. Studying the impact of, and best methods to perform, nursing interventions is crucial if we are to truly drive up the quality of clinical practice in critical care, and positively impact on patient or health service outcomes. There is increasing awareness of the value of RCTs to generate evidence-based practice in nursing. Education on the importance of nursing research, quantitative research methods and basic statistics must be incorporated into undergraduate nursing degree programmes, and role-modelled by clinical academic nurses, to equip the future nursing workforce with the skills they need to conduct impactful nurse led research.

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