

COMMENTARY

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Enhancing training in trials methodology research: insights from doctoral graduates

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Abstract

Training in trials methodology research is important for advancing clinical trials, ensuring the use of robust methods and addressing inefficiencies that can cause research waste. The Trials Methodology Research Partnership (TMRP) provides a specialised doctoral training programme to cultivate expertise in this distinct field. This article offers the perspectives of recent TMRP graduates, providing insights into skill development and professional growth delivered through structured training. These reflections highlight the value of comprehensive doctoral training in adequately equipping the next generation of trial methodologists to address evolving challenges and drive innovation in clinical trials. Recommendations for enhancing the training experience are provided with the aim to support the recruitment, development and retention of future methodologists.

Background

Clinical research plays a fundamental role in evidence-based medicine, informing clinical decision-making and policies about patient care provision [1]. Robust randomised controlled trials (RCTs) are considered the highest level of evidence and the preferred method for evaluating interventions [2]. However, designing and conducting high-quality trials is a challenging endeavour that requires careful planning and specialised methodological expertise. The literature has repeatedly highlighted that many trials are methodologically flawed, partly due to lack of adequately skilled researchers, leading to substandard studies and avoidable research waste [3–7]. A significant proportion of research waste stems from the use of inadequate methods that can inadvertently introduce bias, impacting trial results and potentially compromising patient care.

To address these challenges, trials methodology research (TMR) has emerged as a distinct field aimed at improving the design, conduct, analysis and reporting of trials [8]. TMR seeks to improve and optimise every aspect of the trial process to enhance the reliability and efficiency of trials, whereby improving the evidence base for healthcare. This is a rapidly evolving field and there is an increasing need for well-trained and skilful trial methodologists to ensure rigorous RCTs and reliable findings [9]. To support the trials methodology infrastructure, dedicated methodology hubs have been established in the UK to create a national network that serves the research community (<https://www.methodologyhubs.mrc.ac.uk/>). In 2019, this expanded into the joint initiative of the Medical Research Council (MRC)–National Institute for Health and Care Excellence (NIHR) Trials Methodology Research Partnership (TMRP), known as MRC-NIHR TMRP, bringing together various networks, institutions and partners working in trials methodology. In addition, TMRP collaborated with 25 universities, offering a unique doctoral training programme for 33 Doctor of Philosophy (PhD) students to focus on key areas of RCTs that needed improvement, such as outcomes research, data science, statistics, psychology, epidemiology, social science, informatics and health services research [8].

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Since this is a new training programme, it is important to explore experiences of doctoral alumni. Existing research on doctoral training in related fields provide some understanding about the student experience [10]. These findings are likely to apply to students undertaking a doctorate in trials methodology but may manifest differently due to the unique characteristics of the field, thus requiring further exploration. This article aims to provide the perspectives of two recent TMRP doctoral graduates, providing insights into the training, summarising the skills developed and discussing specific challenges faced. Recommendations for enhancing the student experience are outlined with the aim of supporting the recruitment, development and retention of future trial methodologists.

Doctoral training in trials methodology

Doctoral training provides the opportunity to achieve the highest educational attainment. As defined by the International Standard Classification of Education [11], a doctorate is an advanced research qualification designed to develop specialised expertise, critical thinking skills and rigorous research capabilities. It is a period underpinned by intensive study, independent research and mentorship that leads to an original contribution to knowledge. Doctoral students in trials methodology need to navigate complex scientific and practical challenges, requiring understanding of methodological concepts and development of relevant skills. Due to its interdisciplinary nature, the TMRP doctorate necessitates proficiency across various domains whereby students must be acquainted with existing methodologies but also contribute to advancing the field. This breadth of necessary knowledge can be demanding and common obstacles in doctoral education, such as impostor syndrome [12] and increased stress [13], may be amplified in this context. Upon reflecting on the doctoral journey in trials methodology, several key themes have emerged as pertinent factors that shaped our experiences on the programme as described below.

Skill development and competency building

At the core of the doctoral journey is the development of specialised research skills essential for conducting high-quality research. Importantly, acquisition of these skills needs to be embedded into tailored training relevant to the student's field of research [14]. Nonetheless, obtaining specialised methodological expertise in trial design, conduct and statistical analysis can be challenging due to the rapidly evolving methods and best practices in trials. As the landscape of trials evolves, students need to remain adaptable and develop the ability to understand, critically evaluate and potentially incorporate new methods into their research projects.

Being based in clinical trial units (CTUs) provides an ideal setting for trials methodology candidates to cultivate skills across all aspects of an RCT, including trial design, research ethics, data management, trial conduct and statistical analysis. CTUs offer access to experienced staff who can be approached for guidance. The nurturing environment and hands-on approach enabled us to develop and apply essential skills equipping us with real-world experience complementary to theoretical knowledge.

