CONSORT-PRO
Reporting Template

A template based on recommendations for
reporting clinical trials
with patient-reported outcomes

A Resource from the

About this PRO Reporting Template

Patient-reported outcome (PRO) data from clinical trials can provide valuable evidence to inform shared decision making, labelling claims, clinical guidelines, and health policy. However, PROs are often inadequately reported in trials, thus limiting the value of these data.

To address this issue an international, consensus-based, PRO-specific reporting guidance (the CONSORT-PRO Extension) was developed and published in 2013:

> Calvert M, Blazeby J, Altman DG, et al. Reporting of Patient-Reported Outcomes in Randomized Trials: The CONSORT PRO Extension. JAMA. 2013;309(8):814–822. doi:10.1001/jama.2013.879

This reporting template aims to promote implementation and use of the CONSORT-PRO Extension for trials where PROs are primary or key secondary outcomes. The template is also recommended for use where PROs are exploratory outcomes.

This PRO reporting template is designed to be used in conjunction with both the CONSORT-PRO extension and the CONSORT 2010 statement.[1]

The template recommends integration of key CONSORT-PRO information within relevant sections of the report (e.g., abstract, background, methods, results, and discussion). Additional information from the CONSORT-PRO group,[2] the International Society for Quality of Life Research Reporting Guidelines Task Force,[3] and the PRO Data Presentation Delphi Panel[4] have been included where relevant.

Report writers can confirm that they have successfully adhered to the CONSORT-PRO Extension guideline using the checklist available here: theproteusconsortium.org/resource/the-consort-pro-reporting-guidance-checklist/

Note: The CONSORT-PRO Extension should be used with the CONSORT 2010 Statement and any other relevant CONSORT Extensions, found here: www.consort-statement.org/consort-2010

Table of Contents

Title and Abstract

The PRO should be identified in the abstract as a primary or secondary outcome.

(CONSORT-PRO item P1b)

Explanation:

If a PRO is prespecified as a primary or important secondary outcome in the trial, it should be explicitly stated in the abstract to facilitate indexing and identification of studies to inform clinical care and evidence synthesis.[2]

Example:

"The primary outcome was the change in COPD specific quality of life at 24 months as measured with the chronic respiratory questionnaire total score."[5]

Introduction

Background and objectives

The relevant background and rationale for why PROs were assessed in the RCT should be briefly described.

(CONSORT-PRO item 2a)

Explanation:

The Background or Methods section should provide the rationale for including PROs and why the specific outcomes were selected, thus providing appropriate context for the PRO-specific objectives and hypotheses.[2]

Example:

"Migraine causes severe impairment or bed rest in more than half (57%) of affected people, markedly impairs quality of life both during and between attacks, increases absenteeism and reduces productivity at work, and is associated with increased health care costs(referenced)."[6]

The PRO hypothesis should be stated and should specify the relevant PRO domain(s) if applicable.

(CONSORT-PRO item P2b)

Explanation:

Patient-reported outcome measures may be unidimensional or multidimensional, assessing either one or several aspects of health (e.g., physical and social function, or symptoms such as fatigue). In addition, PRO measures may assess global health or health-related quality of life (HRQOL) at several time points during an RCT. Without a prespecified hypothesis, there is a risk of multiple statistical testing and selective reporting of PROs based on statistically significant results.

Thus, if PRO is a primary outcome, the manner in which multiple comparisons have been addressed should also be provided.[3] It is also recommended that authors report the rationale for the selection of specific PROs and the time frames of interest, including biological or psychosocial evidence for the proposed anticipated benefits or harms where relevant.[2]

If PRO is a primary outcome additional details regarding the hypothesis should be provided, including the rationale for the selected domain(s), the expected direction(s) of change, and the time points for assessment.[3]

Example:

For PRO as a primary endpoint: "The primary null hypothesis was that, for patients with painful bone metastases, pain and narcotic relief from 8 Gy of radiation therapy in a single treatment fraction is equivalent to that from 30 Gy of radiation therapy in 10 treatment fractions. The study was designed to show equivalence if at least 36% of patients in the 8-Gy arm achieved complete pain and narcotic relief (Brief Pain Inventory worst pain score = 0 and not using any narcotic pain medications at 3 months after randomization)."[7]

For PRO as a secondary endpoint: "Potential survival benefit needs to be weighed against the burden of treatment. For this reason, HRQOL, a multidimensional construct(referenced) was included as a secondary end point in the EORTC18991 study . . . The protocol hypothesized that there would be a difference in global HRQOL scale between both arms, showing worse HRQOL in the PEGIFN-α-2b arm. The remaining HRQOL variables were then examined on an exploratory basis."[8]

Methods

Participants

PRO-specific criteria are required only if PROs were used in eligibility or stratification criteria.

