

## ORIGINAL RESEARCH

# Methods used to develop the SPIRIT 2024 and CONSORT 2024 Statements

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**Abstract**

**Objectives:** To describe, and explain the rationale for, the methods used and decisions made during development of the updated SPIRIT 2024 and CONSORT 2024 reporting guidelines.

**Methods:** We developed SPIRIT 2024 and CONSORT 2024 together to facilitate harmonization of the two guidelines, and incorporated content from key extensions. We conducted a scoping review of comments suggesting changes to SPIRIT 2013 and CONSORT 2010, and compiled a list of other possible revisions based on existing SPIRIT and CONSORT extensions, other reporting guidelines, and personal communications. From this, we generated a list of potential modifications or additions to SPIRIT and CONSORT, which we presented to stakeholders for feedback in an international online Delphi survey. The Delphi survey results were discussed at an online expert consensus meeting attended by 30 invited international participants. We then drafted the updated SPIRIT and CONSORT checklists and revised them based on further feedback from meeting attendees.

**Results:** We compiled 83 suggestions for revisions or additions to SPIRIT and/or CONSORT from the scoping review and 85 from other sources, from which we generated 33 potential changes to SPIRIT ( $n = 5$ ) or CONSORT ( $n = 28$ ). Of 463 participants invited to take part in the Delphi survey, 317 (68%) responded to Round 1, 303 (65%) to Round 2 and 290 (63%) to Round 3. Two additional potential checklist changes were added to the Delphi survey based on Round 1 comments. Overall, 14/35 (SPIRIT  $n = 0$ ; CONSORT  $n = 14$ ) proposed changes reached the predefined consensus threshold ( $\geq 80\%$  agreement), and participants provided 3580 free-text comments. The consensus meeting participants agreed with implementing 11/14 of the proposed changes that reached consensus in the Delphi and supported implementing a further 4/21 changes (SPIRIT  $n = 2$ ; CONSORT  $n = 2$ ) that had not reached the Delphi threshold. They also recommended further changes to refine key concepts and for clarity.

**Conclusion:** The forthcoming SPIRIT 2024 and CONSORT 2024 Statements will provide updated, harmonized guidance for reporting randomized controlled trial protocols and results, respectively. The simultaneous development of the SPIRIT and CONSORT checklists has

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been informed by current empirical evidence and extensive input from stakeholders. We hope that this report of the methods used will be helpful for developers of future reporting guidelines. © 2024 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

**Keywords:** Randomized controlled trials; Trial protocols; Reporting guidelines; Reproducibility; CONSORT (CONsolidated Standards Of Reporting Trials); SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)

## 1. Introduction

Well-conducted randomized trials provide the most robust evidence for the benefits of health-care interventions. For stakeholders to make maximum use of the evidence, trials must be reported completely and transparently. Detailed information about the design, conduct and analysis of a trial allows readers to critically appraise the validity of the evidence, evaluate the generalizability of the findings, meaningfully assess risk of bias, and extract information for evidence syntheses.

The CONSORT Statement was first published in 1996 in response to the problem of inadequate reporting of clinical trials [1]. CONSORT was updated in 2001 [2] and again in 2010 [3]. It comprises a checklist of the minimum items that should be included when reporting the results of a completed randomized trial to allow readers to assess validity and includes a flow diagram to be used to report participant progress through the trial.

The SPIRIT Statement, published in 2013, provides reporting recommendations for protocols of randomized trials [4]. Having a transparently and completely reported protocol that prespecifies trial methods can help with identifying post hoc changes, for example, switching of the primary outcome(s). Outcome switching is unfortunately common and can introduce bias to the literature about the effects of an intervention [5,6]. By prespecifying the major trial processes, a SPIRIT-compliant protocol also helps to standardize trial conduct across personnel and sites.

Extensions to the SPIRIT and CONSORT Statements have been developed to provide additional reporting guidance for a range of trial designs, types of data, and interventions [7–29]. These extensions provide valuable additional guidance. However, they can complicate the user experience of implementing reporting guidelines as both the main SPIRIT and CONSORT checklist and one or more extension checklists may need to be used. Many users find using multiple checklists in one paper difficult or burdensome to apply in practice [30,31]. Using SPIRIT should make later use of CONSORT to report trial results easier; however, discrepancies in the wording between the two can cause confusion for users.

SPIRIT and CONSORT are based on empirical evidence and expert stakeholder consensus. As the landscape of trial design, conduct and reporting continues to advance, SPIRIT 2013 and CONSORT 2010 need to be updated to reflect emerging evidence and best practice to remain

relevant and fit for purpose. This paper presents the methods used to develop the SPIRIT and CONSORT 2024 Statements, including a scoping review of comments suggesting changes to SPIRIT 2013 and CONSORT 2010, Delphi consensus process, and consensus meeting, and the motivations behind these choices.

## 2. Material and methods

### 2.1. Process and oversight

This project to update SPIRIT 2013 and CONSORT 2010 followed guidance for developers of health research guidelines [32]. The project was registered on the EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network. Ethical approval was granted by the Central University Research Ethics Committee, University of Oxford (R76421/RE001).

### 2.2. Strategy

In January 2020, the SPIRIT and CONSORT Executive Groups met in Oxford, UK, and decided to merge to form one group. As the SPIRIT and CONSORT Statements are conceptually and practically linked, with overlapping content and similar dissemination and implementation strategies, the two groups decided it was more effective to work together [33]. The SPIRIT and CONSORT Executive Group led this update and formed the main working group for this project. We decided to update the SPIRIT 2013 and CONSORT 2010 Statements together. By doing so, we aimed to align the two checklists and provide users with consistent guidance on how to report key aspects of trial design, conduct, and analysis from trial protocol to final publication. By streamlining and harmonizing reporting from trial design to results reporting, we hope to improve usability and adherence to the checklists, leading to more complete reporting [33]. As there is already considerable conceptual overlap between the two Statements, a simultaneous update was also considered more efficient.