Moreover, having access to a range of training opportunities such as courses, seminars and workshops offered by both the TMRP and our respective universities further enabled the acquisition of a range of skills. Both the University of Nottingham and the University of Leeds provided training tailored to doctoral students in areas such as research integrity, ethics, study design and conduct, project management, presentation skills and thesis writing. Additionally, the TMRP provided access and funding for a variety of training opportunities, for example patient and public involvement; academic writing workshop; and facilitation, consensus building and prioritisation workshop. Alongside regular webinars on diverse aspects of trials methodology research, TMRP provided unique opportunities for students to observe NIHR methodology research funding panel meetings and statistical editors' meetings at a prestigious journal. These experiences enabled TMRP students to connect with each other and network with other scholars.

Professional development challenges

Doctoral students experience a transition at the start of their training, moving towards a more independent way of working that poses challenges [15]. This shift requires ownership for ongoing development, which places emphasis on self-directed learning, critical thinking and problem-solving skills. Students tend to find this difficult, often feeling overwhelmed by the burden of academic expectations and the need to meet key milestones [16]. Furthermore, finding the balance between independence and seeking guidance from supervisors can be difficult to navigate because doctoral candidates are no longer students in the generic sense, yet not fully developed researchers either. Consequently, it was challenging to reconcile this dualistic stance of being autonomous while still relying on the expertise and advice of supervisors.

Forming a disciplinary identity as a trial methodologist was another challenge. This involved identifying specific areas of interest, deepening expertise within the field and enhancing confidence. Networking and integrating into the clinical trials community was vital for professional growth and career development though these can be daunting for doctoral students [17]. Nevertheless,

attending and presenting at conferences, collaborating with external institutions and interacting with industry partners and regulatory bodies are all important activities. These endeavours not only enhance visibility in the field, but also offer valuable opportunities for learning, collaboration and career advancement.

Supervisory team

Supervision is a fundamental component of doctoral education and it plays a pivotal role in shaping the success of the doctoral journey [18]. Therefore, supervisors must possess the academic and interpersonal skills to nurture students and effectively manage the supervisory process while addressing challenges that may arise. Regarding the trials methodology doctoral training, a multidisciplinary supervisory team with adequate expertise is a prerequisite for fostering the professional development of students [19]. The quality of the supervisory relationship can significantly influence the trajectory of the doctoral journey and disagreements between students and supervisors can inevitably inhibit progression [20]. To mitigate this, many universities offer training courses for both students and supervisors with the aim of enhancing effective collaboration and communication. These courses can be beneficial for all parties involved. It is advisable to establish clear expectations early on to define the roles and responsibilities of supervisors, agreeing on frequency and format of meetings and establishing modes and timing of feedback provision on written work.

Personal barriers

Amidst managing the supervisory relationship, training courses, thesis writing and publication pressures, personal barriers can further complicate and even impede the doctoral journey. In our case, some barriers were worsened as we pursued the doctorate under unprecedented circumstances during the coronavirus pandemic. This global health crisis exacerbated the feelings of isolation and loneliness, issues that were already prevalent in the postgraduate community [21, 22]. The need to work remotely from home blurred boundaries between personal and professional life and made it difficult to maintain a healthy work-life balance. Furthermore, the self-imposed demand for quickly understanding the complicated field of trials methodology research and the need to juggle academic responsibilities affected our mental wellbeing and nearly led to burnout which are commonly occurring experiences in doctoral education [23]. The frequently felt impostor syndrome is highly prevalent in doctoral students, which fuelled in us continuous self-doubt that not only undermined the confidence in our capabilities but led to persistent questioning of belongingness in academia [12].

Financial stress also weighed heavily on us. The modest stipend added further strain, which is a universal problem amongst doctoral students [24]. Lack of sufficient funding often forces students to take on extra paid work at the expense of their research and personal wellbeing, potentially jeopardising their completion timelines.

Recommendations for enhancing the student experience

Supervisor training and engagement

Supervisory training at the participating organisations of TMRP should be mandated to ensure up to date knowledge of procedures, information sources and recent developments. Considering the increased stress of students in the early stages of doctoral study [25] coupled with our reflections, we highly recommend that supervisory teams collate a welcome package for new students that contain essential information to help ease the transition into the programme.

Based on our experience, we believe that two competent and committed supervisors are usually sufficient to guide a student to completion. Having had three supervisors proved challenging, burdensome and unnecessary for various reasons. Arranging meetings was difficult due to conflicting schedules. Having three experts with strong and differing views, particularly when providing conflicting comments on written work, can cause confusion in students [20]. If there are disagreements between supervisors, the student feels the need to mediate. Overall, this power imbalance may lead to decisions that students do not fully agree with. Consequently, some meetings felt more directive where supervisors struggled to relinquish control [26]. We believe that supervisors in trials methodology ought to allow greater autonomy for students to explore and implement their ideas within feasible and realistic boundaries.

