RESEARCH METHODOLOGY

How to set up and run a multi-centre trainee-led collaborative project

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Abstract
The multi-centre trainee-led collaborative research model improves the generalizability of results, efficiency of data collection, quality of data and sample size. Although an enormous amount of effort and resources are sometimes required, the final results lead to a standard that is unachievable by conventional studies. In this article, we summarize a step-by-step guide on how to set up and run a multi-centre trainee-led collaborative project.

INTRODUCTION
The main objective of clinical research is to establish evidence that aids clinical decision-making, encourages ongoing research and adds to the existing body of knowledge [1]. Nonetheless, clinical research is still commonly criticized because of small sample size and the lack of generalizability, especially in the field of surgery where single surgeon case series comprise the majority of studies [2]. Limited access to only local patient data, difficulty obtaining funding and a lack of coordination between different units performing similar studies leading to duplication of work are obstacles to the development of high-quality studies. The multi-centre trainee-led collaborative model is one approach that addresses these issues. Multi-centre collaborative research improves the generalizability of results, allows for an accrual of a sufficient diverse patient population in a shorter period of time, improves efficiency and establishes a higher level of evidence [2–4]. The successful conduct of a multi-centre research project requires careful planning and a dedicated team to monitor activity. In this paper, we aim to summarize the steps of setting up and running a multi-centre trainee-led collaborative project.

TRAINEE-LED COLLABORATIVE NETWORKS
Trainee-led collaborative research networks are research organizations run by trainees, established according to geographical location and sub-specialty. A successful trainee collaborative requires the support and participation of people in positions of authority as well as existing institutional trusts and societies. These networks allow trainees to participate in large-scale research, improves their teamwork skills, and leads to co-authorship; particularly important as authorship of literature is mandatory criteria for completion of training [5, 6]. Supervising consultants and other healthcare professionals can also benefit from trainee-led research by completing their revalidation requirement of participating in clinical audit or research [5]. In addition, finding support from funding agencies is easier when approaching them as a trainee-led network, rather than an individual.

DECIDE ON YOUR RESEARCH DESIGN
The first step of any research study is to identify and establish the research question, targeting paucity in the literature. Start by performing a literature search on a topic that interests you and identify any grey areas requiring further research. Focus your research question and obtain support during this process from hospital research teams, consultants, regional collaborative and trial centres. Decide on the methodology required to answer your research question and how it is logistically possible, power the study and do the least amount of harm to the patients in an ethical and cost-effective
manner. This can often be achieved with an observational study, and not necessarily an experimental one. The concept of classifying randomized control trials as the research design that provides real answers while viewing results from observational studies with more caution has recently been challenged [7].

ESTABLISH A PROJECT TEAM

Every research project needs a dedicated team. Establish who the principal investigator or lead, co-lead and co-investigators are early on. Every member of the team must know what their role is and what is expected from them. The principal investigator or lead is responsible for overseeing and driving the project. The co-investigator or co-lead is responsible for managing the project and coordinating the different ongoing activities. The project team needs to include people with the appropriate skill mix and genuine interest. In addition, work on setting up a dedicated study centre to run the day-to-day activities of your project. This centre is a managing hub for the research study, run by a group of trainees, a university centre if available or any group of co-investigators. Various universities have well-established research centres run by individuals with research backgrounds and statisticians, able to manage and run collaborative projects.