(CONSORT-PRO item 4a)

Example: "Eligible patients were aged 18 years or older with a proven diagnosis of cancer and …severity of pain needed to be at least 2 out of 10 according to the Brief Pain Inventory"[9]

Outcomes

Evidence of PRO instrument validity and reliability should be provided or cited if available.

(CONSORT-PRO item P6a)

Explanation:

Ideally, the validity of all PROs used in RCTs should be established in relation to the study target population and a brief rationale for the choice of PRO instrument in the trial should be provided. This rationale may also include the validity of translated or otherwise culturally specific versions of the instrument where relevant. [2]

Clinical use of PRO data requires that the trial results are robust, which depends on a valid and reliable PRO measure being used appropriately.

Example:

"The DLQI [Dermatology Life Quality Index] has well-established reliability and validity when used in a dermatology setting(referenced) and is used frequently in clinical trials of psoriasis(referenced)."[10]

Details of the mode of PRO completion (in particular if a proxy completed the questionnaire on behalf of the patient), and the method of data collection should also ideally be provided particularly when the PRO is the primary outcome.

(CONSORT-PRO item P6a)

Explanation:

The mode of administration of the PRO tool and the methods of collecting data (e.g., telephone, other) should be described. The intended PRO data collection schedule should be provided.[3]

In some instances it may not be possible for the PRO to be completed directly by the patient. If the outcome has been completed by a proxy, this should be reported so that readers can assess any potential bias or effect on the results. Different methods of data collection may also affect the results and lead to potential bias if used differentially between intervention groups. For example, collecting PROs by telephone or in a face-to-face interview may cause patients to respond in a way that differs from what they would self-report on paper in private.[2]

Example:

"Participants were asked to provide data at three time points; four, eight, and 12 months post-randomization, using a self completion questionnaire to eliminate any observer bias."[11]

Sample size

Sample size determination is required only if PRO is a primary study outcome.

(CONSORT-PRO item 7a)

Explanation:

If PRO is a primary outcome there should be a power/sample size calculation relevant to the PRO based on a clinical rationale (e.g., anticipated effect size).[3]

Example:

"Following the guidelines(referenced) for the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-30 (EORTC QLQ-C30) (referenced) and allowing for a 20% loss to follow up, a baseline sample size of 2142 was required with a minimum follow-up of 3 months. This sample size provides 95% power to detect the smallest effect size threshold of 0.1 for the insomnia domain of the QLQ-C30, using a 2-tailed significance level of 1%(referenced)."[12]

Statistical methods

Statistical approaches for dealing with missing data should be explicitly stated for PROs prespecified as primary or important secondary outcomes.

(CONSORT-PRO item P12a)

Explanation:

The level of missing PRO data is often high and can lead to reduced power, is a potential source of bias, and can result in misleading results. Importantly, PRO data often are not missing at random but in relation to the outcome of interest, for example, improvement or deterioration in health status.[2]

Example:

"Analysis of complete cases, last observation carried forward, and imputation of expected and worse scores per time point were provided to check the robustness of the main results."[13]

Results

Participant flow

The number of participants reporting PRO data at baseline and at subsequent time points should be made transparent.

