

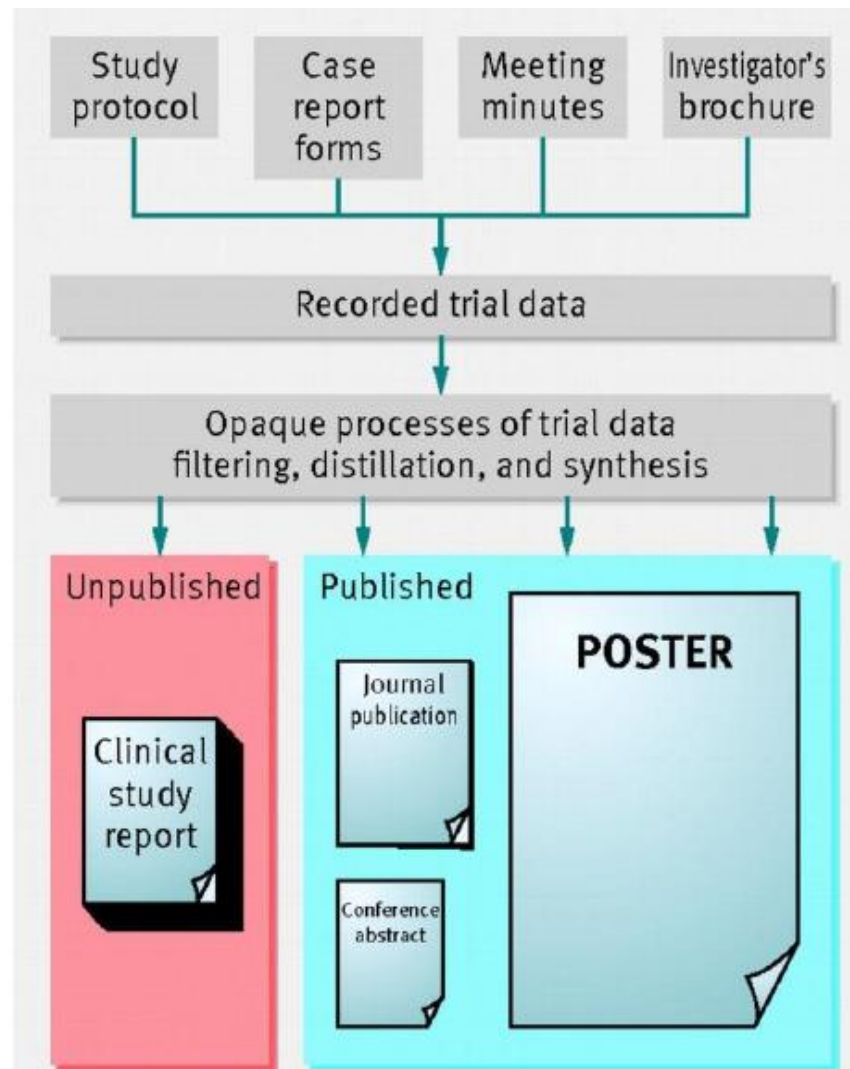


ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ
ΕΡΓΑΣΤΗΡΙΟ ΒΙΟΜΑΘΗΜΑΤΙΚΩΝ



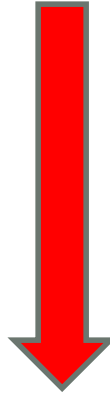
ΠΟΙΟΤΗΤΑ ΑΝΑΦΟΡΑΣ ΚΛΙΝΙΚΩΝ ΜΕΛΕΤΩΝ

Ιωάννα Μπουλιμάρη, MSc, PhD
Παιδίατρος-Νεογνολόγος
Εντεταλμένος Διδάσκων
ΕΡΓΑΣΤΗΡΙΟ ΒΙΟΜΑΘΗΜΑΤΙΚΩΝ
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ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ



Doshi P, Jones M, Jefferson T. Rethinking credible evidence synthesis. *BMJ*. 2012;344:d7898.

Η δημοσίευση των αποτελεσμάτων



Βήμα προς την διαφάνεια



The BMJ's peer review process



Presented at EQUATOR Network and Oxford Clinical Trials Unit 9 March 2015 by Dr Trish Groves
Head of research, BMJ & Editor-in-chief, BMJ Open

4 ερωτήσεις που πρέπει να απαντηθούν όταν διαβάζουμε την αναφορά μιας μελέτης

Για την κριτική ανάγνωση και αξιολόγηση μιας ερευνητικής μελέτης, είναι απαραίτητο να απαντηθούν τέσσερις βασικές ερωτήσεις

