National Institute for Health and Care Excellence

Final

Shared decision making

[D] Evidence review for risk communication

NICE guideline NG197

Evidence reviews underpinning recommendations 1.4.1 to 1.4.11 in the NICE guideline

June 2021

Final

These evidence reviews were developed by the NICE Guideline Updates Team



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ISBN: 978-1-4731-4145-2

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What methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options?

Review question

What methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options?

Introduction

Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care, now or in the future (for example, through advance care planning). It involves healthcare professionals working together with people who use services and their families and carers to choose tests, treatments, management or support packages, based on evidence and informed personal preferences, health beliefs, and values. This involves making sure the person has a good understanding of the risks, benefits and possible consequences of different options through discussion and information sharing.

For the person receiving healthcare to be able to participate in shared decisions, information must be communicated to them. One type of key information that should be communicated to them is risk. Whether it be in a screening, diagnostic or treatment setting.

There are several different ways of communicating risk, and which one is more effective may be the difference in the healthcare participant receiving the information they need to make an informed decision or not.

The aim of this review is to analyse which methods of presenting risk information improve a patient's understanding of the risks and benefits associated with their treatment options.

PICO table

Table 1: PICO table for methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options

Type of review	Effectiveness review
Population	Adults using healthcare services (and their families, carers and advocates) and healthcare providers
Intervention	Methods of presenting information intended to improve a patient's understanding of the risks and benefits associated with their treatment options. For example:

	 Types of statistical presentation or formats for standard information (relative risk vs absolute risk, NNT etc)
	 "Framing" effects – comparing negative framing (for example: chance of death) to positive framing (for example: change of survival)
	Individualised compared to general information
Comparators	Each other No intervention/Normal care
Outcomes	 Accuracy of risk perception Knowledge Anxiety, Decisional regret, time taken or other unintended consequences Quality of life
Study types	Systematic reviews and meta-analyses of primary controlled studies

Methods and process

This evidence review update was developed using the methods and process described in <u>Developing NICE guidelines: the manual</u>. Methods specific to this review question are described in the review protocol in appendix A

Some studies included were Cochrane reviews, and their methods of appraisal have been maintained. For other studies, data was adapted to NICE methodology. These analyses were presented differently in the original reviews, but were adapted to the NICE style, including individual study quality and interpretation of effect as their methodology was not as robust as the Cochrane reviews.

For further details of the methods used see appendix B.

The search strategies used in this review are detailed in appendix C.

Declarations of interest were recorded according to <u>NICE's 2018 conflicts of interest policy.</u>

Clinical evidence

Included studies

A systematic search was carried out to identify systematic reviews of primary controlled studies. Both the original search (up to 18th March 2020) and rerun searches (up to 18th August 2020) found 4,526 references. (see appendix C for the literature search strategy).

4,498 were excluded a title and abstract level, leaving 28 papers for full text screening.

Of the 28 remaining references 20 were excluded after screening full text, leaving 8 papers that matched the criteria set out in the review protocol. 7 of these includes are presented in a quantitative analysis, whilst one presented in a narrative analysis.

Study flow can be found in appendix D

References for included studies can be found in appendix I.

Excluded studies

Details of studies excluded at full text, with reasons for exclusion, is given in appendix H.

Summary of clinical studies included in the evidence review

Study characteristics are presented in Table 2.

