PTJ Manuscript Cafe:
Essentials of Writing and Reviewing Research Papers
Using Standardized Manuscript Checklists

(Handout – 20 pages)

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Writing and Reviewing Manuscripts –
Clinical Trials

Guideline: *CONSORT Statement* (www.consort-statement.org)

CONSORT - **CON**solidated **S**tandards **O**f **R**eporting **T**rials

PTJ endorses:

- the transparent reporting of clinical trials
- the CONSORT statement and its extensions

Authors are required to:

- follow these guidelines
- include a **flow diagram** within the manuscript
- submit the **checklist** for randomized trials of nonpharmacologic treatment as the last page of the manuscript

The International Committee of Medical Journal Editors (ICMJE) has defined clinical trials as any research project that:

- prospectively assigns human subjects to intervention or comparison groups to determine a cause-and-effect relationship between an intervention and an outcome.
- must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration.
- nonrandomized trials are not exempt from the registration requirement if they meet the above criteria.

PTJ policy regarding registry of clinical trials (effective January 1, 2009) of manuscripts being submitted:

- Trials that began enrollment after January 1, 2009, must be registered at or before the onset of patient enrollment.
- Trials that began enrollment before January 1, 2009, must be registered before authors submit their manuscripts, effective for manuscripts submitted on or after January 1, 2009.
- Authors should specify where the trial is registered and the trial's unique registration number in their cover letter.
- www.clinicaltrials.gov

CONSORT 2010 checklist of information to include when reporting a randomised trial*

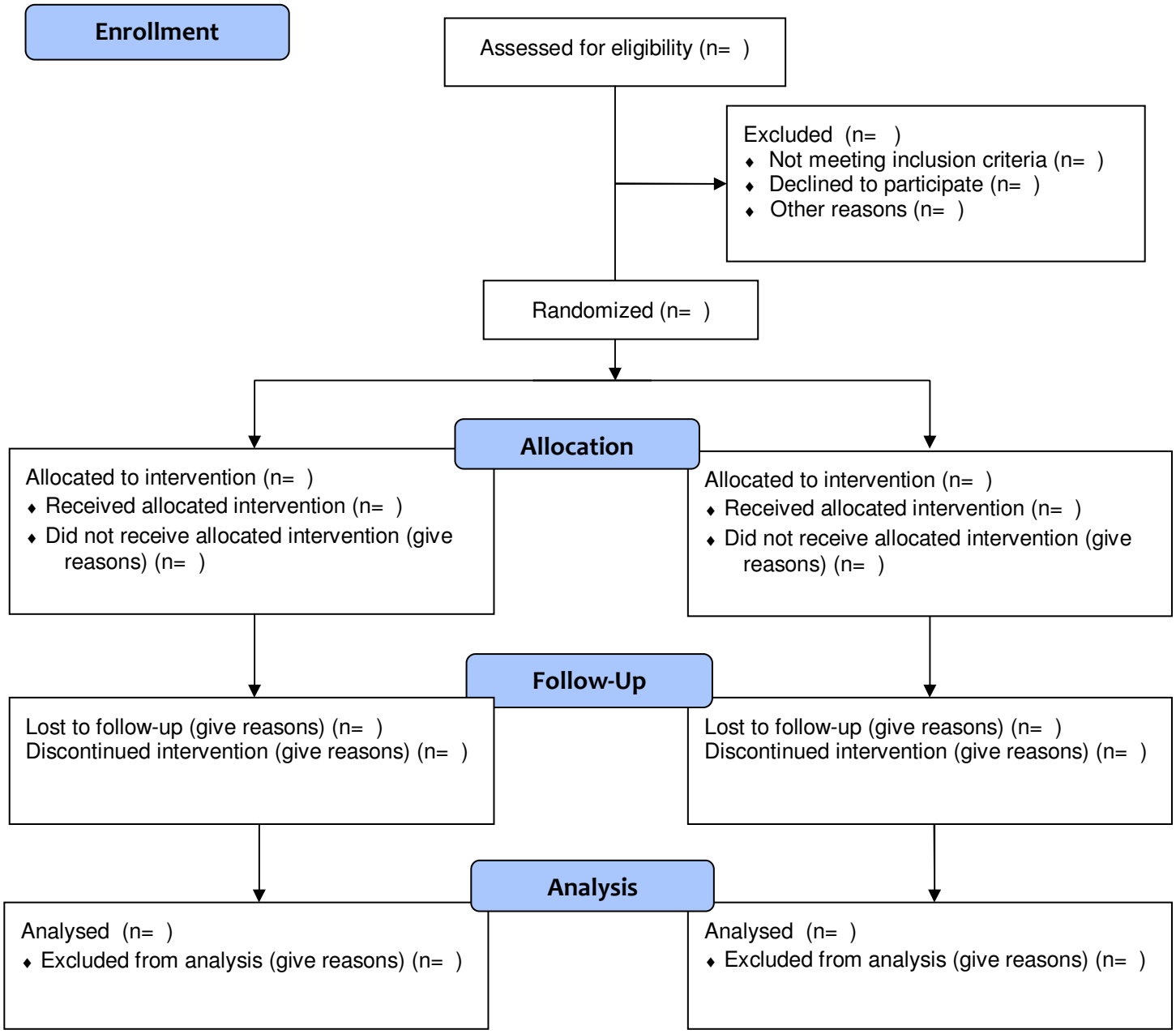
Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	

Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 Flow Diagram



Writing and Reviewing Manuscripts –
Observational and Prognostic Studies (Cohort, Case-Control, Cross-Sectional)

Guideline: *STROBE Statement* (www.strobe-statement.org)

STROBE - **ST**rengthening the Reporting of **OB**servational studies in **E**pidemiology

STROBE checklists are available for:

- cohort
- case-control,
- cross-sectional studies

PTJ endorses:

- the STROBE statement

Authors are required to:

- follow these guidelines
- include a **flow diagram** within the manuscript
- complete the most appropriate **STROBE checklist** for the submitted paper (cohort, case-control, or cross-sectional design), including it as the last page of the manuscript.

STROBE Statement — Checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Reported on page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Writing and Reviewing Manuscripts – Diagnostic Studies

Guideline: *STARD Statement* (www.stard-statement.org)

STARD – STAndards for the **R**eporting of **D**iagnostic accuracy studies

- sensitivity and specificity alone are insufficient for diagnostic studies.
- the likelihood ratio (LR) with CI must be reported
- an interpretation of the clinical relevance of the findings must be included.

PTJ endorses:

- the STARD statement

Authors are required to:

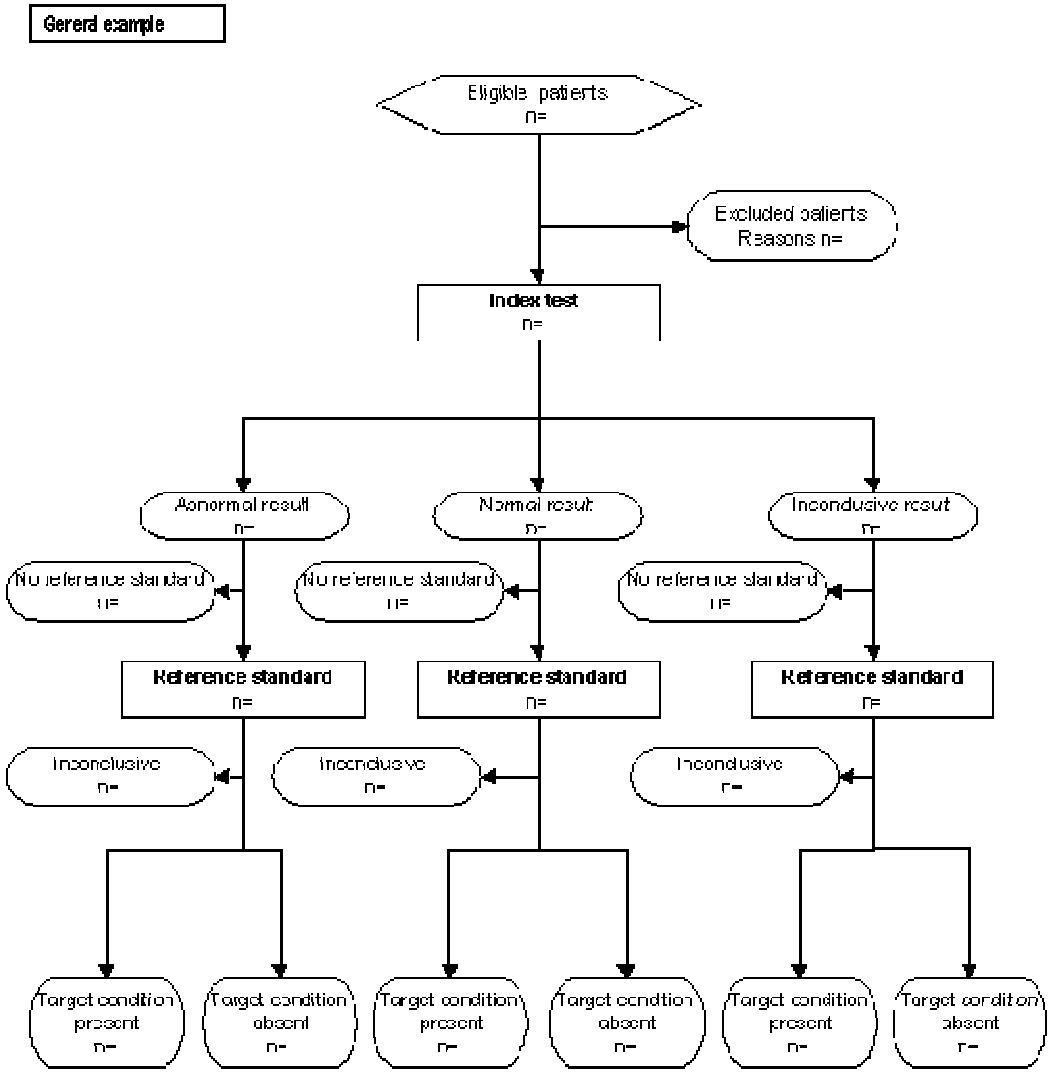
- follow these guidelines
- include a **flow diagram** within the manuscript
- include the completed **STARD checklist** as the last page of the manuscript.

