Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT): a systematic review

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Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT): a systematic review

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ABSTRACT

Objective

To systematically assess adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT). Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials. The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.

Design

Systematic review.

Sample

We identified eight general medical and eight surgical journals, indexed in PubMed and published in 2011, with the highest impact factors in their respective categories.

Main outcomes

Adherence to CONSORT Statement and CONSORT-NPT extension items.

Results

We identified 54 surgical trials (22 published in medical journals and 32 in surgical journals). There were eight items for which there was less than 30% overall compliance (seven were specific to the CONSORT-NPT extension). These seven items related to: a full description of the care providers, centers and blinding status in the abstract (n=7/54, 13%), eligibility criteria for centers performing the interventions (n=13/54, 24%), how adherence of care providers with the protocol was assessed or enhanced (n=7/54, 13%), how clustering by care providers or centers was addressed as it relates to sample size (n=3/54, 6%), how care providers were allocated to each group (n=9/54, 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (n=2/54, 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (n=0/54, 0%).

Conclusions

Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical

compared to surgical journals. Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

ARTICLE SUMMARY

Article focus

- Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials.
- The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.
- Our objective was to carry out a systematic review of adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT).

Key messages

- Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical compared to surgical journals.
- Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

Strengths and limitations of this study

- This study is the first to assess surgical trials reported in both general medical and surgical journals for adherence to the CONSORT-NPT extension.
- However, the final cross-sectional sample was small with only 54 trials. This precluded a detailed statistical analysis.

INTRODUCTION

Randomized controlled trials (RCTs) are designed to determine the association between efficacy of a treatment and clinical outcome. In this regard, they are considered the gold standard of healthcare evidence and the resulting conclusions can significantly affect clinical practice.[1] It is therefore imperative that trials are well designed and correctly executed. However, it is equally important that trials are fully and transparently reported to allow proper critical appraisal by the scientific community.

Key information is often missing from published trials[2, 3] and there may be a correlation between incomplete reporting and poor trial methodology.[4-6] Such missing information can include items as crucial as sample size, details of randomisation, blinding and the choice of primary outcome. In response to this problem, the Consolidated Standards of Reporting Trials (CONSORT) statement was launched in 1996 and aimed to provide a checklist of essential items that authors should report when publishing their study.[7] The CONSORT Statement was updated in 2001 and more recently in 2010 and is now endorsed by more than 600 leading medical journals.[8, 9] Whilst the CONSORT Statement has been credited with improving the reporting standards of RCTs,[10] many recent studies have highlighted remaining deficiencies in both medical[11-14] and surgical literature.[15-18]

Surgical trials are often considered more difficult to design and execute than pharmacological trials.[19] Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials such as difficulty in blinding patients and outcome assessors, variation in surgical technique and experience of operators. In 2008 an extension to the CONSORT Statement was published providing specific recommendations for the reporting of RCTs of non-pharmacological treatment

(CONSORT-NPT).[20] Examples of added items include specifying the eligibility criteria for centres performing the intervention and how care providers are allocated to each trial group.

The aim of this study was to analyse the quality of reporting of RCTs in surgery published in both medical and surgical journals based on the reporting criteria included in the 2010 CONSORT Statement and CONSORT-NPT extension.

METHODS

Search Strategy

We identified the eight general medical and eight surgical journals with the highest ISI impact factors from the "Medicine, General and Internal" and "Surgery" categories respectively of the 2011 Journal Citation Reports provided by Thomson Reuters.[21] All 16 journals (see appendix S1) are indexed on PubMed and a search was then conducted to identify reports of RCTs published in these 16 journals. The search (see appendix S2) combined the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials[22] with the publication year 2011 and journal name (conducted in March 2012). Additionally, the terms "surgery OR surgical OR surgeon" were added when searching the eight general medical journals to restrict results to RCTs in surgery. The search was conducted independently for each journal. All titles and abstracts retrieved from the search were assessed for eligibility by the authors (MN, MM, DH, WT, FC) such that each record was reviewed independently by at least two authors. Studies in which it was not clear whether the inclusion criteria had been met were reviewed in full text and discrepancies were resolved by consensus. All journals included in our sample are published in English.

Inclusion and exclusion criteria

We defined a randomized trial as a prospective study assessing health-care interventions in human participants who were randomly allocated to study groups. Studies were considered eligible for inclusion if they were: (i) reports of a randomized controlled trial, (ii) published in 2011 (either print or online e-publication during 2011), and (iii) the primary aim of the study was considered an interventional therapy. For the purposes of this study, an interventional therapy was defined as a therapy involving (a) some element of

invasion or trauma to the body and (b) the requirement for operator skill to achieve a successful requirement and with the exception of an intervention being used purely to deliver a pharmacological treatment (i.e. catheter delivered drug) (see appendix S2). We excluded reports where (i) one of the trial arms did not contain an interventional therapy as defined above, (ii) a drug was the primary intervention, even in a surgical population (e.g. chemotherapy for ovarian cancer) or (iii) the RCT had been previously published and the current report was merely a follow-up or subgroup analysis using the same cohort of patients.

Data extraction

We created a modified version of the CONSORT checklist which contained all of the 2008 CONSORT-NPT checklist items and all of the standard 2010 CONSORT checklist items. The resulting checklist had a total of 42 items (see appendix S3). Two authors (DH, WT) independently assessed each of the eligible reports against this checklist. Reports were also scored by the same authors for trial quality using the extended version of the Linde Internal Validity Scale (ELIVS) (see table 3, appendix S2). The ELIVS scoring system used in this study was developed from initial work by Jadad et al.[23] and Linde et al.[24] It measures the following quality domains: treatment allocation, randomisation method, allocation concealment, post-randomisation baseline comparison, blinding, handling and reporting of withdrawals and intention to treat analysis. Any discrepancies were resolved by consensus. Inter-observer analysis was assessed by calculating the Cohen's kappa score. Extraction of data from studies was carried out in Microsoft Excel (2010, Microsoft Corporation, Redmond, WA, USA) using a pre-piloted form that was tested on two randomly selected studies from 2010.

For each report, we also extracted the following data: the number of authors, the continent were the study was conducted, multicentre status, number of study participants and

reporting of ethics review and conflict of interest. For each journal included, we obtained the ISI 2011 impact factor and whether or not the journal endorsed (e.g. recommended or required) the CONSORT Statement and CONSORT-NPT extension (information obtained in 2012).

Author survey

We also emailed the corresponding author for each included report, with five questions relating to the CONSORT-NPT extension in April 2013. The questions were: (i) Are you currently aware of the 2008 CONSORT-NPT extension? (ii) Were you aware of the 2008 CONSORT-NPT extension at the time of submission? (iii) Did the journal editorial staff mention the CONSORT-NPT extension to you during the editorial process (other than the instructions for authors on the journal website)? Did the journal peer reviewers mention the CONSORT-NPT extension to you during the review process? (v) Would your choice of journal for submission be affected by whether or not the journal mentions the CONSORT-NPT extension in their online instructions for authors? Each answer could be reported as 'yes', 'no' or 'cannot remember/unsure'.

Outcomes and statistical analysis

Our primary outcome measure was adherence measured as the proportion of articles reporting each individual CONSORT and CONSORT-NPT checklist item. We also compared any differences in adherence between reports published in general medical with those published in surgical journals. All analyses were performed using STATA statistical software version 12.1 (College Station, TX).

RESULTS

Our initial PubMed searches identified 831 possible reports, of which 771 were excluded as ineligible based on the information reported in the title and abstract. Sixty full text articles were retrieved for further assessment of which six were excluded because they were reports of previously published trials. This left 54 RCTs with a combined total of 16,338 patients from 11 journals that met the inclusion criteria (summarised in figure 1).

The baseline characteristics of the included trials are shown in table 1. The medical journals had a tendency toward higher numbers of patients and a larger number of authors as well as a greater proportion of multicentre, higher quality (as measured by the ELIVS scale) trials. The requirement for CONSORT adherence was variable between the medical and surgical journals. Overall, only around half of the articles were published in a journal that required (26/54 studies; 48%) CONSORT adherence (table 1). The percentage of articles published in a journal that mentioned CONSORT in the instructions to peer reviewers (9/54 studies; 27%) was lower.

Table 1. Baseline characteristics of included studies.

	Overall (n=54)	**Medical** (n=22)	**Surgical** (n=32)
Trial characteristics			
No. of patients, median (IQR)	177 (110-410)	363 (195-757)	129 (71-177)
No. of authors, median (IQR)	9 (6-12)	12 (9-17)	7 (6-11)
Impact factor, median (IQR)	7.5 (4.5-30.0)	33.6 (30.0-53.5)	4.6 (4.4-7.5)
Multicentre trials, no. (%)	28 (52)	20 (91)	8 (25)
Ethics review, no. (%)	54 (100)	22 (100)	32 (100)
COI declared, no. (%)	47 (87)	22 (100)	25 (78)
ELIVS Quality score, mean (SD)	5.1 (1.5)	5.8 (1.4)	4.5 (1.3)
Journal CONSORT endorsement			
CONSORT required in ITA, no. (%)	26 (48)	13 (59)	13 (41)
CONSORT recommended in ITA, no. (%)	28 (52)	9 (41)	19 (59)
CONSORT mentioned in ITPR, no. (%)	9 (27)	6 (27)	3 (10)

Adherence of trials to the modified CONSORT checklist was variable ranging from 0-100% for each of the individual 42 checklist items (table 2). The highest scoring trials satisfied 36 of 42 items while the lowest scoring trial satisfied only 18 items (median 27, interquartile range 23-31). There were eight items for which there was less than 30% overall compliance (indicated with an asterisk in table 2). Of these eight items, seven were specific to the CONSORT-NPT extension. These seven items related to the following topics: a full description of the care providers, centers and blinding status in the abstract (item 1b; adherence 13%), eligibility criteria for centers performing the interventions (item 4b; adherence 24%), how adherence of care providers with the protocol was assessed or enhanced (item 5c; adherence 13%), how clustering by care providers or centers was addressed as it relates to sample size (item 7a; adherence 6%), how care providers were allocated to each group (item 8b; adherence 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (item 12b; adherence 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (item 15b; adherence 0%). The non CONSORT-NPT item with less than 30% adherence related to the presentation of both absolute and relative effect sizes for binary outcomes (item 17b; adherence 28%).

Table 2. Adherence of studies to modified CONSORT-NPT checklist.

