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REPORTING OF PATIENT-REPORTED OUTCOMES IN RCTS FOCUSED ON TINNITUS: A META STUDY

Contributions:
A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

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Abstract

Background: The inclusion of patient-reported outcomes (PROs) in randomized controlled trials (RCTs) supplements outcomes of treatment efficacy with the patient's perspectives. The aim of this study was to evaluate reporting completeness of PROs in RCTs pertaining to tinnitus, using the Consolidated Standards of Reporting Trials (Consort-PRO) adaptation.

Material and methods: We performed a search of Medline, Embase, and Cochrane Central Register of Controlled Trials (Central) for published RCTs related to tinnitus with at least one PRO measure from 2006 to 2020. Two investigators screened RCTs for inclusion. Using the Consort-PRO adaptation in an independent, masked fashion, investigators then evaluated all included RCTs. Similarly, all RCTs were evaluated using the Cochrane Collaboration Risk of Bias 2.0 tool. To assess relationships between trial characteristics and completeness of reporting, bivariate regression analyses were used.

Results: From 878 publications, 37 RCTs met inclusion criteria. The mean Consort-PRO completeness of reporting across RCTs was 51.2% (SD = 20.8). Evaluation of our secondary outcome – assessment of study characteristics – demonstrated significantly higher completeness of reporting when (1) the Consort guideline was mentioned within the RCT ($p = 0.01$); (2) trials had 'some concerns' for bias ($p = 0.001$); and (3) trials had 'low' risk of bias ($p = 0.001$).

Conclusions: Our study found that there was subpar Consort-PRO adherence within tinnitus RCTs. Due to the variance in symptom severity in tinnitus and the importance of PROs to clinical practice, we recommend journals include instructions to authors to use the Consort-PRO guideline before they publish RCTs.

Keywords: quality of life • tinnitus • patient reported outcomes • Consort-PRO • meta-epidemiological • risk of bias

RAPORTOWANIE WYNIKÓW RAPORTOWANYCH PRZEZ PACJENTÓW W RCTS DOTYCZĄCYCH SZUMÓW USZNYCH: METAANALIZA

Streszczenie

Wprowadzenie: Włączenie wyników raportowanych przez pacjentów (*patient-reported outcomes*, PROs) do randomizowanych badań z grupą kontrolną (*randomized controlled trials*, RCTs) uzupełnia informację o skuteczności leczenia o perspektywę pacjenta. Celem badania była ocena kompletności raportowania PROs w RCTs dotyczących szumów usznych, z zastosowaniem zaadaptowanych Skonsolidowanych Standardów Raportowania Badań (Consolidated Standards of Reporting Trials Consort-PRO).

Materiał i metody: Przeszukiwaliśmy następujące bazy: Medline, Embase oraz Cochrane Central Register of Controlled Trials (Central), wybierając RCTs zawierające co najmniej jeden pomiar PROs opublikowane w latach 2006–2020. Dwóch badaczy dokonało przesiewu RCTs pod kątem włączenia do badania. Następnie badacze przeprowadzili niezależną, anonimizowaną ocenę wszystkich RCTs włączonych do badania z zastosowaniem zaadaptowanych Consort-PRO. Podobnie wszystkie RCT zostały ocenione z zastosowaniem narzędzia Cochrane Collaboration Risk of Bias 2.0. W celu oceny zależności pomiędzy cechami badania a kompletnością raportowanych wyników przeprowadzono dwuczynnikową analizę regresji.

Wyniki: Na 878 publikacji 37 RCTs spełniało kryteria włączenia do badania. Średnia kompletność raportowania według Consort-PRO dla badanych RCTs wynosiła 51,2% (SD = 20,8). Ocena drugorzędnego wyniku – cech badania – wykazała statystycznie istotnie wyższą kompletność raportowania gdy: 1) wytyczne Consort były wspomniane w RCT ($p = 0.01$); 2) w badaniu wzmiankowano 'pewne obawy' odnośnie stronniczości ($p = 0{,}001$); i 3) badanie miało 'niskie' ryzyko stronniczości ($p = 0{,}001$).

