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Preliminary evidence on the uptake, use and benefits of the CONSORT-PRO extension

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Preliminary evidence on the uptake, use and benefits of the CONSORT-PRO extension

Complete, transparent reporting of randomised controlled trials (RCTs) is essential if readers are to understand study objectives, evaluate methodology and interpret results [1]. Yet many RCTs fail to adequately report this information, resulting in significant research waste [2]. The CONsolidated Standards Of Reporting Trials (CONSORT) Statement 2010 [3] provides a minimum set of evidence-based criteria for high-quality reporting of RCTs. The CONSORT Statement has been endorsed by over 600 medical journals, by major editorial organisations and has been cited in over 8000 publications [4]. Trials published in journals that endorse the CONSORT Statement are reported more completely than those in non-endorsing journals [5]; and improved reporting of RCTs over time in thoracic surgery [6] and traumatic brain injury [7] has been attributed to the use of the CONSORT statement.

Yet the CONSORT Statement does not specifically address the reporting of patient-reported outcomes (PROs). High-quality PRO evidence provides the patient's perspective on the impact of disease and treatment on everyday functioning and quality of life [8] and is critical for a patient-centred approach to clinical care and policy.

The CONSORT-PRO Extension was released in 2013 in response to a recognised need for specialised, expert-endorsed PRO reporting guidance[9]. Prior reviews indicated suboptimal PRO reporting [10,11], which limited the potential for PRO evidence to impact practice, thus representing a waste of research effort. CONSORT-PRO aims to facilitate translation of high-quality PRO evidence to clinical practice and policy [12]. It adds five PRO-specific extension items to the CONSORT-2010 Statement and provides PRO-specific elaborations to nine CONSORT-2010 items [9]. In this paper, the International Society for Quality of Life Research (ISOQOL) Best Practices for PRO Reporting Taskforce (hereafter 'ISOQOL Reporting Taskforce') sought to: 1) assess the uptake of CONSORT-PRO by identifying articles that cited the CONSORT-PRO Extension in the first three years since its release; 2) identify published RCTs that cited CONSORT-PRO and describe their adherence to the statement; 3) compare the quality of PRO reporting in RCTs that cited CONSORT–PRO to a control sample; 4) identify predictors of CONSORT-PRO adherence; 5) identify which journals publish RCTs with PRO endpoints, so that these journals can be included in future knowledge transfer efforts led by the ISOQOL Reporting Taskforce; and 6) describe to what extent journals publishing RCTs with PRO endpoints endorse CONSORT-PRO.

Methods

Identification of publications citing CONSORT-PRO

Medline (Web of Science), EMBASE and Google were systematically searched for all articles that cited the CONSORT-PRO extension: 27 February 2013 (release date)-17 December 2015. This was achieved by identifying the CONSORT-PRO manuscript[9] within each search engine and selecting the 'search citing articles' option. Search results were coded by two authors (RMB, JR) according to publication type, e.g. RCT, systematic reviews, etc.

Adherence to CONSORT-PRO

RCTs that reported PRO results and cited CONSORT-PRO were considered "cases". A comparable control sample of 40 RCTs was identified, frequency-matched[13] to cases on: year of publication, disease (oncology/non-oncology), journal impact factor (IF), and PRO endpoint status (primary or secondary).These variables were agreed by all authors to potentially influence the quality of PRO reporting. Frequency-matching enables a fair comparison by ensuring there is a balanced mix of key variables across the sample. This approach was necessary as it was not possible to match cases and controls individually on each of the four specified variables. Controls were sourced firstly from journals that published cases (n=33 publications, 15 journals) matching on at least one other key variable (publication year, disease, PRO endpoint status), and the remaining RCTs (n=7, from 6 journals) were identified through Medline. The control sample was finalised objectively by the team prior to any publications being evaluated, where each was selected to achieve the best possible balance at the sample level.