Furthermore, the level of engagement significantly varied amongst supervisors with some showing minimal involvement, missing meetings and not providing feedback. This lack of commitment can negatively impact team morale and the student's sense of value [27]. We advise for organisational rules to be established and followed to monitor supervisor engagement, akin to monitoring students, to ensure all members of the supervisory team are actively involved and meaningfully contributing to the student's development.

Improved funding and clear career pathways

It would be beneficial if TMRP could establish a more comprehensive financial support system extending beyond the basic stipend, recognising additional expenses associated with trials methodology research. This supplementary funding could cover conference

attendance, research-related travel, specialised training and materials. Moreover, the partnership should implement equitable distribution of resources across participating institutions to ensure all students have access to opportunities. Finally, TMRP could create a centralised communication platform to disseminate information about training opportunities in a timely manner to allow students to plan their professional development more effectively.

Upon completing the doctorate, postdoctoral research roles are the first positions for many. However, these low-paying, high-pressure, temporary roles provide no contingency or job security [28]. This casualisation of workforce is prevalent in academia, alongside other disciplines and places academics under precarious conditions [29, 30]. These system-wide issues are significant, but the lack of job security stands out as a major concern for trials methodology graduates. The absence of clearly defined career pathways for trial methodologists, including graduates, has also been highlighted [31]. Opportunities for promotion need to be given with transparent criteria that recognise the specialised expertise of trial methodologists. This would entail developing competency frameworks for methodologist roles to allow benchmarking across organisations. Regarding early career methodologists, offering formal mentoring programmes would enhance their prospects. In addition, funding and time should be allocated for attending relevant training and conferences to enable further skill development and aid career advancement.

Placement and teaching experience

To enhance the doctoral training experience in trials methodology research and broaden career prospects, we recommend TMRP to incorporate placement and internship opportunities. These are crucial for developing a well-rounded skill set and exploring diverse career paths. Placements in CTUs, pharmaceutical companies, regulatory bodies and governmental research institutions could provide real-world exposure and networking opportunities. This would allow students to apply their theoretical knowledge in practical settings and build professional networks. Similarly, offering teaching opportunities, such as leading seminars or assisting with undergraduate courses, would help students to develop important communication and leadership skills beyond research [32]. These experiences could be facilitated through partnerships with affiliated institutions and industry collaborators and should be integrated into the doctoral programme timelines to complement research activities. This approach would foster the development of multidimensional and adaptive scholars [33].

Conclusion

Embarking on a doctoral journey in trials methodology research is a privilege that offers unique opportunities to contribute to the advancement of clinical research. Our experience within the TMRP cohort has been both personally and professionally transformative. It helped to develop networks within a vibrant trials methodology community and provided invaluable knowledge and skills. While our collective experience was overwhelmingly positive, the proposed recommendations outlined would further enhance the doctoral training experience. These insights aim to contribute to the improvement of trials methodology training. Refinement of the doctoral programme could lead to well-equipped and adaptable graduates who can address evolving challenges and cultivate innovation in clinical trials.

Abbreviations

CTU	Clinical Trial Unit
MRC	Medical Research Council
ISCED	International Standard Classification of Education
PhD	Doctor of Philosophy
RCT	Randomised controlled trial
TMR	Trials methodology research
TMRP	Trials Methodology Research Partnership
UoN	University of Nottingham

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Authors' contributions

AB conceived the idea and wrote the first draft of the manuscript. Both authors provided intellectual input, contributed to subsequent drafts and approved the final manuscript.