Wnioski: Wyniki naszego badania wskazują, że przestrzeganie wytycznych Consort-PRO w RCTs na temat szumów usznych było poniżej normy. Ze względu na różnice w uciążliwości objawów szumów usznych i znaczenie PRO w praktyce klinicznej zalecamy, aby czasopisma włączyły do instrukcji dla autorów zalecenie stosowania Consort-PRO w publikowanych RCTs.

Słowa kluczowe: jakość życia • szumy uszne • wyniki raportowane przez pacjenta • Consort-PRO • metaanaliza epidemiologiczna • ryzyko stronniczości

Introduction

Tinnitus is a common complaint affecting approximately 20% of the general population [1]. Due to the debilitating nature of tinnitus, its economic cost is not only limited to the direct cost of healthcare, but also includes the indirect costs from lost wages and loss of productivity [2,3]. One study estimated the incremental cost per quality-adjusted life-year amounted to $24,580 in 2011 [4]. Treatment of tinnitus is difficult and often aimed at improving quality of life (QoL) and aiding in return to work and function [5]. While interventions may be successful at treating physical and functional aspects of tinnitus, they do not fully address psychosocial aspects, such as anxiety or depression. For example, one study found that nearly half of patients with tinnitus also had a psychiatric comorbidity [6]. Another study in the field of otolaryngology found assessments of tinnitus had poor correlation to symptoms; thus, the measurement of patient reported outcomes (PROs) adds value to treatment assessment and quality [7]. Given the high prevalence, economic consequences, and psychological effects of tinnitus, it is important to measure PROs to track the effectiveness of interventions.

PROs may be used to make patient care decisions, inform reimbursement decisions, and guide health policy [8]. PROs for tinnitus evaluate patient experience, as limited objective measures exist for quantifying symptoms and severity. While RCTs have typically assessed primary outcomes investigating treatment efficacy, chronic diseases such as tinnitus may require the use of self-reported measures in the absence of objective clinical signs and measures [9]. It is therefore critical that trialists not only measure relevant PRO constructs but also report them in a clear and complete manner.

In 2013, the Consolidated Standards of Reporting Trials (Consort) Statement – the gold standard reporting guideline for clinical trials – was expanded to include information regarding PROs [10]. Consort-PRO includes 5 PRO-specific items that aim to increase transparency of reporting. This addition aims to improve reporting and "facilitate interpretation of PRO results for use in clinical practice" [8]. Some evidence suggests that the use of Consort-PRO has been associated with improved and more complete PRO reporting [11]; however, additional investigations are warranted. Given the importance of PROs to tinnitus, our study seeks to evaluate reporting completeness of PROs in RCTs pertaining to tinnitus, using a Consort-PRO checklist adaptation. In addition, we hypothesize that RCTs published after Consort-PRO was implemented will report their findings more completely.

Material and methods

Study design

This is a meta-epidemiological investigation including data extracted from published RCTs regarding tinnitus. As our study does not meet the regulatory definition of a human participant study, it was not subject to institutional review board oversight. We followed reporting guidelines for meta-epidemiological studies by Murad & Wang [12].

Search strategy

In consultation with a medical research librarian, one investigator (R.O.) used the Ovid interface to search Medline, Embase, and the Cochrane Central Register of Controlled Trials (Central) for published RCTs about tinnitus. To maximize sensitivity for identifying RCTs, the Cochrane highly sensitive search strategy – which is a validated filter for OVID interfaces – was used [13]. The search string used was uploaded to Open Science Framework (OSF) [14].

Eligibility

We included randomized clinical trials that were published between 2006 and 2020, that addressed the symptoms of tinnitus as a primary outcome, and were published in the English language. Observational studies, animal studies, case reports, meta-analyses, systematic reviews, clinical trial protocols, cost-effective studies, secondary analysis, letters to the editor, and trials without a PRO measure were excluded.

