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Participant Information Sheet

Reporting guidelines for clinical trial protocols and reports of implantable neurostimulation devices: the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions

This Delphi survey is part of a research study and you are being invited to take part. Before you decide whether to participate in the research study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask if you would like more information or if there is anything that you do not understand.

We would like to stress that you do not have to participate in the study and should only agree to take part if you want to.

1. What is the purpose of the study?

We aim to develop SPIRIT and CONSORT extensions for clinical trials of implantable neurostimulation devices considering their respective indications. We will name the extensions the SPIRIT-iNeurostim extension and the CONSORT-iNeurostim extension.

2. What are SPIRIT and CONSORT?

The Standard Protocol Items: Recommendations for Interventional Trials (**SPIRIT**) statement was produced to ensure that trial protocols were complete and more likely to produce valid results while The Consolidated Standards of Reporting Trials (**CONSORT**) initiative was created to improve the reporting, clarity and transparency of randomised controlled trials (RCTs) after completion. Together the statements improve reporting at the protocol (planning) stage and the reporting stage of clinical trials.

Most high impact peer-reviewed journals, research institutions, commissioning agencies and national ethics committees endorse SPIRIT and CONSORT statements. This means either they contain a statement about SPIRIT and CONSORT in their “Instructions to Authors/Applicants” or that they recommend or require that authors/applicants adhere to SPIRIT and CONSORT statements. The endorsement of SPIRIT and CONSORT statements has improved the quality of trial reporting.

3. What are SPIRIT and CONSORT extensions?

Extensions of the SPIRIT and CONSORT statements are developed to improve the reporting of trials of specific trial designs, data or interventions. For example, an extension can include items that are specific to an intervention and that should be routinely reported for trials of that intervention in addition to the core items listed in the original SPIRIT and CONSORT statements.

4. Why are we developing SPIRIT and CONSORT extensions for trials of implantable neurostimulation devices?

There are no SPIRIT and CONSORT extensions for clinical trials of implantable neurostimulation devices. Recent systematic reviews show that poor reporting in trials of spinal cord stimulation (SCS), a type of implantable neurostimulation device, are common. Extensions specific to trials of implantable neurostimulation devices will improve the reporting, clarity, and transparency of trials in this area and will improve confidence in the results of clinical trials of implantable neurostimulation devices.

5. Why have I been chosen to take part?

We want to engage with a range of people so that we can get many different views when developing the SPIRIT and CONSORT extensions. You have been invited to take part in the Delphi survey because you either:

- have a condition that can be treated using an implantable neurostimulation device;
- have experience of using an implantable neurostimulation device;
- have expertise in implantable neurostimulation devices;
- have expertise and are interested in trials reporting and methodology (e.g., journal editors, statisticians, methodologists);
- are interested in the reporting of trials of implantable neurostimulation devices (e.g., journal editors, representatives from pain and neurostimulation societies, companies who develop implantable neurostimulation devices).

6. Do I have to take part?

No, you do not have to take part in the study. Your participation is voluntary. If you decide to take part in the study but later decide that you would like to withdraw, you are free to do so at any point and will not need to explain why you wish to withdraw.

7. What should I do if I want to take part in the study?

If you are interested in taking part in the study, then we ask that you access and complete the Delphi survey via the link provided in the email invite.

8. What will happen in the Delphi survey?

The survey will present items for potential inclusion in the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions and will ask you to rate how relevant you think each of the items are to the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions. The survey will also allow you to make comments and suggest items of your own for inclusion.

9. What data will you collect from the Delphi survey?

We will record the ratings you give for each of the items for the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions and any comments or additional items that you suggest.

10. How will my data be used?

Any data you enter during the survey will be anonymised. Data will initially be stored by the DelphiManager software (the software used to create the survey), which is developed and maintained by the COMET (Core Outcome Measures in Effectiveness Trials) initiative. Once data collection is complete, data will be exported and stored on the University of Liverpool drive of the Liverpool Reviews and Implementation Group (LR*i*G). Only the research team will be able to access the data collected. None of the data will be re-used in other studies.

11. When will my data be deleted?

We will delete all of the data collected once the SPIRIT and CONSORT extensions have been published. If you have any further questions about your data, you can contact Dr Rui Duarte who will act as the Data Processor for this study.

12. Will I receive payment or be reimbursed for taking part in the study?

We will not be offering any payment for expenses or reimbursement as part of this study.

13. Are there any risks in taking part?

We do not expect there to be any risk to participants.

14. Are there any benefits in taking part?

You will contribute your expertise and experience to the development of the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions.

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

We will publish at least two peer-reviewed journal articles that will describe the study methods and results. The journal articles will include the completed SPIRIT-iNeurostim and CONSORT-iNeurostim extensions. If you would like to receive a copy of the journal articles, please let us know and we can arrange to send them to you when they are published. We might also present the study results at conferences, either as posters or as presentations. We would like to stress that any data that we collect during the study will be anonymised.

16. What will happen if I want to stop taking part?

We again stress that if you decide to take part in the study but later decide that you would like to withdraw, you are free to do so at any point and will not need to explain why you wish to withdraw.

17. What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Dr Rui Duarte (rduarte@liverpool.ac.uk; +44(0) 151 794 5726) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Ethics and Integrity Office at ethics@liv.ac.uk. When contacting the Research Ethics and Integrity Office, please include details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

18. Who can I contact if I have further questions?

If you have any further questions you can contact Dr Rui Duarte or Dr Rebecca Bresnahan. Their contact details are provided below:

Principal Investigator
Rui Duarte
Whelan Building, University of Liverpool
+44(0) 151 794 5726
rduarte@liverpool.ac.uk

Investigator
Rebecca Bresnahan
Whelan Building, University of Liverpool
+44(0) 151 529 5949
rebecca.bresnahan@liverpool.ac.uk