Journal of Clinical Epidemiology 113 (2019) 168−175

REVIEW

Consolidated Standards of Reporting Trials (CONSORT) extensions covered most types of randomized controlled trials, but the potential workload for authors was high

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Accepted 25 May 2019; Published online 30 May 2019

Abstract

Objectives: Our aim was to determine the coverage of randomized controlled trials (RCTs) by the Consolidated Standards of Reporting Trial (CONSORT) Statement and its extensions and to evaluate the potential workload for authors to adhere to the guidelines.

Study Design and Setting: We identified CONSORT extensions from the CONSORT Web site. We randomly selected a sample of 1,000 RCTs indexed in PubMed in 2016 and recorded whether they were covered by CONSORT extensions for specific study designs or interventions. We evaluated the potential workload for authors by counting the number of documents and pages they have to consult to have a full understanding of the guidelines.

Results: We identified 14 extensions. Only one extension was updated concurrently with the main CONSORT in 2010, three were updated after 2−7 years, and three are still based on CONSORT 2001. Overall, 81% of RCTs are covered by relevant CONSORT guidelines; missing extensions for specific study designs were under development at the time of the search (Nov 2018). However, 6 of 10 extensions covered <2% of the trials. A median [Q1−Q3] of 4 [4−5] documents and 67 [57−78] pages should be consulted.

Conclusion: Most RCTs indexed in PubMed are covered by the CONSORT Statement and extensions, but the potential workload for authors could be high.

Keywords: Randomized controlled trials; CONSORT; Reporting guidelines; Authors' workload; Quality of reporting; CONSORT extensions coverage

1. Introduction

Incomplete reporting of randomized controlled trials (RCTs) leads to an important avoidable waste in research. For example, more than 50% of the published RCTs are unusable because of incomplete reporting [1−3].

To improve transparency, the Consolidated Standards of Reporting Trials (CONSORT) Statement [4−7], an evidence-based minimum set of recommendations for reporting randomized trials, was published in 1996. The CONSORT Statement was revised and updated in 2001 and 2010 (i.e., latest version) [7]. The statement includes a checklist of items and a flow diagram, and since 2001, the CONSORT Statement has been published with an "Explanation and Elaboration" (E&E) document explaining and illustrating each checklist item. Because the CONSORT Statement (hereafter named "main CONSORT") is

Funding: Groupe Hospitalier Paris Centre - Assistance Publique Hopitaux de Paris, Paris, France (Grant number MERRI-AAP- 2017-010).

Ethical approval and consent to participate: Not applicable.

Competing interests: P.R. is a member of the EQUATOR steering committee and director of the French EQUATOR center. I.B. is a member of the CONSORT steering committee. Other authors declare no competing interests.

Consent for publication: Not applicable.

Authors' contributions: L.G., P.R., and I.B. contributed to the concept and design of the study. L.G. contributed to the collection and assembly of data. L.G., P.R., and I.B. contributed to the data analysis and interpretation. L.G. and I.B. contributed to the article writing. All authors contributed to the final approval of the article.

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https://doi.org/10.1016/j.jclinepi.2019.05.030
0895-4356/

What is new?

Key findings

- We showed that the coverage by Consolidated Standards of Reporting Trial (CONSORT) guidelines is very good: 81% of randomized controlled trials indexed in PubMed are covered by relevant CONSORT extensions, and those missing were currently under development at the time of the search.
- However, the potential workload to adhere to all CONSORT guidelines could be high for authors (a median of 4 documents and 67 pages to consult).
- Furthermore, the development and update of extensions are questionable. Several extensions were not based on the latest version of the CONSORT Statement (CONSORT 2010), and new extensions covering less than 2% of trials have been developed.

What this adds to what was known?

- This is the first study evaluating the coverage of and the potential workload to adhere to the CONSORT statement and its extensions.

What is the implication and what should change now?

- The strategy for developing, updating, and implementing reporting guidelines could be improved.
- A new thinking of the CONSORT extensions is needed.

based on the two-arm, parallel-group design, several extensions were developed to consider variations in the standard trial methodology. The extensions provide specific recommendations for reporting specific study designs (e.g., cluster RCTs [8]), specific interventions (e.g., nonpharmacologic treatments [9]), and specific types of data (e.g., harms [10]). Extensions are frequently published with an E&E document and are to be used in conjunction with the main CONSORT Statement and E&E document.

