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

Section/Topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	page1/line3–4	title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	n/a	n/a
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	page3–4/line73–101	Introduction
	2b	Specific objectives or hypotheses	page3–4/line73–101	Introduction
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	page4/line104–115	Methods/par1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a	n/a
Participants	4a	Eligibility criteria for participants	page4–5/line117–127	Methods/par2–3
	4b	Settings and locations where the data were collected	page4–5/line117–127	Methods/par2–3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	page5–7/line129–219	Methods/par4–15
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	page5–7/line129–219	Methods/par4–15
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a	n/a
Sample size	7a	How sample size was determined	n/a	n/a
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a	n/a
Randomisation:			page5–7/line129–219	Methods/par4–15
Sequence generation	8a	Method used to generate the random allocation sequence	page5–7/line129–219	Methods/par4–15
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	page5–7/line129–219	Methods/par4–15
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	n/a	n/a

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	n/a	n/a
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a	n/a
	11b	If relevant, description of the similarity of interventions	n/a	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	page5–7/line129–219	Methods/par4–15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a	n/a
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	page7–8/line223–232	Results/par1
	13b	For each group, losses and exclusions after randomisation, together with reasons	page7–8/line223–232	Results/par1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a	n/a
	14b	Why the trial ended or was stopped	n/a	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	page8/line234–255	Results/para1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	page8/line234–255	Results/par2–3
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)	page8/line234–255	Results/par2–3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	page9/line258–263	Results/par4
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	page9–12/line266–368	Discussion
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	page9–12/line266–368	Discussion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	page9–12/line266–368	Discussion
Other information				
Registration	23	Registration number and name of trial registry	page2/line61	Registration

Protocol	24	Where the full trial protocol can be accessed, if available	page12/line381	Footnote
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	n/a	n/a

*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.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	n/a	n/a
Authors *	Contact details for the corresponding author	n/a	n/a
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	page1–2/line30–38	abstract
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	page2/line39–48	abstract
Interventions	Interventions intended for each group	page2/line39–48	abstract
Objective	Specific objective or hypothesis	page2/line39–48	abstract
Outcome	Clearly defined primary outcome for this report	page2/line39–48	abstract
Randomization	How participants were allocated to interventions	page2/line39–48	abstract
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	page2/line39–48	abstract
Results			
Numbers randomized	Number of participants randomized to each group	page2/line49–56	abstract
Recruitment	Trial status	page2/line49–56	abstract
Numbers analysed	Number of participants analysed in each group	page2/line49–56	abstract
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	page2/line49–56	abstract
Harms	Important adverse events or side effects	page2/line49–56	abstract

Conclusions	General interpretation of the results	page2/line49–56	abstract
Trial registration	Registration number and name of trial register	page2/line49–56	abstract
Funding	Source of funding	n/a	n/a

** this item is specific to conference abstracts*

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

STARD 2015

Section & Topic	Item No	Item	Reported on Page Number/ Line Number	Reported on Section/ Paragraph
TITLE OR ABSTRACT				
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	page 1/line1-3	Title
ABSTRACT				
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	page 1-2/line19-45	Abstract
INTRODUCTION				
	3	Scientific and clinical background, including the intended use and clinical role of the index test	page2/line51-71	Introduction
	4	Study objectives and hypotheses	page2/line51-71	Introduction
METHODS				
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	page 2/line74-82	Methods/paragraph1
Participants	6	Eligibility criteria	page 2-3/line74-96	Methods/paragraph1
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	page 2-3/line74-96	Methods/paragraph1
	8	Where and when potentially eligible participants were identified (setting, location and dates)	page 2-3/line74-96	Methods/paragraph1
	9	Whether participants formed a consecutive, random or convenience series	page 2-3/line74-96	Methods/paragraph1
Test methods	10a	Index test, in sufficient detail to allow replication	page 3/line99-117	Methods/paragraph2-3
	10b	Reference standard, in sufficient detail to allow replication	page 3/line99-117	Methods/paragraph2-3
	11	Rationale for choosing the reference standard (if alternatives exist)	N/A	N/A
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	page 3-5/line117-177	Methods/paragraph4-7
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	page 3-5/line117-177	Methods/paragraph4-7
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	page 3-5/line117-177	Methods/paragraph4-7
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	page 3-5/line117-177	Methods/paragraph4-7

Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	page 3-5/line117-177	Methods/paragraph4-7
	15	How indeterminate index test or reference standard results were handled	page 3-5/line117-177	Methods/paragraph4-7
	16	How missing data on the index test and reference standard were handled	N/A	N/A
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	page 3-5/line117-177	Methods/paragraph4-7
	18	Intended sample size and how it was determined	N/A	N/A
RESULTS				
Participants	19	Flow of participants, using a diagram	page 5-6/line179-220	Result/paragraph1-3
	20	Baseline demographic and clinical characteristics of participants	page 5-6/line179-220	Result/paragraph1-3
	21a	Distribution of severity of disease in those with the target condition	page 5-6/line179-220	Result/paragraph1-3
	21b	Distribution of alternative diagnoses in those without the target condition	N/A	N/A
	22	Time interval and any clinical interventions between index test and reference standard	page 5-6/line179-220	Result/paragraph1-3
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	page 5-6/line179-220	Result/paragraph1-3
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	page 5-6/line179-220	Result/paragraph1-3
	25	Any adverse events from performing the index test or the reference standard	page 5-6/line179-220	Result/paragraph1-3
DISCUSSION				
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	page 6-8/line223-306	Discussion/paragrapn 1-9
	27	Implications for practice, including the intended use and clinical role of the index test	page 6-8/line223-306	Discussion/paragrapn 1-9
OTHER INFORMATION				
	28	Registration number and name of registry	N/A	N/A
	29	Where the full study protocol can be accessed	N/A	N/A
	30	Sources of funding and other support; role of funders	N/A	N/A

AIM

STARD stands for “Standards for Reporting Diagnostic accuracy studies”. This list of items was developed to contribute to the completeness and transparency of reporting of diagnostic accuracy studies. Authors can use the list to write informative study reports. Editors and peer-reviewers can use it to evaluate whether the information has been included in manuscripts submitted for publication.

Explanation

A **diagnostic accuracy study** evaluates the ability of one or more medical tests to correctly classify study participants as having a **target condition**. This can be a disease, a disease stage, response or benefit from therapy, or an event or condition in the future. A medical test can be an imaging procedure, a laboratory test, elements from history and physical examination, a combination of these, or any other method for collecting information about the current health status of a patient.

The test whose accuracy is evaluated is called **index test**. A study can evaluate the accuracy of one or more index tests. Evaluating the ability of a medical test to correctly classify patients is typically done by comparing the distribution of the index test results with those of the **reference standard**. The reference standard is the best available method for establishing the presence or absence of the target condition. An accuracy study can rely on one or more reference standards.

If test results are categorized as either positive or negative, the cross tabulation of the index test results against those of the reference standard can be used to estimate the **sensitivity** of the index test (the proportion of participants with the target condition who have a positive index test), and its **specificity** (the proportion without the target condition who have a negative index test). From this cross tabulation (sometimes referred to as the contingency or “2x2” table), several other accuracy statistics can be estimated, such as the positive and negative **predictive values** of the test. Confidence intervals around estimates of accuracy can then be calculated to quantify the statistical **precision** of the measurements.

If the index test results can take more than two values, categorization of test results as positive or negative requires a **test positivity cut-off**. When multiple such cut-offs can be defined, authors can report a receiver operating characteristic (ROC) curve which graphically represents the combination of sensitivity and specificity for each possible test positivity cut-off. The **area under the ROC curve** informs in a single numerical value about the overall diagnostic accuracy of the index test.

The **intended use** of a medical test can be diagnosis, screening, staging, monitoring, surveillance, prediction or prognosis. The **clinical role** of a test explains its position relative to existing tests in the clinical pathway. A replacement test, for example, replaces an existing test. A triage test is used before an existing test; an add-on test is used after an existing test.

Besides diagnostic accuracy, several other outcomes and statistics may be relevant in the evaluation of medical tests. Medical tests can also be used to classify patients for purposes other than diagnosis, such as staging or prognosis. The STARD list was not explicitly developed for these other outcomes, statistics, and study types, although most STARD items would still apply.

DEVELOPMENT

This STARD list was released in 2015. The 30 items were identified by an international expert group of methodologists, researchers, and editors. The guiding principle in the development of STARD was to select items that, when reported, would help readers to judge the potential for bias in the study, to appraise the applicability of the study findings and the validity of conclusions and recommendations. The list represents an update of the first version, which was published in 2003. More information can be found on http://www.equator-network.org/reporting-guidelines/stard.

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