Table 2: Summary of characteristics of included studies

Table 2. Guillia	Table 2: Summary of characteristics of included studies						
Author	Number of studies	Comparison	Population	Study types			
Akl 2011	35	Natural frequencies vs percentages, risk formats vs each other	Healthcare participants and professionals	Randomised and non- randomised controlled parallel and crossover studies			
Bayne 2020	23	Personalised cancer risk info vs no information	Adults with no previous cancer history	Primary research papers in peer-reviewed journals			
Buchter 2014	10	Verbal risk information vs numerical risk information	Any	RCTs			
Dieng 2014	40 (12 RCT)	General educational intervention vs control	People affected by cancer	RCTs, non-randomised trials, prospective studies			
Edwards 2013	41	Personalised risk communication vs general risk information	People facing real-life decisions about whether to undergo screening	RCTs			
Harris 2020	12 (9 RCT)	Tailored risk information vs control	Adults aged ≥ 18 years.	All study designs			
Stellamans 2017	13	Risk visualisation graphics vs numerical text, Static risk visualisation vs dynamic risk visualisation	Patients or lay people	Peer-reviewed with controlled study design and quantitative evaluation.			
Walker 2015	11	Risk tools vs control, Risk	Primary care practitioners and patients	RCTs			

tools	٧S	other
risk to	ool	S

See appendix E for full evidence tables.

Narrative summary of studies without enough information to GRADE

One study (Stellamans 2017) did not contain enough numerical data to perform a GRADE tool analysis, and thus is presented with a narrative analysis and evidence statements.

Stellamans 2017

This systematic review into computer support graphs that present cancer risk data and their effect on various measures included 13 studies. Ten evaluating static graphs and three evaluating more 'dynamic' formats.

Static graphs reportedly 'improved accuracy, comprehension and behavioural intention', but results were heterogenous and inconsistent. Dynamic formats were not superior and in some cases performed worse in outcomes compared to static formats.

Evidence statement

Up to 13 studies in the low quality systematic review with up to 14,032 participants found:

- no statistically significant effect in perceived risk for icon arrays vs numeric text
- an effect favouring icon arrays in perceived comprehension but an effect favouring numerical text in subjective uncertainty.
- icon arrays produced higher numerical accuracy than bar charts.
- presenting survival data alone vs data of multiple outcomes improved risk accuracy.
- an effect favouring static icon arrays versus animated/dynamic icon arrays in choice accuracy and gist knowledge.

Summary GRADE tables

Intervention vs intervention

Pre-existing systematic review analysis (Akl 2011)

Natural frequencies vs Percentages

Outcomes	Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
Understanding	SMD 0.69 (0.45 to 0.93)	642 (7)	Moderate ¹	Suggest frequency may be understood better than percentages

Outcomes	Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
				(moderate effect size)*

^{*}Study interpreted SMDs using the following rules suggested by the Cochrane Handbook: (< 0.40 represents a small effect size, 0.40 to 0.70 represents a moderate effect size, > 0.70 represents a large effect size.)

1. Outcome is a surrogate for health behaviour

Relative Risk Reduction (RRR) vs Absolute Risk Reductions (APR)

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Outcomes	Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
Understanding	SMD 0.02 (-0.39 to 0.43)	469 (3)	Moderate ¹	Suggest little or no difference in understanding
Perception	SMD 0.41 (0.03 to 0.79)	1116 (5)	Low ^{2,3}	Suggest the RRR may be perceived to be larger than the ARR (moderate effect size)*
Persuasiveness	SMD 0.66 (0.51 to 0.81)	11221 (27)	Moderate ^{2,4}	Suggest RRR are more likely to be persuasive (moderate effect size)

^{*}Study interpreted SMDs using the following rules suggested by the Cochrane Handbook: (< 0.40 represents a small effect size, 0.40 to 0.70 represents a moderate effect size, > 0.70 represents a large effect size.)

- 1. The results were inconsistent. Study did not however downgrade for inconsistency because the SMD is on the border of no to small effects in either direction.
- 2. Outcome is a surrogate for health behaviour.
- 3. The results were inconsistent. In three of the five comparisons RRR was perceived to be larger. Two found little or no difference. The overall estimate was also imprecise with the lower confidence limit bordering on no difference.
- 4. The results were inconsistent. However, the I2 test is very powerful for SMD. In addition, the robustness of the results with the various analytic methods (fixed or random effects model; risk ratios, risk differences or standardized effects) and the magnitude of the effect (average effect across the included studies was moderate or large) limit our concerns about heterogeneity.