Selection process

A systematic review screening platform, Rayyan (https://rayyan.qcri.org/), was used after the completion of the literature search, and our returned studies were combined and uploaded. Two investigators (R.B. and K.S.) performed title and abstract screening in a masked, duplicate fashion. A third author (M.K.) was available for adjudication of disagreements following screening.

Data collection process

Two investigators (R.B. and C.L.) performed masked, duplicate extraction of Consort-PRO adaptation checklist items using a pilot-tested Google form. In order to calibrate extraction, we extracted 3 RCTs that were not in our sample until consensus was achieved. Training for risk of bias extraction was done using material from Cochrane [15]. The risk of bias evaluation was performed in a similar

fashion, two investigators (K.S., S.J.) used a masked, duplicate method. Following data extraction and the risk of bias evaluation, the investigators resolved all discrepancies; a third investigator (B.H.) was available to resolve disagreements.

Data items

We used the Consort-PRO checklist adaptation developed by Mercieca-Bebber [11] to assess the completion of our primary objective in terms of mean percent completion (see scoring of Consort-PRO adaptation). Our secondary objective assessed relationships between the mean completeness of PRO reporting and trial characteristics. As listed in **Table 1**, the trial characteristics analyzed were: (1) year of publication (before or after 2014, a year following the publication of Consort reporting guidelines); (2) intervention of RCT (e.g. drug or surgical technique); (3) conflict of interest statement; (4) journal endorsement of Consort-PRO; (5) citation of Consort-PRO within the publication; (6) whether an RCT used a PRO as a primary or secondary outcome; (7) risk of bias assessed by the Cochrane Risk of Bias 2.0 tool (see *Evaluating risk of bias* below); (8) the length of PRO follow-up time; and (9) sample size of the trial.

Journal endorsements of Consort were recorded as follows: *not mentioned, recommended,* or *required*. This data item was evaluated by reviewing the instructions to authors pages for mention of the guidelines.

We evaluated each RCT for likely sources of bias using the Cochrane Risk of Bias 2.0 tool. The following bias domains were evaluated: (1) bias arising from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in measurement of the outcome; (5) bias in selection of the reported result; and (6) overall risk of bias.

Scoring Consort-PRO

The scoring methodology was adapted from Mercieca-Bebber [11] as follows. Due to the difficulty in verifying this criterion, we removed Item 4a of Consort-PRO (the use of PROs in eligibility or stratification) from scoring in our study. Adherence to this item was coded as 'yes' or 'no'. A maximum value of 0.5 or 1 was allocated when information for an item was present. Items that were scored with the maximum value (1, or 0.5 if the item was double-barreled) were considered 'complete'; however items that did not reach maximum value were considered 'not complete'. RCTs were scored partially complete for item P1b if an RCT reported the PRO measure in the study, but did not identify whether the PRO was a primary or secondary outcome. Item P1b could be scored as 0, 0.5, or 1 depending on the information available. Item 7a was dependent on whether or not the PRO measure was reported as a primary outcome. As a result of this dependency, RCTs with primary PRO outcome could be scored with a maximum of 15, versus RCTs with a secondary outcome which could have a maximum score of 14. We calculated percent completeness of the checklist per RCT by adding items and dividing by the total of possible items.

Evaluating risk of bias

A decision algorithm has been developed by the Cochrane Collaboration to evaluate risk of bias. In the event of partially divergent assessments on bias domains (e.g. if an investigator answered 'yes' and another answered 'partial yes'), the overall risk of bias judgement is not changed. The overall risk of bias domain was evaluated per the Excel tool provided by Cochrane as 'high', 'some concerns', or 'low' risk [16–18].