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References

1. Friedman LM, Furlberg CD, DeMets D. Fundamentals of clinical trials. 4th ed. New York: Springer; 2010.

2. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c332.
3. Altman DG. The scandal of poor medical research. *BMJ*. 1994;308(6924):283–4.
4. Chan AW, Song F, Vickers A, Jefferson T, Dickersin K, Gøtzsche PC, et al. Increasing value and reducing waste: addressing inaccessible research. *The Lancet*. 2014;383(9913):257–66.
5. Yordanov Y, Dechartres A, Porcher R, Boutron I, Altman DG, Ravaud P. Avoidable waste of research related to inadequate methods in clinical trials. *BMJ*. 2015;350:h809.
6. Glasziou P, Chalmers I. Research waste is still a scandal - an essay by Paul Glasziou and Iain Chalmers. *BMJ*. 2018;363:k4645.
7. Van Calster B, Wynants L, Riley RD, van Smeden M, Collins GS. Methodology over metrics: current scientific standards are a disservice to patients and society. *J Clin Epidemiol*. 2021;138:219–26.
8. Medical Research Council. What is trials methodology research? 2015. Available from: <https://www.methodologyhubs.mrc.ac.uk/about/tmrp-what-trials-methodology/>.
9. Piroscia S, Shiely F, Clarke M, Treweek S. Tolerating bad health research: the continuing scandal. *Trials*. 2022;23(1):458.
10. Sverdluk A, Hall NC, McAlpine L, Hubbard K. The PhD experience: a review of the factors influencing doctoral students' completion, achievement and well-being. *Int J Dr Stud*. 2018;13:361–88.
11. International Standard Classification of Education (ISCED). 2011. Available from: <https://uis.unesco.org/en/topic/international-standard-classification-education-isced>.
12. Nori H, Vanntaja M. Too stupid for PhD? Doctoral impostor syndrome among Finnish PhD students. *High Educ*. 2023;86(3):675–91.
13. Andrade D, Ribeiro IJS, Máté O. Academic burnout among master and doctoral students during the COVID-19 pandemic. *Sci Rep*. 2023;13(1):4745.
14. Blaj-Ward L. Skills versus pedagogy? Doctoral research training in the UK Arts and Humanities. *High Educ Res Dev*. 2011;30(6):697–708.
15. Turner G, McAlpine L. Doctoral experience as researcher preparation: activities, passion, status. *Int J Res Dev*. 2011;2(1):46–60.
16. Dickerson SH, Byers VT, Smith RN, Hwang E, Angrove KE, Chandler JL, et al. Survival strategies: doctoral students' perceptions of challenges and coping methods. *Int J Dr Stud*. 2014;9:109–36.
17. Douglas AS. Engaging doctoral students in networking opportunities: a relational approach to doctoral study. *Teach High Educ*. 2023;28(2):322–38.
18. Friedrich-Nel H, Mac KJ. The quality culture in doctoral education: establishing the critical role of the doctoral supervisor. *Innov Educ Teach Int*. 2019;56(2):140–9.
19. Almusaed A, Almssad A. The role of the supervisor on developing PhD students' skills. *Proceedings of International Conference on Humanities, Social and Education Sciences*. 2020;1:25–36.
20. Gunnarsson R, Jonasson G, Billhult A. The experience of disagreement between students and supervisors in PhD education: a qualitative study. *BMC Med Educ*. 2013;13(1):134.
21. Janta H, Lugosi P, Brown L. Coping with loneliness: a netnographic study of doctoral students. *J Furth High Educ*. 2014;38(4):553–71.
22. Phillips R, Seaborne K, Goldsmith A, Curtis N, Davies A, Haynes W, et al. Student loneliness through the pandemic: how, why and where? *Geogr J*. 2022;188(2):277–93.
23. Talapko J, Perić I, Vulić P, Pustijanac E, Jukić M, Bekić S, et al. Mental health and physical activity in health-related university students during the COVID-19 pandemic. *Healthcare*. 2021;9(7):801.
24. Martow JH, Thornton EM, Conlon P, Jones AQ, Lyons S, Khosa D, Hewson J, Roche S, Wright C, Lumley MN. Time to act: mental health and desired university supports among graduate students. *High Educ Res Dev*. 2024;44(3):644–58.
25. Jackman PC, Jacobs L, Hawkins RM, Sisson K. Mental health and psychological wellbeing in the early stages of doctoral study: a systematic review. *Eur J High Educ*. 2022;12(3):293–313.
26. Delamont S, Atkinson P, Parry O. *Supervising the doctorate: a guide to success*. Maidenhead: Open University Press; 2004.
27. Handal G, Lauvås P. Optimal use of feedback in research supervision with master and doctoral students. *Nordic Stud Educ*. 2005;25(3):177–90.
28. Ganapati S, Ritchie TS. Professional development and career-preparedness experiences of STEM Ph.D. students: gaps and avenues for improvement. *PLoS One*. 2021;16(12):e0260328.
29. Ackers L, Oliver L. From flexicurity to flexsecurality?: the impact of the fixed-term contract provisions on employment in science research. *Int Stud Manag Organ*. 2007;37(1):53–79.
30. Smithers K, Spina N, Harris J, Gurr S. Working every weekend: the paradox of time for insecurely employed academics. *Time Soc*. 2022;32(1):101–22.
31. Iflaifel M, Williamson PR, Mitchell EJ. How professional development can be supported for health and care research methodologists: results of the PROfessional developmEnt for Research methodologists (PROSPER) e-Delphi and consensus study. *BMJ Open*. 2024;14(10):e085656.
32. Hillbrink A, Jucks R. 'Me, a teacher?!' – professional role identification and role activation of psychology PhD students. *Stud Grad Postdoctoral Educ*. 2019;10(2):109–25.
33. Patterson CA, Chang CN, Lavadia CN, Pardo ML, Fowler DA, Butler-Purpy K. Transforming doctoral education: preparing multidimensional and adaptive scholars. *Stud Grad Postdoctoral Educ*. 2020;11(1):17–34.

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