- ✓ Ποιο είναι το ερευνητικό ερώτημα (ή ο σκοπός) της μελέτης; (background- purpose)
- ✓ Πώς διεξήχθη η έρευνα (Μεθοδολογία); (study design)
- ✓ Ποια είναι τα κύρια ευρήματα/αποτελέσματα; (results)
- ✓ Πώς ερμηνεύονται τα αποτελέσματα και ποιες είναι οι συνέπειές τους (Συζήτηση/Συμπεράσματα); (conclusion)

Ποιότητα αναφοράς - Ορισμός

- Η **ποιότητα αναφοράς (reporting quality)** μιας κλινικής μελέτης αφορά τον βαθμό στον οποίο η δημοσιευμένη αναφορά παρέχει πλήρεις και διαφανείς πληροφορίες για τον σχεδιασμό, τη διεξαγωγή και την ανάλυση της έρευνας.
- Είναι σημαντικό να **διακρίνεται από τη μεθοδολογική ποιότητα**, καθώς μια μελέτη μπορεί να είναι άρτια σχεδιασμένη αλλά να αναφέρεται με ελλιπή τρόπο, εμποδίζοντας την κριτική αξιολόγηση των αποτελεσμάτων της.

Κριτήρια Υψηλής Ποιότητας Αναφοράς

Μια ποιοτική αναφορά πρέπει να περιλαμβάνει λεπτομέρειες για:

- **Πληθυσμός και Δείγμα:**
Σαφή κριτήρια εισαγωγής και αποκλεισμού, μέθοδο δειγματοληψίας και τελικό μέγεθος δείγματος
- **Τυχαιοποίηση και Τυφλοποίηση:**
Περιγραφή της μεθόδου τυχαιοποίησης και αν τηρήθηκε η "τύφλωση" των συμμετεχόντων και των ερευνητών
- **Αποτελέσματα και Ασφάλεια:**
Πλήρης παρουσίαση των πρωτευόντων και δευτερευόντων καταληκτικών σημείων, καθώς και λεπτομερής αναφορά σε ανεπιθύμητες ενέργειες
- **Στατιστική Ανάλυση:**
Διαφανής περιγραφή των στατιστικών μεθόδων που χρησιμοποιήθηκαν για την ερμηνεία των δεδομένων
- **Δεοντολογία:**
Τήρηση των ηθικών και νομικών κανόνων, με εξασφάλιση της έγκρισης από τις αρμόδιες αρχές (π.χ. ΕΟΦ)

Σημασία της Ποιότητας Αναφοράς

Η σωστή αναφορά είναι κρίσιμη για:

- **Τη Λήψη Κλινικών Αποφάσεων:**

Επιτρέπει στους ιατρούς να αξιολογήσουν αν τα ευρήματα είναι αξιόπιστα και εφαρμόσιμα στους ασθενείς τους

- **Την Έγκριση Φαρμάκων:**

Οι ρυθμιστικές αρχές (π.χ. ΕΟΦ, EMA, FDA) βασίζονται σε λεπτομερείς εκθέσεις κλινικών μελετών (CSR) για να εγκρίνουν νέες θεραπείες

- **Την Αποφυγή "Ερευνητικών Αποβλήτων":**

Η ελλιπής αναφορά καθιστά την έρευνα μη αξιοποιήσιμη, σπαταλώντας πόρους και χρόνο

Κατηγορίες «φτωχής» αναφοράς

- **Μη αναφορά (ή καθυστερημένη αναφορά)** όλης της μελέτης (ακόμη και εάν μερικά αποτελέσματα έχουν δημοσιευτεί)
- **Εσφαλμένη παρουσίαση του σχεδιασμού της μελέτης** (π.χ. να παρουσιαστεί ως τυχαιοποιημένη μια μελέτη ενώ δεν είναι)
- **Ασαφής περιγραφή της Τυχαιοποίησης (Randomization)**
- **Ελλιπής περιγραφή της Τυφλοποίησης (Blinding/Masking)**

- **Απώλειες κατά την παρακολούθηση (Follow-up Losses)**
- **Ανεπαρκής στατιστική ανάλυση**
- **Ελλιπής περιγραφή της Παρέμβασης**

Κατηγορίες «φτωχής» αναφοράς

- **Επιλεκτική αναφορά**
- **Ατελής δημοσίευση**
 - Παράλειψη σημαντικών πτυχών της ερευνητικής μεθόδου π.χ. παρεμβάσεις
 - Ελλιπή αποτελέσματα: τα δεδομένα δεν μπορούν να συμπεριληφθούν σε μετα-ανάλυση
- **Παραπλανητική επεξήγηση** (π.χ. μετα-ερευνητική αλλαγή του στόχου)
- **Ασυνέπειες μεταξύ των πηγών** (π.χ. δημοσίευση έναντι πρωτοκόλλου)