Review of adherence to CONSORT-PRO items

Each publication was reviewed against the CONSORT-PRO checklist adapted for review purposes (**Appendix 1**) by two independent authors (among RMB, JR, PH, LM) and discrepancies were resolved upon discussion (RMB, JR, MK). We adapted the CONSORT-PRO checklist by excluding item 4a (whether PROs used in eligibility or stratification) because it was impossible to check if trials used such criteria, and hence whether reporting was required, without checking the trial protocols. Adherence to this item is described. Additionally, checklist items that included multiple recommendations (e.g. items P2b, P6, 13a, 17a, P20/21) were each divided into separate sub-items for the evaluation, as shown in Appendix 1. Item 7a (PRO sample size calculation) is required only for RCTs with a primary PRO endpoint, and assessed accordingly. For each checklist item, the maximum item score (0.5 or 1) was awarded if the publication reported information required, except for Item P1b, where publications were awarded 1 point if the abstract reported the PRO and its status as a primary or secondary endpoint, 0.5 points if the PRO was mentioned but its endpoint status was unclear, zero points if the PRO was not mentioned in the abstract.

Comparison of adherence to CONSORT-PRO between cases and controls

Two adherence scores were calculated for each publication: 1) the five CONSORT-PRO extension items alone, giving a score out of 7 ('Extension adherence'); and 2) the 'total CONSORT-PRO adherence' (the complete set of CONSORT-PRO items, maximum score: 14 for RCTs with a secondary PRO endpoint and 15 for primary PRO endpoints). Scores were converted to a percentage to enable pooling of all RCTs for analysis, regardless of PRO endpoint status. We conducted two independent t tests, one for each adherence score, to compare mean adherence between cases and controls.

We also compared each group's (cases and controls) overall adherence to CONSORT-PRO items and graded adherence according to pre-specified thresholds. If more than 80% of RCTs within each group addressed the CONSORT-PRO item we interpreted compliance to be "good", "moderate" if 50-79% RCTs addressed the item, and "poor" if ≤49% of RCTs addressed the item.

Predictors of higher CONSORT-PRO score

We pooled cases and controls (n=66) to assess predictors of 'total adherence' and 'extension adherence' scores, running separate general linear models for each score. The models included the following factors: journal endorsement of CONSORT-PRO (three levels: CONSORT-PRO endorsed,

CONSORT or EQUATOR (Enhancing the QUAlity and Transparency Of health Research)[14] endorsed only, No guidelines endorsed); PRO endpoint status (primary/secondary); whether a CONSORT-PRO author was involved in the RCT (Y/N); whether CONSORT-PRO was cited (Y/N) and whether the PRO was reported in a dedicated paper (Y/N); and journal IF as a covariate, using backwards deletion. These covariates were pre-specified by Taskforce members as potentially affecting CONSORT-PRO adherence. We intentionally limited the number of covariates in our model to one predictor per 10 cases to avoid over-fitting [15]. We did not include year of publication in the model due to limited range (2013-2015), but examined this separately using Pearson correlation (α=0.05). All analyses were conducted using IBM SPSS Statistics 24.

Identification of high-impact journals publishing RCTs with PRO endpoints

We identified a list of highest impact journals publishing RCTs with PRO endpoints by searching 45 relevant Thomson Reuters journal subject categories [16] (Appendix 2), which were independently selected and agreed-on by three authors (JR, MP, MB). Journals were ranked by IF (highest to lowest). We then searched Medline using: 1) journal title (working down the list); 2) year (2014-2015); and 3) "Quality of life" OR "patient reported outcome*" AND "randomized controlled trial"; until we had identified the 100 top-ranked journals that published at least one RCT with a PRO endpoint during 2014-2015.

