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QoE

	A	B	C	D	E	F
1		Oordeel opties (waarin zowel quality of evidence als tabblad hiernaast, Bias, zijn meegenomen)		QoE beoordelen. Bij zowel observationeel als RCT -->	Table 5.2: Factors that can reduce the quality of the evidence	
2	Table 5.1: Quality of Evidence Grades			Quality of evidence hangt af van volgende factoren, waaronder design (wat je bij Bias bekijkt)	Factor	Consequence
3	Grade	Definition			Limitations in study design or execution (risk of bias)	↓ 1 or 2 levels
4	High	We are very confident that the true effect lies close to that of the estimate of the effect.			Inconsistency of results	↓ 1 or 2 levels
5	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			Indirectness of evidence	↓ 1 or 2 levels
6	Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.			Imprecision	↓ 1 or 2 levels
7	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			Publication bias	↓ 1 or 2 levels
8					Table 5.3: Factors that can increase the quality of the evidence	
9	VOOR REVIEWS, gebruik dit formulier voor een oordeel en sla deze op				Factor	Consequence
10					Large magnitude of effect	↑ 1 or 2 levels
11					All plausible confounding would reduce the demonstrated effect or increase the effect if no effect was observed	↑ 1 level
12					Dose-response gradient	↑ 1 level

5.1.2h

	G	H	I	J	K	L	M	N	O
1		Quality of evidence is a continuum; any discrete categorisation involves some degree of arbitrariness.							
2	toelichting	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 judgements 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.							
3	zie linksonder Study Design en volgend tabblad voor Risk of Bias. Observatoneel kan hierdoor eigenlijk niet als HIGH beoordeeld worden.								
4	Niet toegelichte heterogeniteit van resultaten (vooral bij syst reviews, als er veel verschillende bevindingen zijn, gemengd bewijs).								
5	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).	Study Design							
6	Kleine steekproef of kleine hoeveelheid events, dus wijd confidence interval	Study design is critical to judgments about the quality of evidence. For recommendations regarding management strategies – as opposed to establishing prognosis or the accuracy of diagnostic tests –							
7	Lastig te achterhalen, gaat erom in hoeverre 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 bijv)	Randomized trials provide, in general, far stronger evidence than observational studies, and rigorous observational studies provide stronger evidence than uncontrolled case series. In the GRADE approach to quality of evidence: Randomized trials without important limitations provide high quality evidence							
8		Observational studies without special strengths or important limitations provide low quality evidence							
9		Limitations or special strengths can, however, modify the quality of the evidence of both randomized trials and observational studies. 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).							
10	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 $0.1 \leq \beta < 0.5$ - 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).	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. 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							
11	Is er gecontroleerd voor plausibele confounders?	(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.							
12									

A	B	C	D	E	F	G	H	I	J	K	L	M
1	RCT's gebruik deze --> tabel 5.4	Table 5.4: Study limitations in randomized controlled trials										
		Explanation										
	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	<p>Lack of allocation concealment 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.)</p> <p>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).</p> <p>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.</p> <p>Selective outcome reporting Incomplete or absent reporting of some outcomes and not others on the basis of the results.</p> <p>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</p>										
2												
3	Risk of bias	Uitleg										
4	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 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.										
5	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—its specific example is bias due to the exclusion of prevalent users, rather than new users, of an intervention										
6	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.										
7	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										
8	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)										
9	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										
	Due to deviation from intended intervention	Bias that arises where there are systematic differences between experimental intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s)										
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14	Tussen studies											
15	- Comparison: bij interventie studies, goed bekijken wat de comparison conditie is en of studies vergelijkbaar zijn met elkaar.											
16	- Outcomes: zijn gebruikte uitkomstmaten vergelijkbaar? (gaat het om intentie van gedrag, zelfrapporteerde naleving, daadwerkelijke naleving, etc)											
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Table 5.5: Study

Explanation
Under- or over-matching in case-control studies
Failure to develop and apply appropriate eligibility criteria (exclusion and inclusion of control population)
Selection of exposed and unexposed in cohort studies from different populations
Flawed measurement of both exposure and outcome
Differences in measurement
Differential surveillance for outcome in exposed
Failure of accurate measurement of all known prognostic factors
Failure to adequately confounding
Failure to match for prognostic factors and/or
Incomplete or inadequately short follow-up
Especially within prospective cohort studies, both