Συνέπειες «φτωχής» αναφοράς

- **Αποδεικτική βάση**

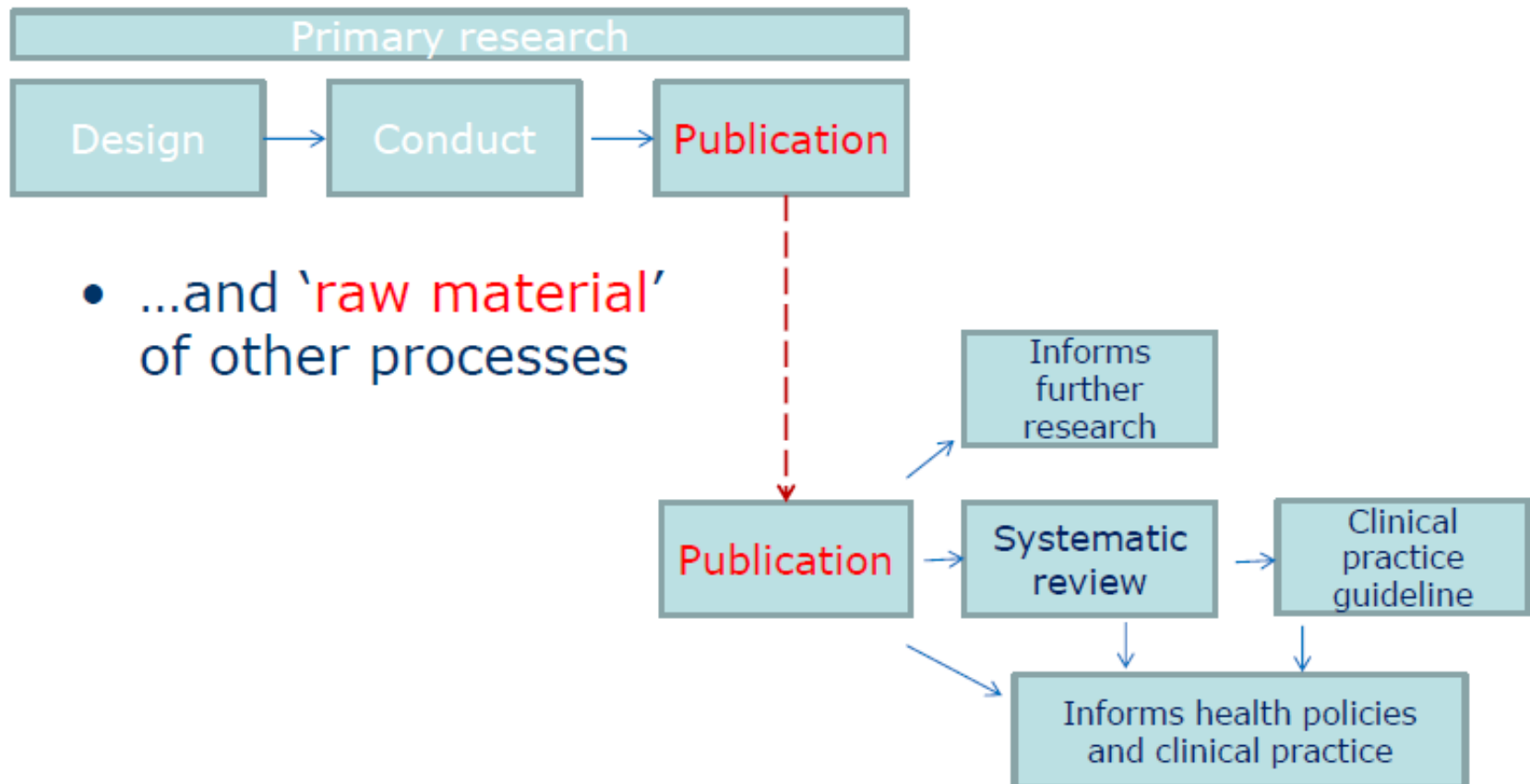
- ✓ Τα υπάρχοντα δεδομένα μπορεί να υποβαθμιστούν/ μην χρησιμοποιηθούν καθώς δεν μπορούν να εκτιμηθούν
- ✓ Αυξάνεται η υπο-αναφορά των μελετών

- **Λήψη αποφάσεων**

- ✓ Οι αποφάσεις των επαγγελματιών υγείας και των ασθενών βασίζονται σε ασθενέστερα τεκμήρια

«Φτωχή» αναφορά = σοβαρά προβλήματα στις συστηματικές ανασκοπήσεις και τις κατευθυντήριες οδηγίες

- Research article is 'end product' of one process ...