Despite an improvement in the completeness of reporting [11], endorsement and adherence to the CONSORT Statement, particularly the extensions, are questionable [12–15]. Our overarching aim was to determine whether the development, updating process, and format of the CONSORT Statement and extensions are in line with users' needs. For this purpose, we first evaluated whether RCTs indexed in PubMed were covered by the main CONSORT and related extensions (i.e., guidelines were available) and whether the new extensions being developed closed the gaps. Second, we explored the implications for authors using the guidelines in terms of the number of documents to retrieve and read (i.e., potential workload).

2. Methods

2.1. Study design

We performed a mapping [16] of the coverage by the CONSORT Statement and extensions for RCTs indexed in PubMed and evaluated the potential workload to adhere to the guidelines.

2.2. Identification of CONSORT guidelines and extensions

We searched the CONSORT Web site [17] to identify all existing CONSORT extensions (search date November 2, 2018). We retrieved the latest version of the Statement and related E&E document for the main CONSORT Statement and all extensions available. When an extension was an update, we retrieved all preceding reports.

For the main CONSORT Statement and each extension, we recorded (1) the publication date of the different versions, (2) the type of documents available (i.e., a statement with the checklist and flow diagram and E&E document explaining and illustrating the items), and (3) the number of pages of the most recent documents retrieved in PDF format.

We checked whether the extension was based on the latest version of the CONSORT Statement (i.e., CONSORT 2010) [7]. We also contacted the CONSORT group to determine whether other extensions or updates of existing extensions were in progress.

2.3. Identification of RCTs indexed in PubMed

2.3.1. Search strategy

We searched MEDLINE via PubMed (search date March 30, 2017) for RCTs indexed in PubMed from January 1, 2016, to January 31, 2016. We used the following search strategy: (''randomized controlled trial'' [Publication Type]) AND ((randomized [Title/Abstract] OR randomised [Title/Abstract])) AND Publication date from January 01, 2016 to January 31, 2016. The 2,481 citations retrieved by our search were randomly ordered and screened until 1,000 reports of RCTs were eligible.

2.3.2. Eligibility criteria

We included all RCTs assessing health-related interventions (e.g., pharmacologic treatments and nonpharmacologic treatments such as surgery; participative interventions such as education, rehabilitation, physiotherapy, or psychotherapy; and other health-related interventions). Articles presenting secondary analyses of RCTs or assessing only cost-effectiveness or diagnostic/screening interventions were excluded.

Table 1. Characteristics of the available CONSORT extensions

Extension type	CONSORT extension	Date of publication	No of documents	No of pages
Design	Cluster trials	2004/update in 2010	1	21
	Noninferiority and equivalence trials	2006/update in 2012	1	11
	Pragmatic trials	2008	1	8
	N-of-1 trials	2015	2	38
	Feasibility and pilot trials	2016	1	29
	Within-person trials	2017	1	22
Intervention	Herbal medicine	2006	2	23
	Nonpharmacologic	2008/update in 2017	1	16/22
	Acupuncture	2002/update in 2010	1	11
	Chinese herbal medicine	2017	1	10
Data	Harms	2004	1	13
	Abstracts	2008	2	12
	Patient-reported outcomes	2013	1	9
	Equity	2017	1	14

Abbreviation: CONSORT, Consolidated Standards of Reporting Trial.

2.4. Data extraction

We recorded the study design, number of groups, type of interventions, comparator, sample size, and medical conditions. We considered that the study was a pragmatic trial and a pilot/feasibility study when it was clearly stated in the title or abstract.

According to the study design and intervention, we determined whether the study was covered by a relevant extension, regardless of whether the extension was based on CONSORT 2010 or 2001. Also, for each extension, we determined the proportion of RCTs for which it was relevant.

To determine the potential workload for users, we considered the workload when users strictly follow the CONSORT recommendations (i.e., use the E&E in conjunction with the checklist and use the extensions in conjunction with the main CONSORT because extensions provide guidance on only the modified items). This allows for a full understanding of the Statement and extension. This potential workload also consists of the maximum workload for a user. Consequently, the workload was the total number of documents and pages of the 2010 CONSORT Statement and its 2010 E&E in addition to all relevant extensions and related E&E documents. For practical reasons, we did not consider the workload for extensions related to the type of data, namely "patient-reported outcomes," "harms," "abstracts", and "equity."

One researcher (L.G.) screened the titles and abstracts of the citations retrieved and recorded data from the abstract. When needed, the full-text article was retrieved to record data not reported in the abstract. As a quality control procedure, another researcher (A.C.) extracted data for 10% of the 1,000 retrieved eligible citations (kappa agreement was 0.91), and discrepancies were resolved by consensus.

