Reporting guidelines for randomised controlled trial reports of implantable neurostimulation devices: the CONSORT-iNeurostim extension

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Summary

Background The Consolidated Standards of Reporting Trials (CONSORT) statement has improved the quality of reporting of randomised trials. Extensions to the CONSORT statement are often needed to address specific issues of trial reporting, including those relevant to particular types of interventions. Methodological and reporting deficiencies in clinical trials of implantable neurostimulation devices are common. The CONSORT-iNeurostim extension is a new reporting guideline for randomised controlled trials evaluating implantable neurostimulation devices.

Methods CONSORT-iNeurostim was developed using the EQUATOR methodological framework including a literature review and expert consultation to generate an initial list of candidate items. The candidate items were included in a two-round Delphi survey, discussed at an international consensus meeting (42 stakeholders including healthcare professionals, methodologists, journal editors and industry representatives from the United States, United Kingdom, Netherlands and other countries), and refined through a checklist pilot (18 stakeholders).

Findings The initial extension item list included 49 candidate items relevant to CONSORT-iNeurostim. We received 132 responses in the first round of the Delphi survey and 99 responses in the second round. Participants suggested an additional 20 candidate items for CONSORT-iNeurostim during the first round of the survey, and those achieving initial consensus were discussed at the consensus meeting. The CONSORT-iNeurostim extension includes 7 new checklist items, including one item for reporting the neurostimulation intervention comprising a separate checklist of 14 items.

Interpretation The CONSORT-iNeurostim extension will promote increased transparency, clarity, and completeness of trial reports of implantable neurostimulation devices. It will assist journal editors, peer-reviewers, and readers to better interpret the appropriateness and generalisability of the methods used and reported outcomes.

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Introduction

The Consolidated Standards of Reporting Trials (CONSORT) initiative was created to improve reporting, clarity and transparency of randomised controlled trials (RCTs).[1] The recommendations contained in the

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CONSORT statement represent the minimum reporting content for an RCT. The CONSORT statement is endorsed by or a mandatory requirement for many high impact peer-reviewed journals, research institutions, research funding agencies and national ethics committees. The CONSORT statement was first published in 1996 with updates in 2001 and 2010.[1] The introduction and requirement to adhere to CONSORT has been shown to improve the quality of reporting of RCTs.[2,3] A further update to the CONSORT statement is underway.[4] Extensions to the CONSORT statement are often developed to improve the reporting of trials of specific study designs, data or interventions and include items that should be routinely reported in addition to the items in the main CONSORT statement. Several extensions have been completed or are in development.[4–8]

Neurostimulation is the modulation of the nervous system's activity through the use of electrical current delivered to a group of nerve cells in sufficient magnitude to activate them. Neurostimulation interventions are used for the management of a range of chronic health conditions such as Parkinson's disease, chronic migraine, treatment-resistant depression and chronic pain (detailed information on different types of neurostimulation interventions and indications are presented in the protocol for these guidelines).[9] Despite the availability of the CONSORT statement and other relevant extensions such as CONSORT Harms and CONSORT Non-pharmacologic treatments, systematic reviews have shown methodological and reporting deficiencies in trials of spinal cord stimulation (SCS) are common.[10,11] Examples of methodological and reporting deficiencies include lack of information on source of funding, extent and method of blinding, role of temporary trial phase in enrolment of participants, programming parameters and adequate reporting of participant withdrawals.[9] Furthermore, the quality of the evidence base in support of SCS has been strongly questioned,[12,13] with repercussions in availability of the therapy in some countries (e.g., Australia).[14] Deficiencies in trial reporting despite availability of more general checklists may have contributed to the variability and limited replicability of neurostimulation studies.[15,16]

A CONSORT extension specifically developed for trials of implantable neurostimulation devices has the potential to improve the reporting, clarity, and transparency and consequently in increased confidence in the results of trials of implantable neurostimulation devices. The CONSORT-iNeurostim extension is an international initiative supported by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network to extend or elaborate on the CONSORT statement specifically as applied to trials of implantable neurostimulation devices.[9] It is complementary to the SPIRIT-iNeurostim extension which aims to promote high-quality reporting of trial protocols evaluating implantable neurostimulation devices.[17] This article describes the methods and processes used to develop the CONSORT-iNeurostim guidelines and provides the checklist and explanations for the new extension items.

Methods

The SPIRIT-iNeurostim and CONSORT-iNeurostim extensions were developed concurrently for randomised trial protocols and reports to harmonise the recommendations and facilitate uptake. The development of the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions were registered on the EQUATOR library of reporting guidelines in February 2021 and the protocol published describing the methods.[9] Development of the guidelines followed the EQUATOR Network methodological framework.[18] The SPIRIT-iNeurostim and CONSORT-iNeurostim extensions adhere to the ACcurate COnsensus Reporting Document (ACCORD) recommendations for reporting consensus based studies.[19] Membership of the SPIRIT-iNeurostim and CONSORT-iNeurostim Working Group, Steering Group, Consensus Group and participants in the checklist pilot are presented in Supplementary Material 1.