- ...and 'raw material' of other processes

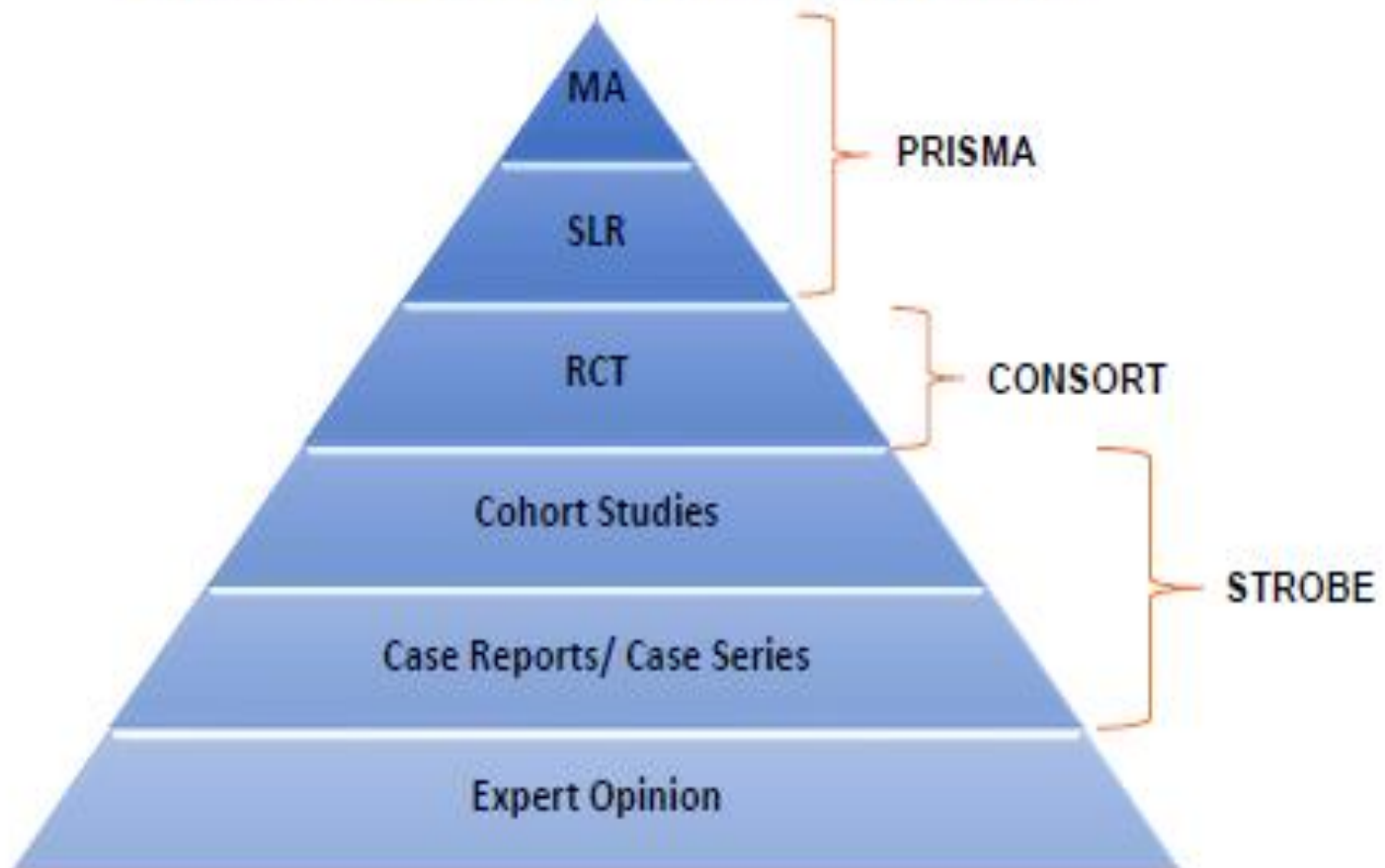
Κατευθυντήριες οδηγίες αναφοράς

- Καθιερώθηκαν από **διεθνείς συνεργατικές ομάδες** που συμπεριλαμβάνουν ερευνητές και εκδότες
- Προσδιορίζουν το **ελάχιστο σύνολο αντικειμένων** που απαιτείται για ξεκάθαρη και διαφανή παρουσίαση της διεξαγωγής και των αποτελεσμάτων της μελέτης
- Σε **μορφή λίστας** (με συνοδευτική επεξηγηματική δημοσίευση)
- Εστιάζει σε **θέματα που μπορεί να εισάγουν bias** στην έρευνα
- **Στηρίζονται σε τεκμήρια** (ή σε ομοφωνία της ομάδας εάν δεν υπάρχουν τεκμήρια)

Κατευθυντήριες οδηγίες αναφοράς

- Είναι **καθοδήγηση**- όχι απαίτηση
- **Βοηθητικό** για συγγραφείς, εκδότες, κριτές και αναγνώστες
- **Όχι εργαλείο** για εκτίμηση της μεθοδολογικής ποιότητας της μελέτης