2.5. Data analysis

Data are summarized as frequency (and %) or median and interquartile range (Q1–Q3). All analyses were performed with R Studio v1.0.143, Boston, MA.

3. Results

3.1. CONSORT guidelines and extensions

From the CONSORT Web site [17], we identified six extensions providing specific recommendations for reporting specific study designs (cluster trials [8], noninferiority and equivalence trials [8,18], pragmatic trials [19], N-of-1 trials [20,21], pilot and feasibility trials [22], within-person trials [23]); four extensions for specific interventions (nonpharmacologic treatments [9], herbal medicinal interventions [24,25], acupuncture [26] and Chinese herbal medicine formulas [27]); and four for specific types of data (patient-reported outcomes [28], harms [10], abstracts [29], and equity [30]). Table 1 describes the characteristics of the extensions available.

Fig. 1 describes the availability of the different versions of the CONSORT Statement and extensions since 1996, when the first CONSORT Statement was published, up to November 2018. Overall, only one extension (acupuncture) was updated concurrently with the update of the 2010 CONSORT Statement; three were updated after 2 years (cluster, noninferiority, and equivalence trials) and 7 years (nonpharmacologic treatments); and three are still based on CONSORT 2001 (i.e., harms, pragmatic studies, and herbal medicine studies). The CONSORT steering committee informed us that two new extensions are about to be published (a new extension for multiple-arm trials and one for cross-over trials), and the extension on harms is being updated.

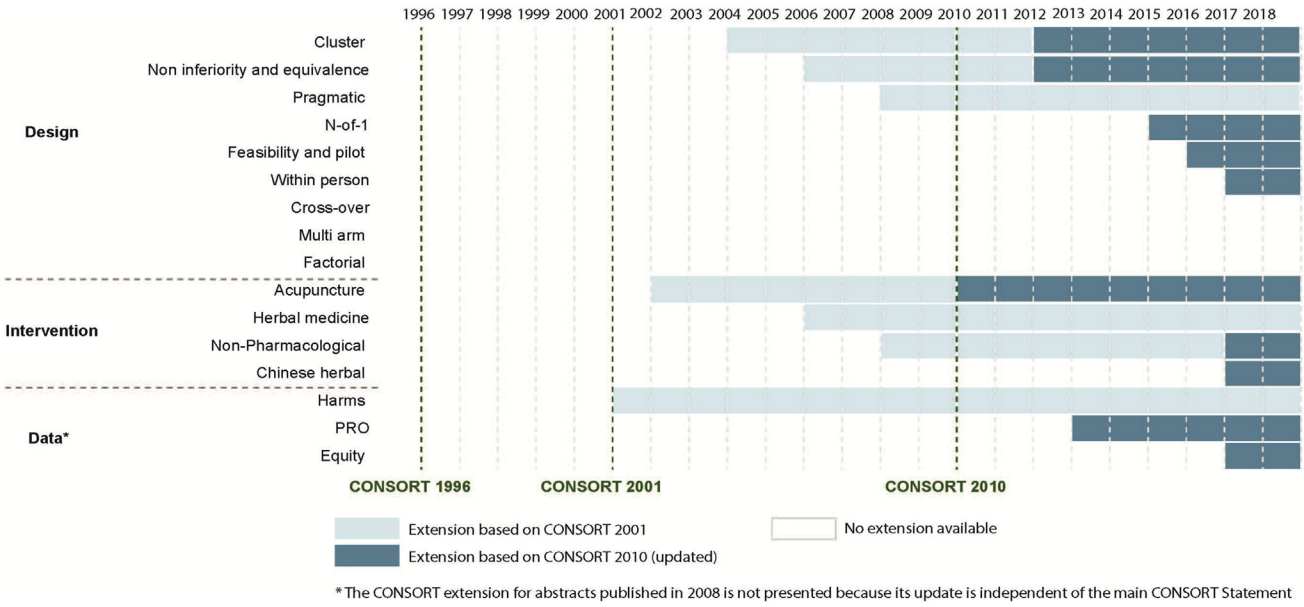

Fig. 1. Timeline of availability of CONSORT extensions. CONSORT, Consolidated Standards of Reporting Trial.