Data analysis

Primary outcomes were addressed by calculating the mean completion percentage of the Consort-PRO adaptation across all RCTs in the sample. Frequencies were reported and percentages for the trial characteristics (listed in *Data items* and **Table 1**). We used bivariate regression models to determine the association between mean completion percentage of Consort-PRO adaptation and the trial characteristics within *Data items* to address our secondary outcome. Lastly, the frequency and percentage of individual items on the Consort-PRO adaptation was reported for all RCTs.

Reproducibility

We uploaded our study protocol, data sheets, analysis scripts, a data dictionary, and extraction forms to OSF so as to promote the transparency, reproducibility, validity, and reliability of our study. This investigation was conducted in tandem with other studies addressing completeness of reporting in other fields of medicine using similar methodology.

Results

Systematic search and screening

Our systematic search returned 878 records. Once duplicates were removed, 583 records were then screened by title and abstract. Following this, 105 RCTs were evaluated through full-text screening. A total of 37 RCTs were included in our final sample. Exclusion reasoning is shown in **Figure 1**.

RCT characteristics

There were 20 of 37 (54.1%; **Table 1**) RCTs published after 2014. The most common intervention was psychosocial therapy (12/37, 32.4%); 18 of the 37 (48.6%) reported no conflict of interest. Nearly half the RCTs (18/37, 48.6%) were published in journals that had no mention of reporting guidelines, and 6 (of 37, 16.2%) RCTs cited Consort reporting in the article. All of the included RCTs had PROs as a primary outcome. The distribution of risk of bias assessments were as follows: 37.8% (14/37) were 'high' risk, 45.9% (17/37) were evaluated as 'some concern,' and 16.2% (6/37) were 'low' risk.

Completeness of reporting according to Consort-PRO adaptation

The mean completeness of reporting across RCTs was 51.2% (SD = 20.82). For all RCTs in this study, item 2a

Table 1. Characteristics of 37 randomized controlled trials and bivariate associations with Consort-PRO completion

Characteristic	Total	Coef. (SE)	*t*	*p*
Year of publication, No. (%)				
< 2014	17 (45.9)	1 [Ref]	–	–
≥ 2014	20 (54.1)	9.06 (6.8)	1.33	0.191
Intervention of RCT, No. (%)				
Combination	2 (5.4)	1 [Ref]	–	–
Device	7 (18.9)	–17.86 (14.22)	–1.26	0.219
Drug	7 (18.9)	0.24 (14.22)	0.02	0.987
Other	1 (2.7)	5 (21.72)	0.23	0.82
Psychotherapy	12 (32.4)	18.61 (13.55)	1.37	0.18
Therapy	4 (10.8)	–2.5 (15.36)	–0.16	0.872
Transcranial magnetic stimulation	4 (10.8)	2.5 (15.36)	0.16	0.872
Includes COI statement, No. (%)				
No statement	16 (43.2)	1 [Ref]	–	–
Reports COI	3 (8.1)	9.1 (13.2)	0.69	0.496
Reports no COI	18 (48.6)	8.17 (7.21)	1.13	0.265
Journal requirement of reporting guidelines, No. (%)				
Not mentioned	18 (48.6)	1 [Ref]	–	–
Not required	1 (2.7)	22.59 (20.97)	1.08	0.289
Recommended	7 (18.9)	–11.22 (9.09)	–1.23	0.226
Required	11 (29.7)	6.53 (7.81)	0.84	0.409
Mention of Consort or Consort-PRO within RCT, No. (%)				
No	31 (83.8)	1 [Ref]	–	–
Yes	6 (16.2)	23.14 (8.57)	2.7	**0.011**
PRO as a primary or secondary outcome, No. (%)				
Primary	37 (100.0)	1 [Ref]	–	–
Overall ROB, No. (%)				
High	14 (37.8)	1 [Ref]	–	–
Some concern	17 (45.9)	23.11 (6.2)	3.73	**0.001**
Low	6 (16.2)	29.84 (8.38)	3.56	**0.001**
Length of PRO follow-up				
3 months or less	13 (38.2)	1 [Ref]	–	–
3+ to 6 months	8 (23.5)	17.28 (9.25)	1.87	0.072
6+ months to 1 year	4 (11.7)	4.36 (11.77)	0.37	0.714
1 year +	9 (26.5)	17.69 (8.92)	1.98	0.057
Sample size				
Mean (SD)	117.1 (115.7)	0.06 (0.03)	2.18	**0.036**