As part of the alignment, we also decided to narrow the scope of SPIRIT to focus on randomized controlled trials only, rather than all trials [4]. This change improves consistency between SPIRIT and CONSORT and allows the SPIRIT Explanation and Elaboration document to provide more focused guidance. Much of SPIRIT 2024 and

**What is new?****Key findings**

- We describe the methods used to develop the SPIRIT and CONSORT 2024 Statements.

**What this adds to what was known?**

- Current empirical evidence and extensive stakeholder input have informed the updated 2024 Statements.
- We have aligned SPIRIT and CONSORT and incorporated items from existing SPIRIT and CONSORT extensions and other reporting guidelines.

**What is the implication and what should change now?**

- Reporting of the methods used to develop and update reporting guidelines is important for transparency and reproducibility.
- This detailed description of the development process may assist those developing and updating future reporting guidelines.

CONSORT 2024 is relevant to nonrandomized trial reports and protocols also; however, authors of such documents can disregard items that are clearly irrelevant, such as those related to randomization.

The 2010 update of the CONSORT checklist minimized changes to the numbering of items from the 2001 version to minimize inconsistencies with extensions that refer to item numbers [34]. However, the order of similar items in SPIRIT 2013 and CONSORT 2010 is inconsistent, and we expected to introduce new items. We, therefore, decided to rearrange checklist items to align the two checklists where appropriate and to ensure logical grouping of conceptually related content, including adding or removing section headings if necessary.

We also decided to incorporate content from key SPIRIT and CONSORT extensions and other relevant checklists where the information is relevant to all (or almost all) randomized controlled trials. We hope that these inclusions will maximize reporting of critical information while reducing the burden on triallists.

The protocol can be accessed via the Open Science Framework [35] and is described here briefly.

### 2.3. Stage 1: scoping review and identifying new evidence

We conducted a scoping review to identify published comments suggesting modifications and additions or

reflecting on strengths or challenges of SPIRIT 2013 or CONSORT 2010. This review has been published separately [36]. We searched four bibliographic databases (Embase and MEDLINE [from January 2010 to June 2022]; Web of Science and Google Scholar [from January 2010 to April 2022]) and other sources (eg, conference proceedings and key websites). We also conducted a broader search for empirical and theoretical evidence related to SPIRIT, CONSORT, and risk of bias in randomized controlled trials. This evidence formed the basis for a subject-specific database, the SPIRIT-CONSORT Evidence Bibliographic database (SCEBdb), as a resource to support the checklist update process. Methods used to create and curate the SCEBdb will be reported in detail elsewhere (manuscript in preparation).

The suggestions identified in the scoping review were combined with evidence from, and recommendations provided by the lead authors of, existing SPIRIT and CONSORT extensions (Harms [16] and Outcomes [8]) and related reporting guidelines (TIDieR [template for intervention description and replication]) [37]. Evidence and recommendations from other sources (CONSORT for Nonpharmacological Treatments [7], personal communications) and revisions to harmonize SPIRIT and CONSORT were also considered. Using the existing SPIRIT 2013 and CONSORT 2010 checklists as the starting points, a preliminary list of possible changes to the checklists was created using the gathered evidence. Owing to the large amount of literature identified, this list of possible changes was too long to feasibly be considered in the next stage of development. The Executive Group, therefore, screened the list and preselected items to ensure a manageable number of items was included in the Delphi survey, with at least two members reviewing each item and resolving disagreements by discussion. Reasons for rejecting items included: the concept was already covered by another proposed item; the concept was already covered in SPIRIT 2013 and/or CONSORT 2010; the item was not relevant to most or all randomized controlled trials; the item was out of scope for a reporting guideline (eg, methodological guidance); or the information was not considered a minimum item for reporting.

### 2.4. Stage 2: Delphi survey

We conducted a Delphi survey among a large international network of stakeholders. The Delphi method is a way of organizing expert communication around a complex issue to reach consensus on a given issue [38]. The Delphi process comprised three rounds in which participants independently and anonymously indicated whether they agreed or disagreed with the addition of suggested new items and with proposed modifications and deletions of SPIRIT 2013 and CONSORT 2010 checklist items. Participants could also suggest additional new items or modifications. During rounds 2 and 3, participants were provided with aggregated results from the previous round to help reconcile individual opinions and achieve group consensus.

#### 2.4.1. Recruitment process and participants

Delphi participants were identified through existing SPIRIT and CONSORT collaborations, including those involved in publishing the SPIRIT 2013 and CONSORT 2010 Statements and their extensions, and through existing professional research networks, patient and public networks, and societies (eg, Society of Clinical Trials, MRC-NIHR Trials Methodology Research Partnership, European Clinical Research Infrastructure Network (ECRIN), Clinical Trials Ontario, Global Health Trials Network, and EDCTP program). We also recruited participants via an Expression of Interest form on the SPIRIT–CONSORT update project website, publicized through a Commentary in *Nature Medicine* [33], and announcements on social media (eg, Twitter) and via the EQUATOR Network.

We aimed to invite at least 200 participants from around the world in diverse roles and from diverse settings (eg, industry and academia), including experienced clinical trial researchers, clinicians, patient and public representation, and representatives from funding bodies, ethics committees, medical journals, and regulatory agencies. We opened the Expression of Interest sign-up form to make the Delphi participation as inclusive as possible by extending access beyond established personal networks, to all interested parties.

Participants were invited to participate in the Delphi survey via a personalized email that explained the project's aims and the Delphi process, and provided a link to the survey. Informed consent was also obtained. Any individuals who indicated that they wished to opt out of the survey were removed from subsequent invitations. In all rounds, the survey remained open for approximately 3 weeks, with at least one reminder email sent 1 week after the initial invitation. All individuals invited to participate in Round 1 were also invited to participate in Rounds 2 and 3 unless they asked not to receive further invitations.

#### 2.4.2. Procedure for selecting items

The Delphi survey was conducted using an online survey tool ([www.onlinesurveys.ac.uk](http://www.onlinesurveys.ac.uk)). Participants were asked to consider the following guiding principles when reviewing existing, new, or modified items for potential inclusion [1]: reporting of the item should facilitate complete and transparent reporting [2]; the item should be relevant to the majority of trials; and [3] the set of items represent the minimum that should be reported in all reports of trial protocols (SPIRIT) and trial publications (CONSORT).