3.2. RCT coverage by the CONSORT statement and extensions

The trial characteristics of the sample of RCTs identified are summarized in Table 2. The study design most frequently used was a two-arm, parallel-group, individual randomized trial 74% (741/1,000), 6% (59/1,000) of the RCTs were pragmatic trials, and 1% (14/1,000) were pilot and feasibility trials. Overall, 55% (553/1,000) of RCTs assessed nonpharmacologic treatments (42% participative interventions and 12% surgical interventions). The median [Q1–Q3] number of participants recruited per trial was 80 [40–219].

Considering the extensions available in 2018, only 19% (186/1,000) of RCTs of our sample were not covered by an extension specific to the study design (multiarm, factorial, and cross-over designs). However, 6 of 10 extensions for design and interventions covered <2% of the trials for each extension type. Since the update of CONSORT in 2010, four new extensions for specific designs and interventions were developed, for within-person trials [23], feasibility and pilot studies [22], N-of-1 studies [20], and Chinese herbal medicine [27]. These extensions covered 0.8%, 1.4%, 0.2%, and 0%, respectively, of the RCTs we examined. The extensions for multiple-arm trials and cross-over trials were being developed at the time of the search. They cover 10% (103/1,000) and 7% (72/1,000), respectively, of the RCTs we examined.

Three extensions are still based on CONSORT 2001: (1) the extension for harms, which is needed for 100% of studies; (2) the extension for pragmatic trials, which is needed for 6% (59/1,000) of studies; and (3) the extension for herbal medicine, which is needed for 1% (11/1,000) of studies.

3.3. Potential workload in meeting the CONSORT guidelines

Table 1 and Appendix 1 report the number of documents and pages to be consulted per study type. Fig. 2 describes the maximal workload according to the study design and intervention. Overall, authors have to consult a median [Q1–Q3] number of 4 [4–5] documents (range 2–6) to adhere to the guidelines, representing a median [Q1–Q3] of 67 [57–78] pages (range 35–98). An additional workload of eight pages is required if the trial is pragmatic, and 29 pages if the trial is a pilot or feasibility trial.

4. Discussion

Our results show that 81% (814/1,000) of RCTs indexed in PubMed are covered by the relevant CONSORT extension(s), and the missing extensions were under development at the time of the search. Four new extensions for specific designs and interventions developed because the CONSORT update cover only from 0% to 1.4% of the trials.

However, the development and updating of the CONSORT Statement and related extensions raise important issues. Particularly, the delay for updating some extensions was too long. For example, the extension for nonpharmacologic treatments, which concerned 54% (553/1,000) of trials indexed in PubMed, was updated 7 years after publication of the 2010 CONSORT Statement. Because extensions are built on the main CONSORT statement (an extension systematically reports the CONSORT item followed by the extension), the lack of update of extensions

Table 2. General characteristics of randomized controlled trials examined (n = 1,000)

RCTs characteristics	*n* (%)
Study design	
Individual double-arm	741 (74.1)
Individual multi-arm	114 (11.4)
Cluster	51 (5.1)
Noninferiority	14 (1.4)
Cross-over	72 (7.2)
N-of-1	2 (0.2)
Within person	8 (0.8)
Pragmatic studies	59 (5.9)
Individual double-arm	47 (4.7)
Individual multi-arm	3 (0.3)
Cluster	3 (0.3)
Noninferiority	0 (0.0)
Cross-over	4 (0.5)
N-of-1	0 (0.0)
Within-person	1 (0.1)
Pilot and feasibility studies	14 (1.4)
Individual double-arm	10 (1.0)
Individual multi-arm	0 (0.0)
Cluster	1 (0.2)
Noninferiority	0 (0.0)
Cross-over	1 (0.1)
N-of-1	0 (0.0)
Within-person	1 (0.1)
Number of study groups	
2	881 (88.1)
3	82 (8.2)
4	31 (3.1)
5	3 (0.3)
6	3 (0.3)
Type of intervention	
Pharmacologic	436 (43.6)
Herbal medicine	11 (1.1)
Nonpharmacologic	553 (55.3)
Surgery	118 (11.8)
Participative intervention	417 (41.7)
Acupuncture	11 (1.1)
Complex interventions	7 (0.7)
Chinese herbal medicine	0 (0)
Type of comparison	
Active treatment (same type)	388 (38.8)
Active treatment (other type)	19 (1.9)
Placebo	237 (23.7)
Usual care	356 (35.6)
Sample size: median (Q1–Q3) [minimum to maximum]	80 (40–215) [6–72,998]

concomitant with the main CONSORT is a major issue for users because the wording of the main CONSORT items as well as the numbering of items will not be consistent.

