

Studies leeg

G	H	I	J	K	L	M	N	O
Risk of bias (study limitations: design, inclusion and sample info, measurement, confounding, follow-up)	Toelichting bias	Type studie (zie werkblad hierna)	Land	Verplichting of advies	Steekproef (grootte, populatie)	Recruitment (opvallende in/excl cr., hoe geworven)	Representatief? (is deze studie vergelijkbaar met NL situatie of populatie?)	Sleutelwoorden (gedrag: determinanten/omstandigheden/redenen/mate van naleving/verschillen/interventies)

Studies leeg

	P	Q	R	S	T	U	V	W
1	Doel studie	Methode (controle groep, etc)	Measures DV en IV (item/schaal/gevalideerd/inte natie/gedrag/self-report)	Confounders	Belangrijkste bevindingen	Beoordeling effect sizes	Verschillen tussen subpopulaties	Link naar studie

Item	Code	Material	Unit	Quantity	Unit Price	Total Price	Remarks
5.1.2e	1
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A	B	C	D	E	F	G
1	Quality of evidence is a continuum; any discrete categorisation involves some degree of arbitrariness.			Table 5.2: Factors that can reduce the quality of the evidence		
2				Factor	Consequence	toelichting
3	While factors influencing the quality of evidence are additive – such that the reduction or increase in each individual factor is added together with the other factors to reduce or increase the quality of evidence for an outcome – grading the quality of evidence involves judgments which are not exclusive. Therefore, GRADE is not a quantitative system for grading the quality of evidence. Each factor for downgrading or upgrading reflects not discrete categories but a continuum within each category and among the categories. When the body of evidence is intermediate with respect to a particular factor, the decision about whether a study falls above or below the threshold for up- or downgrading the quality (by one or more factors) depends on judgment.			Limitations in study design or execution (risk of bias)	↓ 1 or 2 levels	zie linksonder Study Design en volgend tabblad voor Risk of Bias.
4				Inconsistency of results	↓ 1 or 2 levels	Niet toegelichte heterogeniteit van resultaten (vooral bij syst reviews, als er veel verschillende bevindingen zijn, gemengd bewijs).
5				Indirectness of evidence	↓ 1 or 2 levels	Bijvoorbeeld gemeten met een surrogaat maat (niet gedrag, maar intentie of zelfgerapporteerd gedrag) Of nt andere interventie (niet thuisblijven bij klachten maar thuisblijven in het algemeen).
6				Imprecision	↓ 1 or 2 levels	kleine steekproef of kleine hoeveelheid events, dus wijd confidence interval
7	Table 5.1: Quality of Evidence Grades			Publication bias	↓ 1 or 2 levels	Lastig te achterhalen, gaat erom in hoevrre er studies met negatieve of andere resultaten niet zijn gepubliceerd en dus niet zijn opgenomen. Vooral voor syst reviews relevante factor. Bij losse studies gaat het om reporting bias (zijn er resultaten weggelaten die wel relevant zijn, nulbevindingen biv)
8	Grade	Definition		Table 5.3: Factors that can increase the quality of the evidence		
9	High	We are very confident that the true effect lies close to that of the estimate of the effect.		Factor	Consequence	
10	Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different		Large magnitude of effect	↑ 1 or 2 levels	Als er een groot effect wordt gevonden. For simple regression β is like R. Thus I would use R rules of thumb... I use the following with my Psychology students: $\beta < 0.1$ - Small effect size $\beta \in [0.1; 0.5]$ - Medium effect size $\beta \geq 0.5$ - Large effect size. For multiple regression these rules are not that straightforward, but for Social Sciences they seem to hold (also following Cohen's d suggestions).
11	Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.		All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed	↑ 1 level	Is er gecontroleerd voor plausible confounders?
12	Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect		Dose-response gradient	↑ 1 level	
13						
14						
15	Study Design					
16	Study design is critical to judgments about the quality of evidence.					
17	For recommendations regarding management strategies – as opposed to establishing prognosis or the accuracy of diagnostic tests –					
18	randomized trials provide, in general, fir stronger evidence than observational studies, and rigorous observational studies provide stronger evidence than uncontrolled case series.					
19	in the GRADE approach to quality of evidence:					
20	randomized trials without important limitations provide high quality evidence					
21	observational studies without special strengths or important limitations provide low quality evidence					
22						
23	Limitations or special strengths can, however, modify the quality of the evidence of both randomized trials and observational studies.					
24	Note:					
25	Non-randomised experimental trials (quasi-RCT) without important limitations also provide high quality evidence, but will automatically be downgraded for limitations in design (risk of bias) – such as lack of concealment of allocation and tie with a provider (e.g. chart number).					
26	Case series and case reports are observational studies that investigate only patients exposed to the intervention. Source of control group results is implicit or unclear, thus, they will usually warrant downgrading from low to very low quality evidence.					
27	Expert opinion is not a category of quality of evidence. Expert opinion represents an interpretation of evidence in the context of experts' experiences and knowledge. Experts may have opinion about evidence that may be based on interpretation of studies ranging from uncontrolled case series (e.g. observations in expert's own practice) to randomized trials and systematic reviews known to the expert. It is important to describe what type of evidence (whether published or unpublished) is being used as the basis for interpretation.					