Ethical approval

The Institute of Population Health Research Ethics Committee (University of Liverpool) approved the research ethics application (Ref. 9755) for this study. The Participant Information Sheet was included as an attachment to the invitation email sent to potential Delphi participants and potential Consensus Group members. For the Delphi Survey, participants were required to consent to their anonymised data being used before they could complete the survey. The Consensus Group members were required to complete an electronic consent form before participating in the consensus meeting.

Literature review and candidate item generation

An initial list of candidate items was informed by the findings of previous systematic reviews that assessed methods and reporting in RCTs of SCS[10,11] and through a rapid review of published protocols and trials considering the implantable neurostimulation devices conducted by RVD, RB and SC. Details of the rapid review are provided in Supplementary Material 2. The Working Group (comprising trialists, methodologists and clinicians experienced in trials of implantable neurostimulation devices) identified commonly reported methodological details and results from the studies of implantable neurostimulation devices (beyond the items included in the CONSORT checklist) and reframed them as candidate reporting items. Candidate items could include methodological details that are important for replicability or potential sources of bias specific to studies of implantable neurostimulation devices. Candidate items were included in subsequent Delphi surveys.

Delphi consensus process

A two-round Delphi survey was conducted including candidate items for CONSORT-iNeurostim extension using the DelphiManager software (version 5.0), developed and maintained by the Core Outcome Measures in Effectiveness Trials (COMET) initiative. The Delphi survey was piloted by the Working Group members to assess functionality, survey flow, improve wording of items and identify any practical issues.

An international group of stakeholders with expertise in implantable neurostimulation devices were identified and invited via email by the Steering Group to participate in the two-round Delphi survey. Participant characteristics are presented in Supplementary Material 3. To maximise the number of participants, stakeholders were asked to suggest additional experts for participation and relevant societies were asked to circulate information about the survey to their members.

In the first round of the Delphi survey, 49 candidate items were presented for consideration. The first round was open from 1st November to 30th November 2021. Participants were asked to rate the importance of each candidate item using a 9-point scale as follows: 1 to 3, not important; 4 to 6, important but not critical; and 7 to 9, important and critical. Participants could suggest additional candidate items for inclusion in the second round of the Delphi survey. Twenty new candidate items were proposed by participants and included in the second round of the Delphi survey.

In the second round of the Delphi survey, the DelphiManager software platform is programmed to provide participants with their own rating for each candidate item from the first round of the Delphi survey, plus the total number of respondents and the distribution of their ratings (median [interquartile range]) for each candidate item from the first round of the Delphi survey. The second round took place from 10th January to 15th February 2021. Participants were asked to consider their own ratings and the ratings from other Delphi participants while re-scoring the items. Participants were also asked to rate the additional candidate items suggested by participants in the first round of the Delphi survey.

132 responses were received for the first round of the Delphi survey and 99 responses (75% of participants from the first round) were received for the second round. Candidate items with a median rating ≥4 criteria threshold from the second round of the Delphi were considered at a consensus meeting. Items with a score <4 were excluded.

Consensus meeting

The findings of the Delphi survey were discussed at a two-day virtual consensus meeting in April 2022 facilitated by SE and RST. Forty-two international stakeholders including healthcare professionals, methodologists, journal editors and industry representatives discussed a total of 76 candidate items (seven additional items suggested by Delphi participants for SPIRIT-iNeurostim that the Working Group deemed relevant for CONSORT-iNeurostim) and voted for their inclusion in the CONSORT-iNeurostim extension. Consensus meeting participants consisted of members of the iNeurostim Working Group, selected stakeholders that completed the Delphi survey and experts in the field of neurostimulation. Selection was the responsibility of the Working Group and based on participants being representatives of different research areas/expertise, countries and experience with the different type of available neurostimulation interventions. Characteristics of the consensus meeting participants are presented in Supplementary Material 4. Some items suggested by participants in the Delphi survey were of a broad scope; these were split into separate items for clarity, discussion and voting in the consensus meeting. For each candidate item, the median rating (and interquartile ranges) from the second round of the Delphi was presented to the Consensus Group alongside any comments made by participants during the survey. The Consensus Group were asked to anonymously vote electronically (on a Zoom platform) on whether each candidate item should be included in either, or both, of the SPIRIT-iNeurostim or CONSORT-iNeurostim extensions. Items were included in the SPIRIT-iNeurostim or CONSORT-iNeurostim extensions if ≥ 70% of the consensus group voted in favour of its inclusion. The 70% cut-off was pre-specified and was deemed reasonable to demonstrate majority consensus by the Steering Group. The Consensus Group were also invited to comment on the wording of the explanatory text for each item during the consensus meeting and the position of each item relative to the SPIRIT 2013 and CONSORT 2010 checklists.

