RAFT STUDY

Participant Information Sheet

Version 1.1 -23-Sept-2021

Ethics Project ID: FMHS 322-0821

1. You are invited to take part in our research study

- The RAFT study is looking at how we can improve the Reporting of Factorial Trials
- This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part
- Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information
- It is entirely your decision whether to take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason.

2. A summary of the study

The aim of this study is to develop Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) https://www.spirit-statement.org/ and Consolidated Standards of Reporting Trials (CONSORT) http://www.consort-statement.org/ extensions for factorial trials.

Through looking at the relevant literatures we have already identified some important concepts to consider in these extensions. We now want to get your opinion on how important these concepts are, and whether we need to add to these. To do this we are conducting an online survey (using a Delphi method).

3. What is the purpose of the study?

Factorial trials have the potential to offer clinical and economic efficiency for evaluating health care interventions. Factorial trials, in their simplest form (2x2), are when two interventions (A and B) are tested; participants are randomised to receive no intervention, A alone, B alone or both A and B. They represent the potential for efficient evaluation of more than one intervention in the same study, without the need for a larger sample size.

Factorial trials have specific design and analysis considerations in addition to standard items specified in SPIRIT and CONSORT guidance, yet extensions do not exist for factorial trials to facilitate accurate reporting. This is important to aid in critical appraisal and interpretation of these trials for grant reviewers, funding bodies, trial methodologists, editors, reviewers, and readers.

4. Why have I been invited to take part?

You have been invited to take part in this research because you have knowledge and/or previous experience/interest of factorial trials. To take part you must meet the inclusion criteria:

- At least a basic understanding or prior experience of factorial trials
- Availability to respond during the specified data collection period
- Regular access to Broadband internet

5. Do I have to take part?

No. It is up to you to decide if you want to take part in this research. If you agree to participate, we will send you the link to take part. However, you would still be free to withdraw from the study at any time, without giving a reason and without any negative consequences, by letting the researcher (Dr. Sophie Hall) know.

WPD 3.3 NCTU Patient Information Sheet template, V2.0, 24-Apr-2020

6. What would taking part involve?

You will be taking part in a Delphi survey. All data will be collected online, using software called DelphiManager. We will provide you a link and clear instructions on how to use the software. It is straightforward and does not require access to any specialist equipment/programs.

You will have four weeks to complete the first survey round. If you complete the survey, you will be invited to take part in the second round. If you complete the second round you will be invited to the third and final round. Email reminders will be sent out weekly.

What is a Delphi Survey?

A Delphi survey is a process at which to arrive at a group decision, or 'consensus'. A panel of experts (from different backgrounds) are typically asked to rate how important they think something is, in this case how important a list of concepts are when thinking about developing SPIRIT and CONSORT extensions for factorial trials. This will be done in 3 rounds. It is expected that each round will take no longer than 20 minutes to complete.

In this study, in round 1, you will be asked to rate how critical you think 50 items are in relation to the design and reporting of factorial trials, using a 9-point rating scale. You will be given the opportunity to briefly justify why you chose the rating you did (this is optional, you do not have to do this) and change item wordings/suggest new items if you wish to do so.

In round 2 and 3, you will be provided with a summary of scores from other participants along with your own score. You will then be given the chance to change your rating or keep with your original decision. You will have another four weeks to complete round 2 and 3 respectively.

Those items that reach a certain criterion (for example, 70% of the group rate the items as being 'Critical', scoring it 7-9), will be assumed to have reached consensus and therefore considered for inclusion in the final list of items developing the SPIRT and CONSORT extensions.

Proposed Key Dates:

Delphi Survey Round 1: January-February 2022
Delphi Survey Round 2: March-April 2022
Delphi Survey Round 3: May-June 2022

7. What are the possible benefits of taking part?

There will be no direct benefit to you from taking part in this research, but your contribution will help a range of people interested in assessing health care interventions to improve the way in which research is conducted and evaluate the merit of specific research trials.

Participants who complete all **three survey rounds** will be given the opportunity to be entered into a **prize draw** to receive **£100** (GBP equivalent) of online shopping vouchers. Two participants will be randomly selected to receive this prize. The prize winners will be drawn using a random number generator within 3 weeks of the closure of the final survey round (July 2022) and notified via email. The prize cannot be substituted for a cash alternative. You will be given the opportunity to opt out of the prize draw before starting the Delphi survey should you not wish to be entered.

We would like to acknowledge those who contribute to the SPIRIT and CONSORT guidelines by completing the Delphi survey. We plan to report the names of the Delphi participants as an appendix to our reports. We will ask you after the final Delphi questionnaire if you would like to be included in the list of contributors. We will make it clear that participation in the Delphi does not necessarily mean agreement with the final guidelines and that participants had a range of views. If you would prefer to not be included in the list of names, that is fine as well.

8. What are the possible disadvantages and risks of taking part?

WPD 3.3 NCTU Patient Information Sheet template, V2.0, 24-Apr-2020

There are no anticipated risks in taking part in the study. No potentially sensitive information will be collected, and data will be shared anonymously. There will be the option to save and return to the survey to reduce time burden.

9. What if there is a problem?

If you have a concern about any aspect of this project, please speak to the researcher Dr. Sophie Hall or the Chief Investigator Prof Alan Montgomery and co-lead Dr Brennan Kahan, who will do their best to answer your query. The research team should acknowledge your concern and give you an indication of how they intend to deal with it.

If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.
Please quote ref no: FMHS 322-0821

10.What will happen if I don't want to carry on with the study?

Even after you have registered consent, you are free to withdraw from the study at any time without giving any reason. If you withdraw, we will no longer collect any information about you or from you but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

11.How will information about me be used?

Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) will need to use information from you for this research project. This information will include your name and contact details. The researchers will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details, your data will have a code number instead. All information about you will be kept safe and secure.

Once the study has finished, some of the data will be kept so the results can be checked and you can be told what happened in the trial (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the study.

12.What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. After a minimum of 7 years your data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research that you may be interested in taking part in. If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the study.

13.Where can you find about more about how your information is used?

You can find out more about how we use your information:

- by sending an email to sophie.hall@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on 0115 823 1600

14.Who is organising and funding this study? How has it been approved?

WPD 3.3 NCTU Patient Information Sheet template, V2.0, 24-Apr-2020

The study is being organised and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the Medical Research Council (MRC). All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the School of Medicine Research Ethics Committee.

15.Will I be reimbursed for taking part?

Participants will not receive an inconvenience allowance to participate in the study. There will be no costs associated with taking part in the study.

16.What will happen to the results of the study?

If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. The study will also be published on Open Science Framework https://osf.io/, to enable free and widely available sharing of the study. You will not be identified in any publication. We will send you a newsletter with a summary of the study findings unless you ask us not to.

17.How to contact us

Contact details of the study team:

- Dr Sophie Hall: sophie.hall@nottingham.ac.uk
- Professor Alan Montgomery: alan.montgomery@nottingham.ac.uk
- Dr Brennan Kahan: b.kahan@ucl.ac.uk
- Study email: ms-raft-study@nottingham.ac.uk