Abbreviations: Consort-PRO, Consolidated Standards of Reporting Trials – Patient Reported Outcomes; RCT, randomized controlled trial; COI, conflict of interest; ROB, risk of bias.

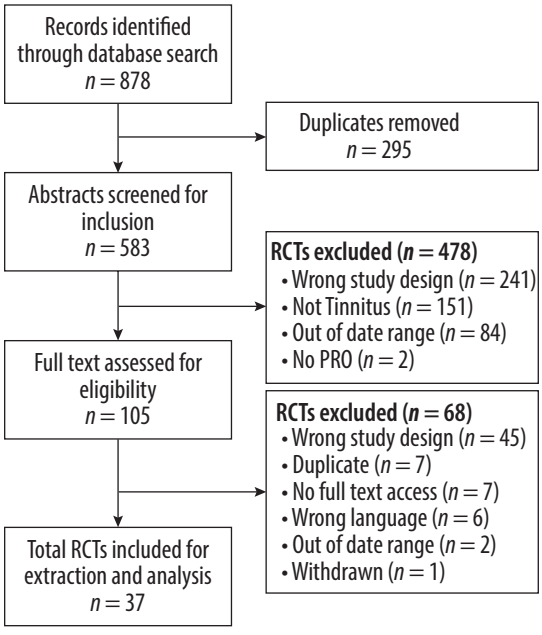

Figure 1. Exclusion criteria

– *rationale for including PRO outcome* – was the most completely reported item (32/37, 86.5%). Item P2bii – *PRO domains in hypothesis* – was not reported in any of the RCTs. Since all studies in our sample used a PRO measure as a primary outcome, item 7a was assessed for all RCTs in our sample with a (16/37, 43.2%) completeness. All other completeness of reporting scores for individual items are shown in **Table 2**.

Associations between PRO outcomes, completion, and study characteristics

Bivariate analyses revealed that RCTs published after 2014 were not more complete than RCTs prior to 2014 (Coef. = 9.06, SE = 6.8; $t = 1.33$, $p = 0.19$). Mention of Consort within the article was associated with 23.1% (SE = 8.57; **Table 1**) more complete reporting when compared to RCTs that did not mention of Consort ($t = 2.70$, $p = 0.011$). RCTs that were not assessed as 'high' risk for the bias assessment had less complete reporting. For instance, 'low' risk RCTs were 29.8% (SE = 8.38) more complete ($t = 3.56$, $p = 0.001$), while RCTs assessed with 'some concerns' reported 23.1% (SE = 6.2) more completely ($t = 3.73$, $p = 0.001$).

Discussion

Our study found that RCTs focused on tinnitus had incomplete PRO reporting with mean Consort-PRO checklist adaptation completeness of 51%. The results from our bivariate analyses showed a significant correlation between higher Consort-PRO completion and both a lower risk of bias as well as whether the Consort guideline was cited within the RCT. In this discussion, we address how completeness of PRO reporting can have effects on the generalizability of PRO measures and demonstrate the need for standardization of PRO reporting.

Due to the limited objective measures that exist for tinnitus symptoms and severity, all the RCTs in our study included PROs as their primary outcome. This finding contrasts with other fields of study where the measurement of PROs as a primary outcome is less common [19–21]. A study of Consort-PRO reporting found a significant association between PROs included as a primary outcome and more complete reporting [22]. A series of studies in oncology found that secondary publications of trials for which PROs were the primary focus were associated with more complete Consort-PRO reporting than trials that included PROs in their primary articles [19–21]. For example, a study by Bylicki [19] found that when PRO data is published separate from the original manuscript, reporting was nearly 2.5 times more complete than the original article. For RCTs specific to tinnitus – where PROs are the primary outcome – we would expect the trend to apply and see higher Consort-PRO scores; however, in our study this was not the case. In fact, compared to these studies, we found specific items that were infrequently reported within our sample.