Evidence Based Medicine Pyramid



Modified by EBM Pyramid; Trustees of Dartmouth College & Yale University

CONSORT

CONsolidated Standards fOr Reporting Trials

CONSORT 1996

Special Communication

Improving the Quality of Reporting of Randomized Controlled Trials

The CONSORT Statement

Colin Begg, PhD; Mildred Cho, PhD; Susan Eastwood, ELS(D); Richard Horton, MB;
David Moher, MSc; Ingram Olkin, PhD; Roy Pliskin, MD; Drummond Rennie, MD;
Kenneth F Schulz, PhD; David G Altman, PhD; Douglas G Altman, PhD

JAMA, August 28, 1996

CONSORT statement

The CONSORT statement: revised recommendations for improving
the quality of reports of parallel-group randomised trials

David Moher, Kenneth F Schulz, Douglas G Altman, for the CONSORT Group* Lancet 2001; 357: 1191-94

Article first published online 11 July 2001
<https://www.trialsjournal.com/content/1/1/1>



RESEARCH

Open Access

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz^{1,2}, Douglas G Altman², David Moher³, for the CONSORT Group

CONSORT

- Βελτιώνει την αναφορά των τυχαιοποιημένων κλινικών μελετών
 - ✓ διευκολύνει την κριτική αξιολόγηση και ερμηνεία των αποτελεσμάτων
- Ενισχύει την διεξαγωγή υψηλής ποιότητας RCTs
 - ✓ διαφανής αναφορά παρουσιάζει τα μειονεκτήματα της έρευνας (εάν υπάρχουν)
 - ✓ Έμμεσα βελτιώνει το σχεδιασμό και την διεξαγωγή

CONSORT

- 585 επιστημονικά περιοδικά υποστηρίζουν την χρήση του CONSORT.
- Περίπου το 50% των επιστημονικών περιοδικών που εμφανίζονται στο Abridged Index Medicus on PubMed.

CONSORT

consort-spirit.org

Smart Adobe Acrobat Αρχειο - e-Prescript...



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Welcome to the SPIRIT-CONSORT website

The SPIRIT-CONSORT guidelines offer a standard way to report trial protocols and findings for randomized trials. This helps authors to report their trials completely and transparently, providing readers with all the information they need to critically appraise, interpret and use the research.

SPIRIT 2025

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trial...

[Read more](#)

CONSORT 2025

The CONSORT (CONsolidated Standards Of Reporting Trials) Statement is an evidence...

[Read more](#)

CONSORT

SPIRIT 2025

The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trial...

[Read more](#)



[Checklist](#)



[Expanded checklist](#)



[Figure](#)



[Statement](#)



[Explanation and Elaboration](#)

CONSORT 2025

The CONSORT (CONsolidated Standards Of Reporting Trials) Statement is an evidence...

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[Checklist](#)



[Expanded checklist](#)



[Flow diagram](#)



[Statement](#)



[Explanation and Elaboration](#)

CONSORT

- Οι οδηγίες CONSORT (Consolidated Standards of Reporting Trials) παρέχουν ένα τυποποιημένο πλαίσιο **30 σημείων (CONSORT 2025)** και ένα **διάγραμμα ροής** για την πλήρη και διαφανή αναφορά τυχαιοποιημένων κλινικών δοκιμών
- **Στόχος** είναι η βελτίωση της ποιότητας των δημοσιεύσεων, μειώνοντας τις μεροληψίες (bias) μέσω λεπτομερούς περιγραφής του σχεδιασμού, της διεξαγωγής και των αποτελεσμάτων της μελέτης

Βασικά Στοιχεία της Δήλωσης CONSORT

- **Λίστα Ελέγχου (Checklist):**

Περιλαμβάνει 30 στοιχεία (τίτλος, περίληψη, εισαγωγή, μέθοδοι, αποτελέσματα, συζήτηση) που πρέπει να καλύπτονται σε μια δημοσίευση

- **Διάγραμμα Ροής (Flow Diagram):**

Απεικονίζει τη ροή των συμμετεχόντων (τυχαιοποίηση, παρέμβαση, παρακολούθηση, ανάλυση)

- **Συνεχής Ενημέρωση:**

Οι πιο πρόσφατες οδηγίες είναι οι CONSORT 2025, οι οποίες αντικαθιστούν τις παλαιότερες (2010) για να αντικατοπτρίζουν τις σύγχρονες μεθοδολογικές εξελίξεις

CONSORT

CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	
	1b	Structured summary of the trial design, methods, results, and conclusions	
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	
	5b	Financial and other conflicts of interest of the manuscript authors	
Introduction			
Background and rationale	6	Scientific background and rationale	
Objectives	7	Specific objectives related to benefits and harms	
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	
Eligibility criteria	12a	Eligibility criteria for participants	
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	