CONSORT Number	Point	Overall adherence, no. (%)	Medical adherence, no. (%)	Surgical adherence, no. (%)
1a	**Title and abstract**	46 (85)	17 (77)	29 (91)
1b		7 (13)*	7 (32)	0
2a	**Background and objectives**	54 (100)	22 (100)	32 (100)
2b		54 (100)	22 (100)	32 (100)
3a	**Trial design**	22 (41)	14 (64)	8 (25)
3b		54 (100)	22 (100)	32 (100)
4a	**Participants**	54 (100)	22 (100)	32 (100)
4b		13 (24)*	7 (32)	6 (19)

5	**Interventions**	48 (89)	19 (86)	29 (91)
5a		39 (72)	20 (91)	19 (59)
5b		50 (93)	20 (91)	30 (94)
5c		7 (13)*	6 (27)	1 (3)
6a	**Outcomes**	48 (89)	22 (100)	26 (81)
6b		54 (100)	22 (100)	32 (100)
7a	**Sample size**	3 (6)*	2 (9)	1 (3)
7b		52 (96)	22 (100)	30 (94)
8a	**Randomisation sequence generation**	30 (56)	12 (55)	18 (56)
8b		9 (17)*	2 (9)	7 (22)
9	**Allocation concealment mechanism**	28 (52)	17 (77)	11 (34)
10	**Randomisation implementation**	18 (33)	13 (59)	5 (16)
11a	**Blinding**	29 (54)	16 (73)	13 (41)
11b		30 (56)	16 (73)	14 (44)
12a	**Statistical methods**	54 (100)	22 (100)	32 (100)
12b		2 (4)*	0	2 (6)
13a	**Participant flow**	0*	0	0
13b		51 (94)	22 (100)	29 (91)
New	**Implementation of intervention**	38 (70)	12 (55)	26 (81)
14a	**Recruitment**	48 (89)	22 (100)	26 (81)
14b		51 (94)	22 (100)	29 (91)
15a	**Baseline data**	52 (96)	22 (100)	30 (94)
15b		0*	0	0
16	**Numbers analysed**	52 (96)	22 (100)	30 (94)
17a	**Outcomes and estimation**	21 (39)	18 (82)	3 (9)
17b		15 (28)*	14 (64)	1 (3)
18	**Ancillary analyses**	42 (78)	20 (91)	22 (29)
19	**Harms**	51 (94)	21 (95)	30 (94)
20	**Limitations**	35 (65)	19 (86)	16 (50)
21	**Generalisability**	24 (44)	14 (64)	10 (31)
22	**Interpretation**	51 (94)	22 (100)	29 (91)
23	**Registration**	49 (91)	22 (100)	27 (84)
24	**Protocol**	25 (46)	18 (82)	7 (22)
25	**Funding**	40 (74)	22 (100)	18 (56)

We did not statistically compare the different adherence rates between the trials published in general medical and surgical journals as originally planned owing to the small

sample size and the large number of hypotheses that could potentially be tested (all 42 checklist items). However, in comparing the percentage adherence rates between the two journal groups, general medical journals typically generated superior adherence. There were three exceptions where surgical journal adherence was more than 10% superior to trials published in medical journals (item 1a, identification as a randomised trial in the title; item 8b, allocation of care providers to each group; item "New", implementation of intervention as it was implemented.

We contacted the lead author for each of the 54 reports to ask about their awareness of CONSORT-NPT. Only 17 authors replied (31% response rate) and so we were therefore not able to perform formal quantitative analysis on the survey results. Based on the replies we received, approximately a third of respondents were aware of CONSORT-NPT at the time of submission, while two thirds are aware of its existence now (table 3). Given the time lapse between manuscript submission and our short survey, about a quarter of respondents were unable to remember whether journal editors and peer reviewers had mentioned CONSORT-NPT during the review process. Finally, a third of respondents agreed that their choice of journal for submission would be affected by whether or not CONSORT-NPT was mentioned in the instructions for authors section of the journal (we did not ascertain the direction of this preference).

Table 3. Results from survey of corresponding authors.

Question no.	Topic	Yes	No	Can't remember / Not sure
1	**Currently aware of NPT**	11 (65%)	5 (35%)	0
2	**Aware of NPT at submission**	6 (35%)	10 (65%)	0

3	**NPT mentioned by editorial staff**	2 (12%)	10 (59%)	5 (29%)
4	**NPT mentioned by peer-reviewers**	1 (6%)	11 (71%)	4 (24%)
5	**NPT endorsement by journal would affect submission choice**	5 (29%)	10 (65%)	1 (6%)

DISCUSSION

Summary of main findings

In this study, we included 54 reports of surgical RCTs published in 2011 from a cross sectional sample of 11 medical and surgical journals. We assessed these reports for their adherence to a combined CONSORT and CONSORT-NPT checklist with two main findings. Firstly, reporting adherence of surgical RCTs to the CONSORT-NPT extension was much poorer than adherence to the main CONSORT checklist. Secondly, general medical journals were broadly superior in their NPT reporting as compared to surgical journals. To our knowledge this is the first study to demonstrate this difference between journal types for the CONSORT-NPT extension and one of only a few studies to document NPT adherence.

Comparison with the literature

The findings from our study are in agreement with the existing literature on CONSORT adherence. A recent systematic review of 53 studies found that reporting has remained sub-optimal despite the CONSORT Statement having been active in various iterations since 1996.[25] However, the authors suggest that journal endorsement does appear to have had a positive impact on adherence. One review that included a comparison between surgical RCTs published in both medical and surgical journals also found that adherence to CONSORT items was significantly superior in medical journals.[16] Both of these articles assessed adherence only to the standard CONSORT Statement. A more recent study that assessed adherence specifically to the CONSORT-NPT extension checklist both before (2004) and after (2010) the checklist was launched found little improvement in NPT specific items (although these have had less time for absorption by the community than the standard

CONSORT Statement).[17] These were reported in less than 50% of trials during 2010. The adherence rates in our study for similar NPT items were even lower.

Limitations

Our study has several limitations. First, we only included studies published in high impact English language journals indexed in PubMed in 2011. In combination with our strict inclusion criteria on what constituted a surgical intervention, this led to a small sample of only 54 RCTs. We were consequently unable to perform detailed statistical analysis on individual checklist items. The decision to limit the cross-sectional sample to one year was made on pragmatic grounds owing to the very lengthy process of scoring the RCTs against the checklist items. It was also for this reason that we restricted the number of journals we searched to the top eight impact factor journals within each specialty.

A second limitation pertains to the cross-sectional nature of our study. We are unable to suggest whether any progress is being made in adherence to the NPT extension. As previously described, an interrupted before-after study found only moderate improvement between 2004 and 2010.[17] Our author survey suggested that there had been an increase in the proportion of authors who were aware of the existence of the CONSORT-NPT extension between the time of submission and now. Whether this translates to improved adherence at the current time is unknown.

A final limitation concerns the author survey. We were restricted in our ability to analyse this data by the poor response rate and the significant time lag between submission of the RCTs (circa 2010) and distribution of the survey to corresponding authors in 2013.

Implications for authors and journals

The CONSORT-NPT items with the poorest adherence were predominantly related to details on the implementation of the intervention, the providers (surgeons) and the centres. The CONSORT-NPT extension was specifically created to encourage reporting of these intervention specific items given their importance in generalising a trial intervention to non-trial populations. As an example, two early symptomatic carotid surgery trials, NASCET and ACAS,[26, 27] both had restrictive criteria for selecting which surgeons and centres were permitted to perform the intervention. Consequently, one large national cohort study that followed on from these trials did not see as large an improvement in patient outcomes.[28] The study pointed out that less than 4% of all US hospitals providing carotid endarterectomy were included in NASCET and indeed that Medicare patients treated at trial hospitals had a lower risk of dying than at other hospitals.

We might anecdotally expect CONSORT-NPT items to be more vigorously enforced by surgical journals. This is on the basis that surgeons (who would likely form a greater component of the journal's editorial board and peer reviewers) would be more familiar with the multiple elements of the intervention and the importance of these elements in their own practice. Naturally therefore, they might be keener to see these reported more thoroughly in manuscripts reporting RCTs. Our results appear to suggest the opposite in that general medical journals displayed superior NPT adherence. It is difficult to ascertain whether this finding is confounded by the much larger impact factor of the general medical journals in our sample and the potential for a self-fulfilling prophecy (i.e. better reported trials opt preferentially to try and publish in the high impact medical journals rather than such RCTs being well reported as a prime result of enforcement by the medical journal).

The literature on CONSORT adherence failures is extensive and is developing similarly for the CONSORT-NPT extension.[25] Now that the problem has been well documented, the focus will likely shift towards identifying actionable areas for intervention.

In the first instance, we suggest that qualitative interviews and focus groups with stakeholders at surgical trials departments will be important. Identifying the precise barriers to adherence will better inform the community on how best to improve reporting and where the greatest impact can be had. For example, does the problem lie with restrictive word counts, lack of time, lack of enforcement or simply just lack of awareness? How far would journals be prepared to go with enforcement? Would this be a viable option for smaller impact journals, perhaps fearful of driving authors away by enforcing reporting guidelines too rigidly?

These are all important questions that could be further elucidated by qualitative research in this field. New guidance on surgical RCT methodology[29] and calls for greater investment in surgical research[30] should be combined with greater awareness of the CONSORT-NPT extension. Reporting standards, like trial design are not static but need to adapt to the changing research landscape. CONSORT therefore needs to respond to proposals for new reporting standards such as those proposed by the IDEAL Collaboration[29] in future NPT extensions. Notably, the All Trials movement pushing for transparency of pharmaceutical trials has garnered much attention from the public and press over recent months.[31] This momentum has added weight to the growing call for thorough reporting to be considered a core duty of clinician researchers rather than just a desirable trait.

Conclusion

The findings from this cross sectional review of surgical trials suggest that adherence to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical compared to surgical journals. A combination of more qualitative research to identify areas for specific

intervention and a continuing effort to raise awareness of the CONSORT-NPT extension among stakeholders will be important going forward.

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COMPETING INTERESTS

SH, Centre for Statistics in Medicine, is a member of the CONSORT group. PM is the Chair of the IDEAL Collaboration.