Journals endorsing CONSORT-PRO

The "Instructions to Authors" of each of these journals' websites were screened to determine whether they recommended compliance with EQUATOR, CONSORT and/or CONSORT-PRO guidelines, the strength of these recommendations and whether authors were required to submit CONSORT checklists or flow diagrams, by two authors (JR, MP) and discrepancies were settled with a third author (MB). Recommendations were coded on a study-specific ordinal-scale, as follows: 1) "mandatory:" defined as use of strong language in relation to reporting guidance, e.g. "must conform", "mandatory", "required"; 2)"strongly recommended:" journals that recommended use of guidelines without mandating them, and used less binding language, e.g. "please send", "should submit"; and 3)"suggested:" journals that simply suggested use of reporting guidelines, e.g. "we encourage you", "will not insist on", "may provide" or 4) "mentioned without recommendation:" if guidelines were cited in author instructions but no specific recommendations were made, e.g. "to find reporting guidelines, visit…"; or 5) "No mention:" when no recommendations or reference to reporting guidelines were provided.

Results

Publications citing CONSORT-PRO

We identified 214 unique articles that cited CONSORT-PRO (Figure 1); 27 (13%) articles in 2013, 90 (42%) in 2014, 94 (44%) for 2015 (at 17 December) and a further 3 (1%) dated ahead of print to 2016. The journals citing CONSORT-PRO most often were *Health and Quality of Life Outcomes, Journal of Clinical Oncology, PLOS One and Quality of Life Research, each with 6 (3%) citing articles; Cancer (n=5, 2%);* and *Journal of Clinical Epidemiology* (n=4, 2%).

Twenty-eight (13%) of the citing articles were RCTs, two of which were excluded from further analysis as they cited CONSORT-PRO incorrectly (i.e. the RCT did not include a PRO endpoint and should rather have cited CONSORT-2010 (**Figure 1**)). Remaining citations were from opinion or discussion papers (n=69, 32%), systematic reviews (n=40, 25%), other original research reports (n=20, 9%), guidelines/development of guidelines (n=13, 6%), methodological studies (n=14, 7%), non-patient studies (n=8, 4%), non-English original research (n=5, 2%), research protocols (n=2, 1%) and conference presentations (n=2, 1%). Of the 26 RCTs, the majority were oncology trials (n=10, 39%), fibromyalgia (n=3, 11%), haematology (n=2, 8%), genetic counselling (n=2, 8%) and weight management (n=2, 8%). 44/214 citing articles (including 3 RCTs) had a co-author who was involved in the development of CONSORT-PRO[12,9] or its predecessor, the ISOQOL PRO reporting standards [17].

RCT adherence to CONSORT-PRO: comparison of cases to controls

Overall adherence to CONSORT-PRO

Characteristics of RCT "cases" (RCTs that cited CONSORT-PRO) and "controls" are presented in **Table 1**, and RCTs are listed in **Appendix 3**. The 26 cases had significantly higher total CONSORT-PRO adherence scores (mean 77.7% of items, range: 46.7-100%), compared to controls (mean 67.6%, range: 25.0-96.4%), t=2.64, p=0.01.

For the extension adherence score, a larger difference was found between cases (mean 77.5%, range 28.6-100%) and controls (mean 59.5%, range 21.4-92.9%), t=4.50, p<0.001.

Item-level comparisons are presented in **Table 2**. Cases and controls had good overall compliance to Items 2a (Rationale for PRO endpoint) and Item 17ai (reporting results of appropriate PRO domains); and both groups had poor compliance for Items P1b (PRO identified as RCT endpoint in abstract), and P6aiii (mode of questionnaire administration). Overall, cases had good compliance for a higher proportion of items (53% compared to 26% for controls), and a lower proportion of items with poor compliance (11% compared to 32% for controls).

Regarding item 4a, which was excluded from our scoring, none of the included RCTs described using PROs in stratification procedures, however 10 (15%) reported PRO-specific eligibility criteria, including inclusion of participant reaching a threshold PRO score (n=4, 6%) RCTs, ability to complete questionnaires (n=3, 5%), timely submission of baseline questionnaire (n=2, 3%). A further 9 (14%) RCTs described PRO-relevant eligibility criteria, including language proficiency (n=7, 11%) and ability to comply with trial procedures (n=2, 3%). Of these 19 RCTs reporting PRO-specific or relevant eligibility criteria, 6 (21%) were cases and 12 (63%) had a primary PRO endpoint.