CONSORT

Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	
	16b	Explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	
	21c	How missing data were handled in the analysis	
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	
	22b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	
	23b	If relevant, why the trial ended or was stopped	

CONSORT

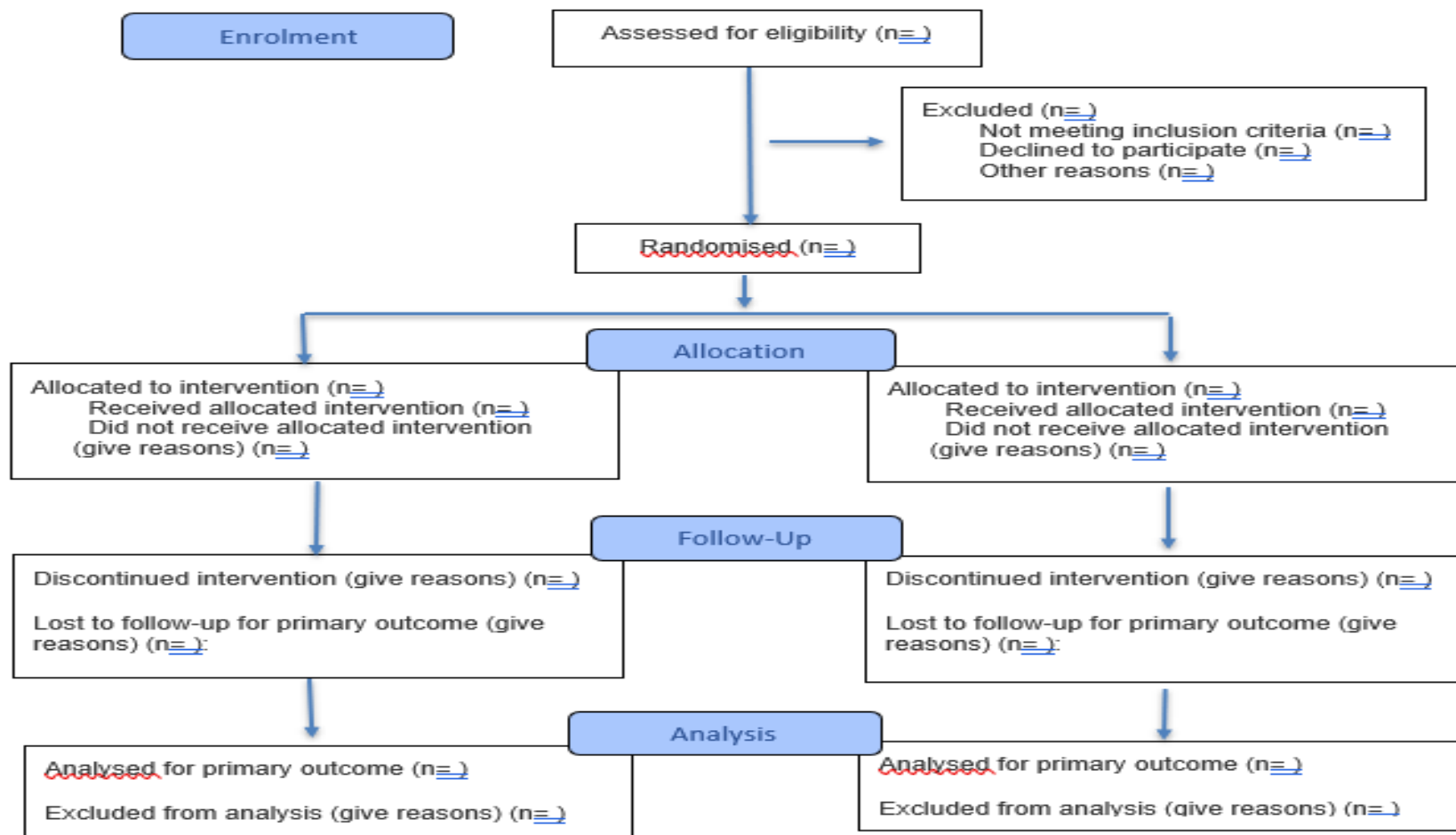
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	
	24b	Concomitant care received during the trial for each group	
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: - the number of participants included in the analysis - the number of participants with available data at the outcome time point - result for each group, and the estimated effect size and its precision (such as 95% confidence interval) - for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. <https://dx.doi.org/10.1136/bmj-2024-081123>.

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Flow diagram of the progress through the phases of a randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)





Enhancing the QUALity and
Transparency Of health Research



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CONSORT 2025 Statement: updated guideline for reporting randomised trials

Reporting guideline
provided for?
(i.e. exactly what the
authors state in the paper)

Reporting of randomised trials.