STARD checklist for reporting of studies of diagnostic accuracy

(version January 2003)

Section and Topic	Item #		On page #
TITLE/ABSTRACT/ KEYWORDS	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading 'sensitivity and specificity').	
INTRODUCTION	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.	
METHODS			
Participants	3	The study population: The inclusion and exclusion criteria, setting and locations where data were collected.	
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	
Test methods	7	The reference standard and its rationale.	
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	
	13	Methods for calculating test reproducibility, if done.	
RESULTS			
Participants	14	When study was performed, including beginning and end dates of recruitment.	
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	
	20	Any adverse events from performing the index tests or the reference standard.	
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	
	22	How indeterminate results, missing data and outliers of the index tests were handled.	
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	
	24	Estimates of test reproducibility, if done.	
DISCUSSION	25	Discuss the clinical applicability of the study findings.	

STARD Flow Chart Example



Writing and Reviewing Manuscripts –
Qualitative Studies

Guideline: *QUALRES Statement* (www.qualres.org)

QUALRES – QUALitative **RES**earch reporting

PTJ endorses:

- the QUALRES guidelines

Authors are required to:

- follow these guidelines

- there are two sets of acceptable guidelines
    - Malterud's guidelines
    - Crabtree and Miller's guidelines

Guidelines for Authors and Reviewers of Qualitative Research

The following guidelines are found in Malterud, K. (2001). "Qualitative Research: Standards, challenges and guidelines." The Lancet 358: p. 485.

Aim

- Is the research question a relevant issue?
- Is the aim sufficiently focused, and stated clearly?
- Does the title of the article give a clear account of the aim?

Reflexivity

- Are the researcher's motives, background, perspectives, and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?

Method and design

- Are qualitative research methods suitable for exploration of the research question?
- Has the best method been chosen with respect to the research question?

Data collection and sampling

- Is the strategy for data collection clearly stated (usually purposive or theoretical, usually not random or representative)?
- Are the reasons for this choice stated?
- Has the best approach been chosen, in view of the research question?
- Are the consequences of the chosen strategy discussed and compared with other options?
- Are the characteristics of the sample presented in enough depth to understand the study site and context?

Theoretical Framework

- Are the perspectives and ideas used for data interpretation presented?
- Is the framework adequate, in view of the aim of the study?
- Does the author account for the role given to the theoretical framework during analysis?

Analysis

- Are the principles and procedures for data organization and analysis fully described, allowing the reader to understand what happened to the raw material to arrive at the results?
- Were the various categories identified from theory or preconceptions in advance, or were they developed from the data?
- Which principles were followed to organize the presentation of findings?
- Are strategies used to validate results presented, such as cross-checks for rivaling explanations, member checks, or triangulation? If such strategies are not described in this section, they should appear as validity discussion later in the report.

Findings

- Are the findings relevant with respect to the aim of the study?
- Do they provide new insight?
- Is the presentation of the findings well organized and best suited to ensure that findings are drawn from systematic analysis of material, rather than from preconceptions?
- Are quotes used adequately to support and enrich the researcher's synopsis of the patterns identified by systematic analysis?