A	B	C	D	E	F	G	H	I	J	K	L	
				Table 5.4: Study limitations in randomized controlled trials								
				Lack of allocation concealment				Explanation Those enrolling patients are aware of the group (or period in a crossover trial) to which the next enrolled patient will be allocated (a major problem in "pseudo" or "quasi" randomized trials with allocation by day of week, birth date, chart number, etc.).				
1				Lack of blinding				Patient, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are allocated (or the medication currently being received in a crossover trial).				
2				Incomplete accounting of patients and outcome events				Loss to follow-up and failure to adhere to the intention-to-treat principle in superiority trials; or in noninferiority trials, loss to follow-up, and failure to conduct both analyses considering only those who adhered to treatment, and all patients for whom outcome data are available. The significance of particular rates of loss to follow-up, however, varies widely and is dependent on the relation between loss to follow-up and number of events. The higher the proportion lost to follow-up in relation to intervention and control group event rates, and differences between intervention and control groups, the greater the threat of bias.				
3	RISK OF BIAS = Limitations in the study design and execution may bias the estimates of the treatment effect. Our confidence in the estimate of the effect and in the following recommendation decreases if studies suffer from major limitations. The more serious the limitations are, the more likely it is that the quality of evidence will be downgraded. Numerous tools exist to evaluate the risk of bias in randomized trials and observational studies.											
				Selective outcome reporting				Incomplete or absent reporting of some outcomes and not others on the basis of the results.				
4	Risk of bias	Uitleg		Other limitations				Stopping trial early for benefit. Substantial overestimates are likely in trials with fewer than 500 events and that large overestimates are likely in trials with fewer than 200 events. Empirical evidence suggests that formal stopping rules do not reduce this bias. Use of unvalidated outcome measures (e.g. patient-reported outcomes). Carryover effects in crossover trial. Recruitment bias in cluster-randomized trials.				
5	None											
6	Due to confounding	Baseline confounding occurs when one or more prognostic variables (factors that predict the outcome of interest) also predicts the intervention received at baseline. ROBINS I can also address time-varying confounding, which occurs when individuals switch between the interventions being compared and when post-baseline prognostic factors affect the intervention received after baseline.										
7	In participant selection	When exclusion of some eligible participants, or the initial follow-up time of some participants, or some outcome events is related to both intervention and outcome, there will be an association between interventions and outcome even if the effects of the interventions are identical. This form of selection bias is distinct from confounding—a specific example is bias due to the inclusion of prevalent users, rather than new users, of an intervention.										
8	Due to missing data	Bias that arises when later follow-up is missing for individuals initially included and followed (such as differential loss to follow-up that is affected by prognostic factors); bias due to exclusion of individuals with missing information about intervention status or other variables such as confounders.										
9	In measurement of predic/outcome	Bias introduced by either differential or non-differential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects.										
10	In selection of reported result	Selective reporting of results in a way that depends on the findings and prevents the estimate from being included in a meta-analysis (or other synthesis)										
11	In misclassification of intervention (randomization)	Bias introduced by either differential or non-differential misclassification of intervention status. Non-differential misclassification is unrelated to the outcome and will usually bias the estimated effect of intervention towards the null. Differential misclassification occurs when misclassification of intervention status is related to the outcome or the risk of the outcome, and is likely to lead to bias.										
12	Due to deviation from intended intervention	Bias that arises when there are systematic differences between implementation of intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s).										
13												
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15	Tussen studies											
16	- Comparison: bij interventie studies, goed bekijken wat de comparison conditie is en of studies vergelijkbaar zijn met elkaar.											
17	- Outcomes: zijn gebruikte uitkomstmaten vergelijkbaar? (gaat het om intentie van gedrag, zelfgerapporteerde naleving, daadwerkelijke naleving, etc)											
18												
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20											Table 5.5: Study limitations in observational studies	
21											Explanation	
22											<ul style="list-style-type: none"> • Under- or over-matching in case-control studies 	
23											<ul style="list-style-type: none"> • Failure to develop and apply appropriate eligibility criteria (inclusion of control population) • Selection of exposed and unexposed in cohort studies from different populations 	
24											<ul style="list-style-type: none"> • Differences in measurement of exposure (e.g. recall bias in case-control studies) • Differential surveillance for outcome in exposed and unexposed in cohort studies 	
25											<ul style="list-style-type: none"> • Flawed measurement of both exposure and outcome 	
26											<ul style="list-style-type: none"> • Failure of accurate measurement of all known prognostic factors • Failure to match for prognostic factors and/or adjustment in statistical analysis 	
											<ul style="list-style-type: none"> • Incomplete or inadequately short follow-up <p>Especially within prospective cohort studies, both groups should be followed for the same amount of time.</p>	

