Exploring Stakeholder Perspectives about N-of-1 Clinical Trials and Single-Case Designs

Participant Information Sheet (version 3)

Study Investigators	Institution
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Before you decide to participate in this study, it is important that you understand why the research is being conducted and what it will involve if you agree to participate. Please read the following information carefully and take time to decide whether you wish to take part.

What is the purpose of the study?
Most treatment guidelines are developed based on research that focuses on how groups of patients respond to a treatment ***on average*** (i.e. findings from a randomised controlled trial). However, response to treatment may vary substantially from one patient to another. Traditional research designs may not identify patients who do not respond or who are harmed by a particular treatment. N-of-1 clinical trials and single-case designs have emerged as a rigorous scientific method that can identify individual patient response to interventions. This study aims to explore stakeholder perspectives about N-of-1 studies and in particular the barriers and facilitators for conducting N-of-1 clinical trials and single-case design studies in clinical practice.

What does participation in the study involve?
The researcher will schedule an appointment with you to complete an interview in person or via telephone or video call (e.g. Zoom or Teams). The researcher will collect some personal details through a brief online survey and provide a link to a video describing what N-of-1 clinical trials and single-case design studies are. Then at the interview they will ask you a series of open-ended questions about your views on these study designs. The interview will be audio-recorded and transcribed to ensure data accuracy.

What is the duration of the study?
The study involves a one-time interview, which will take 30-40 minutes to complete.

Where will the study take place?
Interviews will be conducted face-to-face at The University of Queensland or via telephone or video call.

What are the risks of participating in the study?
Participation in the study will involve no physical or psychological risk.

What are the benefits of participating in the study?
By participating in this study, you will be providing valuable information that will inform strategies to improve awareness and uptake of N-of-1 clinical trials and single-case design studies in the healthcare context.

What happens if something goes wrong while participating in the study?
You can contact the lead researcher if you have any concerns while participating in this study (details at end of information sheet). If the chief investigator is unable to resolve your concern, or you wish to make a complaint regarding the study, we will provide you with the contact details of a University Ethics Coordinator.

What happens if I change my mind about participation?
You are free to withdraw from the study at any stage. You do not need to give a reason for withdrawing.

Are my data confidential?
Yes. All paperwork and electronic data you provide will be labeled using a unique number to maintain data anonymity. Therefore, there will be no means of identifying you by the answers you provide to any questions. Your personal contact details will be stored separately from the data you provide for the study.

What will happen to the data I provide?
Audio files will be transcribed electronically and will be kept anonymous. The encrypted electronic data will be stored in a password-protected computer, which can be accessed only by the study team. Paper documents (e.g. consent forms and interview transcripts) will be kept in a locked cabinet inside a locked office in the Centre for Clinical Research.

What will happen at the end of the study?
We will offer you the opportunity to review your interview transcript for data accuracy. You will receive a summary of the findings from the study after the data from all interviews have been analysed together.

Thank you for reading this information leaflet.

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with project staff (contactable using the details at the end of this information sheet), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on MEDICINELNR@UQ.EDU.AU

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