Discussion

- Are questions about internal validity (what the study is actually about), external validity (to what other settings the findings or notions can be applied), and reflexivity (the effects of the researcher on processes, interpretations, findings, and conclusions) addressed?
- Has the design been scrutinized?
- Are the shortcomings accounted for and discussed, without denying the responsibility for choices taken?
- Have the findings been compared with appropriate theoretical and empirical references?
- Are a few clear consequences of the study proposed?

Presentation

- Is the report easy to understand and clearly contextualized?
- Is it possible to distinguish between the voices of the informants and those of the researcher?

References

- Are important and specific sources in the field covered, and have they been appropriately presented and applied in the text?

A Worksheet for Assessing Qualitative Articles

Created by William Miller and Benjamin Crabtree for *The Journal of Family Practice*. This worksheet is printed in Frankel, RM. (1999). "Standards of Qualitative Research." In BF Crabtree and WL Miller (Eds.) Doing Qualitative Research (2nd edition) p. 341. Thousand Oaks: sage Publications.

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1. Determine relevance - is this manuscript worth taking the time to read? If the answer to any of the following questions is no, it may be better to read other manuscripts first.

Based on the abstract:

- Did the authors study an outcome that patients would care about? (Be careful to avoid results that require extrapolation to an outcome that truly matters to patients.) **Yes** (go on). **No** (stop)

- Is the problem common to your practice, and is the intervention feasible? **Yes** (go no). **No** (stop).

- Will this information, if true, require you to change your current practice? **Yes** (go on). **No** (stop).

2. Determine Validity: If the answer to all three questions above is yes, then continued assessment is mandatory. Study design flaws are common; fatal flaws are arresting.

- Was the appropriate method used to answer the question? **Yes**. **No** (stop).
    - Interviews should be used to study perception. Observational methods are required to evaluate behavior.

- Was appropriate and adequate sampling used to answer the question? **Yes**. (Go on.) **No** (Stop).
    - Participants, events and so on are selected to maximize appropriate information, the richest information relevant to the research question. Random sampling is rarely used. Assurance that enough people were studied to provide sufficient information should be found in the description. Negative or disconfirming evidence should be sought.

- Was an iterative process of collecting and analyzing data used and data saturation achieved? **Yes**. (Go on.) **No** (Stop).
-
    - In qualitative research, the investigative team learns about the topic as the research progresses. The study design should consist of data collection and analysis, followed by more data collection and analysis, in an iterative fashion, until no new information is obtained.
- Was a thorough analysis presented? **Yes**. (Go on.) **No** (Stop).
    - A good qualitative study not only presents the findings but provides a thorough analysis of the data. Beward of studies that simply present superficial descriptions without interpretation. Something new should be learned.

- Are the background, training, and preconceptions of the investigators described? **Yes**. (Go on.) **No** (Stop).
    - Because the investigators are being relied on for analysis of the data, we must know their training and biases. Knowing these characteristics, we can use them to evaluate their conclusions. Are the researchers' original preconceptions are changed or are they surprised by the study results as they emerge?

Writing and Reviewing Manuscripts –
Systematic Reviews and Meta-Analyses

Guideline: *PRISMA Statement* (www.prisma-statement.org)

PRISMA – Preferred **R**eporting **I**tems for **S**ystematic Reviews and **M**eta-**A**nalyses

PTJ endorses:

- the PRISMA statement

Authors are required to:

- follow these guidelines
- submit a **flow diagram**
- include the **checklist** as the last page of the manuscript