Predictors of higher CONSORT-PRO score

There were three significant predictors of higher CONSORT-PRO total adherence score: 'citing CONSORT-PRO', 'journal endorsing CONSORT-PRO' and 'dedicated PRO paper' (R^2=0.48, p<0.001). In the model for the 5 extension items only, there were two significant predictors: 'citing CONSORT-PRO', 'journal endorsing CONSORT-PRO'(R^2=0.36, p<0.001).

We did not observe a relationship between year of publication and CONSORT-PRO total adherence score (r=0.11, p=0.39) or Extension adherence score (r=0.05, p=0.68).

Journals publishing RCTs with PRO endpoints

The journal subject categories search resulted in a list of 2,976 journals. The target of identifying the 100 top-ranked journals publishing RCTs with PRO endpoints was reached after reviewing 324 journals (IF range 55.873 to 4.613, **Appendix**). The 100 top journals published 397 RCTs with PRO endpoints during 2014 and 2015 (**Table 3**). Most of these RCTs were published in oncology (n=98 RCTs, 25%) and in general and internal medicine journals (n=52 RCTs, 13%).

Of the 26 RCTs (19 journals) included as cases in this study, 13 RCTs (50%) were published in seven journals on this top-100 list, namely: *Health Technology Assessment, Journal of Clinical Oncology, the European Journal of Cancer, European Urology, Lancet Neurology, Lancet Oncology, Pain*.

Journals endorsing CONSORT-PRO and strength of guideline recommendations

Of the 100 top-ranked journals that published a RCT with a PRO endpoint, 80 mentioned CONSORT in their instructions to authors and 11 mentioned CONSORT-PRO (**Table 4;** shaded grey). For 38 journals, it was mandatory for authors to adhere to the CONSORT guidelines. In contrast, no journals deemed it mandatory for authors to use CONSORT-PRO guidelines. A total of 14 journals requested a CONSORT checklist be completed, eight requested a CONSORT flowchart, and 38 requested both.

Seven of the 100 highest-impact journals published 13 (50%) of the 26 RCT cases in this study, and all seven journals strongly or moderately endorsed the CONSORT Statement; 4/7 (57%) cited the EQUATOR Network (without making a strong recommendation for using EQUATOR guidelines); and 2/7 (29%) endorsed CONSORT-PRO.

Of all 66 RCTs included in this study as cases or controls, 15 RCTs (23%) were published in two journals that specifically endorsed CONSORT-PRO (Namely *Journal of Clinical Oncology and PLOS One)* and 37 (56%) RCTs (published in 14 journals) endorsed use of CONSORT-2010 or the EQUATOR guidelines without specifically endorsing CONSORT-PRO. The remaining journals failed to endorse any reporting guidelines.

Discussion

This is the first study to describe the uptake of the CONSORT-PRO extension, and its association with the completeness of PRO reporting. CONSORT-PRO has been highly cited since its publication, although many of these citations are in review articles and discussion papers written by PRO experts rather than clinical trials experts. This has served the purpose of disseminating the guidance within relevant research contexts. The increasing number of RCTs citing CONSORT-PRO is encouraging. It suggests increased understanding of the need for complete and transparent PRO reporting for clear communication of research findings, the value of high-quality PRO data generally, and growing awareness of CONSORT-PRO.

Only 26 RCTs appropriately cited CONSORT-PRO during the study period, which represents a minute proportion of RCTs reporting PRO results overall in that period, given 26,337 RCTs with PRO endpoints were registered between 2007-2013 [18], and that we identified 397 RCTs including PROs published 2014-2015 in the 100 top-ranked PRO RCT journals alone.

