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Risk of bias (study limitations: design, inclusion and sample info, measurement, confounding, folluw-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
Doel studie	Methoda (controla groop atc)	Measures DV en IV (item/schaal/gevalideerd/inte ntie/gedrag/self-report)	Confounders	Belangrijkste bevindingen	Beoordeling effect sizes	Verschillen tussen subpopulaties	Link nəər studie

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	A	В	С	D	E	F	G		
1		of evidence is a continuum; any discrete categorisation involves	some deg	ree of	Table 5.2: Factors that can reduce the	quality of the evidence			
2	arbitrar	iness.			Factor	Consequence	toelichting		
	While fa	ctors influencing the quality of evidence are additive - such that the	reduction	or increase in	Limitations in study design or execution	↓ 1 or 2 levels			
3	each ind	vidual factor is added together with the other factors to reduce or in	ncrease the	quality of	(risk of bias)	\$ 1 GI 2 IOIGS	zie linksonder Study Design en volgend tabblad voor Risk of Bias.		
		for an outcome – grading the quality of evidence involves judgeme . Therefore, GRADE is not a quantitative system for grading the quality of the system for grading the system for grading the quality of the system for grading the system for gradin							
	factor fo	downgrading or upgrading reflects not discrete categories but a co	ntinuum w	ithin each	Inconsistency of results	↓ 1 or 2 levels	Niet toegelichte heterogeniteit van resultaten (vooral bij syst reviews, als er		
4	category	and among the categories. When the body of evidence is intermedi	ate with re	spect to a			veel verschillende bevindingen zijn, gemengd bewijs).		
		factor, the decision about whether a study falls above or below the ding the quality (by one or more factors) depends on judgment.	e threshold	for up- or			Bijvoorbeeld gemeten met een surrogaat maat (niet gedrag, maar intentie of		
	oowngra	ung me quanty (by one of more factors) depends on judgment.			Indirectness of evidence	↓ 1 or 2 levels	zelfgerapporteerd gedrag) Of nt andere interventie (niet thuisblijven bij		
5							klachten maar thuisbiljven in het algemeen).		
6					Imprecision	↓ 1 or 2 levels	Kleine steekproef of kleine hoeveelheid events, dus wijd confidence interval		
							Lastig te achterhalen, gaat erom in hoevrre er studies met negatieve of andere		
	Table 5.1:	Quality of Evidence Grades			Publication bias	↓ 1 or 2 levels	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		
7			-				resultaten weggelaten die wel relevant zijn, nulbevindingen bijv)		
8	Grade	Definition			Table 5.3: Factors that can increase the	e quality of the evidence			
	High	We are very confident that the true effect lies close to that of the			Factor	Consequence			
9		estimate of the effect.							
							Als er een groot effect wordt gevonden. For simple regression β is like R. Thus I		
		We are moderately confident in the effect estimate: The true effect is				↑ 1 or 2 levels	would use R rules of thumb I use the following with my Psychology students:		
	Moderate	likely to be close to the estimate of the effect, but there is a possibility that it is substantially different			Large magnitude of effect	T I or 2 levels	$\beta \le 0.1$ - Small effect size $\beta \ge [0.1; 0.5]$ - Medium effect size $\beta \ge 0.5$ - Large effect size. For multiple regression these rules are not that straightfoward, but for		
19925		possionity dat it is substantiany direction					Social Sciences they seem to hold (also following Cohen's d suggestions).		
10			0						
					All plausible confounding would reduce				
	Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.			the demonstrated effect or increase the	↑ 1 level	Is er gecontroleerd voor plausibele confounders?		
		be substantially different from the estimate of the effect.			effect if no effect was observed				
11									
	Very Low	We have very little confidence in the effect estimate: The true effect			Dose-response gradient	↑ 1 level			
12	very Low	is likely to be substantially different from the estimate of effect			isoseresponse gradient	T TOVET			
13									
14		and statement of							
15 16		Study Design Study design is critical to judgments about the quality	£						
17		For recommendations regarding management strategies			accuracy of diagnostic tests -				
17 18		randomized trials provide, in general, far stronger evidence	e than obse	rvational studies, and rigorous o	bservational studies provide stronger evide	ence than uncontrolled case series.			
19 20		In the GRADE approach to quality of evidence:	1 15	(January)					
20		randomized trials without important limitations provide hi observational studies without special strengths or important							
22									
23		Limitations or special strengths can, however, modify the	quality of t	he evidence of both randomized	trials and observational studies.				
24		Note:							
		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							
25		number)							
		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							
26		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 (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							
27		unpublished) is being used as the basis for interpretation.							
L		,				1			