(CONSORT-PRO item 13a)

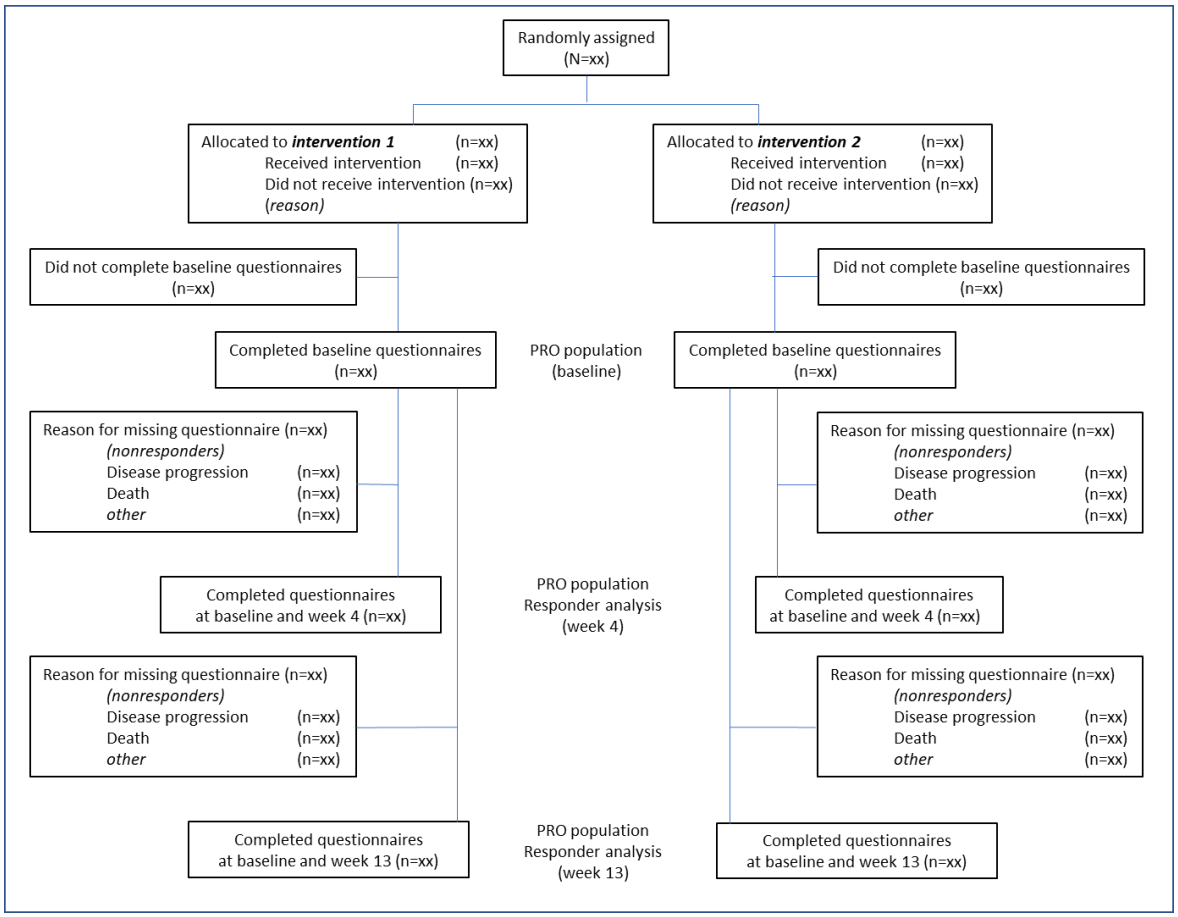
Explanation:

The flow of participants through the trial in relation to PROs, including information on the reason for missing PRO data, should be reported to help readers interpret the PRO results and assess potential for bias.[2]

When graphs are utilized, the sample size available at each assessment timepoint should be represented.

Example:

CONSORT Flow Diagram



Baseline data

Include baseline PRO data when collected.

(CONSORT-PRO item 15)

Explanation:

Baseline PRO data may be used by clinicians and policy makers to assess the relevance and generalizability of trial findings.

Example:

Table 1. Example Presentation of Baseline Patient-Reported Outcome Data

Baseline Demographic data for 106 Patients with chronic pain	Intervention 1	Intervention 2
Patients, *n (%)*	52	54
Age, *mean (SD)*	67 (11)	67 (12)
Sex, *n (%)*		
Men	23 (44)	23 (43)
Women	29	31
Pain indication, *n (%)*		
Neuropathic	16	11
Olfactory	9	16
Musculoskeletal	6	5
Other	21	21
VAS: Pain, *mean (SD)*	62 (22)	55 (26)
EORTC QLQ-30: global health status, *mean (SD)* score	37 (23)	37 (20)
Abbreviations: EORTC QLQ-C30, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (higher score means better quality of life), SD standard deviation; VAS visual analog scale.		