	M	N	O	P
1			5.1.2h	
2			1. Were the criteria for inclusion in the sample clearly defined?	The authors should provide clear inclusion and exclusion criteria that they developed prior to recruitment of the study participants.
3			2. Were the study subjects and the setting described in detail?	The study sample should be described in sufficient detail so that other researchers can determine if it is comparable to the population of interest to them. The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location, and time period.
4			3. Was the exposure measured in a valid and reliable way?	The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measure can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure is needed. Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include intra-observer reliability and inter-observer reliability.
5			4. Were objective, standard criteria used for measurement of the condition?	It is useful to determine if patients were included in the study based on either a specified diagnosis or definition. This is more likely to decrease the risk of bias. Characteristics are another useful approach to matching groups, and studies that did not use specified diagnostic methods or definitions should provide evidence on matching by key characteristics.
6			5. Were confounding factors identified?	Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify the potential confounders and measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.
7			6. Were strategies to deal with confounding factors stated?	Strategies to deal with effects of confounding factors may be dealt within the study design or in data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustment in data analysis, assess the statistics used in the study. Most will be some form of multivariate regression analysis to account for the confounding factors measured.
8			7. Were the outcomes measured in a valid and reliable way?	Importantly, determine if the measurement tools used were validated instruments as this has a significant impact on outcome assessment validity. Having established the objectivity of the outcome measurement (e.g. lung cancer instrument), it is important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use of the instrument? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, or level of responsibility in the piece of research being appraised?
9			8. Was appropriate statistical analysis used?	As with any consideration of statistical analysis, consideration should be given to whether there was a more appropriate alternate statistical method that could have been used. The methods section should be detailed enough for reviewers to identify which analytical techniques were used (in particular, regression or stratification) and how specific confounders were measured. For studies utilizing regression analysis, it is useful to identify if the study identified which variables were included and how they related to the outcome. If stratification was the analytical approach used, were the strata of analysis defined by the specified variables? Additionally, it is also important to assess the appropriateness of the analytical strategy in terms of the assumptions associated with the approach as differing methods of analysis are based on differing assumptions about the data and how it will respond.
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