PRISMA 2009 Checklist

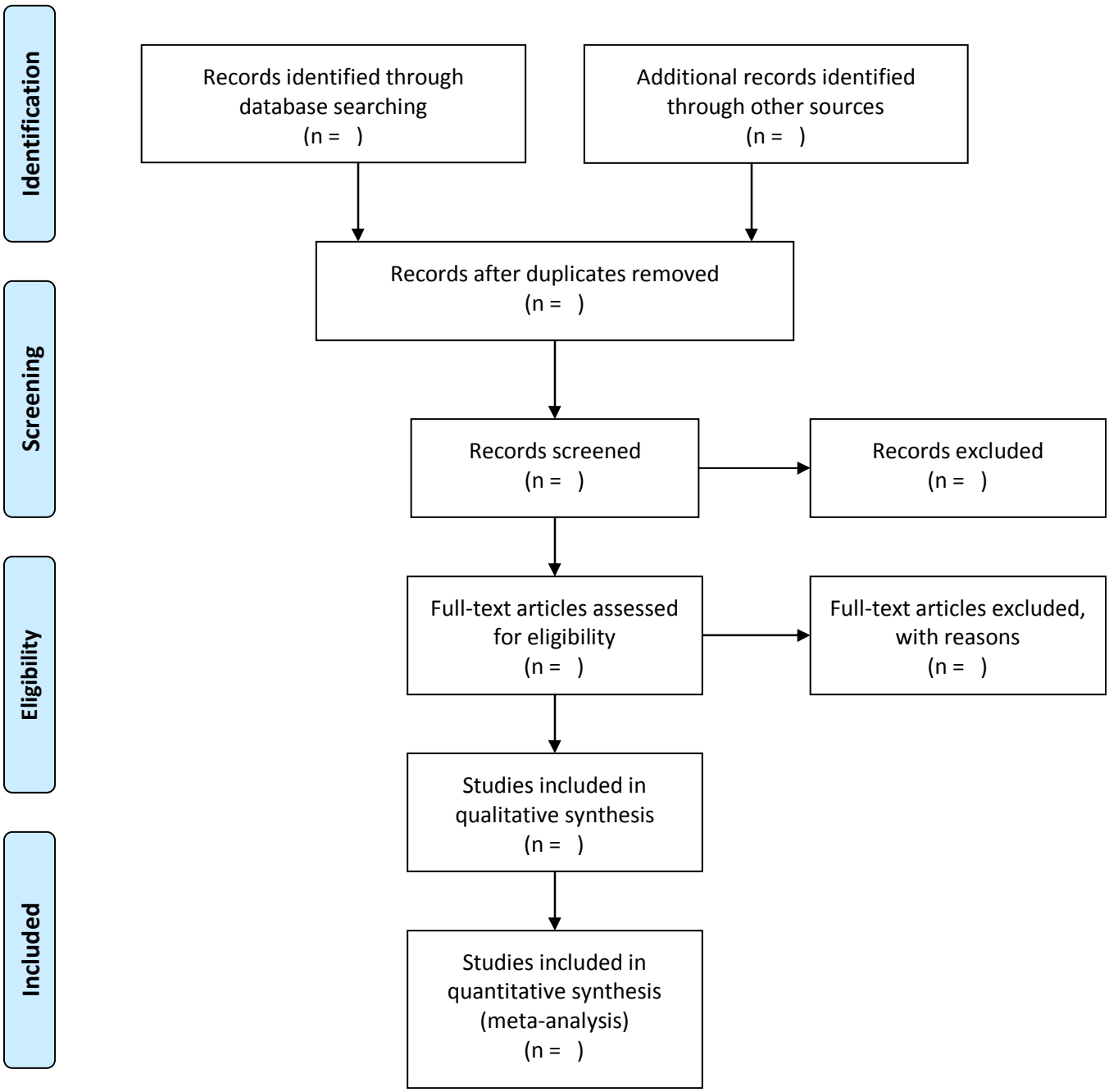
Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
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.	
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.	
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.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
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).	
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.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
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.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
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.	

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).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
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.	
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.	
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).	
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.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
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).	
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).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
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.	

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**.

PRISMA 2009 Flow Diagram



Writing and Reviewing Manuscripts –
Case Reports

Guideline: *Case Report Checklists (available at www.ptjournal.org)*

Case Reports describe various aspects of clinical practice related to the field of physical therapy. Case Reports differ from Research Reports in that they do not test hypotheses or establish cause-and-effect relationships.

Types of Case Reports considered by *PTJ:*

- Diagnosis/Prognosis
- Clinical Measurement Procedures
- Intervention
- Application of Theory to Practice
- Risk Management
- Administrative/Educational Process
- "Full" Traditional Case Report

Checklist for Case Reports Focusing on Intervention

Emphasis is on the intervention aspect of patient care. May cover the development of a new intervention or a modification to an existing intervention to deal with a clinical problem. Concentrate detail in the rationale for the new or modified intervention, the development process, the direct application to the patient, and the setting in which it is used. Remember that the patient history and examination should indicate why the patient is appropriate for the new or modified intervention. Include the outcome, but less detail is needed there.