Checklist pilot

The Consensus Group were given the opportunity to comment on final wording and whether the checklists and items included reflected discussions from the consensus meeting. The initial CONSORT-iNeurostim extension was refined through a pilot of the checklist with 18 participants to ensure clarity of wording of the new items. The checklist was piloted by experts not involved in the consensus meeting. Final changes to the CONSORT-iNeurostim checklist were made in the wording of items only, to improve clarity.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. Authors had full access to the data in the study. All authors were responsible for the decision to submit the manuscript.

Consensus recommendations

Three items were included as presented during the consensus meeting (i.e., as singular items) whereas 24 items were merged and combined into four items [three candidate items merged for Item 1a/b(i); two candidate items merged for Item 4a(i); 17 candidate items merged into 14 checklist items for Item 5(i) and two candidate items merged for Item 19(i)].

Thirty-three candidate items were excluded at the consensus meeting because <70% of the Consensus Group voted in favour of their inclusion. A further 17 items were excluded by the Working Group after the consensus meeting (despite that ≥70% of the Consensus Group voted in favour their inclusion) because the Working Group considered that 11 items were covered by the current CONSORT statement and six items were beyond the scope of the CONSORT-iNeurostim extension (Supplementary Material 5).

The final CONSORT-iNeurostim extension recommends seven new checklist items that should be reported by authors in addition to the current CONSORT statement for reports of trials of implantable neurostimulation devices (Table 1). One of the items (5(i)) consists of an intervention checklist, developed to include 14 checklist items specific to the neurostimulation procedure as the intervention under evaluation, control, or comparator (Table 2).

Title and abstract

CONSORT-iNeurostim Item 1a/b (i). In the title and/or abstract, state: the type of neurostimulation that was investigated; the neurological structure or nerve that was stimulated; and the clinical indication for neurostimulation.

Explanation

Stating the key aspects of a trial (i.e., the type of neurostimulation, the neurological structure and the clinical indication that were studied) facilitates database indexing. Appropriate indexing of a trial report enables a publication to be identified by search strategies and improves its visibility to electronic database users. Ideally, authors should state this information in the title, however, this may not be possible if the journal imposes a word limit on the title.

Examples. "Anterior pallidal deep brain stimulation for Tourette's syndrome: a randomised, double-blind, controlled trial".[20]

"Double blinded randomised trial of subcutaneous trigeminal nerve stimulation as adjuvant treatment for major unipolar depressive disorder".[21]

"We aimed to examine pain relief and the extent of spinal cord activation with ECAP-controlled closed-loop versus fixed-output, open-loop spinal cord stimulation for the treatment of chronic back and leg pain."[22]

Introduction

CONSORT-iNeurostim Item 2a (i). Describe the intended position of the neurostimulation intervention in the treatment pathway for the clinical indication.

Explanation

Surgery is required to implant the electrode contacts, leads and pulse generator of implantable neurostimulation devices. Common adverse events include infection and pain at the implantation site[23–28] and lead migration and breakage.[23–26,28] Less common adverse events include haematoma and haemorrhage[23,24,26,27] which can, although very rarely, result in death.[26] For this reason, invasive neurostimulation is generally considered a treatment option for people for whom conventional medical management has failed, i.e., people with drug-resistant conditions.[29] It is therefore insightful to the reader that the authors describe the position of the neurostimulation intervention in the treatment pathway for the clinical indication. This should be based on the most recent national or international guidelines for the condition. It may include information about the type and number of failed interventions required for a patient to be eligible for implantation.

Examples. "Besides lifestyle modifications and a few drugs of limited long-term efficacy and associated with high rates of adverse effects, bariatric surgery has been the main, most successful therapeutic alternative for over a decade. Among the laparoscopic procedures most frequently performed, gastric bypass and the sleeve gastrectomy have been most effective and the adjustable gastric band (LAGB) has been associated with the lowest rate of early postoperative complications. … all but LAGB cause permanent changes to the gastrointestinal tract, and all are associated with major peri- and postoperative complications. Consequently, bariatric surgery is ultimately offered to a small proportion of patients with obesity. Gastric electrical stimulation (GES) to treat obesity was introduced in animal experiments nearly 20 years ago."[30]

Methods

CONSORT-iNeurostim Item 4a (i)

Specify whether the study design included a neurostimulation trial phase prior to permanent device implantation and, if so, describe the trial phase methods and the eligibility criteria required for patients to proceed to permanent device implantation.