-	A	В	с	D	E Table 5.4	F Study li		G ns in r	H andomiz	red contr	olled trials	К		L
				Lack of al						Explanatio Those enro (or period i enrolled pa problem in trials with	lling patients are aware n a crossover trial) to w tient will be allocated ("pseudo" or "quasi" ra allocation by day of we	hich the next a major ndomized		
					Lack of bl	inding					chart numb Patient, car	er, etc.). egivers, those recording	g outcomes,	
1											are aware o	icating outcomes, or da f the arm to which pati	ents are	
					Incomplet	e account	ing of p	oatients	and out	come	received in Loss to foll	or the medication current a crossover trial). ow-up and failure to ac	lhere to the	
2					events						or in nonin	 treat principle in supe feriority trials, loss to fer anduct both analysis or 	ollow-up, and	
											only those	onduct both analyses ec who adhered to treatme whom outcome data as	nt, and all	
	estimate of the effect and in the followin grecommend limitations are, the more likely it is that the quality of ev	ecution may bias the estimates of the treatment effect. Ourconfidence in the ation decreases if studies suffer from major limitations. The more serious the idence will be downgraded.Numerous tools exist to evaluate the risk of bias in attrials and observational studies									The signifi- follow-up, dependent follow-up a proportion	cance of particular rates however, varies widely on the relation between and number of events. I lost to follow-up in rela n and control group events	s of loss to and is loss to The higher the ation to	
3		1									differences	between intervention a greater the threat of bis	nd control	
					Selective	outcome r	eporting	g			Incomplete outcomes a	or absent reporting of nd not others on the ba	some	
					Other limi	tations					results. Stopping tr	ial early for benefit. Su tes are likely in trials w	bstantial	
											than 500 ev	ents and that large ove als with fewer than 200	restimates are	
4	Risk of bias	Uitleg									Empirical of stopping ru	vidence suggests that f les do not reduce this b	ormal ias.	
											patient-rep	alidated outcome measu orted outcomes) effects in crossover tria		
											Recruitmer	t bias in cluster-randor	nized trials	
5	None													
		Baseline confounding occurs when one or more prognostic variables (factors that predict the												
6	Due to confounding	encerner comotioning occurs when one or more prognostic winkness (actors rank preact the outcome of interest) also prodicts the intervention received at backine. 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.												
-		e manne an an de Manneterne												
7	n participant selection	When existion 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 intervention and outcome even if the effects of the intervention are identical. This form of selection bias is distinct from confounding—A specific example is bias due to the inclusion of prevent users, after them new users, of an intervention.												
I														
	Tun ka missing data													
	Due to missing data	Blas 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.												
	n measurement of predic/outcome													
9		Bus introduced by either differential or non-differential errors in measurement of outcome data. Such blas can arise when outcome assessors are aware of intervention tatus, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects												
10	n 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)												
1	n misclassification of intervention (randomization)	Bis introduced by either differential or non-differential inicidoalfeation of intervention status Non-differential mixtubalfeation is surveited to the sourcem and will usually this the estimated effect or intervention towards the null Differential mixtubalfeation courses when mixtubalfeation of intervention status is related to the differential mixtubalfeation courses when mixtubalfeation of intervention status is related to the source of the relation have an advanced and difference to share as the relation of the relation of the source of the relation of the related to the source of the relation of the source of the relation of the relation of the relation of the relation of the source of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the relation of the source of the relation of the relation of the source of the source of the relation of the source of the relation of the source of the source of the source of the source of the relation of the source of the source of the source of the relation of the source of the source of the relation of the source of the relation of the source of the source of the source of the relation of the source of the source of t												
12	Due to deviation from intended intervention	comparator groups in the care provided, which represent a deviation from the intended												
13		intervention(s)					_							
5	Tussen studies	like wat de comparison conditie is on of -tthe				_	-			-				
6 7		ijken wat de comparison conditie is en of studies vergelijkbaar zijn met elkaar. elijkbaar? (gaat het om intentie van gedrag, zelfgrapporteerde naleving, daadwei	kelijke nal	eving, etc)						-				
8												Table 5.5: Study limi	itations in obser	vational studie
9													Explanation	
20												Failure to develop and apply appropriate	 Under- or in case-control 	over-matching studies
												eligibility criteria (inclusion of control population)	 Selection of unexposed in c from different p 	of exposed and cohort studies populations
21					-	-	-						 Difference 	e in
													measurement o	f exposure (e.g.
2												Flawed measurement	recall bias in ca studies)	ase-control
1												of both exposure and outcome	Differentia	al surveillance
													for outcome in unexposed in c	exposed and
23						_				-				
													 Failure of a measurement or 	
												Failure to adequately	prognostic facto	
24							-			-		control confounding	 Failure to r 	match for
													prognostic facto adjustment in s analysis	ors and/or
25										-				
												Incomplete or inadequately short follow-up	Especially with cohort studies, should be follo same amount o	wed for the