Relative Risk Reduction vs Number Needed to Treat

Outcomes	Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
Understanding	SMD 0.73 (0.43 to 1.04)	182 (1)	Moderate ^{1,2}	Suggest RRR may be understood better than NNT (large effect size)*
Perception	SMD 1.15 (0.8 to 1.5)	970 (3)	Moderate,3	suggest the RRR may be perceived to be larger than the NNT (large effect size)
Persuasiveness	SMD 0.65 (0.51 to 0.8)	9582 (22)	Moderate ^{2,3}	Suggest RRR are more likely to be persuasive (moderate effect size)

^{*}Study interpreted SMDs using the following rules suggested by the Cochrane Handbook: (< 0.40 represents a small effect size, 0.40 to 0.70 represents a moderate effect size, > 0.70 represents a large effect size.)

- 1. Only one comparison evaluated this outcome
- 2. Outcome is a surrogate for health behaviour.
- 3. The results were inconsistent. In three of the five comparisons RRR was perceived to be larger. Two found little or no difference. The overall estimate was also imprecise with the lower confidence limit bordering on no difference.

Absolute risk reductions (ARR) vs Number Needed to Treat (NNT)

Outcomes	Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
Understanding (correct estimation or interpretation of risk)	SMD 0.42 (0.12 to 0.71)	182 (1)	Moderate ^{1,2}	Suggest ARR may be understood better than NNT (moderate effect size)*
Perception (rating on a scale of perceived effectiveness)	SMD 0.79 (0.43 to 1.15)	949 (3)	Moderate ^{2,3}	Suggest the ARR may be perceived to be larger than NNT (large effect size)
Persuasiveness	SMD 0.05 (- 0.04 to 0.15)	9024 (20)	Moderate ^{2,4}	Suggest little or no difference in persuasiveness.

Outcomes Average effect	Number of participants (comparisons)	Quality of the evidence (GRADE)	Comments
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^{*}Study interpreted SMDs using the following rules suggested by the Cochrane Handbook: (< 0.40 represents a small effect size, 0.40 to 0.70 represents a moderate effect size, > 0.70 represents a large effect size.)

- 1. Only one comparison evaluated this outcome
- 2. Outcome is a surrogate for health behaviour.
- 3. The results were inconsistent. In three of the five comparisons RRR was perceived to be larger. Two found little or no difference. The overall estimate was also imprecise with the lower confidence limit bordering on no difference.
- 4. The results were inconsistent. We did not however downgrade for inconsistency because the SMD is in the borders of no to small effects in either direction.

Novel analysis or analysis adapted to NICE methodology

Verbal risk information vs Numerical risk information (Buchter 2014)

Outcome	Sample Size	Effect estimate	MID S	Qualit y	Interpretation of effect
Perceived likelihood of AE occurrence	892	MD 1.07 (0.90, 1.25)	+/- 0.60	Very low	Effect (Favours verbal risk information)

Risk tools vs other risk tools (Walker 2015)

Outcome	Sample Size	Effect estimate	MIDS	Quality	Interpretation of effect
Patient knowledge	435	MD 0.20 (-0.28, 0.68)	+/- 1.25	Low	No meaningful difference
Patient satisfaction	435	MD 0.20 (-0.97, 1.37)	+/- 3.10	Low	No meaningful difference

Intervention vs control

Pre-existing systematic review analysis (Edwards 2013)

Main outcome: Personalised risk communication vs general risk information

Outcome	Assumed risk	Corresponding risk	Relative effect	Sample size (studies)	Quality (GRADE)
Informed decision	202 per 1000	480 per 1000 (350 to 612)	OR 3.65 (2.13 to 6.23)	2444	High ^{2,3,4,5}
making MMIC ¹				(3 studies)	

- 1. MMIC: Multi-dimensional measure of informed choice
- 2. Significant heterogeneity among studies but all studies have same direction of effect and hence not downgraded
- 3. Good quality randomised studies with low risk of bias
- 4. All studies consistently demonstrating odds ratio of >2 and quality upgraded by one point