Explanation

This item may not be applicable to all types of implantable neurostimulation devices. A neurostimulation trial phase aims to identify people who may benefit from implantable neurostimulation devices in

Section/Item	Item No.	Description	Ext. No.	Extension description
Title and abstract				
	1a	Identification as a randomised trial in the title	1a/b(i)	In the title and/or abstract, state:
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		• the type of neurostimulation that was investigated • the neurological structure or nerve that was stimulated • the clinical indication for neurostimulation
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	2a (i)	Describe the intended position of the neurostimulation intervention in the treatment pathway for the clinical indication
	2b	Specific objectives and hypotheses		
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio		
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		
Participants	4a	Eligibility criteria for participants	4a (i)	Specify whether the study design included a neurostimulation trial phase prior to permanent device implantation and, if so, describe the trial phase methods and the eligibility criteria required for patients to proceed to permanent device implantation
	4b	Settings and locations where the data were collected		
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5 (i)	See Table 2. Intervention checklist
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		
Sample size	7a	How sample size was determined		
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		
	8b	Type of randomisation; details of any restriction (such as blocking and block size)		
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes		
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		
Results				
Participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13a (i)	Where applicable, report the number of patients who had an unsuccessful neurostimulation trial and therefore were not eligible for permanent device implantation
	13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment	14a	Dates defining the periods of recruitment and follow-up		
	14b	Why the trial ended or was stopped		
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group		
Number analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups		

(Table 1 continues on next page)

Section/Item	Item No.	Description	Ext. No.	Extension description
(Continued from previous page)				
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)		
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19 (i)	Where applicable, report any adverse events related to the surgical procedure, implanted hardware and/or neurostimulation. Specifically, report any incidents of lead migration, lead fracture, cerebrospinal fluid leak, pocket pain, skin erosion, infection, diminished effect, muscle spasm, haematoma and battery malfunction or depletion
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		
Generalisability	21	Generalisability (external validity, applicability) of the trial findings		
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		
Other information				
Registration	23	Registration number and name of trial registry		
Protocol	24	Where the full trial protocol can be accessed, if available		
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25 (i)	State the source(s) of funding for device costs

Table 1: **CONSORT-iNeurostim checklist.**

the long-term and enables patients to experience neurostimulation prior to permanent device implantation. Trials of SCS and peripheral nerve stimulation typically include a neurostimulation trial phase[31] and there is an increasing trend for trials of DBS to include a neurostimulation trial phase as new applications are investigated.[32] Specifically, in the NICE technology appraisal guidance for SCS for patients with chronic pain of neuropathic or ischaemic origin,[29] NICE recommends that only patients who have a successful trial phase should undergo permanent SCS device implantation. Evidence-based consensus recommendations on patient selection and temporary trial phase for SCS have been published.[33,34]

The duration of neurostimulation trial periods can vary from several minutes during surgery, referred to as "on-table" trials, to several days or weeks, referred to as "home" trials.[35] For "home" trials, implanters may use permanent anchored leads ("definitive" trials) or temporary percutaneous leads ("temporary" trials).[36] A trial phase may also be used to confirm appropriate lead location and/or to optimise stimulation parameters. It is important to report whether the trial parameters match exactly what was provided in the permanent implant, and rationale presented if the parameters were different.

If the trial included a neurostimulation trial phase, it is important that the authors describe the methods for the trial phase in sufficient detail to enable replication, including the reasons for the stimulation trial phase and the eligibility criteria required for patients to proceed to full implantation. This information may be based on the most recent national or international guidelines for the condition of interest. For example, for SCS for chronic pain, multi-specialty, multi-society guidelines on patient selection and SCS trial recommend that improved pain relief of ≥50% must be demonstrated using a validated outcome instrument, during or at the end of trial, to be considered successful.[33] It is also recommended that therapeutic efficacy should be evaluated multidimensionally, using validated measures for functional improvement, stable or decreased analgesic use, overall satisfaction, in addition to pain relief.[33]

Examples. "Successful trial stimulation was determined by the subject achieving at least a 50% lower limb pain relief during the trial phase and expressing a desire to go on to a permanent implant."[37]

"The eFITT was performed with a temporary lead introduced inside the gastric cavity, fixed to the stomach wall and connected to a system analyzer and electrical stimulator. Patients who experienced nausea, salivation, satiety, bloating, belching, epigastric discomfort or other manifestations attributable to the stimulation, and described as disagreeable to a level 3 on a visual analog scale ranging from 1 to 4, were candidates for implantation of the system."[30]

Item	Description
1. Neurostimulation device	1a) State the model and manufacturer of the neurostimulation device and all other hardware components
	1b) Specify the number and type of leads and electrode contacts required
	1c) Specify the distance between electrode contacts
2. Implant procedure	2a) Describe the surgical approach used to implant the device including the use of anaesthesia
	2b) Specify the neurological structure or nerve targeted
	2c) Where applicable, describe how the correct positioning of leads was confirmed
3. Programming	3a) Describe the stimulation parameters including pulse width (duration), frequency, amplitude and waveform programme
	3b) Specify whether stimulation was adjustable or pre-set
	3c) For personalised stimulation, describe how optimal stimulation parameters were achieved and state whether any additional hardware was required
	3d) State the number and duration of stimulation sessions per day when the stimulation was not used continuously during the entire day
4. Neurostimulation control or comparator (where applicable)	4a) If active, subtherapeutic, subthreshold or sham stimulation was used as a comparator, provide details for Items 1 to 3 if dissimilar from the intervention
	4b) If subtherapeutic, subthreshold or sham stimulation was used, justify and describe how it was achieved
5. Management	5a) Describe how the patient handheld programmer was managed
	5b) If sham stimulation was used as the control, describe how sham sensations were managed

[a]The CONSORT-iNeurostim intervention checklist is designed to replace item 5 of CONSORT for reporting of trial reports. This intervention checklist should be read in conjunction with the explanations of the CONSORT-iNeurostim items provided in the main text.

