

DELPHI-LIST

Treatment allocation

D1 Was a method of randomisation performed? Yes / No / Don't know

D2 Was the treatment allocation concealed? Yes / No / Don't know

D3 Were the groups similar at baseline regarding
the most important prognostic indicators? Yes / No / Don't know

D4 Were eligibility criteria specified? Yes / No / Don't know

D5 Was the outcome assessor blinded? Yes / No / Don't know

D6 Was the care provider blinded? Yes / No / Don't know

D7 Was the patient blinded? Yes / No / Don't know

D8 Were point estimates and measures of variability
presented for the primary outcome measures? Yes / No / Don't know

D9 Did the analysis include an intention-to-treat
analysis? Yes / No / Don't know

Verhagen AP, de Vet HCW, de Bie RA, Kessels AGH, Boers M, Bouter LM, Knipschild PG. The Delphi list; a criteria list for quality assessment of Randomized Clinical Trials for conducting systematic reviews developed by Delphi consensus. *J. Clin Epid.* 1998;51:1235-41.

GENERAL APPENDIX

D1 Words as random and randomisation are used

D2 A concealed treatment allocation means: a random (unpredictable) assignment sequence is generated by an independent person not responsible for determining eligibility of the patients. This person: - has no information about the patients included in the trial; - has no influence on the assignment sequence or the decision about eligibility of the patients.

Score a YES if:

- Some form of centralised randomization scheme, such as having to provide participant details by phone to receive treatment group allocation
- A scheme controlled by a pharmacy
- In a pharmaceutical study, sequential administration of pre-numbered or coded containers to enrolled participants.
- Assignment envelopes, provided that they are sequentially numbered, sealed, and opaque.
- Other combinations which appear to provide assurance of adequate concealment.

Score Dont' know if:

- Assignment envelopes, without description of adequate safeguards.
- Use of a "list" or "table"
- Drawing of 'lots', tossing of coin/dice
- A trial in which the description suggests adequate concealment , but other features are suspicious - for example, markedly unequal control and trial groups.
- Method of randomisation not stated

Score NO if:

- Alternation
- Case record numbers, dates of birth, day of the week, or any other such approach.
- Any allocation procedure transparent before assignment, such as an *open list* of random numbers.

D3 The reviewer determines when the groups are regarded similar. Also a precise description which prognostic indicators are regarded as important should be specified in order to score a 'yes'.

This item addresses possible confounders which randomization may not have allocated equally to each group.

Score YES if:

- groups are demonstrably comparable in respect of potential prognostic indicators on inspection of the characteristics on entry. Means with some expression of the variation eg SD, SE, confidence limits are required **OR**
- differences between groups are adjusted for in the analysis (stratification, Mantel-Haenzel technique, logistic regression, multiple regression, multivariate techniques.)

Score Don't know if:

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- description of the treatment groups at baseline, either in text or table, is inadequate to confirm comparability for all plausibly important confounders.

Score NO if:

- statistically significant or clinical relevant differences between the groups are present but no adjustment has been made in the analysis.
- baseline data do not include all those randomised.

D4 The precise description of which eligibility criteria should be specified in order to score a 'yes' depends on the choices of the reviewer.

Score YES if:

- the inclusion and exclusion criteria are clearly defined.

Score Don't know if:

- the inclusion and exclusion criteria are listed but inadequately defined

Score NO if:

- The inclusion and exclusion criteria are not defined or such that is not possible to determine how the sample was made up.

D5 The reviewer determines when enough information about the blinding is given in order to score a 'yes'. For example: The reviewer might state that blinding should be evaluated and successful for a 'yes' score.

In order to score a 'YES' the authors should state explicitly that the observer or all possible outcome assessors were blinded. In case the patient scores the outcome measures, the patient should be blinded or naïve.

Score Don't know if:

- there is a small or moderate chance of unblinding of assessors
- it is unclear whether the assessors who could have been blinded were blinded.

Score NO if:

- there has been no attempt to blind assessors to the assignment of treatment.
- the nature of the trial interventions makes blinding of assessors impossible.

D6 The reviewer determines when enough information about the blinding is given in order to score a 'yes'. For example: The reviewer might state that blinding should be evaluated and successful for a 'yes' score.

In order to score a 'YES' the authors should state explicitly that the care giver was blinded.

Score Don't know if:

- there was a small/moderate chance of unblinding of treatment providers
- it is unclear whether the treatment providers were blinded to the allocation.

Score NO if:

- the providers of care were informed of the treatment allocation before outcome assessment and analysis.
- surgery or a physical modality was one or more, but not all arms of the trial.
- not possible or not implied

D7 The reviewer determines when enough information about the blinding is given in order to score a 'yes'. For example: The reviewer might state that blinding should

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Delphi-list

be evaluated and successful for a 'yes' score.

In order to score a 'YES' the authors should state explicitly that the patient was blinded, meaning that effective action has been taken to blind participants to assignment.

Score Don't know if:

- there is a small or moderate chance of unblinding of subjects
- in a drug study, or a study in which forms of surgery with identical skin incisions, or in a study comparing a physical modality with a sham, it is unclear whether participants were made aware, or could have become aware, of their assignment prior to measurement of outcomes.

Score NO if:

- the study involves surgery or a physical modality in one arm but not the other.
- participants became aware of their allocation before outcome assessment and analysis.

D8 The word and means that both point estimates and measures of variability should be presented. With point estimates we mean: means, medians, modes etc; and with measures of variability we mean: standard deviations, 95% confidence intervals etc.

D9 'Intention-to-treat' means analysing all randomised patients for the most important outcome measures, and on the most important moments of effect measurement irrespective of non-compliance and co-interventions. This is an important item to which reviewers will wish to pay special attention. Numbers of and reasons for withdrawal or exclusion are required. Many trials fail to describe adequately how they handled this problem. Some provide data but do not carry out an intention to treat analysis; if sufficient data is present for the reviewer to do so then this is satisfactory.

Score YES if:

- Adequate detail of withdrawals and exclusions after randomization exists, and an intention to treat analysis has been, or can be carried out.

Score Don't know if:

- Inadequate detail exists to allow the reviewer to check or carry out an intention to treat analysis.

Score NO if:

- Number and reasons for withdrawal

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Delphi-list

Specific Appendix

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