[CONSORT 2025 Checklist \(Download from CONSORT-SPIRIT website\)](#)



Reporting guidelines for main study types

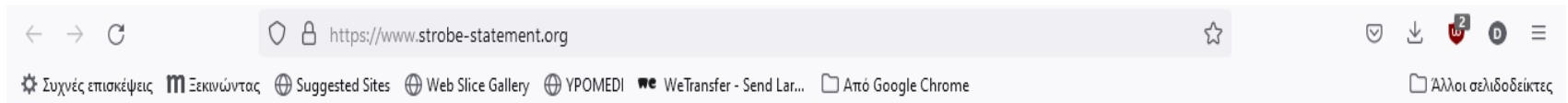
Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical		

STROBE

STrengthening the **R**eporting of **OBs**ervational Studies



www.strobe-statement.org



STROBE

Strengthening the reporting of observational studies in epidemiology

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What is STROBE?

STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **Strengthening the Reporting of OBservational studies in Epidemiology**.

For STROBE-related entries in PubMed click [here](#).

Aims and use of STROBE

Incomplete and inadequate reporting of research hampers the assessment of the strengths and weaknesses of the studies reported in the medical literature. Readers need to know what was planned (and what was not),

Documents

- ✓ STROBE Checklist:
cohort, case-control, and
cross-sectional studies
(combined)
Download [PDF](#) | [Word](#)
- ✓ STROBE Checklist (wide):
cohort, case-control, and
cross-sectional studies
(combined)
Download [PDF](#) | [Word](#)
- ✓ STROBE Checklist:

STROBE

22 ερωτήσεις (items)

- Cohort
- case-control
- cross-sectional studies

STROBE checklist

TITLE & ABSTRACT

1. Title & Abstract

INTRODUCTION

2. Background / Rationale
3. Objectives

METHODS

4. Study design
5. Setting
6. Participants
7. Variables
8. Data sources / Measurement
9. Bias
10. Study size
11. Quantitative variables
12. Statistical methods

RESULTS

13. Participants
14. Descriptive data
15. Outcome data
16. Main results
17. Other analyses

DISCUSSION

18. Key results
19. Limitations
20. Interpretation
21. Generalizability

OTHER INFORMATION

22. Funding

STROBE

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

	Item No	Recommendation
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) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case

STROBE

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) <i>Cohort study</i>—If applicable, explain how loss to follow-up was addressed <i>Case-control study</i>—If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i>—If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

STROBE

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) <i>Cohort study</i>—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i>—Report numbers of outcome events or summary measures over time <i>Case-control study</i>—Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i>—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

STROBE

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.

PRISMA

**Preferred Reporting Items for Systematic Reviews and
Meta-Analyses**

Welcome to the PRISMA website

PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) is a guideline designed to improve the reporting of systematic reviews. PRISMA provides authors with guidance and examples of how to completely report why a systematic review was done, what methods were used, and what results were found. The main PRISMA reporting guideline ([PRISMA 2020](#)) primarily provides guidance for the reporting of systematic reviews evaluating the effects of interventions. PRISMA 2020 is complemented by various [PRISMA extensions](#), which provide guidance for the reporting of different types or aspects of systematic reviews and other types of evidence synthesis (e.g. scoping reviews).

Key PRISMA 2020 documents

- [Checklist](#)
- [Expanded checklist](#)
- [Flow diagram](#)
- [Statement paper](#)