Table 2: **CONSORT-iNeurostim intervention checklist.**[a]

CONSORT-iNeurostim item 5 (i). Intervention checklist

Explanation

Well-described methods of interventions are essential for research replicability and enable readers to assess the external validity of research findings. Table 2 lists the additional methodological details that authors must report to comprehensively describe the methods for implantable neurostimulation devices.

Neurostimulation device

It is important that authors state the model and manufacturer of all hardware components of the neurostimulation device, including the leads and number of electrode contacts, especially if any of the hardware components are non-standard. Other clinical and research groups should be able to replicate the device setup.

Implant procedure

Authors should describe the approach to implant the neurostimulation device and include details about the implanter, their level of expertise and any specific training received. Where applicable, authors should describe how lead positioning was confirmed, e.g., by imaging technology or by adequate paraesthesia coverage (≥80%) of a target area.

Programming

Neurostimulation waveforms are well-described in the literature.[38–43] Authors may reference publications and provide description of the waveforms in the trial report or in the supplementary material. Authors should mention whether the type of stimulation investigated is experimental or used in routine clinical practice. If "cycling" of stimulation was used (i.e., a period of active, therapeutic stimulation followed by a pause in stimulation), describe the length of both the active and passive cycles. As a minimum, authors should provide the stimulation parameters used including pulse width, frequency and amplitude or a range for each parameter. Authors should also consider presentation of neural dosing expressed as charge per pulse (amplitude [mA] x pulse width [ms]) or charge per second (amplitude [mA] x frequency [Hz] x pulse width [ms]),[44] consequent evidence of neural response (measured through evoked compound action potentials [ECAPs, mV][45] or other mechanisms).

Neurostimulation control or comparator (where applicable)

The same level of detail provided for the active intervention should be provided when describing the control arm. In parallel RCTs that used an inactive or sham comparator, authors should explain if and how the stimulation provided was subtherapeutic, subthreshold or sham.

Management

In trials where participants are blind to stimulation received or in trials that include sham stimulation, the handheld programmer is often withheld from patients to avoid breaking the blind (because the implantable pulse generator [IPG] battery will not deplete, and most programmers show IPG charge level). From a safety perspective, if the handheld programmer was withheld from patients, safety provisions must be made to ensure that patients are able to switch off the neurostimulation device in an emergency. Authors should state how the

patient handheld programmer was managed, and if it was withheld, provide justification. When sham is used as the control, authors should clarify how unwanted stimulation sensations were managed to prevent unblinding of participants.

Examples. "AXIUM Neurostimulator System (Spinal Modulation; LLC, Menlo Park, CA, a wholly owned subsidiary of St Jude Medical). The system is composed of percutaneous leads designed to stimulate the DRG, an external trial pulse generator, and an implantable pulse generator. SCS: SCS was delivered with a commercially available system (RestoreUltra and RestoreSensor; Medtronic, Minneapolis, MN)."[37]

"Aside from the difference in stimulation modes, patients in both treatment groups received the same care, with the device, implant procedure, and programming process being the same for both groups."[22]

"Leads were implanted between T5 and T12 with the majority being placed between T7 and T11 … ECAP-guided programming included ECAP acquisition, collection of dose–response data, and determination of individual sensitivity. The dose–response data show the relationship between the charge delivered (current amplitude x pulse duration [μC per pulse]) and the corresponding neural response (ECAP amplitude [μV]). This data was collected at the patient perception threshold, the level of greatest patient comfort (prescribed level), and the highest level of stimulation the patient could tolerate (maximum)."[46]

"Devices of participants assigned to therapeutic stimulation were programmed to a stimulation frequency of 20Hz, a pulse width of 214ms, and participant-specific pulse amplitudes and electrode configurations to elicit tonic multifidus contractions for 10 seconds twice per minute during the stimulation session. Devices of participants assigned to sham (low-level) stimulation were programmed to unipolar stimulation from the most proximal electrode on the lead ipsilateral to the location of the IPG with 4 stimulation pulses of 0.4mA and 31ms to measure impedance at the initiation and 3 stimulation pulses of 0.1mA and 31ms delivered every two minutes during the stimulation session. All participants were instructed and trained to deliver two 30-minute stimulation sessions per day while in prone or side-laying position using their wireless activator."[47]

Results

CONSORT-iNeurostim Item 13a (i)

Where applicable, report the number of patients who had an unsuccessful neurostimulation trial and therefore were not eligible for permanent device implantation.