We acknowledge that failure to cite CONSORT-PRO does not imply failure to use CONSORT-PRO; we merely use this metric to estimate the extent of awareness. We acknowledge potential barriers to citing CONSORT-PRO; for example some journals restrict the number of publication references and there is no obligation for authors who use CONSORT-PRO to cite it. Nonetheless, we suspect the main barrier to use of CONSORT-PRO is a widespread lack of awareness of its existence and/or importance.

Our finding that citing CONSORT-PRO was related to higher total CONSORT-PRO scores suggests that use of CONSORT-PRO facilitates more complete and transparent reporting. We observed an even larger difference between cases and controls for the extension adherence score. One possible explanation is that control RCTs used CONSORT-2010 to prepare their publications (nine CONSORT-PRO items are adapted from general items of CONSORT-2010). Alternatively, some of the 26 RCTs cases may not have used the full CONSORT-PRO checklist; rather only the five extension items, in preparing their manuscripts. If the latter is the case, this is a knowledge transfer concern requiring attention, as reporting the five extension items alone will omit key information and limit the potential for PRO results to impact clinical practice. For example, the need to report baseline PRO results and the number of participants included in PRO analyses are adapted from CONSORT-2010. There was also a large range in the CONSORT-PRO adherence scores of cases, revealing that awareness of CONSORT-PRO does not guarantee complete reporting. Many RCT abstracts mentioned the PRO but failed to indicate whether it was a primary or secondary endpoint. Again, these are knowledge transfer concerns requiring intervention to improve reporting practices and to ensure PRO results are interpreted accurately so they can appropriately inform patient care.

Recent reviews confirm that reporting of PRO endpoints remains unsatisfactory overall; particularly regarding the reporting of PRO hypotheses, methodology, missing data, and generalisability of results [19-26]. Failing to report this information is wasteful as it limits the potential for readers to appraise the effect of interventions on patient health status, and the potential for PRO systematic reviews to impact clinical recommendations and health policy [27,28]. It may also decrease clinicians' confidence in the value of PRO data [29]. These aforementioned reviews [19-24] predominately include RCTs published before CONSORT-PRO. We expect that adherence to CONSORT-PRO will improve with time, as awareness and uptake increases. We observed an upward trend in the number of CONSORT-PRO citations annually; from 27 in 2013 to 94 in 2015.

Our review highlighted that most high-impact journals publishing PRO RCTs do not yet recommend use of CONSORT-PRO. In fact, many failed to recommend any EQUATOR guidelines. Journal endorsement of reporting guidance was a significant predictor of higher CONSORT-PRO adherence scores in this study. Half the RCTs that cited CONSORT-PRO appeared in a top-ranked journal, all of which journals (n=7) recommended at least one of these reporting guidelines in their instructions to authors.

Therefore, the ISOQOL Reporting Taskforce urges journals to endorse EQUATOR guidelines, including CONSORT-PRO, particularly those that publish RCTs with PROs. Many journals already require submission of a CONSORT checklist and participant flow diagram, which may explain improvements in RCT reporting generally when assessed against CONSORT 2010 [6,7,5], lending further credibility to our argument that greater journal endorsement of CONSORT-PRO will improve the standard of PRO reporting. The fact that we obtained controls (i.e. articles that reported PRO RCTs but did not

cite CONSORT-PRO) from journals that endorsed CONSORT-PRO (albeit not strongly) potentially indicates that the strength of the recommendation may be an important factor in determining adherence to reporting guidelines.

Similar to past reviews [19,21,23], we found that reporting of PRO endpoints in a dedicated publication was a predictor of more complete reporting. Whilst detailed secondary PRO publications should be encouraged as they allow for presentation of additional analyses, the principal PRO findings should be reported in accordance with CONSORT-PRO and in the main RCT publication to facilitate interpretation of PRO results within the context of other endpoints, and to provide the patients' perspective to complement other trial information. This is particularly important to ensure PRO research efforts are not wasted.

Strengths

This is a comprehensive analysis of the uptake and impact of CONSORT-PRO using mixed methods. Publications that evidently used CONSORT-PRO were reviewed against comparable controls. All RCT publications and journal instructions to authors were independently reviewed by at least two authors using objective criteria.