Numbers analyzed

For each group, number of participants (denominator) included in each PRO analysis and whether the analysis was by original assigned groups.

(CONSORT-PRO item 16)

Outcomes and estimation

For multi-dimensional PROs, results from each domain and time point specified for analysis. **(CONSORT-PRO item 17a)**

Explanation:

The potential for selective reporting of PROs is increased because study measures often contain multiple scales and items. In general, all PRO results should be presented alongside other outcome data to facilitate the clinical integration of the important findings with other prespecified outcomes.[2]

If PRO is a primary outcome the analysis of PRO data should account for survival differences between treatment groups if relevant.[3]

Example:

Table 2. Example of Treatment effects on Quality of Life Outcomes

Variable	Mean change from baseline[a]		Treatment Effect (95% CI)	*P* value
	Intervention 1	Intervention 2		
Treatment effects on quality of life outcomes at 12-months[a]				
EORTC QLQ-30				
Pain[b]	4.0	12.6	8.5 (-1.0 to 18.1)	0.08
Fatigue[b]	1.9	11.1	9.2 (0.6 to 17.9)	0.04
Emotional function[c]	11.4	1.7	9.8 (2.7 to 16.9)	0.009
Physical function[c]	7.8	0.1	7.8 (0.9 to 14.7)	0.03
Global health status[c]	8.5	4.1	4.4 (-0.9 to 10.7)	0.16

Abbreviations: EORTC QLQ-C30, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire

[a] Values are mean changes from baseline adjusted for age and the baseline value of the outcome variable using repeated-measures analysis of covariance model

[b] higher score means worse outcome

[c] higher score means better outcome

Ancillary analyses

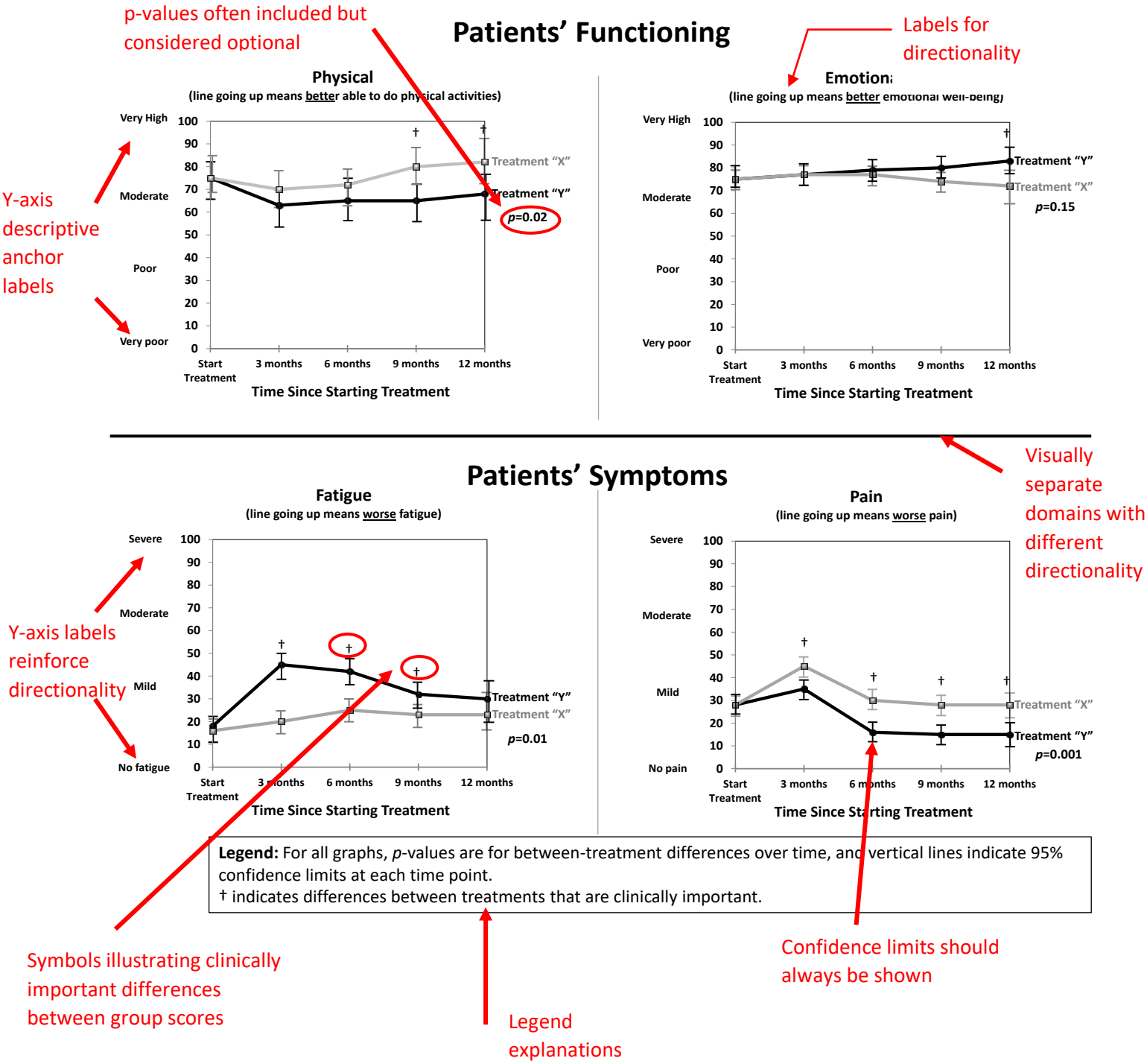
Results of any other PRO analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory, should be presented, where relevant.