Explanation

A temporary trial phase may be necessary to assess the patient's response to an implantable neurostimulation device (Fig. 1). Explanation of the need to report whether a temporary trial phase took place, and the required details is presented in CONSORT-iNeurostim Item 4a (i). The number of patients with an unsuccessful temporary screening trial phase may depend on type of neurostimulation modality being used, setting and criteria for a trial to be deemed a success. Trial success rates have been reported to range from as low as 41.4%–91.6%.[48–50] High rates of unsuccessful screening trials, or lack of consideration of unsuccessful screening trials in data analysis can affect the response rates at the primary endpoint and subsequent follow-ups, potentially resulting in a misleading interpretation of findings.

Examples. "Seven of the patients in TG withdrew before the screening trial; of the remaining 47, an unsuccessful screening trial was observed for 5 (11%) patients and 42 (89%) patients had a successful screening trial and were implanted with an SCS system."[51]

"Of 83 patients randomised to the SCS arm, 80 underwent trial stimulations, 74 (92.5%) of whom had successful trials, and 69 patients ultimately received permanent implants."[52]

CONSORT-iNeurostim Item 19 (i)

Where applicable, report any adverse events related to the surgical procedure, implanted hardware and/or neurostimulation. Specifically, report any incidents of lead migration, lead fracture, cerebrospinal fluid leak, pocket pain, skin erosion, infection, diminished effect, muscle spasm, haematoma and battery malfunction or depletion.

Explanation

There are several adverse events which relate to hardware and/or neurostimulation and medical causes. Neurostimulation has its specific complications, however as noted during the Consensus Group meeting, harms are generally poorly reported. The CONSORT Harms 2022 statement should be used to guide the reporting of harms in RCTs.[53] However, the CONSORT Harms 2022 statement does not consider disease or technology specific harms as is the case with implantable neurostimulation devices. The Consensus Group considered that some of the harms listed in this item are device/clinical indication specific and are important for inclusion in CONSORT-iNeurostim. CONSORT-iNeurostim Item 19 (i) should be used as a complement to the CONSORT Harms 2022 statement and not as a replacement.

Examples. "The most frequently occurring device-related AE in the DRG arm was implantable pulse generator (IPG) pocket pain with 10 events reported by 10 patients (13.2%). On the other hand, the most frequently occurring device-related AE in the SCS arm was loss of stimulation due to lead migration with 8 events reported by 8 (10.5%) patients."[37]