The proliferation of extensions is associated with an important burden for authors; three-quarters of studies required reading four to five documents. For example, for a pragmatic randomized cluster trial evaluating a surgical procedure, the authors should read five documents: (1) the CONSORT Statement and (2) its E&E document [12] along with the CONSORT extensions for (3) cluster trials, (4) nonpharmacologic treatments, and (5) pragmatic trials—thus, five documents for a total of 103 pages. It is unrealistic to expect authors, peer-reviewers, and editors to rely on and adhere to all relevant guidelines.

To our knowledge, this is the first study evaluating the coverage of and workload to adhere to the CONSORT Statement and its extensions. Previous studies showed that endorsement of the CONSORT guidelines by journals has improved over time [12]. However, endorsement is not always associated with clear instructions to authors, and editorial policies to enforce CONSORT are needed [12,31,32]. Furthermore, instructions to authors rarely request adherence to CONSORT extensions [12]. A mapping of the reporting of trials included in Cochrane reviews showed a decrease in waste related to poor reporting over time, but reporting remains suboptimal [11].

Several initiatives and tools were developed and evaluated to improve adherence to CONSORT guidelines. The COBWEB tool aimed at summarizing key elements that needed to be reported from two CONSORT guidelines. With an RCT, the authors showed that the tool could improve the completeness of reporting [33]. Another initiative, consisting of an online tool, WebCONSORT, aimed at optimizing the use of CONSORT extensions by combining the checklists, did not show convincing results [34].

Our results should have important implications (Table 3). First, the strategy for developing, updating, and implementing the CONSORT and extensions should be discussed: What should be the strategy related to extensions when the main CONSORT is updated? Can authors rely on an extension for a specific study type that is not updated based on the last CONSORT? and Should we still rely on only the classical format of the Statement associated with the E&E document for dissemination of the guidelines?

Second, a new thinking of the CONSORT extensions is needed in which authors would have all the reporting recommendations summarized in one customized document per study type; this could help reduce the burden on authors and the number of pages and documents to consult. Authors could use tools such as COBWEB [33], which develops templates that could take into account all CONSORT recommendations from the main CONSORT, E&E document, and the extensions for abstracts and harms altogether in one document along with the special recommendations for the study type.

The study has some limitations. First, we considered only RCT reports indexed in PubMed. However, PubMed is the primary information resource for clinicians and researchers, and it has been used in other large epidemiologic