(CONSORT-PRO item 18)

Graphical illustration of PRO results

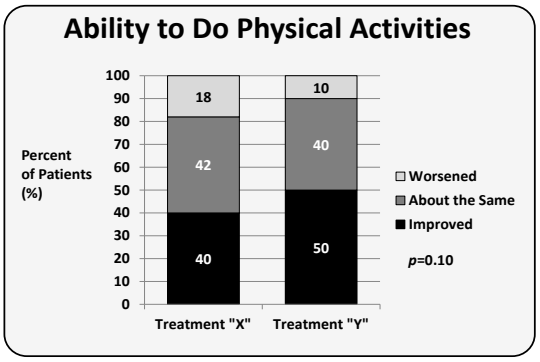
The following recommendations for graphically presenting PRO data in peer-reviewed publications were developed by the PRO Data Presentation Delphi Panel.[4]

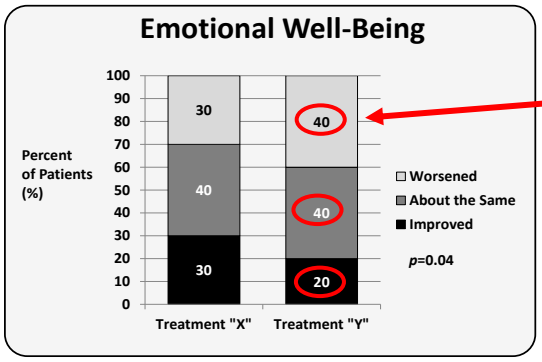
Example for average scores over time:



Example for proportion meeting a responder definition (in addition to stacked bar charts, as shown, bar charts and pie charts are reasonable alternatives)**:**

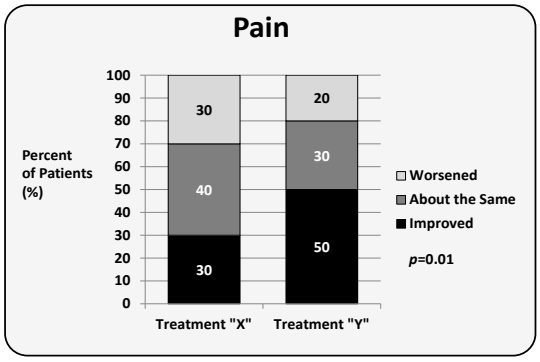
Status of 100 patients 9 months after starting treatment

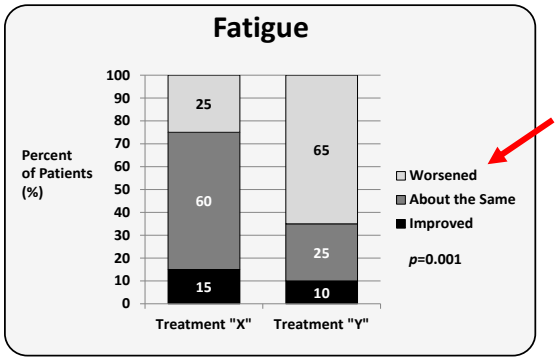




Data labels annotated on each slice so stacked proportions can be read directly

No horizontal line separating domains since directionality not relevant with proportions





Legend replicated for easy access and order is the same as stacked bar sections

Discussion

Limitations & generalizability

PRO-specific limitations and implications for generalizability and clinical practice.