Limitations

We attempted to choose controls from the same journals as the case RCTs, to ensure controls were of a comparable quality to cases. However this may have come at a cost to the representativeness in terms of overall standard of PRO reporting, particularly given that many of these journals endorsed some key reporting guidelines. It is possible that our control sample represents a higher-than-average picture of the overall standard of PRO-reporting, and that in reality, the difference in reporting standards of RCTs that do not use CONSORT-PRO guidance compared to those that do is likely to be much larger. Similarity of journals between groups may explain why we did not observe a relationship between journal IF and CONSORT-PRO adherence scores. We excluded the item on PRO eligibility or stratification criteria because we could not check trial protocols to determine whether this item should be reported, however we observed that a higher proportion of trials in the control sample reported PRO-specific or relevant criteria. Our approach of excluding this item from scoring has assumed that trials only reported this item if relevant to their trial. We do not believe that inclusion of this item in our adherence scoring would have impacted our results. Our review focuses on the first three years since CONSORT-PRO was published. It may be too early to observe the benefits of CONSORT-PRO guidance; these may become more evident over time as awareness and uptake increases. A similar review to ours should be undertaken in future.

Not all journals are listed in Thomson Reuter ratings and sorting methods other than by highest IF could have been used, e.g. by number of RCTs published. We focussed our study on RCT publications and journals, however other important stakeholders, such as funding bodies and professional research and clinical societies, also play an important role in the promotion of CONSORT-PRO [12]. Some notable examples of research organisations already promoting CONSORT-PRO include the EQUATOR network [14], CONSORT [30] and UK NIHR Research Design Service Resource[31] websites, which include direct links to CONSORT-PRO. Future research should review the extent to which key research and professional organisations, as well as the largest health research funding organisations, endorse CONSORT-PRO.

Conclusions

Reporting of PROs was more complete in RCT publications that cited CONSORT-PRO than in control publications. Additionally, reporting of the PRO endpoint in a dedicated publication, journal endorsement of CONSORT-PRO, and citing CONSORT-PRO were significant predictors of higher total CONSORT-PRO adherence scores. Many key journals do not endorse CONSORT-PRO in their instructions to authors. Although this should not stop authors from using CONSORT-PRO, journals are ideally placed to show leadership in recommending reporting guidance to facilitate scientifically robust reporting and to ultimately reduce research waste. The ISOQOL Reporting Taskforce endeavours to continue educating researchers on the importance of complete PRO reporting by disseminating and promoting CONSORT-PRO through health research journals, professional and research organisations and funding bodies.

Declaration of interests

Co-authors Calvert, Brundage and King were involved in the original development of CONSORT-PRO, however received no direct benefit from the findings reported here. Prof. Calvert has received grant funding from Macmillan, NIHR, Health Foundation and consultancy payments from Astellas Pharma, and Ferring Pharma, all of which are outside the submitted work. The potential conflicts have not had an impact on the design, conduct, or reporting of the submitted work. This project did not receive any funding.

Authors' Contributions

Rebecca Mercieca-Bebber: study concept, study design, study coordination, data collection, major analysis, data interpretation, wrote manuscript, edited and approved final manuscript.

Julie Rouette: study design, data collection, analysis, data interpretation, edited and approved final manuscript.

Melanie Calvert: study concept, study design, data interpretation, edited and approved final manuscript.

Madeleine King: study design, data interpretation, edited and approved final manuscript.

Lori McLeod: data collection, edited and approved final manuscript.

Patricia Holch: data collection, edited and approved final manuscript.

Michael Palmer: data collection, edited and approved final manuscript.

Michael Brundage: study concept, study design, data collection, data interpretation, edited and approved final manuscript.

Ethics statement

This article is an analysis of PRO reporting of RCTs and of journals' instructions to authors. It did not involve direct study of human participants, and therefore, human research ethics approval was not required.

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