5. Personalised risk communication is delivered as a part of the interventions. Informed choice and uptake are promoted by influencing many other elements such as knowledge, perceived risk etc. leading to indirectness of evidence and hence downgraded by a point

Additional outcomes: Personalised risk communication vs general risk information

Outcome	Assumed	Corresponding risk			Quality (GRADE)
Knowledge	risk -	-	SMD 0.4	(studies)	Moderate ^{1,14}
regarding screening test/ condition concerned - calculated risk score (numerical) versus general information various continuous scales			(0.23, 0.56)	588 (1 study)	Woderate
Knowledge regarding screening test/ condition concerned - calculated risk score (categorised) versus general information various continuous scales		-	SMD 0.57 (0.32, 0.82)	260 (1 study)	Low ^{2,11,14}
Knowledge regarding screening test/ condition concerned - personal risk factor list versus general information various continuous scales		-	SMD 0.89 (0.75 to 1.04)	838 (2 studies)	High ^{4,6,13,14}
Knowledge regarding screening test/ condition concerned - calculated	244 per 100	457 per 1000 (291 to 633)	OR 2.6 (1.27 to 5.34)	1413 (3 studies)	High ^{4,6,13,14}

risk score (numerical) versus general information proportion with good knowledge					
Knowledge regarding screening test / condition concerned - personal risk factor list v general information proportion with good knowledge	166 per 100	586 per 1000 (535 to 636)	OR 7.13 (5.79 to 8.79)	2107 (2 studies)	High ^{6,12,14}
Accurately- perceived Risk proportion of participants who perceived risk accurately	225 per 1000	324 per 1000 (218 to 450)	OR 1.65 (0.96 to 2.81)	1264 (3 studies)	Low ^{7,8,13,14}
Anxiety - all groups various continuous scales	-	-	-0.13 SMD (-0.29 to 0.03)	1848 (6 studies)	Very Low ^{5,8,9,14}

- 1. This study was high risk for reporting bias. Four risk of bias items were low risk and four were unclear risk. Quality downgraded by a point.
- 2. Seven out of nine risk of bias items were unclear. Quality downgraded by a point.
- 3. One out of two studies included in this analysis was of very good quality. The other study had mostly unclear risk of bias. Overall not downgraded the quality for this analysis.
- 4. Two out of three studies had more than four risk of bias items assessed as low risk. The other study had most unclear risk of bias items. Overall quality was not downgraded.
- 5. Substantial/ significant heterogeneity of results exists and all studies did not show similar direction of effect. Quality downgraded by a point.
- 6. Consistently large effects favouring personalised risk communication and hence upgraded the quality by one point.
- 7. Most risk of bias items were unclear with some high risk items. Quality downgraded by one point.
- 8. Pooled estimate includes no effect and hence downgraded by one point.
- 9. Two out of six studies had more than four risk of bias items assessed as low risk. The remaining studies had most risk of bias items assessed as unclear. Quality downgraded by one point.
- 10. Control risk was used as baseline risk due to lack of studies that measure this in detail to be presented as baseline risk for the population.
- 11. Sample size less than the Optimal Information size (OIS). Quality downgraded by one point.
- 12. Both studies were of low risk of bias and hence not downgraded.
- 13. Significant heterogeneity among studies but all studies have same direction of effect and hence quality not downgraded.