(CONSORT-PRO items P20/P21)

Explanation:

The limitations and generalizability issues uniquely related to the PRO components of the trial should be explicitly discussed. Readers need to be able to assess generalizability and any potential sources of bias.

In addition to the design and conduct issues relevant to the generalizability of the RCT overall, several PRO–specific limitations (including both patient- and center-level characteristics) may affect generalizability of the PRO results. For example, if PRO assessments are limited to a subgroup of the main trial population, it is recommended to provide reasons why patients were excluded from the PRO study (such as where appropriate translations were unavailable). If PRO data are missing, it is particularly important to discuss the potential reasons in relation to the clinical context and implications for interpretation, as well as the interpretation of any supportive (e.g., sensitivity) analyses undertaken. Furthermore, because many of the previously described methodological details of PROs assessment may affect the RCT results, the potential influence of these details on the interpretation of the PRO findings is recommended where suspected to be important.

Example:

"A potential source of bias was the overall amount of missing HRQL forms over the course of the assessment period, with more missing data in the Gemcitibine arm . . . this problem tempers our ability to generalize these longer-term effects to future patients."[14]

"Non-attenders at one year, however, might have had a different symptom profile and overall quality of life than attenders, and therefore some degree [of] selection bias is possible."[15]

Interpretation

PRO data should be interpreted in relation to clinical outcomes including survival data, where relevant.

(CONSORT-PRO item 22)

Explanation:

The clinical significance of PRO results is often not discussed in RCT reports but should be interpreted in relation to other important clinical outcomes such as survival, especially in trials for which there are clinically relevant trade-offs between PROs and survival outcomes. Further interpretation of PRO results may include discussion of a minimal important change or a responder definition (if validated for the particular PRO instrument used in the study), comparison with other similar RCTs, or linking the clinical significance of the PRO results to the other trial outcomes such as toxicity rates.

Example:

"Patients who received cetuximab experienced significantly less HRQL deterioration and a longer time before clinically significant deterioration occurred. These results are important, because . . . although cetuximab monotherapy . . . results in improved overall survival, progression free survival, recurrence rates and disease control rate . . . the magnitude of these benefits . . . was not large."

Conclusion: "[C]etuximab offers important HRQL benefits and survival benefits for pre-treated patients with advanced CRC."[16]

Other information

If PRO is a primary outcome, a copy of the PRO instrument should be included if it has not been published previously.