#### 2.4.3. Delphi Round 1

Round 1 of the Delphi survey was open from 10 to 31 October 2022. Participants were asked to rate on a 5-point Likert scale the extent to which they agreed with the inclusion of each item in the updated SPIRIT and CONSORT checklists: 1 = strongly disagree, 2 = somewhat disagree, 3 = neutral, 4 = somewhat agree, 5 = strongly agree. A free-text box was provided for comments on each item to allow participants to justify their decision or suggest

wording changes. Two free-text boxes were provided at the end of the survey, one for SPIRIT and one for CONSORT, to suggest additional new checklist items.

Delphi participants were asked to rate only new and modified checklist items and proposed deletions from the existing checklists. Existing SPIRIT and CONSORT checklist items with no proposed changes were included in the Delphi survey for completeness, but these items were not scored. Participants were provided with two free-text boxes at the end of the survey, one for SPIRIT and one for CONSORT, to provide general comments on these unmodified items collectively.

The free-text comments were reviewed to identify potential changes or additions to the survey items to be included in subsequent Delphi rounds.

#### 2.4.4. Delphi Round 2

Round 2 of the Delphi survey was open from 24 November to 15 December 2022. Participants were provided with an anonymized summary of the group ratings from Round 1. Using the same format as Round 1, participants were presented with each item, including new items suggested during Round 1, and were asked to express the extent to which they agreed with the inclusion of each item in the updated SPIRIT and CONSORT checklists, considering the structured feedback to inform their responses. Items that reached a high level of agreement in Round 1 were presented for information purposes only, with no voting on these items, although a free-text box at the end of the survey was provided for any comments. A high level of agreement was defined as  $\geq 80\%$  of participants responding to that item agreed (scored it 4 or 5) or disagreed (scored 1 or 2) with the proposed change.

#### 2.4.5. Delphi Round 3

Round 3 of the Delphi survey was open from 11 to 31 January 2023. Participants were provided with an anonymized summary of the group ratings from Round 2. They were presented with items that were newly introduced or modified in Round 2 and asked to express the extent to which they agreed with the inclusion of the items in the updated checklists. Round 1 items not reaching a high level of agreement after two rounds of voting with no changes to wording were not rated in Round 3, but were presented for information and a free-text box was provided at the end of the survey for comments on these items collectively. Items that reached a high level of agreement in Rounds 1 or 2 were presented for information purposes only.

Free-text comments on individual proposed items from each round of the Delphi survey were organized into conceptually related topic areas and these were grouped into three broad types of comment: supporting the change, recommending modification/clarification or highlighting problems, and opposing the change. Comments were organized using NVivo Pro 12. Recurring comments about each survey item were summarized under these three categories.



### 2.5. Stage 3: expert consensus meeting

After the Delphi survey, a consensus meeting comprising two 4.5-hour sessions was convened via Zoom, on 1 and 2 March 2023. The aim of the meeting was to discuss the Delphi survey results and obtain advisory input on whether to include proposed new and/or modified SPIRIT and CONSORT checklist items in the update and whether any substantive changes were needed. Thirty invited international experts, representing the stakeholder groups included in the Delphi survey, attended.

The meeting was facilitated by the SPIRIT–CONSORT Executive Group. Before the meeting, participants were sent the results of the Delphi survey and summary of the main comments for each item. During the meeting, each new and modified SPIRIT and CONSORT checklist item was discussed and agreement sought. An anonymous poll via Zoom's polling function was used to help establish the level of support for items where the discussion indicated differing opinions; these polls were advisory and no formal consensus threshold was specified. Participants were asked whether we should make the proposed change to the checklist, with the response options “yes”, “no”, or “unsure”. Separate polls were conducted for SPIRIT and CONSORT where an item was relevant to both checklists but discussion indicated support for the change differed between the two checklists. Supplementary polls were used where deemed necessary by the session chair to gauge opinion on other issues (eg, refining or merging items) or to inform the discussion (eg, to gauge perception of whether current reporting is deficient). The Executive Group members did not vote in any polls. Polls were not used for items where the discussion indicated clear consensus.

### 2.6. Stage 4: checklist revision

After the expert consensus meeting, the Executive Group held a 2-day in-person writing meeting in Oxford on 25 and 26 April 2023. The format and wording of each new and/or modified SPIRIT and CONSORT checklist item was reviewed and agreed on, considering the summarized comments from the Delphi survey and the consensus meeting discussions and polls. The draft checklists were then circulated to consensus meeting participants to confirm whether they represented the group consensus or needed clarification. SPIRIT and CONSORT items were further revised by the Executive Group in response to this feedback.

## 3. Results

### 3.1. Stage 1: scoping review and identifying new evidence

The scoping review [36] identified 93 documents with 114 comments [36]. Of these, 37 comments were

suggestions for modifications of existing checklist items (36 for CONSORT; 1 for both SPIRIT and CONSORT) and 46 were suggestions for new items (37 for CONSORT; 9 for both SPIRIT and CONSORT). The remaining 31 comments were reflections on challenges or strengths of SPIRIT 2013 and/or CONSORT 2010.

Another 85 items were generated from the CONSORT extension for Harms [16], the CONSORT extension for Outcomes [8], the TIDieR checklist [37], SAGER (sex and gender equity in research) guidelines [39], GRIPP2 (guidance for reporting involvement of patients and the public) checklist [40], open science best practices, and personal communications.

After the collated suggestions were screened, 33 potential revisions (survey items) were proposed for consultation in Round 1 of the Delphi survey, including additions, modifications, and deletions (Additional file 1).

As of February 2024, the SCEBdb included 821 publications to be used as an evidence foundation for the Explanation and Elaboration documents that will supplement the 2024 SPIRIT and CONSORT Statements.