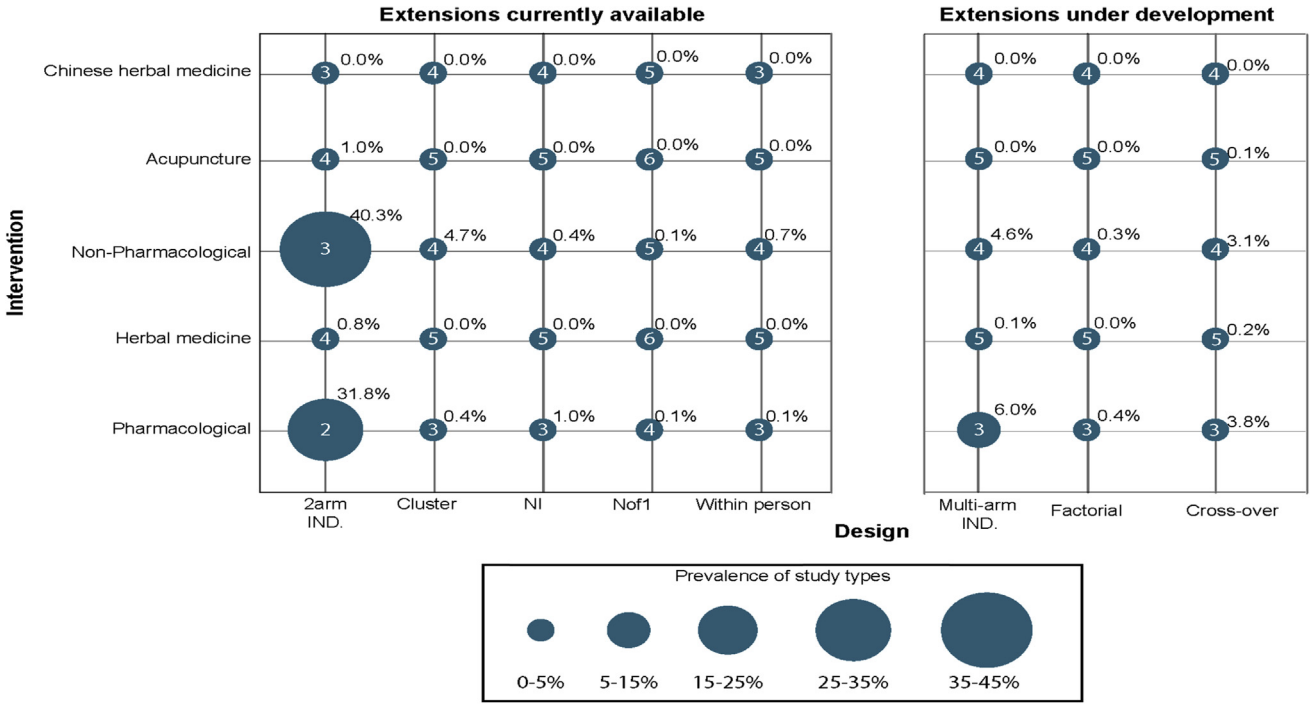

Fig. 2. Coverage and authors' potential workload to adhere to the CONSORT Statement and extensions. CONSORT, Consolidated Standards of Reporting Trial. The numbers inside the nodes represent the number of CONSORT guidelines to be consulted per study type. The size of the node is proportional to the study type prevalence reported in percentages beside the node. Extensions for pragmatic trials and feasibility/pilot studies are not demonstrated because they could be applied as a third dimension to most study designs.

studies on the quality of reporting [35,36]. Second, we assessed the authors' potential workload in terms of the need to consult several CONSORT statements and extensions, assuming that the number of documents/pages to be consulted is linked with the time needed and thus the potential workload. Furthermore, we did not consider that the potential workload may vary depending on the level of experience of authors with CONSORT guidelines. Some authors might choose to look only at the extension checklist(s) and refer to the E&E document only for certain items for further explanation. Third, we considered only the extensions listed on the CONSORT Web site, which probably underestimates the complexity and potential workload for authors. Specific reporting guidelines such as the template

Table 3. Proposal for improving the process of developing updating and reporting the CONSORT Statement and extensions

Process	Issues in the current process	Proposals for improvement
Development of the CONSORT extensions	The number of extensions developed and published is high, not always in line with users' needs. The high number of extensions implies that authors have to identify, retrieve, read, and combine several extensions to write up a single article.	The development of extensions should be prioritized and in line with users' needs (e.g., prevalence of the study types in the literature or registries)
Update of the main CONSORT	Updates of the main CONSORT are not planned with a concomitant update of existing extensions. The delay in updating extensions can be long. Extensions are built on the main CONSORT Statement (an extension systematically reports the CONSORT item followed by the extension) Consequently, an extension not based on the updated CONSORT checklist can be confusing and difficult to use because of inconsistencies in the numbering, content, and wording of items.	An updated version of each extension considering the changes made in the main CONSORT Statement should be made available concomitant with the publication of the updated version of the main CONSORT. This does not imply that a full process for updating the extension is necessary.
Format of the CONSORT Statement and extensions	The format of the guidelines requires that authors review several resources to acquire enough knowledge on all reporting recommendations. The workload to consult several documents could be high.	We propose to develop online tools such as writing aid tools (e.g., COBWEB) that would provide a template and checklist combining all necessary extensions.

Abbreviation: CONSORT, Consolidated Standards of Reporting Trial.

for intervention description and replication [37] or the CONSORT-SPI [38] extension dedicated to social and psychological interventions were not listed on the Web site. Finally, for practical reasons, we did not consider the burden related to using the extensions for data (patient-reported outcomes, harms, abstracts, and equity); therefore, the authors' potential workload demonstrated is underestimated because the extensions for harms and abstracts are needed for all types of studies, and there is an additional burden to be considered with patient-reported outcomes or for equity studies.

In conclusion, the coverage of the CONSORT extensions for the different study designs and interventions is high, but there is a need to rethink the strategy for developing and updating the CONSORT Statement and related extensions and also the format of the guidelines to reduce authors' potential workload and perhaps increase adherence.

Acknowledgments

The authors thank Anthony Chauvin for contributing to the double selection and extraction of data and Elise Diard for her help in designing the figures. They also thank Laura SMALES (BioMedEditing, Toronto, Canada) who proofread this article.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2019.05.030.

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