Only a few studies in our sample stated the mode of administration of PRO questionnaires. An important part of the PRO validation process depends on the mode of administration [23]. For example, the collection of a PRO by a face-to-face interview may change the way a patient answers versus a private self-reported paper questionnaire [8]. One study found poor reporting of PRO administration methods and deviations from the trial protocol were common, along with data that supported the need for more consistent modes of administration [24]. Failure to report the administration mode may reduce the validity of PRO use in future studies or in the general population [25].

Complete reporting of methods allows for the evaluation of the quality of evidence being presented in a clinical trial. Of concern, only 43% of RCTs in our study reported statistical methods of obtaining sample size. This agrees with a systematic review by Kikidis [26] which found that in addition to lack of reporting of sample size determination in RCTs regarding tinnitus, there were other flaws in methodology that were related to randomization and number of participants. These gaps in reporting of methodology lead to decreased reliability of tinnitus RCTs, as it limits the reproducibility of these trials. The consequences of these limitations directly impede patient care by preventing research and progress towards treatment for a disease that is common and debilitating [27].

Further, demographic tables including baseline PRO measures were included in only 32% of RCTs extracted. Lacking this information makes it difficult to predict the validity of trial findings. For example, a study about the use of PROs within pediatric otolaryngology found that they were intended for adult populations, thereby reducing their reliability when used on children [28,29]. It is pertinent to the reliability of a PRO measure that the participant characteristics of the study are reported adequately, as the validity of the PRO is contingent on the population to which it is applied [28]. Additionally, due to the wide range of tinnitus symptom severity, there is inherent heterogeneity within these patient populations, making it vital to accurately describe the study demographics and clinical characteristics to ensure generalizability of clinical trial findings to other tinnitus patients [27].

Table 2. Completion of Consort-PRO adaptation by primary objective designation

Consort-PRO item (*N* = 37)	Complete	Not complete
	n (%)	*n* (%)
Introduction		
P1b. Abstract – PRO as primary/secondary outcome	12 (32.4)	25 (67.6)
2a. Rationale for including PRO outcome	32 (86.5)	5 (13.5)
P2bi. PRO hypothesis present	5 (13.5)	32 (86.5)
P2bii. PRO domains in hypothesis	0 (0)	37 (100)
Methods		
P6ai. Evidence of PRO instrument validity	29 (78.4)	8 (21.6)
P6aii. Statement of the person completing the questionnaire	30 (81.1)	7 (18.9)
P6aiii. Mode of administration (paper, e-PRO)	5 (13.5)	32 (86.5)
P7a. How sample size was determined (not required unless PRO is a primary outcome)*	16 (43.2)	21 (56.8)
P12a. Statistical approach for dealing with missing data (imputation, exclusion, other)	13 (35.1)	24 (64.9)
Results		
13ai. Report no. questionnaires submitted/available for analysis at baseline	27 (73.0)	10 (27.0)
13aii. Report no. questionnaires submitted/available for analysis at principal time point for analysis	21 (56.8)	16 (43.2)
15. Demographics table includes baseline PRO	12 (32.4)	25 (67.6)
16. Number of pts (denominator) included in each PRO analysis	14 (37.8)	23 (62.2)
17ai. PRO results reported for the hypothesised domains and time point specified in the hypothesis – OR reported for each domain of the PRO questionnaire if no PRO hypothesis provided	13 (35.1)	24 (64.9)
17aii. Results include confidence interval, effect size or some other estimate of precision	31 (83.8)	6 (16.2)
18. Results of any subgroup/adjusted/exploratory analyses	6 (16.2)	31 (83.8)
Discussion		
P20. PRO study limitations	22 (59.5)	15 (40.5)
P21. Implications of PRO results for generalizability, clinical practice	30 (81.1)	7 (18.9)
22. PROs interpreted in relation to clinical outcomes	23 (62.2)	14 (37.8)

* Item P7a only applies to PROs identified as primary outcomes.