References

1. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Bmj. 2010;340:c332.
2. Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD, CONSORT PRO Group ft. Reporting of Patient-Reported Outcomes in Randomized Trials: The CONSORT PRO Extension. JAMA. 2013;309(8):814-22.
3. Brundage M, Blazeby J, Revicki D, Bass B, de Vet H, Duffy H, Efficace F, King M, Lam CLK, Moher D, Scott J, Sloan J, Snyder C, Yount S, Calvert M. Patient-reported outcomes in randomized clinical trials: development of ISOQOL reporting standards. Qual Life Res. 2013;22(6):1161-75.
4. Snyder C, Smith K, Holzner B, Rivera YM, Bantug E, Brundage M. Making a picture worth a thousand numbers: recommendations for graphically displaying patient-reported outcomes data. Qual Life Res. 2019;28(2):345-56.
5. Bischoff EWMA, Akkermans R, Bourbeau J, van Weel C, Vercoulen JH, Schermer TRJ. Comprehensive self management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: randomised controlled trial. BMJ : British Medical Journal. 2012;345:e7642.
6. Holroyd KA, Cottrell CK, O'Donnell FJ, Cordingley GE, Drew JB, Carlson BW, Himawan L. Effect of preventive (β blocker) treatment, behavioural migraine management, or their combination on outcomes of optimised acute treatment in frequent migraine: randomised controlled trial. BMJ. 2010;341:c4871.
7. Hartsell WF, Scott CB, Bruner DW, Scarantino CW, Ivker RA, Roach M, 3rd, Suh JH, Demas WF, Movsas B, Petersen IA, Konski AA, Cleeland CS, Janjan NA, DeSilvio M. Randomized trial of short- versus long-course radiotherapy for palliation of painful bone metastases. Journal of the National Cancer Institute. 2005;97(11):798-804.
8. Bottomley A, Coens C, Suciu S, Santinami M, Kruit W, Testori A, Marsden J, Punt C, Salès F, Gore M, Mackie R, Kusic Z, Dummer R, Patel P, Schadendorf D, Spatz A, Keilholz U, Eggermont A. Adjuvant therapy with pegylated interferon alfa-2b versus observation in resected stage III melanoma: a phase III randomized controlled trial of health-related quality of life and symptoms by the European Organisation for Research and Treatment of Cancer Melanoma Group. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2009;27(18):2916-23.
9. Chow E, van der Linden YM, Roos D, Hartsell WF, Hoskin P, Wu JS, Brundage MD, Nabid A, Tissing-Tan CJ, Oei B, Babington S, Demas WF, Wilson CF, Meyer RM, Chen BE, Wong RK. Single versus multiple fractions of repeat radiation for painful bone metastases: a randomised, controlled, non-inferiority trial. The Lancet Oncology. 2014;15(2):164-71.
10. Revicki DA, Willian MK, Menter A, Gordon KB, Kimball AB, Leonardi CL, Langley RG, Kimel M, Okun M. Impact of adalimumab treatment on patient-reported outcomes: results from a Phase III clinical trial in patients with moderate to severe plaque psoriasis. The Journal of dermatological treatment. 2007;18(6):341-50.
11. Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Haase AM, Taylor AH, Fox KR, Costelloe C, Searle A, Baxter H, Winder R, Wright C, Turner KM, Calnan M, Lawlor DA, Peters TJ, Sharp DJ, Montgomery AA, Lewis G. Facilitated physical activity as a treatment for depressed adults: randomised controlled trial. BMJ : British Medical Journal. 2012;344:e2758.

12. Tait M-A, Costa DSJ, Campbell R, Norman R, Schug S, Rutherford C. A Quality-of-Life Evaluation Study Assessing Health-Related Quality of Life in Patients Receiving Medicinal Cannabis (the QUEST Initiative): Protocol for a Longitudinal Observational Study. JMIR Res Protoc. 2021;10(11):e32327.
13. Bottomley A, Biganzoli L, Cufer T, Coleman RE, Coens C, Efficace F, Calvert HA, Gamucci T, Twelves C, Fargeot P, Piccart M. Randomized, controlled trial investigating short-term health-related quality of life with doxorubicin and paclitaxel versus doxorubicin and cyclophosphamide as first-line chemotherapy in patients with metastatic breast cancer: European Organization for Research and Treatment of Cancer Breast Cancer Group, Investigational Drug Branch for Breast Cancer and the New Drug Development Group Study. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2004;22(13):2576-86.
14. Moinpour CM, Vaught NL, Goldman B, Redman MW, Philip PA, Millwood B, Lippman SM, Seay TE, Flynn PJ, O'Reilly EM, Rowland KM, Wong RP, Benedetti J, Blanke CD. Pain and emotional well-being outcomes in Southwest Oncology Group-directed intergroup trial S0205: a phase III study comparing gemcitabine plus cetuximab versus gemcitabine as first-line therapy in patients with advanced pancreas cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2010;28(22):3611-6.
15. Welton AJ, Vickers MR, Kim J, Ford D, Lawton BA, MacLennan AH, Meredith SK, Martin J, Meade TW. Health related quality of life after combined hormone replacement therapy: randomised controlled trial. Bmj. 2008;337:a1190.
16. Au HJ, Karapetis CS, O'Callaghan CJ, Tu D, Moore MJ, Zalcberg JR, Kennecke H, Shapiro JD, Koski S, Pavlakis N, Charpentier D, Wyld D, Jefford M, Knight GJ, Magoski NM, Brundage MD, Jonker DJ. Health-related quality of life in patients with advanced colorectal cancer treated with cetuximab: overall and KRAS-specific results of the NCIC CTG and AGITG CO.17 Trial. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2009;27(11):1822-8.