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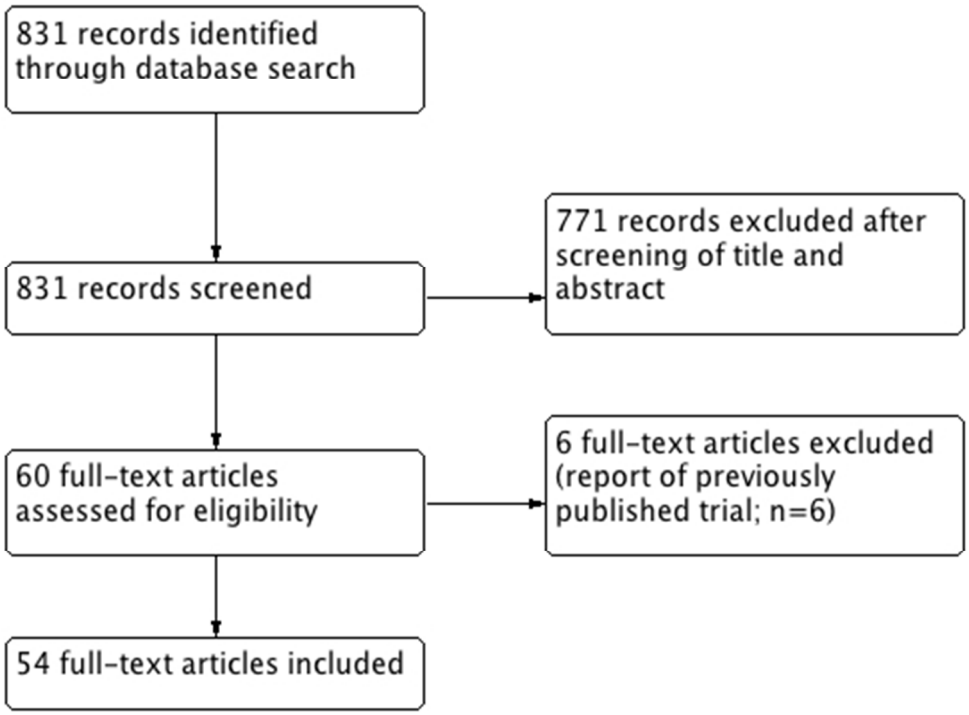

Figure 1. Flow diagram of study selection.
176x133mm (72 x 72 DPI)

APPENDIX S1

Search strategy for medical journals

Databases: **PubMed** <1948 to Present>

Search Strategy:

1	randomized controlled trial [pt]	(319493)
2	controlled clinical trial [pt]	(83422)
3	randomized [tiab]	(258027)
4	placebo [tiab]	(138836)
5	drug therapy [sh]	(1500313)
6	randomly [tiab]	(177741)
7	trial [tiab]	(298335)
8	groups [tiab]	(1179377)
9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	(2938926)
10	animals [mh] NOT humans [mh]	(3648479)
11	#9 NOT #10	(2515800)
12	2011[dp]	(980498)
13	"N Engl J Med"[Journal]	(66892)
14	(Surgery OR Surgical OR Surgeon)	(3293015)
15	#11 AND #12 AND #13 AND #14	(54)

NB: searches 1 to 11 are taken directly from the Cochrane Handbook, box 6.4a. These steps form the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision); PubMed format'.

COMPRESSED SEARCH – New England Journal of Medicine (NEJM) – 54 RESULTS

((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh])) AND (2011[dp]) AND (surgery OR surgical OR surgeon) AND ("N Engl J Med"[Journal])

Search strategy for surgical journals

Databases: **PubMed** <1948 to Present>

Search Strategy:

1	randomized controlled trial [pt]	(319493)
2	controlled clinical trial [pt]	(83422)
3	randomized [tiab]	(258027)
4	placebo [tiab]	(138836)
5	drug therapy [sh]	(1500313)
6	randomly [tiab]	(177741)
7	trial [tiab]	(298335)
8	groups [tiab]	(1179377)
9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	(2938926)
10	animals [mh] NOT humans [mh]	(3648479)
11	#9 NOT #10	(2515800)
12	2011[dp]	(980498)
13	"Ann Surg"[Journal]	(27081)
14	#11 AND #12 AND #13	(109)

NB: searches 1 to 11 are taken directly from the Cochrane Handbook, box 6.4a. These steps form the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision); PubMed format'.

COMPRESSED SEARCH – Annals of Surgery – 109 RESULTS

((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh])) AND (2011[dp]) AND ("Ann Surg"[Journal])

APPENDIX S2

CRITERIA FOR SELECTING STUDIES

INCLUSION CRITERIA:

- Randomized clinical trial
- Human subjects
- Published in 2011 (this can include EITHER print or e-publication during 2011)
- Primary aim of study considers an interventional therapy
    - For the purpose of this study, this is defined as a therapy involving:
        - Some element of invasion or trauma to the body
        - The requirement for operator skill to achieve a successful requirement
        - With the exception of an intervention being used purely to deliver a pharmacologic treatment (i.e. catheter delivered drug)

EXCLUSION CRITERIA:

- One of the trial arms does not contain an interventional therapy as defined above
- Drug treatment as the primary intervention, even in a surgical population (e.g. chemotherapy for ovarian cancer)
- Trial has previously been reported

EXAMPLES of excludable studies:

- Drug/fluid/blood in both arms (no interventional therapy)
- Psychological/educational training in both arms (no interventional therapy)
- Intervention in one arm but only used to deliver a drug (e.g. catheter infusion of local anaesthetic or delivery of thrombolysis)
- Endoscopy, colonoscopy enteroscopy in both arms with no explicit intention stated to use intervention therapy (i.e. procedure was intended for imaging purposes)
- Subgroup analysis of a previously reported trial
- Long term follow-up data of a previously reported trial

Journal Information

Journal	Abbreviated code	2011 ISI Impact Factor	Number of Results	Number of included RCTs
MEDICAL				
New England Journal of Medicine	NEJM	53.298	54	7
The Lancet	LANC	38.278	58	6
Journal of the American Medical Association	JAMA	30.026	41	4
Annals of Internal Medicine	ANIM	16.733	19	1
PLOS Medicine	PLOS	16.269	4	2
BMJ	BMJ	14.093	26	2
Archives of Internal Medicine	ARIM	11.462	14	0
Canadian Medical Association Journal	CMAJ	8.217	12	0
SURGICAL				
Annals of Surgery	ANSU	7.492	109	11
American Journal of Transplantation	AJT	6.394	76	0
Endoscopy	ENDO	5.210	63	3
Journal of Neurology, Neurosurgery and Psychiatry	JNNP	4.764	93	2
British Journal of Surgery	BJS	4.606	121	13
Journal of the American College of Surgeons	JACS	4.549	59	0
American Journal of Surgical Pathology	AJSP	4.352	24	0
Archives of Surgery	ARCH	4.239	58	3
TOTAL			**831**	**54**

APPENDIX S3

Modified CONSORT Number	Point	Guideline to use when scoring	Present in 2008 NPT?	2008 NPT Extension points to be aware of when scoring
1a	**Title and abstract**	2010	Yes (combined a/b)	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status
1b				
2a	**Background and objectives**	2010	Yes (combined a/b)	N/A
2b				
3a	**Trial design**	2010	No	N/A
3b				
4a	**Participants**	2010	Yes (combined a/b)	When applicable, eligibility criteria for centers and those performing the interventions
4b				
5	**Interventions**	2010	Yes (split a/b/c)	Precise details of both the experimental treatment and comparator
5a				Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants
5b				Details of how the interventions were standardized
5c				Details of how adherence of care providers with the protocol was assessed or enhanced
6a	**Outcomes**	2010	Yes (combined a/b)	N/A
6b				
7a	**Sample size**	2010	Yes (combined a/b)	When applicable, details of whether and how the clustering by care providers or centers was addressed
7b				
8a	**Randomisation sequence generation**	2010	Yes (combined a/b)	When applicable, how care providers were allocated to each trial group
8b				
9	**Allocation concealment mechanism**	2010	Yes	N/A
10	**Randomisation implementation**	2010	Yes	N/A

Modified CONSORT Number	Point	Guideline to use when scoring	Present in 2008 NPT?	2008 NPT Extension points to be aware of when scoring
11a	**Blinding**	2010	Yes (split a/b)	Whether or not those administering co-interventions were blinded to group assignment
11b				If blinded, method of blinding and description of the similarity of interventions
12a	**Statistical methods**	2010	Yes (combined a/b)	When applicable, details of whether and how the clustering by care providers or centers was addressed
12b				
13a	**Participant flow**	2010	Yes (combined a/b)	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
13b				
New in NPT	**Implementation of intervention**	**2008 NPT**	Yes	Details of the experimental treatment and comparator as they were implemented
14a	**Recruitment**	2010	Yes (combined a/b)	N/A
14b				
15a	**Baseline data**	2010	Yes	(2010 Point 15) N/A
15b		**2008 NPT**	Yes	(2008 NPT Extension) When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
16	**Numbers analysed**	2010	Yes	N/A
17a	**Outcomes and estimation**	2010	Yes (combined a/b)	N/A
17b				
18	**Ancillary analyses**	2010	Yes	N/A
19	**Harms**	2010	Yes	N/A
20	**Limitations**	2010	No	N/A
21	**Generalisability**	2010	Yes	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial

22	**Interpretation**	2010	Yes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
23	**Registration**	2010	No	N/A
24	**Protocol**	2010	No	N/A
25	**Funding**	2010	No	N/A

Tables 1 and 2. Tables showing the modified CONSORT scoring checklist to take into account the 2008 NPT extension guidelines whilst scoring against the general points in the 2010 standard CONSORT statement

ELIVS Number	Point	Further detail
E1	**Treatment allocation**	Was it randomised?
E2	**Randomisation method**	Appropriate method of randomisation described
E3	**Allocation concealment**	Appropriate steps taken to conceal allocation sequence
E4	**Post-randomisation baseline comparison**	Usually located in a table. Showing both groups are similar post randomisation for all known prognostically important factors
E5	**Patients blinded**	Method of blinding described and is appropriate
E6	**Evaluators blinded**	Method of blinding described and is appropriate
E7i	**Handling and reporting of withdrawals**	Full accounting for all patients who entered the trial
E7ii	**Intention to treat analysis**	Per protocol analysis can be provided in addition but there must also be ITT analysis

Table 3. Extended Linde Internal Validity Scale

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix S2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7-8
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	n/a
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n/a
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-11
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-18
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT): a cross-sectional study

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Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT): a cross-sectional study

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ABSTRACT

Objective

To systematically assess adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT). Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials. The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.

Design

Cross-sectional study.

Sample

We identified eight general medical and eight surgical journals, indexed in PubMed and published in 2011, with the highest impact factors in their respective categories.

Main outcomes

Adherence to CONSORT Statement and CONSORT-NPT extension items.

Results

We identified 54 surgical trials (22 published in medical journals and 32 in surgical journals). There were eight items for which there was less than 30% overall compliance (seven were specific to the CONSORT-NPT extension). These seven items related to: a full description of the care providers, centers and blinding status in the abstract (n=7/54, 13%), eligibility criteria for centers performing the interventions (n=13/54, 24%), how adherence of care providers with the protocol was assessed or enhanced (n=7/54, 13%), how clustering by care providers or centers was addressed as it relates to sample size (n=3/54, 6%), how care providers were allocated to each group (n=9/54, 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (n=2/54, 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (n=0/54, 0%).