Novel analysis or analysis adapted to NICE methodology

Personalised cancer risk info vs control (Bayne 2020)

Outcome	Sample Size	Effect estimate	MIDS	Quality	Interpretation of effect
Absolute risk accuracy (Bayne 2020)	841	RR 4.57 (1.16, 18.06)	0.80 , 1.25	Very low	Effect (favours intervention)
Comparative risk accuracy (Bayne 2020)	627	RR 1.40 (0.71, 2.73)	0.80 , 1.25	Very low	Could not differentiate

Education intervention (general) vs control (Dieng 2014)

Outcome	Sample Size	Effect estimate	MIDS	Quality	Interpretation of effect
Risk	1590	SMD -0.12	+/- 0.50	Very	No meaningful
perception		(-0.39, 0.16)		low	difference
Risk	486	RR 1.28	0.80 ,	Very	Could not differentiate
accuracy		(0.92, 1.80)	1.25	low	

Tailored risk information vs control (Harris 2020)

Outcome	Sample Size	Effect estimate	MIDS	Quality	Interpretation of effect
Risk perception	23	MD 8.04	+/-	Low	Effect
(susceptibility)		(5.58, 10.50)	1.50		

Risk tool vs control (Walker 2017)

Outcome	Sample Size	Effect estimate	MIDS	Quality	Interpretation of effect
Risk perception	1890	OR 1.07 (0.85, 1.35)	NA	NA	NA
Patient knowledge	942	SMD 0.79 (0.46, 1.12)	+/- 0.50	Very low	Effect (Favours control)
Patient satisfaction	905	MD 3.90 (2.97, 4.82)	+/- 3.95	Very low	Less than MID (Favours intervention)
Anxiety/worry (Cancer)	45	MD 0.11 (-1.05, 1.27)	+/- 0.99	Low	Could not differentiate

Quality assessment of clinical studies included in the evidence review

Individual systematic reviews which were considered for inclusion as a source of data (rather than solely as a source of primary studies) were quality assessed using the ROBIS tool, with each classified into one of the following three groups:

 High quality – It is unlikely that additional relevant and important data would be identified from primary studies compared to that reported in the review, and unlikely that any relevant and important studies have been missed by the review.

- Moderate quality It is possible that additional relevant and important data would be identified from primary studies compared to that reported in the review, but unlikely that any relevant and important studies have been missed by the review.
- Low quality It is possible that relevant and important studies have been missed by the review.

Each individual systematic review was also classified into one of three groups for its applicability as a source of data, based on how closely the review matches the specified review protocol in the guideline. Studies were rated as follows:

- Fully applicable The identified review fully covers the review protocol in the guideline.
- Partially applicable The identified review fully covers a discrete subsection of the review protocol in the guideline (for example, some of the factors in the protocol only).
- Not applicable The identified review, despite including studies relevant to the review question, does not fully cover any discrete subsection of the review protocol in the guideline.

See appendix E for appraisal of individual studies.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.4.1 to 1.4.11 and the research recommendation on risk communication. Other evidence supporting these recommendations can be found in the evidence reviews on patient decision aids (review 1.3b).

The committee's discussion of the evidence

Outcomes that matter most

The committee agreed that the perception and understanding of risk were important outcomes in looking at the effect of risk communication interventions. They stated that people understanding their risk is key in ensuring that they are making an informed decision about their healthcare. Understanding is evidenced by accurate interpretation, application to one's situation, making a decision (with others – clinicians or family as appropriate) and communicating this with the healthcare professional.

The committee had concerns that knowledge as an outcome was not clearly defined in all of the systematic reviews, and that there are different types of knowledge that can be measured. It did not give knowledge as much consideration in this evidence as in other reviews that inform this guideline, where it has been more clearly defined.

The committee chose not to use persuasiveness as a key outcome, because persuasiveness is not necessarily a positive outcome in shared decision making or indicative of informed choice. People may be persuaded to make decisions that are not consistent with their beliefs and values. This was not a primary or secondary outcome in the protocol so aligned with the intended outcomes of study.

Quality of the evidence

The committee agreed that the recommendations from the patient experience guideline were mostly still applicable for the risk communication element of shared decision making. More onus needed to be placed on ensuring risks, benefits and consequences are communicated once peoples expressed personal values and preferences have been elicited, so that the risk communication can take place in line with these.