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Bias

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	5.1.2h	
1		
	1.Were the criteria for inclusion in the sample	The authors should provide clear inclusion and exclusion criteria that they
	clearly defined?	developed prior to recruitment of the study participants.
2		
		The study sample should be described in sufficient detail so that other
	2.Were the study subjects and the setting described in	researchers can determine it it is comparable to the population of interest to then The authors should provide a clear description of the population from which the study participants were selected or recruited, including demographics, location,
	detail?	study participants were selected or recruited, including demographics, location, and time period.
3		
		The study should clearly describe the method of measurement of exposure. Assessing validity requires that a 'gold standard' is available to which the measur
	3.Was the exposure measured in a valid and	can be compared. The validity of exposure measurement usually relates to whether a current measure is appropriate or whether a measure of past exposure
	reliable way?	is needed. Reliability refers to the processes included in an epidemiological study to check repeatability of measurements of the exposures. These usually include
4		intra-observer reliability and inter-observer reliability.
	4.Were objective, standard	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.
	criteria used for measurement of the	Characteristics are another useful approach to matching groups, and studies tha did not use specified diagnostic methods or definitions should provide evidence of
5	condition?	matching by key characteristics.
		Typical confounders include baseline characteristics, prognostic factors, or concomitant exposures (e.g. smoking). A confounder is a difference between the
	5.Were confounding factors identified?	comparison groups and it influences the direction of the study results. A high quality study at the level of cohort design will identify thepotential confounders an
6		measure them (where possible). This is difficult for studies where behavioral, attitudinal or lifestyle factors may impact on the results.
*		Strategies to deal with effects of confounding factors may be dealt within the stu
	6.Were strategies to deal with confounding factors	designer to data analysis. By matching or stratifying sampling of participants, effects of confounding factors can be adjusted for. When dealing with adjustmer
-	stated?	in data analysis, assess the statistics used in the study. Most will be some form multivariate regression analysis to account for the confounding factors measured
7		Importantly, determine if the measurement looks used were validated instruments
	7 Were the outcomes	importanity, 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
	measured in a valid and	cancer instrument is important to establish how the measurement was conducted. Were those involved in collecting data trained or educated in the use
	reliable way?	the instrument/s? (e.g. radiographers). If there was more than one data collector, were they similar in terms of level of education, clinical or research experience, o
8		level of responsibility in the piece of research being appraised?
		As with any consideration of statistical analysis, consideration should be given to whether there use a more appropriate alternate statistical method that could have
		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
	8.Was appropriate statistical	stratification) and how specific confounders were measured. For studies tilizing regression analysis, it is useful to identify if the study identified which variables
	analysis used?	were included and how they related to the outcome. If startification 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 basedon differing assumptions about the data
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Sheet1

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