Conclusions

Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical

compared to surgical journals. Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

ARTICLE SUMMARY

Article focus

- Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials.
- The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.
- Our objective was to carry out a systematic review of adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT).

Key messages

- Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical compared to surgical journals.
- Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

Strengths and limitations of this study

- This study is the first to assess surgical trials reported in both general medical and surgical journals for adherence to the CONSORT-NPT extension.
- However, the final cross-sectional sample was small with only 54 trials. This precluded a detailed statistical analysis.

INTRODUCTION

Randomized controlled trials (RCTs) are designed to determine the association between efficacy of a treatment and clinical outcome. In this regard, they are considered the gold standard of healthcare evidence and the resulting conclusions can significantly affect clinical practice.[1] It is therefore imperative that trials are well designed and correctly executed. However, it is equally important that trials are fully and transparently reported to allow proper critical appraisal by the scientific community.

Key information is often missing from published trials[2, 3] and there may be a correlation between incomplete reporting and poor trial methodology.[4-6] Such missing information can include items as crucial as sample size, details of randomisation, blinding and the choice of primary outcome. In response to this problem, the Consolidated Standards of Reporting Trials (CONSORT) statement was launched in 1996 and aimed to provide a checklist of essential items that authors should report when publishing their study.[7] The CONSORT Statement was updated in 2001 and more recently in 2010 and is now endorsed by more than 600 leading medical journals.[8, 9] Whilst the CONSORT Statement has been credited with improving the reporting standards of RCTs,[10] many recent studies have highlighted remaining deficiencies in both medical[11-14] and surgical literature.[15-18]

Surgical trials are often considered more difficult to design and execute than pharmacological trials.[19] Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials such as difficulty in blinding patients and outcome assessors, variation in surgical technique and experience of operators. In 2008 an extension to the CONSORT Statement was published providing specific recommendations for the reporting of RCTs of non-pharmacological treatment

(CONSORT-NPT).[20] Examples of added items include specifying the eligibility criteria for centres performing the intervention and how care providers are allocated to each trial group.

The aim of this study was to analyse the quality of reporting of RCTs in surgery published in both medical and surgical journals based on the reporting criteria included in the 2010 CONSORT Statement and CONSORT-NPT extension.

METHODS

Search Strategy

We identified the eight general medical and eight surgical journals with the highest ISI impact factors from the "Medicine, General and Internal" and "Surgery" categories respectively of the 2011 Journal Citation Reports provided by Thomson Reuters.[21] All 16 journals (see appendix S1) are indexed on PubMed and a search was then conducted to identify reports of RCTs published in these 16 journals. The search (see appendix S2) combined the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials[22] with the publication year 2011 and journal name (conducted in March 2012). Additionally, the terms "surgery OR surgical OR surgeon" were added when searching the eight general medical journals to restrict results to RCTs in surgery. The search was conducted independently for each journal. All titles and abstracts retrieved from the search were assessed for eligibility by the authors (MN, MM, DH, WT, FC) such that each record was reviewed independently by at least two authors. Studies in which it was not clear whether the inclusion criteria had been met were reviewed in full text and discrepancies were resolved by consensus. All journals included in our sample are published in English.

Inclusion and exclusion criteria

We defined a randomized trial as a prospective study assessing health-care interventions in human participants who were randomly allocated to study groups. Studies were considered eligible for inclusion if they were: (i) reports of a randomized controlled trial, (ii) published in 2011 (either print or online e-publication during 2011), and (iii) the primary aim of the study was considered an interventional therapy. For the purposes of this study, an interventional therapy was defined as a therapy involving (a) some element of

invasion or trauma to the body and (b) the requirement for operator skill to achieve a successful requirement and with the exception of an intervention being used purely to deliver a pharmacological treatment (i.e. catheter delivered drug) (see appendix S2). We excluded reports where (i) one of the trial arms did not contain an interventional therapy as defined above, (ii) a drug was the primary intervention, even in a surgical population (e.g. chemotherapy for ovarian cancer) or (iii) the RCT had been previously published and the current report was merely a follow-up or subgroup analysis using the same cohort of patients.

Data extraction

We created a modified version of the CONSORT checklist which contained all of the 2008 CONSORT-NPT checklist items and all of the standard 2010 CONSORT checklist items. The resulting checklist had a total of 42 items (see appendix S3). Two authors (DH, WT) independently assessed each of the eligible reports against this checklist. Reports were also scored by the same authors for trial quality using the extended version of the Linde Internal Validity Scale (ELIVS) (see table 3, appendix S2). The ELIVS scoring system used in this study was developed from initial work by Jadad et al.[23] and Linde et al.[24] It measures the following quality domains: treatment allocation, randomisation method, allocation concealment, post-randomisation baseline comparison, blinding, handling and reporting of withdrawals and intention to treat analysis. Any discrepancies were resolved by consensus. Inter-observer analysis was assessed by calculating the Cohen's kappa score (score 0.74 based on disagreement of 268/2,268 points). Extraction of data from studies was carried out in Microsoft Excel (2010, Microsoft Corporation, Redmond, WA, USA) using a pre-piloted form that was tested on two randomly selected studies from 2010.

For each report, we also extracted the following data: the number of authors, the continent were the study was conducted, multicentre status, number of study participants and

reporting of ethics review and conflict of interest. For each journal included, we obtained the ISI 2011 impact factor and whether or not the journal endorsed (e.g. recommended or required) the CONSORT Statement and CONSORT-NPT extension (information obtained in 2012).

Author survey

We also emailed the corresponding author for each included report, with five questions relating to the CONSORT-NPT extension in April 2013. The questions were: (i) Are you currently aware of the 2008 CONSORT-NPT extension? (ii) Were you aware of the 2008 CONSORT-NPT extension at the time of submission? (iii) Did the journal editorial staff mention the CONSORT-NPT extension to you during the editorial process (other than the instructions for authors on the journal website)? Did the journal peer reviewers mention the CONSORT-NPT extension to you during the review process? (v) Would your choice of journal for submission be affected by whether or not the journal mentions the CONSORT-NPT extension in their online instructions for authors? Each answer could be reported as 'yes', 'no' or 'cannot remember/unsure'.

Outcomes and statistical analysis

Our primary outcome measure was adherence measured as the proportion of articles reporting each individual CONSORT and CONSORT-NPT checklist item. We also compared any differences in adherence between reports published in general medical with those published in surgical journals. All analyses were performed using STATA statistical software version 12.1 (College Station, TX).

RESULTS

Our initial PubMed searches identified 831 possible reports, of which 771 were excluded as ineligible based on the information reported in the title and abstract. Sixty full text articles were retrieved for further assessment of which six were excluded because they were reports of previously published trials. This left 54 RCTs with a combined total of 16,338 patients from 11 journals that met the inclusion criteria (summarised in figure 1).

The baseline characteristics of the included trials are shown in table 1. The medical journals had a tendency toward higher numbers of patients and a larger number of authors as well as a greater proportion of multicentre, higher quality (as measured by the ELIVS scale) trials. The requirement for CONSORT adherence was variable between the medical and surgical journals. Overall, only around half of the articles were published in a journal that required (26/54 studies; 48%) CONSORT adherence (table 1). The percentage of articles published in a journal that mentioned CONSORT in the instructions to peer reviewers (9/54 studies; 27%) was lower.

Table 1. Baseline characteristics of included studies. Abbreviations: COI, conflict of interest; ELIVS, extended linde internal validity scale; IQR, inter-quartile range; ITA, instructions to authors; ITPA, instructions to peer reviewers.

	Overall (n=54)	**Medical journals** (n=22)	**Surgical journals** (n=32)
Trial characteristics			
No. of patients, median (IQR)	177 (110-410)	363 (195-757)	129 (71-177)
No. of authors, median (IQR)	9 (6-12)	12 (9-17)	7 (6-11)
Impact factor, median (IQR)	7.5 (4.5-30.0)	33.6 (30.0-53.5)	4.6 (4.4-7.5)
Multicentre trials, no. (%)	28 (52)	20 (91)	8 (25)
Ethics review, no. (%)	54 (100)	22 (100)	32 (100)
COI declared, no. (%)	47 (87)	22 (100)	25 (78)
ELIVS Quality score, mean (SD)	5.1 (1.5)	5.8 (1.4)	4.5 (1.3)
Journal CONSORT endorsement			
CONSORT required in ITA, no. (%)	26 (48)	13 (59)	13 (41)
CONSORT recommended in ITA, no. (%)	28 (52)	9 (41)	19 (59)

CONSORT mentioned in ITPR, no. (%)	9 (27)	6 (27)	3 (10)

Adherence of trials to the modified CONSORT checklist was variable ranging from 0-100% for each of the individual 42 checklist items (table 2). The highest scoring trials satisfied 36 of 42 items while the lowest scoring trial satisfied only 18 items (median 27, interquartile range 23-31). There were eight items for which there was less than 30% overall compliance (indicated with an asterisk in table 2). Of these eight items, seven were specific to the CONSORT-NPT extension. These seven items related to the following topics: a full description of the care providers, centers and blinding status in the abstract (item 1b; adherence 13%), eligibility criteria for centers performing the interventions (item 4b; adherence 24%), how adherence of care providers with the protocol was assessed or enhanced (item 5c; adherence 13%), how clustering by care providers or centers was addressed as it relates to sample size (item 7a; adherence 6%), how care providers were allocated to each group (item 8b; adherence 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (item 12b; adherence 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (item 15b; adherence 0%). The non CONSORT-NPT item with less than 30% adherence related to the presentation of both absolute and relative effect sizes for binary outcomes (item 17b; adherence 28%).