TITLE

- ❑ State that the manuscript is a case report
- ❑ Maximum length = 150 characters (including punctuation and spaces)

ABSTRACT

- ❑ Word limit = 275 words or fewer
- ❑ Structure: background and Purpose, Case description, Outcomes, Discussion
- ❑ State manuscript word count at the end of the abstract

BODY OF MANUSCRIPT

- ❑ Manuscript word count = 3,500 words or fewer (excluding abstract and references). List the word count at bottom of abstract. Additional materials may be submitted as an appendix that would appear online only.
- ❑

Background and Purpose

- ❑ Provide an underlying theoretical basis for the development of a new intervention or for the modification of an existing intervention.
- ❑ Provide a scholarly discussion on the gaps in the literature and in practice for treating the target problem, based on biological, physiological, biomechanical, psychosocial, or any other knowledge and theory.
- ❑ End with a purpose statement that clearly indicates the focus of the case as it relates to the intervention (eg, "The purpose of this case report is to describe the development and demonstrate the use of a new intervention for ... ").

Case Description: Patient History and Systems Review

- ❑ Provide detailed demographic characteristics and history (eg, chief complaints, other relevant medical history, prior or current services related to the current episode, comorbidities) in sufficient detail to demonstrate that the patient is appropriate for the intervention.
- ❑ Use relative dates (eg, years or months or days relative to onset of injury or to start of treatment) rather than absolute dates (ie, calendar dates). Reader will more easily grasp the chronology of events when the amount of time since the event or start of treatment is reported (don't force the reader to calculate the amount of time).
- ❑ Explain patient/family goals for physical therapy.

Clinical Impression #1

- ❑ Explain why you believe that the patient is a good candidate for the intervention, based on the data collected thus far.
- ❑ Describe the plan for examination for further determining whether the patient is appropriate for this type of intervention (ruling in or ruling out relevant differential diagnoses, prognostic factors that suggest appropriateness for the intervention approach).

Examination

- ❑ Describe any tests needed to confirm that the patient is appropriate for the intervention as stated in the first clinical impression.
- ❑ Clearly explain all examination data.

Clinical Impression #2

- ❑ Discuss why the patient is appropriate for use of the target intervention, based on the examination data.
- ❑ Describe the plan for examination to determine the outcome of the intervention (measures to be used, follow-up time points), offering hypotheses about what should be observed if the intervention were to be successful.

Intervention

- ❑ Describe the intervention, including how the intervention was developed and how it was applied to the patient, in sufficient detail that others can replicate the procedure.
- ❑ May use tables, figures, and appendixes to enhance the detailed description.
- ❑ Provide the parameters of the intervention (ie, intensity, frequency, and duration) and rules for progression.
- ❑ State changes in treatment over time, along with the rationale for the changes.
- ❑ List any co-interventions that the patient may have received but that are not directly related to the purpose of the case; detailed descriptions may not be necessary.

Outcome

- ❑ If not already in the examination section, provide operational definitions of the outcome measures and their purpose, and cite evidence for reliability and validity. Priority is given to validated outcome measures. If reliability and validity have not been estimated for a measure, acknowledge this, and make presumptive arguments that the measurements would be reasonably reliable and valid for the purpose of the case.
- ❑ Present the outcomes over the time points indicated in the follow-up plan.
- ❑ Compare follow-up outcomes to baseline.
- ❑ Use tables and figures to enhance the description.

Discussion

- ❑ Reflect back on how the intervention may have assisted in addressing the target problem. This should be done in the context of other co-interventions that may have been provided. The key points of development and application should be tied back to the rationale for the treatment and literature on previous treatment approaches for a similar problem.
- ❑ Offer suggestions for further research.

REFERENCES

- ❑ Cite no more than 30.

TABLES and FIGURES

- ❑ Use no more than 6 tables and figures total. (For more information, visit Tips for Tables and Figures.)

CONFLICT OF INTEREST

- **PTJ** has adopted the International Committee of Medical Journal Editors (ICMJE) initiative to standardize a format for disclosing competing interests. For more information, please refer to the *JAMA* editorial at http://jama.ama-assn.org/cgi/content/full/303/1/75. Each author is required to complete the ICMJE Uniform Disclosure Form for Potential Conflicts of Interest and upload it along with the manuscript. This information will be held in confidence by the Editor in Chief during the review process and, if the paper is accepted for publication, will be shared with readers as appropriate. We thank authors for their assistance in this effort.

STATISTICAL CONSULTANT

Authors

- Consider having a statistician review your study
    - PRIOR to starting the study
    - PRIOR to submitting manuscript

Reviewers

- Don't worry about the statistics
- PTJ has retained statistical consultants to assist with reviewing

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