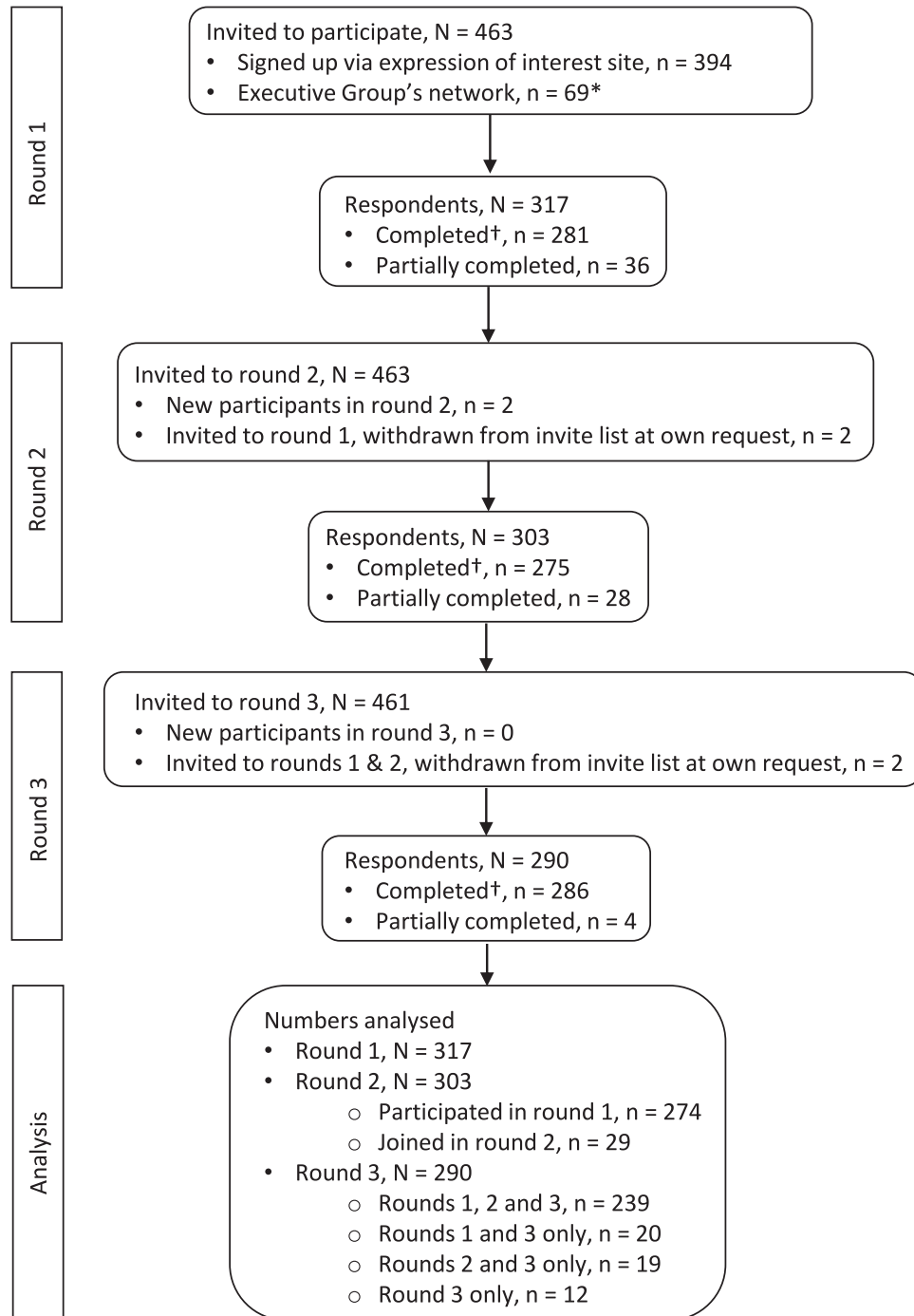
### 3.2. Stage 2: Delphi survey

In the Delphi survey, 317/463 (68%) of invited participants responded to Round 1, 303/463 (65%) to Round 2, and 290/461 (63%) to Round 3. Participant flow is summarized in Figure 1. Delphi respondent characteristics are shown in Table 1. In Round 1, there were similar numbers of men (53%) and women (45%), and just over half of participants were based in the UK (37%) or USA (15%). Most participants worked in an academic setting (74%), with 48% having 15 or more years of trial-related experience and 46% having conducted more than five randomized trials. A broad range of stakeholder roles were represented, the most frequent being statisticians/methodologists/epidemiologists (62%), systematic reviewers/guideline developers (22%), trial investigators (20%), clinicians (18%) and journal editors (15%).

Figure 2 summarizes the progress of items through each round of the Delphi survey, and the quantitative results are summarized in Additional files 2–4.

Round 1 of the Delphi survey included 33 items: 5 SPIRIT items (4 proposed new checklist items and 1 modified item) and 28 CONSORT items (15 proposed new checklist items, 11 modified items and 2 proposed deleted items). Following Round 1 of the Delphi survey, 12 CONSORT items (5 new; 7 modified) reached consensus, with  $\geq 80\%$  of participants rating these items as agree or strongly agree. No SPIRIT items reached consensus. Tables 2 and 3 show the Delphi ratings for each SPIRIT and CONSORT item.

Round 1 free-text comments identified one new potential item for both CONSORT and SPIRIT, on plain language summaries. They also indicated that three of the proposed new/modified items that had been presented for rating were



\*One invitee who was directly invited and also signed up via the Expression of Interest website is included in the n value for invitation via the Executive Group's network only