Our results also demonstrated low adherence to PRO domain reporting. Only 13% of RCTs in our study had a hypothesis, and none provided complete reporting of PRO domains within the hypothesis. Importantly, results of each PRO domain were only reported by about one-third of the studies included. Further, a study reviewing PRO reporting in oncology RCTs found that over half of RCTs reported results for PRO domains [19]. Although the inconsistent reporting of domains could be specific to certain fields of medicine, for tinnitus especially it may be PRO specific. More than half of the RCTs in our study used the Tinnitus Handicap Inventory (THI), which is the most commonly used PRO for the assessment of tinnitus and has been validated in multiple languages [30]. Originally the THI was described with three domains – functional, emotional, and catastrophic – but our study found only one RCT that gave the results of all three. Psychometric evaluations of the THI have reported that, upon examining several structural models through factor analytic techniques, a one-factor solution, in which the 3 original subscales are combined, produced the best model fit. Hence, they recommended that the THI be reported as a single-scale score which measures a unidimensional construct [31]. The inconsistencies in the reporting of domains of the THI further elucidates the need for standardization of these PROs.

Several studies have shown that clinician confidence in using PROs in clinical practice is lacking [32–35]. Perhaps one area worth further investigation is the way in which PROs are reported in RCTs. Because our study found that Consort-PRO adherence was deficient, we recommend that trialists adhere strictly to reporting guidelines in order to provide the most information and context to clinician readers. Deficiencies in completeness of reporting of

PROs used in tinnitus RCTs creates challenges in reproducibility and use, as PRO administration and response must be clearly stated in order to precisely apply results to clinical practice and future RCTs.

Our study found incomplete overall Consort-PRO adherence. Though we included studies in our analysis that were completed prior to the publication of the Consort-PRO checklist, our study found that there was no significant improvement in completeness of outcome reporting. This finding might have occurred because of a lack of awareness of the Consort-PRO checklist, as well as the challenges experienced while running a clinical trial. For that reason, we recommend that journals require the use of Consort and Consort-PRO for RCTs, as the literature shows that mention of these is correlated with more complete reporting [24]. Additionally, we agree with the recommendations of Powell [28] that the increased use of PROs in RCTs among different populations will increase the utility of PROs; however, without complete reporting of PRO outcomes it is difficult to mitigate bias and assess the quality of evidence for clinical decision making.

Strengths and limitations

Our study has both strengths and limitations. In regards to the first, we trained each investigator for each instrument. Investigators who extracted studies with the risk of bias tool completed training from Cochrane and those who extracted with the Consort-PRO checklist adaptation extracted RCTs until consensus was reached. Additionally, they performed screening and extraction in duplicate and in a masked fashion. Another strength of our study is the reproducibility and transparency we achieved by making our protocol accessible through the open science framework [14]. Our study also has limitations, the first of which is the subjectivity of investigator response within Cochrane's Risk of Bias tool and the Consort guideline [36]. Although we did a full systematic search including Medline, Embase, and Central, there are likely RCTs that were not included which may have been pertinent to our study. Lastly, due to the meta-epidemiological study design, our results and conclusions may not be generalizable to the field of otolaryngology.

Conclusions

Our study found poor overall Consort-PRO adherence in tinnitus RCTs. We found deficiencies in reporting of specific methodological and statistical items, and in study results. These deficiencies create uncertainties in the validity of PROs used and the generalizability of the evidence in the RCTs. Our results show specific areas for improvement, which is vital to further disseminating research and making progress towards improving symptom severity and quality of life in patients with tinnitus.

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