Table 2. Adherence of studies to modified CONSORT-NPT checklist. *Headings in bold are covered within the CONSORT-NPT extension. Non-bold are exclusive to CONSORT 2010 Statement. Further details available in Appendix S3.*

CONSORT Number	Point	Overall adherence, no. (%)	Medical adherence, no. (%)	Surgical adherence, no. (%)
1a	**Title and abstract**	46 (85)	17 (77)	29 (91)
1b		7 (13)*	7 (32)	0
2a	**Background and objectives**	54 (100)	22 (100)	32 (100)
2b		54 (100)	22 (100)	32 (100)

3a	Trial design	22 (41)	14 (64)	8 (25)
3b		54 (100)	22 (100)	32 (100)
4a	**Participants**	54 (100)	22 (100)	32 (100)
4b		13 (24)*	7 (32)	6 (19)
5	**Interventions**	48 (89)	19 (86)	29 (91)
5a		39 (72)	20 (91)	19 (59)
5b		50 (93)	20 (91)	30 (94)
5c		7 (13)*	6 (27)	1 (3)
6a	**Outcomes**	48 (89)	22 (100)	26 (81)
6b		54 (100)	22 (100)	32 (100)
7a	**Sample size**	3 (6)*	2 (9)	1 (3)
7b		52 (96)	22 (100)	30 (94)
8a	**Randomisation sequence generation**	30 (56)	12 (55)	18 (56)
8b		9 (17)*	2 (9)	7 (22)
9	**Allocation concealment mechanism**	28 (52)	17 (77)	11 (34)
10	**Randomisation implementation**	18 (33)	13 (59)	5 (16)
11a	**Blinding**	29 (54)	16 (73)	13 (41)
11b		30 (56)	16 (73)	14 (44)
12a	**Statistical methods**	54 (100)	22 (100)	32 (100)
12b		2 (4)*	0	2 (6)
13a	**Participant flow**	0*	0	0
13b		51 (94)	22 (100)	29 (91)
New	**Implementation of intervention**	38 (70)	12 (55)	26 (81)
14a	**Recruitment**	48 (89)	22 (100)	26 (81)
14b		51 (94)	22 (100)	29 (91)
15a	**Baseline data**	52 (96)	22 (100)	30 (94)
15b		0*	0	0
16	**Numbers analysed**	52 (96)	22 (100)	30 (94)
17a	**Outcomes and estimation**	21 (39)	18 (82)	3 (9)
17b		15 (28)*	14 (64)	1 (3)
18	**Ancillary analyses**	42 (78)	20 (91)	22 (29)
19	**Harms**	51 (94)	21 (95)	30 (94)
20	Limitations	35 (65)	19 (86)	16 (50)
21	**Generalisability**	24 (44)	14 (64)	10 (31)
22	**Interpretation**	51 (94)	22 (100)	29 (91)
23	Registration	49 (91)	22 (100)	27 (84)
24	Protocol	25 (46)	18 (82)	7 (22)
25	Funding	40 (74)	22 (100)	18 (56)

We did not compare the different adherence rates in a statistically formal way between the trials published in general medical and surgical journals as originally planned owing to the small sample size and the large number of hypotheses that could potentially be tested (all 42 checklist items). General medical journals tended to report better adherence to checklist items than surgical journals.

We contacted the lead author for each of the 54 reports to ask about their awareness of CONSORT-NPT. Only 17 authors replied (31% response rate) and so we were therefore not able to perform formal quantitative analysis on the survey results. Based on the replies we received, approximately a third of respondents were aware of CONSORT-NPT at the time of submission, while two thirds are aware of its existence now (table 3). Given the time lapse between manuscript submission and our short survey, about a quarter of respondents were unable to remember whether journal editors and peer reviewers had mentioned CONSORT-NPT during the review process. Finally, a third of respondents agreed that their choice of journal for submission would be affected by whether or not CONSORT-NPT was mentioned in the instructions for authors section of the journal (we did not ascertain the direction of this preference).

Table 3. Results from survey of corresponding authors. Abbreviations: NPT, non-pharmacological treatment CONSORT extension statement.

Question no.	Topic	Yes	No	Can't remember / Not sure
1	**Currently aware of NPT**	11 (65%)	5 (35%)	0
2	**Aware of NPT at submission**	6 (35%)	10 (65%)	0
3	**NPT mentioned by editorial staff**	2 (12%)	10 (59%)	5 (29%)
4	**NPT mentioned by peer-reviewers**	1 (6%)	11 (71%)	4 (24%)
5	**NPT endorsement by journal would affect submission choice**	5 (29%)	10 (65%)	1 (6%)

DISCUSSION

Summary of main findings

In this study, we included 54 reports of surgical RCTs published in 2011 from a cross sectional sample of 11 medical and surgical journals. We assessed these reports for their adherence to a combined CONSORT and CONSORT-NPT checklist with two main findings. Firstly, reporting adherence of surgical RCTs to the CONSORT-NPT extension was much poorer than adherence to the main CONSORT checklist. Secondly, general medical journals were broadly superior in their NPT reporting as compared to surgical journals. To our knowledge this is the first study to demonstrate this difference between journal types for the CONSORT-NPT extension and one of only a few studies to document NPT adherence.

Comparison with the literature

The findings from our study are in agreement with the existing literature on CONSORT adherence. A recent systematic review of 53 studies found that reporting has remained sub-optimal despite the CONSORT Statement having been active in various iterations since 1996.[25] However, the authors suggest that journal endorsement does appear to have had a positive impact on adherence. One review that included a comparison between surgical RCTs published in both medical and surgical journals also found that adherence to CONSORT items was significantly superior in medical journals.[16] Both of these articles assessed adherence only to the standard CONSORT Statement. A more recent study that assessed adherence specifically to the CONSORT-NPT extension checklist both before (2004) and after (2010) the checklist was launched found little improvement in NPT specific items (although these have had less time for absorption by the community than the standard

CONSORT Statement).[17] These were reported in less than 50% of trials during 2010. The adherence rates in our study for similar NPT items were even lower.

Limitations

Our study has several limitations. First, we only included studies published in high impact English language journals indexed in PubMed in 2011. In combination with our strict inclusion criteria on what constituted a surgical intervention, this led to a small sample of only 54 RCTs. We were consequently unable to perform detailed statistical analysis on individual checklist items. The decision to limit the cross-sectional sample to one year was made on pragmatic grounds owing to the very lengthy process of scoring the RCTs against the checklist items. It was also for this reason that we restricted the number of journals we searched to the top eight impact factor journals within each specialty.

A second limitation pertains to the cross-sectional nature of our study. We are unable to suggest whether any progress is being made in adherence to the NPT extension. As previously described, an interrupted before-after study found only moderate improvement between 2004 and 2010.[17] Our author survey suggested that there had been an increase in the proportion of authors who were aware of the existence of the CONSORT-NPT extension between the time of submission and now. Whether this translates to improved adherence at the current time is unknown. A third limitation includes the fact that we did not assess study protocols for adherence to CONSORT criteria. Some authors may have included additional study details within the protocol.

A final limitation concerns the author survey. We were restricted in our ability to analyse this data by the poor response rate and the significant time lag between submission of the RCTs (circa 2010) and distribution of the survey to corresponding authors in 2013.

Implications for authors and journals

The CONSORT-NPT items with the poorest adherence were predominantly related to details on the implementation of the intervention, the providers (surgeons) and the centres. The CONSORT-NPT extension was specifically created to encourage reporting of these intervention specific items given their importance in generalising a trial intervention to non-trial populations. As an example, two early symptomatic carotid surgery trials, NASCET and ACAS,[26, 27] both had restrictive criteria for selecting which surgeons and centres were permitted to perform the intervention. Consequently, one large national cohort study that followed on from these trials did not see as large an improvement in patient outcomes.[28] The study pointed out that less than 4% of all US hospitals providing carotid endarterectomy were included in NASCET and indeed that Medicare patients treated at trial hospitals had a lower risk of dying than at other hospitals.

We might anecdotally expect CONSORT-NPT items to be more vigorously enforced by surgical journals. This is on the basis that surgeons (who would likely form a greater component of the journal's editorial board and peer reviewers) would be more familiar with the multiple elements of the intervention and the importance of these elements in their own practice. Naturally therefore, they might be keener to see these reported more thoroughly in manuscripts reporting RCTs. Our results appear to suggest the opposite in that general medical journals displayed superior NPT adherence. It is difficult to ascertain whether this finding is confounded by the much larger impact factor of the general medical journals in our sample and the potential for a self-fulfilling prophecy (i.e. better reported trials opt preferentially to try and publish in the high impact medical journals rather than such RCTs being well reported as a prime result of enforcement by the medical journal). Overall, the wealth of potential confounders makes it difficult to conclude why medical journals displayed superior adherence.

The literature on CONSORT adherence failures is extensive and is developing similarly for the CONSORT-NPT extension.[25] Now that the problem has been well documented, the focus will likely shift towards identifying actionable areas for intervention. In the first instance, we suggest that qualitative interviews and focus groups with stakeholders at surgical trials departments will be important. Identifying the precise barriers to adherence will better inform the community on how best to improve reporting and where the greatest impact can be had. For example, does the problem lie with restrictive word counts, lack of time, lack of enforcement or simply just lack of awareness? How far would journals be prepared to go with enforcement? Would this be a viable option for smaller impact journals, perhaps fearful of driving authors away by enforcing reporting guidelines too rigidly?

These are all important questions that could be further elucidated by qualitative research in this field. New guidance on surgical RCT methodology[29] and calls for greater investment in surgical research[30] should be combined with greater awareness of the CONSORT-NPT extension. Reporting standards, like trial design are not static but need to adapt to the changing research landscape. CONSORT therefore needs to respond to proposals for new reporting standards such as those proposed by the IDEAL Collaboration[29] in future NPT extensions. Notably, the All Trials movement pushing for transparency of pharmaceutical trials has garnered much attention from the public and press over recent months.[31] This momentum has added weight to the growing call for thorough reporting to be considered a core duty of clinician researchers rather than just a desirable trait.

Conclusion

The findings from this cross sectional review of surgical trials suggest that adherence to CONSORT-NPT extension items is much poorer than to the standard CONSORT

Statement. Adherence also appears to be superior in general medical compared to surgical journals. A combination of more qualitative research to identify areas for specific intervention and a continuing effort to raise awareness of the CONSORT-NPT extension among stakeholders will be important going forward.

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COMPETING INTERESTS

SH, Centre for Statistics in Medicine, is a member of the CONSORT group. PM is the Chair of the IDEAL Collaboration.

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DATA SHARING STATEMENT

Electronic data collection sheets are available on request.

CONTRIBUTORSHIP

MN, CFC, MM conceived of the study. MN, CFC, MM, PM, SH were involved in the design. MN, DH, WT, CFC, MM indpedently identified studies for inclusion. DH and WT collected data from includable studies. MN analysed the data and wrote the first draft of the report. All authors contributed to subsequent drafts and approved the final version of the manuscript.

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Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT): a cross-sectional study~~systematic review~~

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ABSTRACT

Objective

To systematically assess adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT). Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials. The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.

Design

Cross-sectional study. ~~Systematic review.~~

Sample

We identified eight general medical and eight surgical journals, indexed in PubMed and published in 2011, with the highest impact factors in their respective categories.

Main outcomes

Adherence to CONSORT Statement and CONSORT-NPT extension items.