†Ranked each item

**Figure 1.** Flow of participants and responses in the Delphi survey.

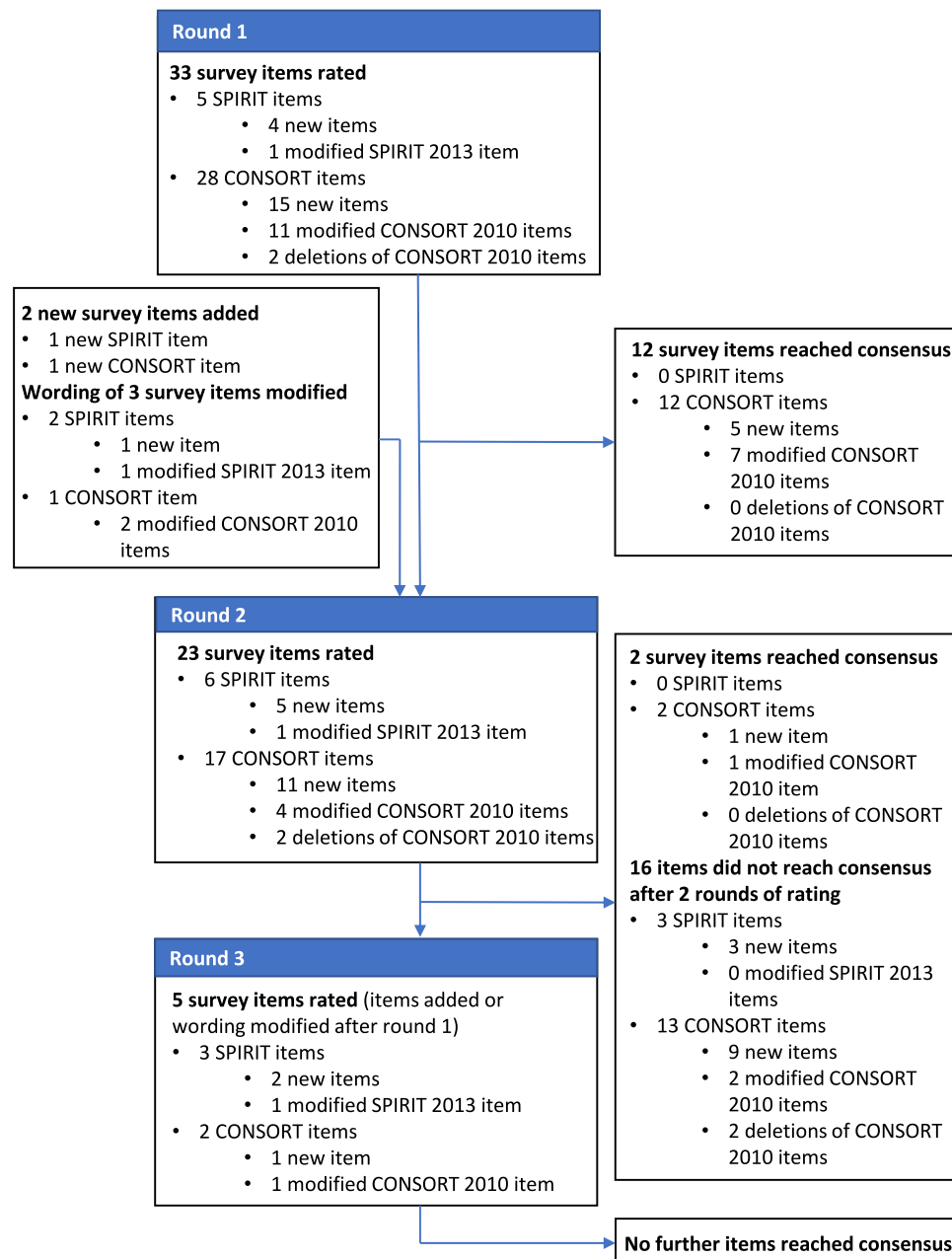
unclear. We, therefore, proposed a new checklist item for SPIRIT and CONSORT on plain language summaries. We also revised the three identified items to improve clarity

based on the Round 1 comments (Additional file 5). These new and revised items were included in Round 2 for rating by participants.

**Table 1.** Demographics and characteristics of Delphi respondents

Characteristic	Round 1 (N = 317) n (%)	Round 2 (N = 303) n (%)	Round 3 (N = 290) n (%)
<b>Gender</b>			
Man	168 (53)	162 (53)	148 (51)
Woman	142 (45)	134 (44)	131 (45)
Prefer not to say	7 (2)	6 (2)	7 (2)
Other	0 (0)	0 (0)	1 (0)
Not stated	0 (0)	1 (0)	3 (1)
<b>Geographic location</b>			
Europe	174 (55)	174 (57)	167 (58)
North America	69 (22)	70 (23)	69 (24)
Asia	31 (10)	34 (11)	27 (9)
Australia/Oceania	19 (6)	15 (5)	18 (6)
South America	7 (2)	6 (2)	5 (2)
Africa	3 (1)	3 (1)	2 (1)
Other <sup>a</sup>	0 (0)	1 (0)	1 (0)
Not stated	14 (4)	0 (0)	1 (0)
<b>Employment sector</b>			
Academic	233 (74)	228 (75)	225 (78)
Industry	29 (9)	33 (11)	24 (8)
Charity	7 (2)	7 (2)	6 (2)
Other <sup>b</sup>	47 (15)	33 (11)	33 (11)
Not stated	1 (0)	2 (1)	2 (1)
<b>Duration of trial-related experience</b>			
Less than 1 y	6 (2)	5 (2)	3 (1)
1–5 y	51 (16)	45 (15)	45 (16)
6–14 y	106 (33)	109 (36)	95 (33)
15 y or more	153 (48)	143 (47)	145 (50)
Not stated	1 (0)	1 (0)	2 (1)
<b>Number of randomized trials conducted</b>			
0	81 (26)	76 (25)	77 (27)
1	14 (4)	15 (5)	13 (4)
2–5	76 (24)	73 (24)	63 (22)
More than 5	146 (46)	139 (46)	134 (46)
Not stated	0 (0)	0 (0)	2 (1)
<b>Main role(s) related to clinical trials<sup>c</sup></b>			
Methodologist/statistician/epidemiologist	198 (62)	189 (62)	185 (64)
Systematic reviewer/clinical guideline developer	69 (22)	73 (24)	66 (23)
Trial investigator	62 (20)	73 (24)	62 (21)
Clinician	58 (18)	56 (18)	55 (19)
Journal editor	47 (15)	42 (14)	36 (12)
Patient or public representative	15 (5)	16 (5)	17 (6)
Regulatory agency/ethics	17 (5)	10 (3)	11 (4)
Funder	4 (1)	3 (1)	2 (1)
Other <sup>d</sup>	27 (9)	28 (9)	23 (8)
Not stated	0 (0)	2 (1)	1 (0)

<sup>a</sup> One participant specified two countries in two continents as a free-text response in Rounds 2 and 3.<sup>b</sup> Responses specified by participants included NHS, journal, government, regulatory agency, nonprofit, retired.<sup>c</sup> Participants could select multiple responses so values sum to > 100%.<sup>d</sup> Responses specified by participants included trial management, medical writing.