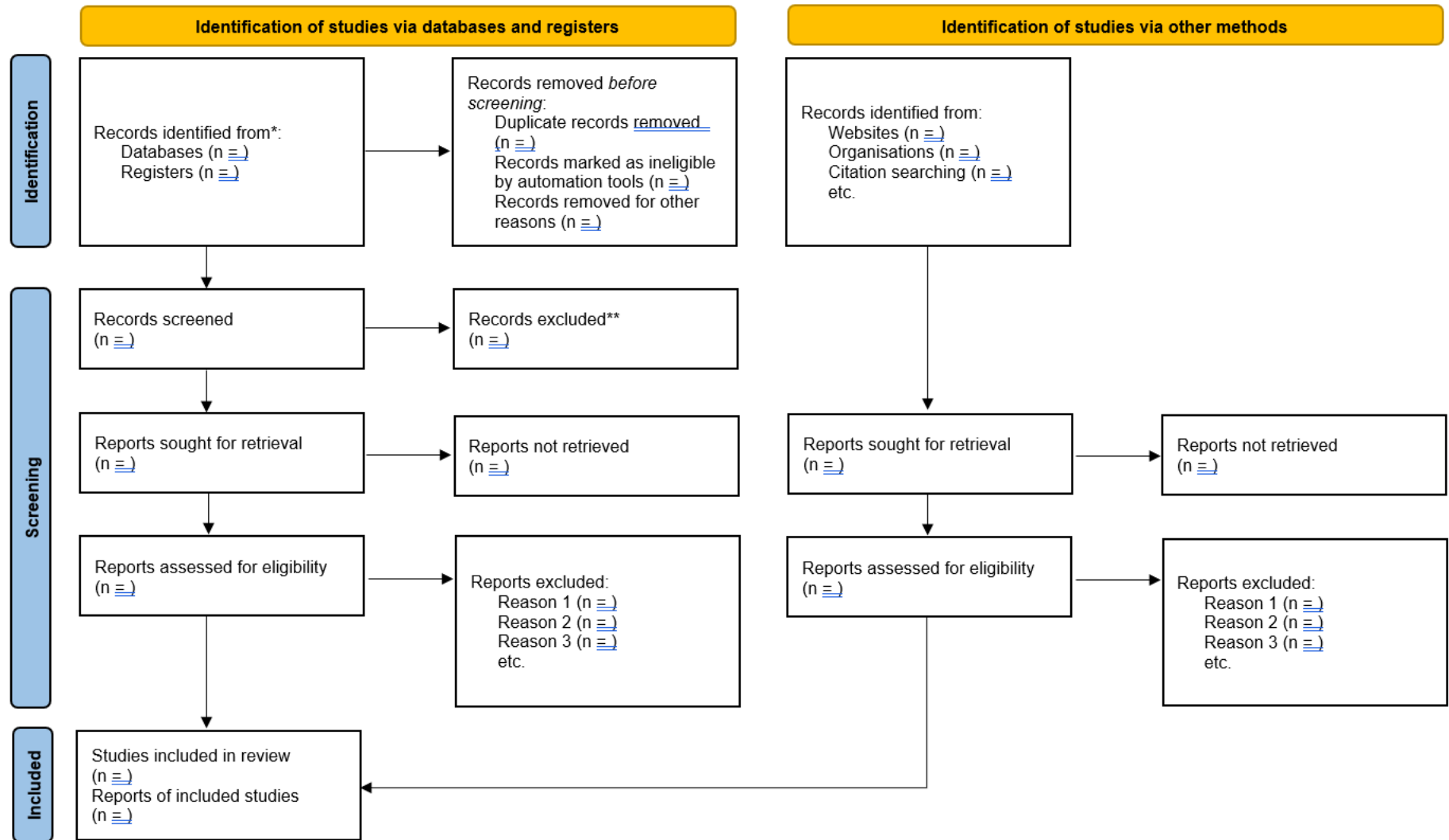
Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	



PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect <u>estimate</u> and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources





Analysis of the quality of reporting of randomized controlled trials in anticoagulant versus antiplatelet medication for venous thromboembolism prophylaxis as governed by the CONSORT statement

Eirini Beneki^{1,2} · Christos Vrysis³ · Elias Zintzaras^{1,4,5} · Chrysoula Doxani¹

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STARD

STAndards for **R**eporting of **D**iagnostic Accuracy

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.

30 ερωτήσεις (items)

Section & Topic	No	Item
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)
ABSTRACT		
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)
INTRODUCTION		
	3	Scientific and clinical background, including the intended use and clinical role of the index test
	4	Study objectives and hypotheses
METHODS		
<i>Study design</i>	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)
<i>Participants</i>	6	Eligibility criteria
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)
	8	Where and when potentially eligible participants were identified (setting, location and dates)
	9	Whether participants formed a consecutive, random or convenience series
<i>Test methods</i>	10a	Index test, in sufficient detail to allow replication
	10b	Reference standard, in sufficient detail to allow replication
	11	Rationale for choosing the reference standard (if alternatives exist)
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test
	13b	Whether clinical information and index test results were available to the assessors of the reference standard
<i>Analysis</i>	14	Methods for estimating or comparing measures of diagnostic accuracy
	15	How indeterminate index test or reference standard results were handled
	16	How missing data on the index test and reference standard were handled
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory
	18	Intended sample size and how it was determined
RESULTS		
<i>Participants</i>	19	Flow of participants, using a diagram
	20	Baseline demographic and clinical characteristics of participants
	21a	Distribution of severity of disease in those with the target condition
	21b	Distribution of alternative diagnoses in those without the target condition
	22	Time interval and any clinical interventions between index test and reference standard
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)
	25	Any adverse events from performing the index test or the reference standard
DISCUSSION		
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability
	27	Implications for practice, including the intended use and clinical role of the index test
OTHER INFORMATION		
	28	Registration number and name of registry
	29	Where the full study protocol can be accessed
	30	Sources of funding and other support; role of funders