Results

We identified 54 surgical trials (22 published in medical journals and 32 in surgical journals). There were eight items for which there was less than 30% overall compliance (seven were specific to the CONSORT-NPT extension). These seven items related to: a full description of the care providers, centers and blinding status in the abstract (n=7/54, 13%), eligibility criteria for centers performing the interventions (n=13/54, 24%), how adherence of care providers with the protocol was assessed or enhanced (n=7/54, 13%), how clustering by care providers or centers was addressed as it relates to sample size (n=3/54, 6%), how care providers were allocated to each group (n=9/54, 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (n=2/54, 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (n=0/54, 0%).

Conclusions

Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical

compared to surgical journals. Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

ARTICLE SUMMARY

Article focus

- Surgical trials are considered more difficult to design and execute than pharmacological trials. Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials.
- The CONSORT-NPT extension was designed to address these issues but adherence in both medical and surgical journals has not been assessed.
- Our objective was to carry out a systematic review of adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacologic treatments (NPT).

Key messages

- Adherence of surgical trials to CONSORT-NPT extension items is much poorer than to the standard CONSORT Statement. Adherence also appears to be superior in general medical compared to surgical journals.
- Raising awareness and conducting qualitative research to identify areas for specific intervention will be important going forward.

Strengths and limitations of this study

- This study is the first to assess surgical trials reported in both general medical and surgical journals for adherence to the CONSORT-NPT extension.
- However, the final cross-sectional sample was small with only 54 trials. This precluded a detailed statistical analysis.

INTRODUCTION

Randomized controlled trials (RCTs) are designed to determine the association between efficacy of a treatment and clinical outcome. In this regard, they are considered the gold standard of healthcare evidence and the resulting conclusions can significantly affect clinical practice.[1] It is therefore imperative that trials are well designed and correctly executed. However, it is equally important that trials are fully and transparently reported to allow proper critical appraisal by the scientific community.

Key information is often missing from published trials[2, 3] and there may be a correlation between incomplete reporting and poor trial methodology.[4-6] Such missing information can include items as crucial as sample size, details of randomisation, blinding and the choice of primary outcome. In response to this problem, the Consolidated Standards of Reporting Trials (CONSORT) statement was launched in 1996 and aimed to provide a checklist of essential items that authors should report when publishing their study.[7] The CONSORT Statement was updated in 2001 and more recently in 2010 and is now endorsed by more than 600 leading medical journals.[8, 9] Whilst the CONSORT Statement has been credited with improving the reporting standards of RCTs,[10] many recent studies have highlighted remaining deficiencies in both medical[11-14] and surgical literature.[15-18]

Surgical trials are often considered more difficult to design and execute than pharmacological trials.[19] Furthermore, the original CONSORT Statement does not address some aspects that are vital to the transparent reporting of surgical trials such as difficulty in blinding patients and outcome assessors, variation in surgical technique and experience of operators. In 2008 an extension to the CONSORT Statement was published providing specific recommendations for the reporting of RCTs of non-pharmacological treatment

(CONSORT-NPT).[20] Examples of added items include specifying the eligibility criteria for centres performing the intervention and how care providers are allocated to each trial group.

The aim of this study was to analyse the quality of reporting of RCTs in surgery published in both medical and surgical journals based on the reporting criteria included in the 2010 CONSORT Statement and CONSORT-NPT extension.

METHODS

Search Strategy

We identified the eight general medical and eight surgical journals with the highest ISI impact factors from the "Medicine, General and Internal" and "Surgery" categories respectively of the 2011 Journal Citation Reports provided by Thomson Reuters.[21] All 16 journals (see appendix S1) are indexed on PubMed and a search was then conducted to identify reports of RCTs published in these 16 journals. The search (see appendix S2) combined the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials[22] with the publication year 2011 and journal name (conducted in March 2012). Additionally, the terms "surgery OR surgical OR surgeon" were added when searching the eight general medical journals to restrict results to RCTs in surgery. The search was conducted independently for each journal. All titles and abstracts retrieved from the search were assessed for eligibility by the authors (MN, MM, DH, WT, FC) such that each record was reviewed independently by at least two authors. Studies in which it was not clear whether the inclusion criteria had been met were reviewed in full text and discrepancies were resolved by consensus. All journals included in our sample are published in English.

Inclusion and exclusion criteria

We defined a randomized trial as a prospective study assessing health-care interventions in human participants who were randomly allocated to study groups. Studies were considered eligible for inclusion if they were: (i) reports of a randomized controlled trial, (ii) published in 2011 (either print or online e-publication during 2011), and (iii) the primary aim of the study was considered an interventional therapy. For the purposes of this study, an interventional therapy was defined as a therapy involving (a) some element of

invasion or trauma to the body and (b) the requirement for operator skill to achieve a successful requirement and with the exception of an intervention being used purely to deliver a pharmacological treatment (i.e. catheter delivered drug) (see appendix S2). We excluded reports where (i) one of the trial arms did not contain an interventional therapy as defined above, (ii) a drug was the primary intervention, even in a surgical population (e.g. chemotherapy for ovarian cancer) or (iii) the RCT had been previously published and the current report was merely a follow-up or subgroup analysis using the same cohort of patients.

Data extraction

We created a modified version of the CONSORT checklist which contained all of the 2008 CONSORT-NPT checklist items and all of the standard 2010 CONSORT checklist items. The resulting checklist had a total of 42 items (see appendix S3). Two authors (DH, WT) independently assessed each of the eligible reports against this checklist. Reports were also scored by the same authors for trial quality using the extended version of the Linde Internal Validity Scale (ELIVS) (see table 3, appendix S2). The ELIVS scoring system used in this study was developed from initial work by Jadad et al.[23] and Linde et al.[24] It measures the following quality domains: treatment allocation, randomisation method, allocation concealment, post-randomisation baseline comparison, blinding, handling and reporting of withdrawals and intention to treat analysis. Any discrepancies were resolved by consensus. Inter-observer analysis was assessed by calculating the Cohen's kappa score (score 0.74 based on disagreement of 268/2,268 points). Extraction of data from studies was carried out in Microsoft Excel (2010, Microsoft Corporation, Redmond, WA, USA) using a pre-piloted form that was tested on two randomly selected studies from 2010.

For each report, we also extracted the following data: the number of authors, the continent were the study was conducted, multicentre status, number of study participants and

reporting of ethics review and conflict of interest. For each journal included, we obtained the ISI 2011 impact factor and whether or not the journal endorsed (e.g. recommended or required) the CONSORT Statement and CONSORT-NPT extension (information obtained in 2012).

Author survey

We also emailed the corresponding author for each included report, with five questions relating to the CONSORT-NPT extension in April 2013. The questions were: (i) Are you currently aware of the 2008 CONSORT-NPT extension? (ii) Were you aware of the 2008 CONSORT-NPT extension at the time of submission? (iii) Did the journal editorial staff mention the CONSORT-NPT extension to you during the editorial process (other than the instructions for authors on the journal website)? Did the journal peer reviewers mention the CONSORT-NPT extension to you during the review process? (v) Would your choice of journal for submission be affected by whether or not the journal mentions the CONSORT-NPT extension in their online instructions for authors? Each answer could be reported as 'yes', 'no' or 'cannot remember/unsure'.

Outcomes and statistical analysis

Our primary outcome measure was adherence measured as the proportion of articles reporting each individual CONSORT and CONSORT-NPT checklist item. We also compared any differences in adherence between reports published in general medical with those published in surgical journals. All analyses were performed using STATA statistical software version 12.1 (College Station, TX).

RESULTS

Our initial PubMed searches identified 831 possible reports, of which 771 were excluded as ineligible based on the information reported in the title and abstract. Sixty full text articles were retrieved for further assessment of which six were excluded because they were reports of previously published trials. This left 54 RCTs with a combined total of 16,338 patients from 11 journals that met the inclusion criteria (summarised in figure 1).

The baseline characteristics of the included trials are shown in table 1. The medical journals had a tendency toward higher numbers of patients and a larger number of authors as well as a greater proportion of multicentre, higher quality (as measured by the ELIVS scale) trials. The requirement for CONSORT adherence was variable between the medical and surgical journals. Overall, only around half of the articles were published in a journal that required (26/54 studies; 48%) CONSORT adherence (table 1). The percentage of articles published in a journal that mentioned CONSORT in the instructions to peer reviewers (9/54 studies; 27%) was lower.

Table 1. Baseline characteristics of included studies. Abbreviations: COI, conflict of interest; ELIVS, extended linde internal validity scale; IQR, inter-quartile range; ITA, instructions to authors; ITPA, instructions to peer reviewers.

	Overall (n=54)	Medical journals (n=22)	Surgical journals (n=32)
Trial characteristics			
No. of patients, median (IQR)	177 (110-410)	363 (195-757)	129 (71-177)
No. of authors, median (IQR)	9 (6-12)	12 (9-17)	7 (6-11)
Impact factor, median (IQR)	7.5 (4.5-30.0)	33.6 (30.0-53.5)	4.6 (4.4-7.5)
Multicentre trials, no. (%)	28 (52)	20 (91)	8 (25)
Ethics review, no. (%)	54 (100)	22 (100)	32 (100)
COI declared, no. (%)	47 (87)	22 (100)	25 (78)
ELIVS Quality score, mean (SD)	5.1 (1.5)	5.8 (1.4)	4.5 (1.3)
Journal CONSORT endorsement			
CONSORT required in ITA, no. (%)	26 (48)	13 (59)	13 (41)
CONSORT recommended in ITA, no. (%)	28 (52)	9 (41)	19 (59)

CONSORT mentioned in ITPR, no. (%)	9 (27)	6 (27)	3 (10)

Adherence of trials to the modified CONSORT checklist was variable ranging from 0-100% for each of the individual 42 checklist items (table 2). The highest scoring trials satisfied 36 of 42 items while the lowest scoring trial satisfied only 18 items (median 27, interquartile range 23-31). There were eight items for which there was less than 30% overall compliance (indicated with an asterisk in table 2). Of these eight items, seven were specific to the CONSORT-NPT extension. These seven items related to the following topics: a full description of the care providers, centers and blinding status in the abstract (item 1b; adherence 13%), eligibility criteria for centers performing the interventions (item 4b; adherence 24%), how adherence of care providers with the protocol was assessed or enhanced (item 5c; adherence 13%), how clustering by care providers or centers was addressed as it relates to sample size (item 7a; adherence 6%), how care providers were allocated to each group (item 8b; adherence 17%), how clustering by care providers or centers was addressed as it relates to statistical methods (item 12b; adherence 4%), a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group (item 15b; adherence 0%). The non CONSORT-NPT item with less than 30% adherence related to the presentation of both absolute and relative effect sizes for binary outcomes (item 17b; adherence 28%).