**Figure 2.** Flow of items presented for rating through the Delphi survey. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Round 2 included 23 items: 6 SPIRIT items (5 proposed new checklist items and 1 modified item) and 17 CONSORT items (11 proposed new checklist items, 4 modified items and 2 proposed deleted items). Following Round 2 of the Delphi survey, two more CONSORT items (one new; one modified) reached consensus, with  $\geq 80\%$  of participants rating these items as agree or strongly agree. No SPIRIT items reached consensus.

In Round 3, participants were asked to rate only the five items that had been added or modified after Round 1: three SPIRIT items (one proposed new checklist item and one modified item), and two CONSORT items (one

new and one modified item). Participants were asked to comment only on the remaining items that had not yet reached consensus. No items reached consensus in Round 3.

Delphi survey participants provided 3580 free-text comments across the three rounds (2261 in Round 1; 976 in Round 2; 343 in Round 3). [Additional file 6](#) presents topic areas that arose from the comments on individual items. The comment summaries for each item are presented in [Additional file 7](#) in the format that they were supplied to the participants of the expert consensus meeting (Stage 3), alongside the voting results.



**Table 2.** SPIRIT Delphi survey results

Survey item	Consensus in round 1	Consensus in round 2	Consensus in round 3
<b>Introduction items</b>			
Research question: Describe research question using the estimand framework (ie, health condition, target population, end point, intercurrent events and how they are addressed, and population-level summary) [New item]	75.6%	69.6%	N/A
Objectives: Specific objectives related to benefits and harms [Modify SPIRIT item 7] ( <sup>a</sup> Note: wording revised after round 1)	62.6%	74.6%	76.8%
<b>Methods items</b>			
Statistical methods: Whether analyses by sex and gender will be conducted; provide a rationale if not [New item]	48.7%	45.7%	N/A
Monitoring: Frequency and procedures for monitoring trial conduct. If there is no monitoring, give justification [New item] ( <sup>a</sup> Note: wording revised after round 1)	59.1%	66.7%	71.9%
<b>Other items</b>			
Patient and public involvement and engagement: Whether, how, and when patient and/or public representatives were or will be involved in designing the trial, including choice of research question, intervention and outcome measures, trial conduct, recruitment, and plans for dissemination [New item]	78.2%	70.7%	N/A
Plain-language summary: Summary of trial design and methods using simple language, understandable to a reader with no knowledge of the topic. [New item] ( <sup>a</sup> Note: item added after round 1)	N/A	70.5%	73.7%

<sup>a</sup> Consensus is defined as the percentage of participants who responded to the item rating it as “agree” or “strongly agree”.

General comments, not relating to a specific item, were also reviewed and grouped into topic areas. These comments primarily raised concerns around the overall burden to authors created by extending reporting requirements and potential negative consequences. For example, participants proposed that a short and simple checklist has a better chance of being used; that including more items in the checklist makes it more likely that some will be omitted, which might include the most important ones; that SPIRIT and CONSORT are intended to be minimum reporting requirements, so we should distinguish between “need to know” and “nice to know” and recognize what is realistically feasible; and that we need to consider what will realistically fit within the word limits of a standard journal article. A summary of these general comments was presented to the expert consensus meeting participants before discussion of the individual items.

### 3.3. Stage 3: expert consensus meeting

[Additional file 8](#) summarizes the discussions that took place regarding each item during the expert consensus meeting. The meeting participants were broadly supportive of most items that reached consensus on the Delphi survey, but suggested refinements to the wording of most items. There were three proposed changes that reached consensus on the Delphi survey but that the consensus meeting participants disagreed with or did not strongly support implementing: addition to CONSORT of new items “Roles and responsibilities: Names, affiliations, and roles of manuscript contributors” and “Funding: Financial and other

competing interests for principal investigators for the overall trial”, and modification of CONSORT 2010 item 13a (participant flow) to specify reporting of the information for benefits and harms. [Additional file 9](#) provides details of these conflicts and the rationale for the consensus group’s conclusions.

Among items that did not reach consensus in the Delphi survey, the suggestion to reflect the estimand framework in SPIRIT and CONSORT, although also ultimately rejected by the consensus meeting participants, generated substantial discussion. Participants recognized that many of the rejected items were potentially useful information to have about a trial, but in the interests of keeping the checklists to a manageable length, they were not deemed minimum essential items. There were four proposed changes that did not reach consensus in the Delphi survey but that the consensus meeting participants supported implementing: modification of SPIRIT item 7 and CONSORT item 2b (objectives) to specify reporting of this information related to benefits and harms, and addition to SPIRIT and CONSORT of an item on patient and public involvement (see [Additional file 9](#) for further details).

The consensus group also recommended merging some items and separating others. These recommendations are summarized in [Additional file 9](#).

### 3.4. Stage 4: checklist revision

We further refined the wording of individual draft SPIRIT and CONSORT checklist items and generated draft SPIRIT 2024 and CONSORT 2024 checklists, considering