PREPARE A STUDY PROTOCOL

The study protocol is an integral part of your multi-centre collaborative project. This is a document that defines and justifies the research question; outlines the aims, objectives and outcome measures of the study; elaborates on the study population, data analysis, recruitment criteria; and assesses any confounding variables and ethical considerations [1, 8]. For multi-centre collaborative studies, each participating site should adhere to the same recruiting model [8]. Details on the role of participating site teams, local site registration, study administration and publication policy should be included as well in the protocol. The method of data collection and storage should also be explained in detail. The REDCap web application is a secure software platform that supports data capture for research studies [9, 10]. It is an excellent tool to use when setting up a multi-centre collaborative study, allowing you to manage and store data securely in one location. The data collection tool should be kept short and concise, with clear tabs to avoid confusion during the data collection process. Working with a statistician early on during this process helps avoid coding problems once the results are ready for analysis. How many collaborators are allowed from each site, and how the final published paper will be cited as should also be accounted for in the protocol. Deciding on how many patients should be recruited by each collaborator in order to be eligible as an author is an important detail that should be included as well. Careful consideration should be given to avoid making authorship too inclusive leading to poor data quality or too restrictive leading to poor recruitment. Contributions made by collaborators should be recognized as per standardized guidelines for reporting of authorship in collaborative research [11]. Once the study protocol is completed, it should be included in a document bundle along with an invitation letter and a frequently asked questions sheet, which should be sent across to all interested sites.

ADVERTISE

Advertising for your multi-centre collaborative project before the launch date is essential. It is important to understand if others are interested in your project and to engage hospital sites early on, preparing them to establish a local study team prior to the launch date. Advertising can be done using social media platforms such as Twitter and Instagram. Twitter is a powerful tool that helps establish your project presence. Following medical professionals that are interested in your area of research and tagging them in your posts will increase your recruitment. Having no hospital sites participating from certain geographical regions is a common pitfall of collaborative research. Use your local trainee research networks, consultant networks, specialist societies and personal acquaintances to target specific regions with low participation.

LAUNCH

Timing your launch date is essential. Trainees rotate to different posts at various months during the year. Therefore, it is important to time your launch date in order to give collaborators enough time to complete the project before they switch jobs. Certain collaborating sites may decide to join later on after your launch date, and it is important to continue allowing others to participate, in order to increase your overall study numbers. Continue managing your project by sending weekly or monthly newsletters and motivate collaborators by releasing information such as the overall number of sites that are participating or information on which hospital has the most data uploaded. Your local study centre should also be responsible for following up with and answering any questions that collaborators may have. Regular meetings, at least monthly, are also essential to discuss all aspects of the project and act as a quality control method. Furthermore, set a deadline for sites to upload data, but be flexible and willing to change it if circumstances dictate.

FINAL STEPS

Once all sites have uploaded data, aim to collate and analyse the information carefully while working with a statistician. Prepare parts of the manuscript, such as the Introduction and Methods sections early on, and plan where you want to publish your results.
COMMON CHALLENGES

Various challenges can be faced while running a multi-centre collaborative study. Firstly, having few centres signing up for your project can limit your overall study numbers. Aim to advertise for your project early on and use every method available to inform others of your projects. Secondly, sites may not submit all their data by the established deadline. Be flexible and ready to change your deadlines, but strict enough by not allowing the project to carry on for several months after the original deadline. Aim to identify the reasons why certain trusts are struggling to commit to deadlines and organize a virtual online meeting inviting all collaborators to discuss their experiences. Keep your data collection method concise and simple, code your data carefully prior to starting and avoid asking collaborators to collect complex information that is difficult to retrieve from patient records. Be aware that most hospital sites will not have electronic patient records from previous years and requiring collaborators to retrieve information from paper records can be time consuming. Third, confidentiality and data storage methods should be carefully planned prior to your launch date. Using online platforms such as REDCap to securely store data can be very efficient. Finally, a clear way of managing missing data should be established early on. Aim to include details on how to manage missing data in your study protocol and communicate back with sites that are missing vital information. Strict criteria regarding the percentage of variables without missing data should be set in place (ex. 80%) in order to accept results from a participating centre in your final analysis.

CONCLUSIONS

Setting up and running a multi-centre collaborative project takes an enormous amount of effort and resources but improves efficiency of data collection, quality of data, generalizability of results and overall sample size, thereby leading to a standard of observational study that is unachievable by conventional studies. Research collaborative provide an avenue for such research to be conducted while also providing doctors in training opportunities to participate in such large-scale studies.

CONFLICT OF INTEREST STATEMENT

None declared.

FUNDING

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REFERENCES