Table 2. Adherence of studies to modified CONSORT-NPT checklist. *Headings in bold are covered within the CONSORT-NPT extension. Non-bold are exclusive to CONSORT 2010 Statement. Further details available in Appendix S3.*

CONSORT Number	Point	Overall adherence, no. (%)	Medical adherence, no. (%)	Surgical adherence, no. (%)
1a	**Title and abstract**	46 (85)	17 (77)	29 (91)
1b		7 (13)*	7 (32)	0
2a	**Background and objectives**	54 (100)	22 (100)	32 (100)
2b		54 (100)	22 (100)	32 (100)

3a	Trial design	22 (41)	14 (64)	8 (25)
3b		54 (100)	22 (100)	32 (100)
4a	**Participants**	54 (100)	22 (100)	32 (100)
4b		13 (24)*	7 (32)	6 (19)
5	**Interventions**	48 (89)	19 (86)	29 (91)
5a		39 (72)	20 (91)	19 (59)
5b		50 (93)	20 (91)	30 (94)
5c		7 (13)*	6 (27)	1 (3)
6a	**Outcomes**	48 (89)	22 (100)	26 (81)
6b		54 (100)	22 (100)	32 (100)
7a	**Sample size**	3 (6)*	2 (9)	1 (3)
7b		52 (96)	22 (100)	30 (94)
8a	**Randomisation sequence generation**	30 (56)	12 (55)	18 (56)
8b		9 (17)*	2 (9)	7 (22)
9	**Allocation concealment mechanism**	28 (52)	17 (77)	11 (34)
10	**Randomisation implementation**	18 (33)	13 (59)	5 (16)
11a	**Blinding**	29 (54)	16 (73)	13 (41)
11b		30 (56)	16 (73)	14 (44)
12a	**Statistical methods**	54 (100)	22 (100)	32 (100)
12b		2 (4)*	0	2 (6)
13a	**Participant flow**	0*	0	0
13b		51 (94)	22 (100)	29 (91)
New	**Implementation of intervention**	38 (70)	12 (55)	26 (81)
14a	**Recruitment**	48 (89)	22 (100)	26 (81)
14b		51 (94)	22 (100)	29 (91)
15a	**Baseline data**	52 (96)	22 (100)	30 (94)
15b		0*	0	0
16	**Numbers analysed**	52 (96)	22 (100)	30 (94)
17a	**Outcomes and estimation**	21 (39)	18 (82)	3 (9)
17b		15 (28)*	14 (64)	1 (3)
18	**Ancillary analyses**	42 (78)	20 (91)	22 (29)
19	**Harms**	51 (94)	21 (95)	30 (94)
20	Limitations	35 (65)	19 (86)	16 (50)
21	**Generalisability**	24 (44)	14 (64)	10 (31)
22	**Interpretation**	51 (94)	22 (100)	29 (91)
23	Registration	49 (91)	22 (100)	27 (84)
24	Protocol	25 (46)	18 (82)	7 (22)
25	Funding	40 (74)	22 (100)	18 (56)

We did not ~~statistically~~ compare the different adherence rates in a statistically formal way between the trials published in general medical and surgical journals as originally planned owing to the small sample size and the large number of hypotheses that could potentially be tested (all 42 checklist items). ~~However, in comparing the percentage adherence rates between the two journal groups,~~G ~~g~~eneral medical journals tended to report better adherence to checklist items than surgical journals.~~typically generated superior adherence. There were three exceptions where surgical journal adherence was more than 10% superior to trials published in medical journals (item 1a, identification as a randomised trial in the title; item 8b, allocation of care providers to each group; item "New", implementation of intervention as it was implemented.~~

We contacted the lead author for each of the 54 reports to ask about their awareness of CONSORT-NPT. Only 17 authors replied (31% response rate) and so we were therefore not able to perform formal quantitative analysis on the survey results. Based on the replies we received, approximately a third of respondents were aware of CONSORT-NPT at the time of submission, while two thirds are aware of its existence now (table 3). Given the time lapse between manuscript submission and our short survey, about a quarter of respondents were unable to remember whether journal editors and peer reviewers had mentioned CONSORT-NPT during the review process. Finally, a third of respondents agreed that their choice of journal for submission would be affected by whether or not CONSORT-NPT was mentioned in the instructions for authors section of the journal (we did not ascertain the direction of this preference).

Table 3. Results from survey of corresponding authors. Abbreviations: NPT, non-pharmacological treatment CONSORT extension statement.

Question no.	Topic	Yes	No	Can't remember / Not sure
1	**Currently aware of NPT**	11 (65%)	5 (35%)	0
2	**Aware of NPT at submission**	6 (35%)	10 (65%)	0
3	**NPT mentioned by editorial staff**	2 (12%)	10 (59%)	5 (29%)
4	**NPT mentioned by peer-reviewers**	1 (6%)	11 (71%)	4 (24%)
5	**NPT endorsement by journal would affect submission choice**	5 (29%)	10 (65%)	1 (6%)

DISCUSSION

Summary of main findings

In this study, we included 54 reports of surgical RCTs published in 2011 from a cross sectional sample of 11 medical and surgical journals. We assessed these reports for their adherence to a combined CONSORT and CONSORT-NPT checklist with two main findings. Firstly, reporting adherence of surgical RCTs to the CONSORT-NPT extension was much poorer than adherence to the main CONSORT checklist. Secondly, general medical journals were broadly superior in their NPT reporting as compared to surgical journals. To our knowledge this is the first study to demonstrate this difference between journal types for the CONSORT-NPT extension and one of only a few studies to document NPT adherence.

Comparison with the literature

The findings from our study are in agreement with the existing literature on CONSORT adherence. A recent systematic review of 53 studies found that reporting has remained sub-optimal despite the CONSORT Statement having been active in various iterations since 1996.[25] However, the authors suggest that journal endorsement does appear to have had a positive impact on adherence. One review that included a comparison between surgical RCTs published in both medical and surgical journals also found that adherence to CONSORT items was significantly superior in medical journals.[16] Both of these articles assessed adherence only to the standard CONSORT Statement. A more recent study that assessed adherence specifically to the CONSORT-NPT extension checklist both before (2004) and after (2010) the checklist was launched found little improvement in NPT specific items (although these have had less time for absorption by the community than the standard

CONSORT Statement).[17] These were reported in less than 50% of trials during 2010. The adherence rates in our study for similar NPT items were even lower.

Limitations

Our study has several limitations. First, we only included studies published in high impact English language journals indexed in PubMed in 2011. In combination with our strict inclusion criteria on what constituted a surgical intervention, this led to a small sample of only 54 RCTs. We were consequently unable to perform detailed statistical analysis on individual checklist items. The decision to limit the cross-sectional sample to one year was made on pragmatic grounds owing to the very lengthy process of scoring the RCTs against the checklist items. It was also for this reason that we restricted the number of journals we searched to the top eight impact factor journals within each specialty.

A second limitation pertains to the cross-sectional nature of our study. We are unable to suggest whether any progress is being made in adherence to the NPT extension. As previously described, an interrupted before-after study found only moderate improvement between 2004 and 2010.[17] Our author survey suggested that there had been an increase in the proportion of authors who were aware of the existence of the CONSORT-NPT extension between the time of submission and now. Whether this translates to improved adherence at the current time is unknown. A third limitation includes the fact that we did not assess study protocols for adherence to CONSORT criteria. Some authors may have included additional study details within the protocol.

A final limitation concerns the author survey. We were restricted in our ability to analyse this data by the poor response rate and the significant time lag between submission of the RCTs (circa 2010) and distribution of the survey to corresponding authors in 2013.

Implications for authors and journals

The CONSORT-NPT items with the poorest adherence were predominantly related to details on the implementation of the intervention, the providers (surgeons) and the centres. The CONSORT-NPT extension was specifically created to encourage reporting of these intervention specific items given their importance in generalising a trial intervention to non-trial populations. As an example, two early symptomatic carotid surgery trials, NASCET and ACAS,[26, 27] both had restrictive criteria for selecting which surgeons and centres were permitted to perform the intervention. Consequently, one large national cohort study that followed on from these trials did not see as large an improvement in patient outcomes.[28] The study pointed out that less than 4% of all US hospitals providing carotid endarterectomy were included in NASCET and indeed that Medicare patients treated at trial hospitals had a lower risk of dying than at other hospitals.

We might anecdotally expect CONSORT-NPT items to be more vigorously enforced by surgical journals. This is on the basis that surgeons (who would likely form a greater component of the journal's editorial board and peer reviewers) would be more familiar with the multiple elements of the intervention and the importance of these elements in their own practice. Naturally therefore, they might be keener to see these reported more thoroughly in manuscripts reporting RCTs. Our results appear to suggest the opposite in that general medical journals displayed superior NPT adherence. It is difficult to ascertain whether this finding is confounded by the much larger impact factor of the general medical journals in our sample and the potential for a self-fulfilling prophecy (i.e. better reported trials opt preferentially to try and publish in the high impact medical journals rather than such RCTs being well reported as a prime result of enforcement by the medical journal). Overall, the wealth of potential confounders makes it difficult to conclude why medical journals displayed superior adherence.

The literature on CONSORT adherence failures is extensive and is developing similarly for the CONSORT-NPT extension.[25] Now that the problem has been well documented, the focus will likely shift towards identifying actionable areas for intervention. In the first instance, we suggest that qualitative interviews and focus groups with stakeholders at surgical trials departments will be important. Identifying the precise barriers to adherence will better inform the community on how best to improve reporting and where the greatest impact can be had. For example, does the problem lie with restrictive word counts, lack of time, lack of enforcement or simply just lack of awareness? How far would journals be prepared to go with enforcement? Would this be a viable option for smaller impact journals, perhaps fearful of driving authors away by enforcing reporting guidelines too rigidly?

These are all important questions that could be further elucidated by qualitative research in this field. New guidance on surgical RCT methodology[29] and calls for greater investment in surgical research[30] should be combined with greater awareness of the CONSORT-NPT extension. Reporting standards, like trial design are not static but need to adapt to the changing research landscape. CONSORT therefore needs to respond to proposals for new reporting standards such as those proposed by the IDEAL Collaboration[29] in future NPT extensions. Notably, the All Trials movement pushing for transparency of pharmaceutical trials has garnered much attention from the public and press over recent months.[31] This momentum has added weight to the growing call for thorough reporting to be considered a core duty of clinician researchers rather than just a desirable trait.

Conclusion

The findings from this cross sectional review of surgical trials suggest that adherence to CONSORT-NPT extension items is much poorer than to the standard CONSORT

Statement. Adherence also appears to be superior in general medical compared to surgical journals. A combination of more qualitative research to identify areas for specific intervention and a continuing effort to raise awareness of the CONSORT-NPT extension among stakeholders will be important going forward.

