Trainee Tips for Conducting a Clinical Trial during the Clinical Psychology Doctorate

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The research component of doctoral training in clinical psychology may seem either daunting or exciting, depending not only on previous experience but also the type of research chosen. As a first-year trainee a wide range of possible research studies may be possible, provided there are people willing to supervise the research. Ascertaining the feasibility of a particular research project within the timeframe of the professional doctorate, however, can be a nebulous process. In this article, I share reflections on the experience of conducting a feasibility randomised controlled trial as part of the clinical psychology thesis, and practical advice to make the process less daunting for trainee clinical psychologists interested in conducting a clinical trial for their clinical psychology doctoral research. As a trainee, the general advice I encountered from peers when it came to choosing a research topic was to follow the 'path of least resistance'. In practice, this meant choosing studies where the initial stages, especially obtaining ethical approval, had been completed, or, even better, studies where the data had already been collected. While this is practical advice, I would argue that the doctorate in clinical psychology provides an excellent context in which to conduct a clinical trial – your supervisors will most likely be clinicians with expert knowledge and excellent links to local services, you will be able to seek advice from other academics within the department, and the University can provide study indemnity that otherwise can be very challenging to obtain. Conducting a clinical trial will undoubtedly raise a number of challenges and require significant and consistent time investment. However, I believe that planning and leading a trial, especially if you are interested in being involved in research after clinical psychology training, can provide an invaluable experience and skillset. Moreover, as clinicians we often refer to findings from clinical trials to inform our practice and I believe that the experience of conducting one gives you not only an appreciation of the effort required, but also a better understanding of the advantages and limitations of this methodology.

As a first-year trainee, I decided that the 'path of most resistance' was the one for me and chose to conduct a feasibility randomised-controlled trial of a post-stroke cognitive rehabilitation intervention for my thesis. Online search results suggest that it is relatively rare for trials to be conducted during clinical psychology training, but having seen that several others had done this before (such as Majumdar & Morris, 2019), I felt confident that, although potentially difficult, it was achievable. Now, having completed my degree without needing an extension, I concur that it can be done and is worth doing. Here are my tips for running a clinical trial during clinical psychology training.

1. Choose supervisors that are experts in the field and who have conducted trials themselves.

   My experience of conducting a trial was made significantly more manageable and less stressful by my two supervisors, both of whom were incredibly supportive and knowledgeable. Conducting doctoral research can be quite an isolating experience and it is extremely important to feel that you can rely on the expertise of your supervisors at all stages of the process.

2. Start early and expect delays.

   While the advice to start early is quite generic and universally applicable, when conducting a clinical trial with limited time available, particularly if NHS ethical approval is required, it is essential to start early and assume there will be delays along the way, because there most likely will be. Putting together a Gantt Chart is a good starting point, as it will give you not only an overview of the timeline, but also serve as a 'to do' list.

3. Decide between a feasibility or 'full-scale' trial.

   It is important to acknowledge from the outset, that as a trainee, you need to divide your time and focus between the research component, academic assignments and clinical elements of your doctorate. Participant recruitment is noted time and time again as one of the main challenges and causes for delay when conducting research, and not meeting recruitment targets (i.e., having an under-powered dataset) significantly affects the conclusions you can draw from your study. As certain populations can be very challenging to recruit from, this is an important consideration to make at the very beginning. When I was planning my project, my supervisors advised that a way to mitigate this potential challenge is to conduct a feasibility randomised-controlled trial instead of a full-scale trial, a route which I am very glad we decided to take. The difference between the two is that when conducting a feasibility trial, you aim to establish whether the study procedures can be done (e.g. by looking at recruitment rate) and are acceptable to your participants, rather than whether the intervention is effective. Alternatively, conducting a pilot study, which is a small-scale version of a full trial or a part of it, is an option to consider. This type of research is increasingly seen as an essential precursor for full-scale randomised-controlled trials (see Eldridge et al., 2016; Whitehead, Sully & Campbell, 2014).

Conducting a feasibility trial allowed me to gain experience in all the key aspects of planning and running a trial but reduced the risks (and stress!) associated with meeting recruitment targets. An additional methodological consideration is that you may not have the necessary resources to ensure that, if you were to conduct a full trial, bias is reduced as much as possible (e.g. data collection and analysis being conducted by different researchers).