**Table 3.** CONSORT Delphi survey results

Survey item	Consensus <sup>a</sup> in round 1	Consensus in round 2	Consensus in round 3
<b>Introduction items</b>			
Research question: Describe research question using the estimand framework (ie, health condition, target population, end point, intercurrent events and how they are addressed, and population-level summary) [New item]	74.6%	70%	N/A
Background and objectives: Specific objectives related to benefits and harms [Modify CONSORT item 2b] ( <sup>a</sup> Note: wording revised after round 1)	63.4%	74.4%	75.9%
<b>Methods items</b>			
Trial design: Important changes to methods after trial commencement (eg, changes to eligibility criteria, intervention details, outcomes, analyses), with reasons [Modify CONSORT item 3b]	95.3%	N/A	N/A
Participants: Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centers and individuals who delivered the interventions (eg, surgeons, psychotherapists) [Modify CONSORT item 4a]	82.6%	N/A	N/A
Recruitment: Strategies for achieving adequate participant enrollment to reach target sample size [New item]	58.3%	57.7%	N/A
Interventions: Who delivered the interventions. For each category of intervention provider (eg, psychologist, nursing assistant), describe their expertise, background and any specific training given [New item]	69.3%	70.1%	N/A
Interventions: If intervention adherence or fidelity was assessed, describe how and by whom, any strategies used to maintain or improve fidelity, and the extent to which the intervention was delivered as planned [New item]	79.7%	75.8%	N/A
Interventions: Relevant concomitant care and interventions that were permitted or prohibited during the trial [New item]	82.0%	N/A	N/A
Outcomes: Completely defined prespecified primary and secondary outcome measures for both benefits and harms, including the specific measurement variable, analysis metric, method of aggregation, and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended [Modify CONSORT item 6a]	85.7%	N/A	N/A
Outcomes: Any changes to trial outcomes after the trial commenced, with reasons, including any outcomes for benefits or harms that were not prespecified in protocol or registry [Modify CONSORT item 6b]	90.7%	N/A	N/A
Sample size: How sample size was determined, including clinical and statistical assumptions supporting the sample size calculation [Modify CONSORT item 7a]	92.7%	N/A	N/A
Statistical methods: Definition of analysis population relating to protocol nonadherence (eg, as randomized analysis), and any statistical methods to handle missing data [New item]	86.0%	N/A	N/A
<b>Results items</b>			
Protocol deviations: If applicable, any significant protocol deviations during the conduct of the trial [New item]	81.8%	N/A	N/A
Participant flow: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for both benefits and harms [Modify CONSORT item 13a]	78.6%	83.7%	N/A
Participant flow: Number of participants experiencing each type of (important) intercurrent event [New item]	70.9%	72.1%	N/A
Baseline data: A table showing baseline demographic and clinical characteristics for each group, eg, age, gender, and ethnicity [Modify CONSORT item 15]	74.6%	79.7%	N/A
Numbers analysed: For each group, number of participants (denominator) included in each analysis of benefits and harms, whether the analysis was by original assigned groups, and whether any exclusions were made [Modify CONSORT item 16]	85.3%	N/A	N/A
Outcomes and estimation: For trials with continuous primary outcomes, a figure displaying the values for each participant or the distribution is recommended [New item]	60.3%	61.0%	N/A
Ancillary analyses: Results of all other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory [Modify CONSORT item 18]	74.4%	72.6%	N/A
<b>Discussion items</b>			
Generalisability: Generalisability (external validity, applicability) of the trial findings [Delete item]	39.1%	50.2%	N/A
Interpretation: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence [Delete item]	38.5%	44.7%	N/A

(Continued)

Table 3. Continued

Survey item	Consensus <sup>a</sup> in round 1	Consensus in round 2	Consensus in round 3
Interpretation: If done, potential implications of sex and gender on the trial results and analyses [New item]	51.9%	46.7%	N/A
Other items			
Roles and responsibilities: Names, affiliations, and roles of manuscript contributors [New item]	79.3%	82.8%	N/A
Roles and responsibilities: Composition, roles, and responsibilities of the coordinating center, steering committee, end point adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable [New item]	69.2%	63.9%	N/A
Funding: Financial and other competing interests for principal investigators for the overall trial [New item]	89.6%	N/A	N/A
Protocol: Where the full trial protocol and other relevant documents (including the Statistical Analysis Plan) can be accessed [Modify CONSORT item 24]	92.7%	N/A	N/A
Data sharing: Statement on whether individual deidentified participant data will be shared, what data will be shared, when data will be available, for how long, and how it can be accessed [New item]	83.5%	N/A	N/A
Patient and public involvement and engagement: Whether, how, and when patient and/or public representatives were involved in designing the trial, including choice of research question, intervention and outcome measures, trial conduct, recruitment, and plans for dissemination [New item]	76.5%	70.8%	N/A
Plain-language summary: Summary of trial design, methods, results and conclusions using simple language, understandable to a reader with no knowledge of the topic. [New item] ( <sup>a</sup> Note: item added after round 1)	N/A	71.1%	74.3%

<sup>a</sup> Consensus is defined as the percentage of participants who responded to the item rating it as “agree” or “strongly agree”.

the free-text comments from the Delphi and the discussion and poll results from the expert consensus meeting. SPIRIT 2024 contains 34 items and CONSORT 2024 contains 30 items.

[Additional file 10](#) summarizes decisions made that deviated from the original proposed checklist revisions or the Delphi and expert consensus group recommendations. We also revised items in SPIRIT 2013 and CONSORT 2010 where changes had not been proposed for rating in the Delphi survey. We divided some items to separate conceptually diverse concepts. For example, we separated SPIRIT 2013 item 20c (analysis population and missing data) into two subitems in the updated SPIRIT checklist: 27b (definition of who will be included in each analysis) and 27c (methods to handle missing data). We also adjusted the location of some checklist content. For example, part of CONSORT 2010 item 5 (interventions) relates to how the intervention was administered. We moved this from the Methods section of the 2010 checklist to form a new item in the Results section of the updated checklist. We removed SPIRIT 2013 items 31b (authorship), 32 (informed consent materials), 33 (biological specimens), and 34 (access to data).

We recognized that several items in the updated checklists were conceptually related to open science practices. We, therefore, grouped these items in both SPIRIT 2024 and CONSORT 2024 under a new “open science” subheading. We aligned SPIRIT and CONSORT wording where appropriate. For example, the item on trial registration in CONSORT 2010 was “registration number and name of trial registry” vs “trial identifier and registry name” in

SPIRIT 2013. These two items were harmonized and augmented to “name of trial registry, identifying number (with URL) and date of registration” in both SPIRIT 2024 and CONSORT 2024.

Further minor changes were made to checklist wording to reflect feedback received from the expert consensus group. We also tested the CONSORT checklist with a group of early-career ( $n = 5$ ), midcareer ( $n = 3$ ) and senior ( $n = 2$ ) statisticians and researchers, representing eight different native languages. They read the checklist and worked together to extract the information requested by each item from a published trial report, identifying discrepancies in understanding and confusing wording. We made minor changes to the wording of several items in both the SPIRIT and CONSORT checklists on the basis of feedback from this group.