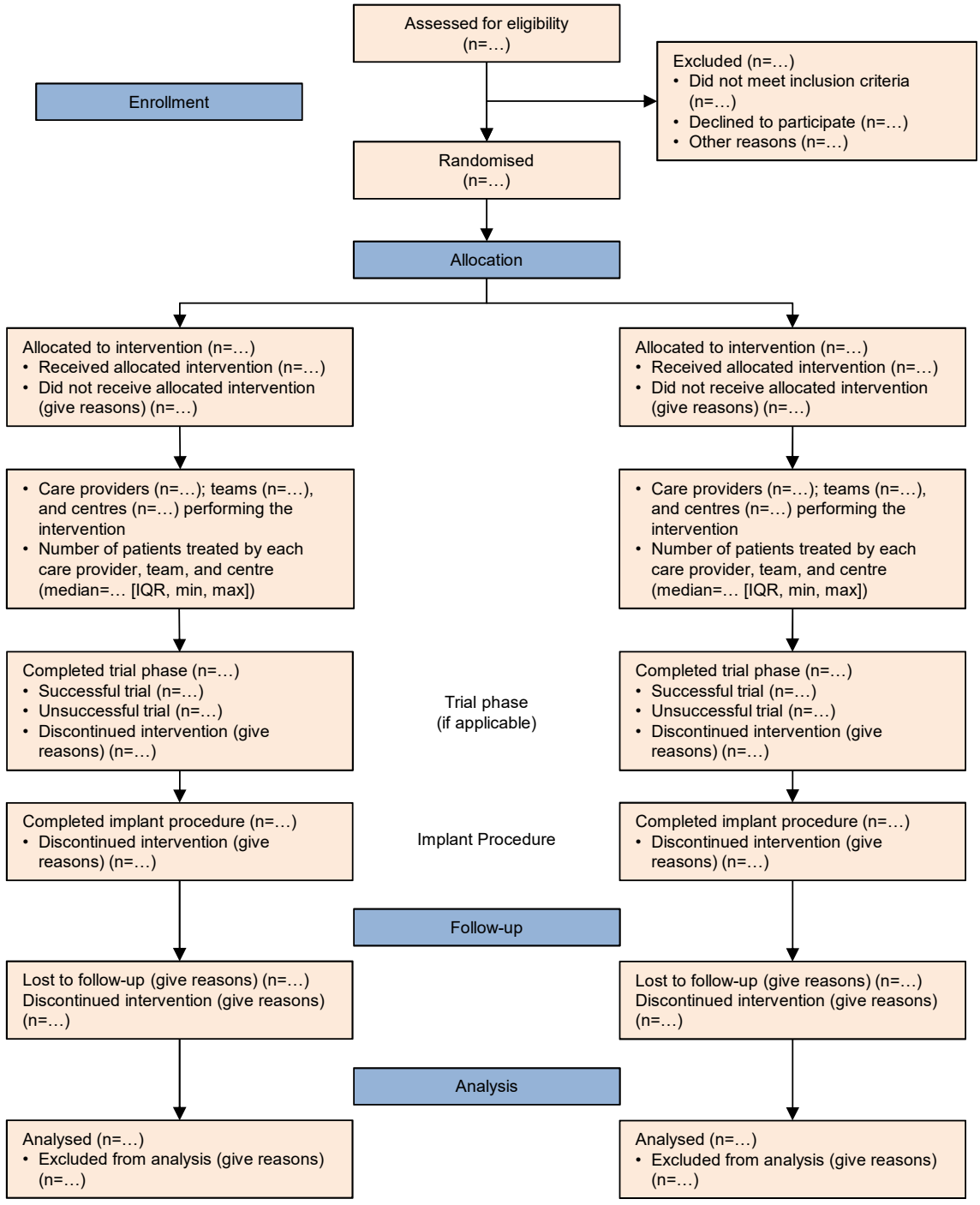

Fig. 1: CONSORT 2010 flow diagram—adapted for clinical trials that compare two different implantable neurostimulation interventions (a CONSORT 2010 flow diagram—adapted for clinical trials that compare an implantable neurostimulation intervention to an alternative non-neurostimulation intervention is presented in Supplementary Material 6). IQR, interquartile range; max, maximum; min, minimum.

"Seven unrelated SAEs were reported in 7/204 (3%) participants, and all events were reviewed by the CEC and adjudicated as unrelated. Including the above, a total of 27 participants (13%) underwent a total of 30 surgical interventions during which 19 systems were explanted (9%), one system reimplanted (1%), 4 pulse

generators repositioned (2%), and 6 participants had their leads replaced (3%). Reasons for explant were lack of effectiveness (9), infection (6), and safety precaution before MRI scan (4)."[47]

Other information

CONSORT-iNeurostim item 25 (i)

State the source(s) of funding for device costs.

Explanation

Information regarding the funding source(s) for device costs is required for determining risk of bias and for quality assessing trials. It is especially important that authors explicitly state the funding source(s) for device costs if different from the sponsor of the trial. A systematic review of 46 RCTs assessing SCS for adults and adolescents with pain reported that while most (82%) RCTs reported the source(s) of funding, less than half (41.2%) of RCTs specified the role of the sponsor (e.g., involvement in data collection and analysis, overseeing manuscript preparation or supplying devices).[11] A Cochrane systematic review of studies of medicines and medical devices (including RCTs, observational studies and cohort studies) found that studies that were funded by the manufacturing company of the medicine/device being investigated more often reported statistically significant efficacy results (i.e., p-value less than the pre-defined significance level; typically $p < 0.05$) and conclusions that favoured the manufacturer's medicine or device compared to non-industry sponsored studies.[54] Further, patients may be denied access to implantable neurostimulation devices for insurance reasons for example and accept participation in Investigational Device Exemption trials to access the device for free which may potentially result in inflated treatment effects. Similar effects may occur for patients with free healthcare access to implantable neurostimulation devices (e.g., in the UK NHS).

Examples. "Costs for devices, procedures, and medical visits related to the trial were covered by the sponsor for all participants; therefore, no risk of unblinding by insurance billing existed."[47]

"Spinal cord stimulation is commissioned for the management of chronic neuropathic pain in England, devices were therefore provided through the National Health Service as routine clinical care."

Discussion

The CONSORT-iNeurostim extension provides international consensus-based recommendations on the information that should be reported in randomised trials of implantable neurostimulation devices. The items in the CONSORT-iNeurostim extension should be considered alongside the CONSORT 2010 statement and other relevant recommendations for trials.[1,53,55] An update to the CONSORT 2010 statement is ongoing.[4] The update may improve the wording and clarity of previous items and add new items that have recently gained recognition. However, it will not consider condition or intervention specific items as those presented in the current extension.

The CONSORT-iNeurostim extension comprises 7 checklist items, one of which is an intervention checklist that includes 14 subitems. The intervention checklist relates to aspects that are often neglected when reporting trials of implantable neurostimulation devices. However, these items are essential to ensure the intervention can be replicated not only for the purpose of other research studies but also for patient benefit in clinical practice.