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COMPETING INTERESTS

SH, Centre for Statistics in Medicine, is a member of the CONSORT group. PM is the Chair of the IDEAL Collaboration.

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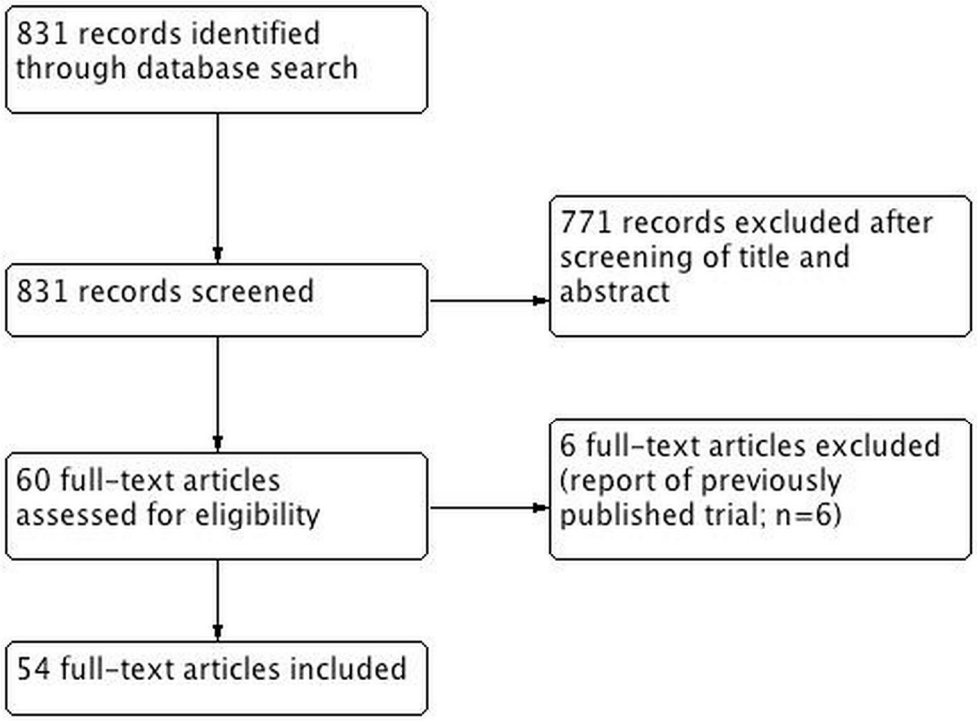

Figure 1. Flow diagram of study selection.
120x90mm (300 x 300 DPI)

APPENDIX S1

Search strategy for medical journals

Databases: **PubMed** <1948 to Present>

Search Strategy:

1	randomized controlled trial [pt]	(319493)
2	controlled clinical trial [pt]	(83422)
3	randomized [tiab]	(258027)
4	placebo [tiab]	(138836)
5	drug therapy [sh]	(1500313)
6	randomly [tiab]	(177741)
7	trial [tiab]	(298335)
8	groups [tiab]	(1179377)
9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	(2938926)
10	animals [mh] NOT humans [mh]	(3648479)
11	#9 NOT #10	(2515800)
12	2011[dp]	(980498)
13	"N Engl J Med"[Journal]	(66892)
14	(Surgery OR Surgical OR Surgeon)	(3293015)
15	#11 AND #12 AND #13 AND #14	(54)

NB: searches 1 to 11 are taken directly from the Cochrane Handbook, box 6.4a. These steps form the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision); PubMed format'.

COMPRESSED SEARCH – New England Journal of Medicine (NEJM) – 54 RESULTS

((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh])) AND (2011[dp]) AND (surgery OR surgical OR surgeon) AND ("N Engl J Med"[Journal])

Search strategy for surgical journals

Databases: **PubMed** <1948 to Present>

Search Strategy:

1	randomized controlled trial [pt]	(319493)
2	controlled clinical trial [pt]	(83422)
3	randomized [tiab]	(258027)
4	placebo [tiab]	(138836)
5	drug therapy [sh]	(1500313)
6	randomly [tiab]	(177741)
7	trial [tiab]	(298335)
8	groups [tiab]	(1179377)
9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	(2938926)
10	animals [mh] NOT humans [mh]	(3648479)
11	#9 NOT #10	(2515800)
12	2011[dp]	(980498)
13	"Ann Surg"[Journal]	(27081)
14	#11 AND #12 AND #13	(109)

NB: searches 1 to 11 are taken directly from the Cochrane Handbook, box 6.4a. These steps form the 'Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision); PubMed format'.

COMPRESSED SEARCH – Annals of Surgery – 109 RESULTS

((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh])) AND (2011[dp]) AND ("Ann Surg"[Journal])

APPENDIX S2

CRITERIA FOR SELECTING STUDIES

INCLUSION CRITERIA:

- Randomized clinical trial
- Human subjects
- Published in 2011 (this can include EITHER print or e-publication during 2011)
- Primary aim of study considers an interventional therapy
    - For the purpose of this study, this is defined as a therapy involving:
        - Some element of invasion or trauma to the body
        - The requirement for operator skill to achieve a successful requirement
        - With the exception of an intervention being used purely to deliver a pharmacologic treatment (i.e. catheter delivered drug)

EXCLUSION CRITERIA:

- One of the trial arms does not contain an interventional therapy as defined above
- Drug treatment as the primary intervention, even in a surgical population (e.g. chemotherapy for ovarian cancer)
- Trial has previously been reported

EXAMPLES of excludable studies:

- Drug/fluid/blood in both arms (no interventional therapy)
- Psychological/educational training in both arms (no interventional therapy)
- Intervention in one arm but only used to deliver a drug (e.g. catheter infusion of local anaesthetic or delivery of thrombolysis)
- Endoscopy, colonoscopy enteroscopy in both arms with no explicit intention stated to use intervention therapy (i.e. procedure was intended for imaging purposes)
- Subgroup analysis of a previously reported trial
- Long term follow-up data of a previously reported trial

Journal Information

Journal	Abbreviated code	2011 ISI Impact Factor	Number of Results	Number of included RCTs
MEDICAL				
New England Journal of Medicine	NEJM	53.298	54	7
The Lancet	LANC	38.278	58	6
Journal of the American Medical Association	JAMA	30.026	41	4
Annals of Internal Medicine	ANIM	16.733	19	1
PLOS Medicine	PLOS	16.269	4	2
BMJ	BMJ	14.093	26	2
Archives of Internal Medicine	ARIM	11.462	14	0
Canadian Medical Association Journal	CMAJ	8.217	12	0
SURGICAL				
Annals of Surgery	ANSU	7.492	109	11
American Journal of Transplantation	AJT	6.394	76	0
Endoscopy	ENDO	5.210	63	3
Journal of Neurology, Neurosurgery and Psychiatry	JNNP	4.764	93	2
British Journal of Surgery	BJS	4.606	121	13
Journal of the American College of Surgeons	JACS	4.549	59	0
American Journal of Surgical Pathology	AJSP	4.352	24	0
Archives of Surgery	ARCH	4.239	58	3
TOTAL			**831**	**54**

APPENDIX S3

Modified CONSORT Number	Point	Guideline to use when scoring	Present in 2008 NPT?	2008 NPT Extension points to be aware of when scoring
1a	**Title and abstract**	2010	Yes (combined a/b)	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status
1b				
2a	**Background and objectives**	2010	Yes (combined a/b)	N/A
2b				
3a	**Trial design**	2010	No	N/A
3b				
4a	**Participants**	2010	Yes (combined a/b)	When applicable, eligibility criteria for centers and those performing the interventions
4b				
5	**Interventions**	2010	Yes (split a/b/c)	Precise details of both the experimental treatment and comparator
5a				Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants
5b				Details of how the interventions were standardized
5c				Details of how adherence of care providers with the protocol was assessed or enhanced
6a	**Outcomes**	2010	Yes (combined a/b)	N/A
6b				
7a	**Sample size**	2010	Yes (combined a/b)	When applicable, details of whether and how the clustering by care providers or centers was addressed
7b				
8a	**Randomisation sequence generation**	2010	Yes (combined a/b)	When applicable, how care providers were allocated to each trial group
8b				
9	**Allocation concealment mechanism**	2010	Yes	N/A
10	**Randomisation implementation**	2010	Yes	N/A

Modified CONSORT Number	Point	Guideline to use when scoring	Present in 2008 NPT?	2008 NPT Extension points to be aware of when scoring
11a	**Blinding**	2010	Yes (split a/b)	Whether or not those administering co-interventions were blinded to group assignment
11b				If blinded, method of blinding and description of the similarity of interventions
12a	**Statistical methods**	2010	Yes (combined a/b)	When applicable, details of whether and how the clustering by care providers or centers was addressed
12b				
13a	**Participant flow**	2010	Yes (combined a/b)	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
13b				
New in NPT	**Implementation of intervention**	**2008 NPT**	Yes	Details of the experimental treatment and comparator as they were implemented
14a	**Recruitment**	2010	Yes (combined a/b)	N/A
14b				
15a	**Baseline data**	2010	Yes	(2010 Point 15) N/A
15b		**2008 NPT**	Yes	(2008 NPT Extension) When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
16	**Numbers analysed**	2010	Yes	N/A
17a	**Outcomes and estimation**	2010	Yes (combined a/b)	N/A
17b				
18	**Ancillary analyses**	2010	Yes	N/A
19	**Harms**	2010	Yes	N/A
20	**Limitations**	2010	No	N/A
21	**Generalisability**	2010	Yes	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial

22	**Interpretation**	2010	Yes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
23	**Registration**	2010	No	N/A
24	**Protocol**	2010	No	N/A
25	**Funding**	2010	No	N/A

Tables 1 and 2. Tables showing the modified CONSORT scoring checklist to take into account the 2008 NPT extension guidelines whilst scoring against the general points in the 2010 standard CONSORT statement

ELIVS Number	Point	Further detail
E1	**Treatment allocation**	Was it randomised?
E2	**Randomisation method**	Appropriate method of randomisation described
E3	**Allocation concealment**	Appropriate steps taken to conceal allocation sequence
E4	**Post-randomisation baseline comparison**	Usually located in a table. Showing both groups are similar post randomisation for all known prognostically important factors
E5	**Patients blinded**	Method of blinding described and is appropriate
E6	**Evaluators blinded**	Method of blinding described and is appropriate
E7i	**Handling and reporting of withdrawals**	Full accounting for all patients who entered the trial
E7ii	**Intention to treat analysis**	Per protocol analysis can be provided in addition but there must also be ITT analysis

Table 3. Extended Linde Internal Validity Scale

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix S2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7-8
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	n/a
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a

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Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	n/a
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	n/a
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-11
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	n/a
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-18
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

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