#### 4. Discussion

Transparent reporting of the methods used to develop reporting guidelines is important to support community trust in the recommendations made and to allow future guideline developers to use and adapt the approaches used [41–43]. Here, we describe the methods used and decisions made during the process of developing the SPIRIT 2024 and CONSORT 2024. The process included a literature review, Delphi consultation, expert consensus meeting, and writing meeting, which allowed for input from a broad range of stakeholders with different backgrounds and experience.

In updating SPIRIT 2013 and CONSORT 2010 we aimed to reflect developments in evidence and best practice relating to randomized controlled trial reporting; to align the two checklists to provide more consistent guidance throughout the trial process, from design to reporting; to reflect emerging open science policies and best practice, such as those relating to data sharing; and to include key points from extensions and other guidelines to simplify the user experience.

During the update process, we sought to balance requiring reporting of all the information that readers need to evaluate and use a trial report or protocol, while not making the guidelines so burdensome that they become unusable to authors. The reach of CONSORT, in particular, has led to it being widely discussed in the literature, with many opinions on content that should be added [36]. Conversely, our contributors raised concerns about checklist length and usability at all stages in this update process. Throughout this project, we have asked contributors to consider which content is critical to trial interpretation and relevant to most, if not all, randomized controlled trials. The final checklists represent consensus on the minimum content that should be reported.

A key strength of this project is the close coordination of the SPIRIT and CONSORT guidelines. Although there is considerable conceptual overlap between SPIRIT 2013 and CONSORT 2010, they were developed separately and there are inconsistencies in the precise information that is recommended and how it is described. SPIRIT 2024 and CONSORT 2024 have been harmonized where appropriate. We hope that this will boost reporting completeness by reducing the burden on researchers. Writing a SPIRIT-compliant protocol will make the subsequent reporting of trial results much easier for researchers, as much of the necessary information will already be set down in a form that clearly corresponds to the CONSORT recommendations.

Another strength of this project is the scope of stakeholder input. The scoping review identified many published comments about SPIRIT 2013 and CONSORT 2010. It is possible that evidence not explicitly linked by authors to recommendations about SPIRIT or CONSORT may have been overlooked when the potential new and revised items were initially drafted. However, the concurrently developed SCEBdb provided a broader overview of empirical and theoretical evidence related to reporting and risk of bias in clinical trials and supported the writing of the Explanation and Elaboration documents that accompany the checklists.

To our knowledge, the Delphi survey received the largest number of responses to date for a reporting guideline development project. Participants contributed extensive expertise, covering a wide range of roles and many cumulative years of experience in trials. By inviting free-text responses, we were able to gain in-depth insights into their views. By launching an open call for Delphi participants in a major journal [33], we may also have reached stakeholders whose voices might not otherwise have been heard.

However, the demographics of participants were nonetheless limited. Most responses were from participants working in academic settings and participants with extensive experience in randomized controlled trials. Low-and-middle income countries, where English is not the primary language and early-career researchers, were not well-represented. We may, therefore, have missed items of interest to these groups and wording changes that might better suit them.

For reasons of feasibility, in Rounds 2 and 3 of the Delphi survey we provided participants with summarized ratings from the previous round but not summarized comments. As participants did not have access to the rationales and explanations supporting other respondents' ratings when revoting, the value added by using multiple rounds of voting may have been limited.

Owing to the number of recommendations in the literature and the extent of feedback in the Delphi, the Executive Group screened proposed items at each stage of the process to ensure manageable numbers of items were presented for the wider consultation. As a result, the perspectives of the Executive Group may have been prioritized over those of other groups. The in-depth discussions at the wider expert consensus meeting and subsequent input from the consensus group, with their extensive experience and diverse range of expertise, may have helped to mitigate the impact of this limitation.

## 5. Conclusions

The SPIRIT 2024 and CONSORT 2024 Statements provide updated guidance for reporting randomized controlled trial protocols and results, respectively. The development of the updated guidance was informed by current empirical evidence and extensive input from stakeholders. SPIRIT and CONSORT have been harmonized and content from key extensions has been incorporated to facilitate more complete reporting by simplifying the user experience. We hope that this account of the methods used will provide insight for checklist users into the consensus underpinning the recommendations and a useful resource for future guideline developers.

## Ethics approval and consent to participate

Ethical approval was granted by the Central University Research Ethics Committee, University of Oxford (R76421/RE001). All Delphi participants provided informed consent to participate.

## CRedit authorship contribution statement

**Ruth Tunn:** Data curation, Formal analysis, Investigation, Project administration, Visualization, Writing —



original draft. **Isabelle Boutron:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **An-Wen Chan:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **Gary S. Collins:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **Asbjørn Hróbjartsson:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **David Moher:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **Kenneth F. Schulz:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing — review & editing. **Jennifer A. de Beyer:** Methodology, Project administration, Writing — review & editing. **Camilla Hansen Nejstgaard:** Data curation, Formal analysis, Investigation, Writing — review & editing. **Lasse Østengaard:** Data curation, Formal analysis, Investigation, Writing — review & editing. **Sally Hopewell:** Conceptualization, Formal analysis, Funding acquisition, Methodology, Project administration, Resources, Supervision, Writing — original draft.

### Data availability

Deidentified summary-level quantitative data from the Delphi survey are available in [Additional Files 2–4](#).

### Declaration of competing interest

R. T. received support from the Medical Research Council—National Institute of Health and Care Research (MRC-NIHR). S. H. received support from MRC-NIHR. G. S. C. received support from MRC-NIHR. J. A. d. B. received support from MRC-NIHR. S. H., I. B., A.-W. C., A. H., K. F. S., and D. M. are members of the SPIRIT—CONSORT Executive Group. G. S. C. is director of the UK EQUATOR Centre. D. M. is director of the Canadian EQUATOR Centre. I. B. is deputy director of the French EQUATOR Centre. J. A. d. B. is a member of the UK EQUATOR Centre. D. M., A. H., and I. B. are members of the editorial board of the *Journal of Clinical Epidemiology*. Other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

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### Supplementary data

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