4. Decide on recruitment sources.

Another important consideration is where you will recruit your study participants from. A notorious difficulty is securing the necessary ethical approvals to recruit from the NHS. While there are advantages and disadvantages to NHS recruitment, is it important to decide early-on about whether you want to pursue this, as obtaining ethical approval will require significant liaison with clinicians and R&D departments from NHS Trusts you plan to recruit from, as well as liaison with the study sponsor, to arrange indemnity cover once the study commences. My supervisors and I decided that NHS recruitment would be essential for our study. Although the process of obtaining ethical approval was difficult, I am very glad I did it, as should I need to do it again in the future, I would feel quite confident in my knowledge of the system. My advice is to allow at least six months to prepare the application for HRA approval. I found that once the application is submitted, the process is fairly streamlined. One other recruitment source that I would recommend exploring is existing participant databases. To find out more about this, the best starting point would be to speak with your supervisors, as well as liaising with other researchers from your institution who recruit from the same clinical populations. My suggestion is to try to find out more about how other researchers have found recruiting from the clinical population you are interested in to help you decide on recruitment sources. Some clinical populations, such as people diagnosed with Parkinson's, are very active in research and you may only need to advertise with one or two organisations, whereas other clinical populations might be less engaged in research, for a variety of reasons. If you are going to recruit from both NHS and non-NHS sources, you may want to consider making an application for University ethics while the HRA process is ongoing, as this is faster and it will allow you to get a head-start recruiting from non-NHS sources.

5. Be organised at all stages of the process.

   It will be very important to have an organising system for all your files, as you will most likely have multiple iterations of the same documents. Another tip would be to keep track of your thinking process when making various decisions during the study planning stage (e.g., whether to recruit through the NHS or not), as when you are later writing your thesis and during the viva you will need to explain your rationale. A legal requirement for full trials is to have a study master file where you keep all the documentation, with separate folders for the proposal / protocol, intervention materials, study data etc. I recommend having a master file regardless of which type of trial you are conducting and keeping everything in a secure shared folders that you and your supervisors have access to.

6. Build positive relationships with fellow researchers.

   I decided to highlight the importance of a positive relationship with research supervisors by making it the first tip in the list, because I believe it is essential to feel supported throughout this process. It is also important to look towards peers for support and to ask others for help and advice, especially if they have experience conducting research similar to yours. Should you collaborate with clinicians or services for recruitment, it is extremely important to establish good communication, ask for their input, and provide regular updates.

7. Build positive relationships with study participants.

   The importance of participant and public involvement is not the main focus of this article, but it is important to note that the earlier you can talk to people from the clinical population you are researching, the better. My experience has been that people are very friendly and willing to help. Being able to get feedback from stroke survivors when I was planning my study helped me make important decisions (e.g., between having a waitlist or active control). I was also able to later reference this input in my study protocol and thesis.

   It is crucial to build rapport with your study participants. Participation in clinical trials tends to involve a significant time commitment and it is rightfully very important that people feel appreciated for their contribution. How you achieve this will depend on your study; it is easier to build positive relationships in person. My study was

conducted fully online, and to compensate for this I made an effort to have regular communication with participants. In addition, my study involved a screening call at the beginning which, on reflection, was a fantastic opportunity to build rapport.

8. Choose a topic that you are passionate about.

   While it is possible to discover an interest in new subjects, considering that conducting a trial already presents significant challenges, I believe that choosing to research a topic you know you feel passionate about will make the process much more rewarding and make it easier to remain motivated along the way. Moreover, researching a clinical population you want to work with as a qualified psychologist will give you a significant advantage when applying for roles.

This advice, although not exhaustive and based on my experience, hones in on key factors you may want to consider, both when deciding whether you want to do a clinical trial in the first place, and throughout the process of planning and running it. Undertaking research of any type is difficult, but it can also be fun and rewarding, and it is important to hold onto this when challenges (almost) inevitably arise. Looking back, I am very glad I chose to conduct a trial during my clinical training and feel proud of being able to achieve this. If this type of research is of interest to you, it is my hope this article will be useful.

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