The field of neurostimulation, and SCS in particular has been under scrutiny recently.[13,56] Such scrutiny is welcomed as it raises the research interest in these technologies and its applications. However, some recent research, despite methodological adequacy, had shortcomings in the interpretation of its findings.[57,58] An essential consideration is that findings for one type of neurostimulation are not generalisable to all types of neurostimulation or clinical conditions.[59–61] Further, it is essential to understand whether the type of neurostimulation being evaluated is an experimental type of neurostimulation or routinely used in clinical practice. The intervention checklist aims to improve the reporting of essential items to better understand the intervention being delivered.

A number of initial candidate items and those suggested during the Delphi survey did not meet the threshold for inclusion in the CONSORT-iNeurostim extension (Supplementary Material 7). Even if not for all neurostimulation interventions, some of the items that did not meet the inclusion threshold may be useful when reporting the trial. We would therefore encourage researchers to review the full list of candidate items in the Supplementary material. It is also important that the correct terminology is employed when describing the neurostimulation intervention.[62] In addition, researchers should also consider complementary extensions such as for Harms,[53] and Non-pharmacologic treatments.[8] Given the availability of other potentially relevant extensions, an effort to consolidate extensions may be a valuable endeavour.

A collaboration between the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), the Institute of Neuromodulation (ION) and the International Neuromodulation Society (INS) recently developed recommendations for research design for RCTs of SCS. However, the IMMPACT/ION/INS recommendations are not required to be adhered to when reporting randomised trial results. In addition, IMMPACT/ION/INS recommendations are not applicable to all implantable neurostimulation devices. The recommendations in the current CONSORT-iNeurostim extension are consistent with previous recommendations.[10,63]

The SPIRIT-iNeurostim and CONSORT-iNeurostim extensions were developed with contributions from international stakeholders from methods groups (ACTTION, CONSORT, EQUATOR), neuromodulation societies (IASP SIG neuromodulation, ION, INS, NSUKI), journal editors and industry representatives. Importantly, the stakeholders' experience covered all different types of implantable neurostimulation devices currently available. Nevertheless, there was limited representation of gastroelectrical stimulation expertise during the consensus group. Further, the current study was set in the current context of neurostimulation interventions. As new implantable neurostimulation devices emerge, it will be important to continue to evaluate and adapt the SPIRIT-iNeurostim and CONSORT-iNeurostim extensions to ensure these are appropriate for the newer technologies. The SPIRIT-iNeurostim and CONSORT-iNeurostim Working Group will monitor the need for updates.

The CONSORT-iNeurostim aims to promote increased transparency, clarity, and completeness in reporting trials of implantable neurostimulation devices. We encourage journals that publish trials of implantable neurostimulation devices to endorse the CONSORT-iNeurostim extension and require its completion and submission alongside trial reports. The purpose of such endorsement and requirement is to encourage authors to include this information in the trial reports and to facilitate journal editors' and peer-reviewers' assessment of the manuscripts.

Contributors

RVD, SE, ST, RBN and RST conceptualised the study. RVD, SE, ST and RST obtained the funding for the study. All authors contributed to the study design. RB and RVD contributed to data acquisition and analysis. All authors contributed to interpretation of the data. RB and RVD wrote the first draft of the manuscript. All authors contributed to drafts of the manuscript and approved the final version of the manuscript. RVD and RB have accessed and verified the data. All authors were responsible for the decision to submit the manuscript.

Data sharing statement

Data supporting this study are included within the article and/or supporting materials. After publication of all project's manuscripts, additional data are available through request from the corresponding author.

Declaration of interests

RVD reports consultancy fees from Mainstay Medical, Medtronic Ltd and Saluda Medical outside the submitted work. He is an employee of Saluda Medical; the employer had no role in the submitted work besides its contribution as a stakeholder. SE reports consultancy fees from Mainstay Medical, Medtronic Ltd, and Saluda Medical outside the submitted work. He has received Department Research funding from Saluda Medical, and Boston Scientific. ST reports consultancy fees from Boston Scientific Corp, Mainstay Medical and Saluda Medical outside the submitted work. He has received department research funding from the National Institute of Health Research. RBN serves as an unpaid officer of the nonprofit Neuromodulation Foundation, Inc., to which grants and support have been provided by Abbott, Boston Scientific Corp, Medtronic Ltd, Nevro Corp, Nuvectra, and Stimwave Inc outside the submitted work. He receives royalties from Abbott. GB has a consulting agreement with Nevro Corp, Mainstay Medical, Boston Scientific and Abbott. He has received department research funding from Mainstay Medical and Saluda Medical. RML is an uncompensated consultant for Biotronik, Abbott, Nalu, and Saluda Medical, and has stock options from Nalu and Saluda Medical. RST reports consultancy fees from Medtronic Ltd, Nevro Corp and Saluda Medical outside the submitted work. The views expressed in this article are those of the author(s) and not necessarily those of the NIHR, or the Department of Health and Social Care. All other authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2024.102932.

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