The committee felt that there was a wide range of very heterogenous evidence in the subject area of risk communication, and that it wasn't possible to recommend a specific form of risk communication for any specific clinical setting, and instead wanted to allow clinicians to personalise their risk communication to the clinical context as they see fit, and also to the patients values and preferences.

Benefits and harms

The committee agreed that effective risk communication can often be supported in a structured way through the use of high-quality patient decision aids (see review of the evidence for PDAs conducted as part of this guideline).

The committee agreed that discussing risk using the word "risk" alone could be seen as unnecessarily negative because of the way people interpret the word risk, and therefore it agreed that it would be more useful to refer to "risks, benefits and consequences" to convey the range of meanings covered by healthcare professionals use of the word 'risk'.

The committee highlighted that the risk communication discussion was a key part of the person being able to make an informed choice, and that this was in line with the Montgomery

ruling. The committee stated that in order for the person to make an informed choice the decision made should align with the persons values and preferences.

The committee had concerns around relative risk reductions being used in isolation in practice, as they felt they could be very persuasive (in shared decision making, practitioners do not seek to persuade, but to inform and support decisions in a balanced way). It questioned how useful persuasiveness is as an outcome as it does not link to the reality of the treatment or screening procedure but rather the effect the risk measure has on the person reading it. It cited examples including how 50% can seem like a large increase despite this potentially being an increase of 2 in 1000 to 3 in 1000. It also said ARR is often given alongside RRR to provide a different view of risk to the patient.

Whilst there was evidence that numbers needed to treat (NNT) performed worse than both Absolute Risk Reduction and Relative Risk Reduction, the committee commented that there were some situations where using NNTs alongside other measures, for example in discussing antibiotic use, could be beneficial.

The committee wanted to acknowledge that often personalised risk and benefit information is not available, perhaps due to the lack of access to a database containing the patient information to inform the personalisation. This means often clinicians are using more generalised risk information and there is no standardisation of which ones should be presented. It stated that healthcare professionals should have access to personalised risk calculations wherever possible.

In regards to framing, the committee noted that only mentioning positive or negative framing could bias a decision, and thus both should be presented if possible, for example telling people how many in a hundred an intervention will work for, and how many in a hundred it will not work for. It also acknowledged that mentioning both could cause confusion between intervention and control for a patient if there are multiple numbers to remember. The clinician needs to use their judgement on an individual basis to decide the most appropriate way to communicate risk, where framing is required.

The committee noted that not all patients will be responsive to quantitative risk, and some will prefer verbal presentation, but that verbal concepts can lead to overestimation of risk, and that if numerical data are available this should be given precedence as outlined in the recommendation from the patient experience guideline. The committee agreed that people's interpretation of descriptors like 'rare' and 'uncommon' vary greatly. The committee agreed that healthcare practitioners needed to have patient understanding at the centre of risk communication, and framed the recommendations with this in mind.

The committee discussed how there needs to be different approaches to risk communication based on the severity of the decision or setting. For example, when people are thinking about gradual long-term risk reduction such as hypertension compared to considering more immediate risks relating to surgery. This is because numbers and even pictures do not speak for themselves in a neutral and objective way and must be contextualised by a healthcare professional.

The committee wanted risk communication tools (for example, patient decision aids) based on high quality data to be used wherever possible (as long as it was acceptable to patients), but understood this isn't always possible, and didn't wish to limit widespread use of shared decision making by placing a requirement for risk communication in the recommendations.

The committee noted that risks, benefits and consequences of not taking medication or having no intervention should also be discussed.

The committee also discussed the use of the term likelihood instead of risk, as well as 'risk, benefit and consequences'. It stated that it should be made clear that risk communication isn't "guess work", but acknowledged that using phrases such as 'people like you' should only be made when the clinician is sure that the patient's characteristics are sufficiently close

to the study characteristics of included trials that support the evidence for using a treatment using the statistics for the risk calculations. People could interpret that phrase in a number of different ways. A risk calculation also has inherent uncertainty in itself, for example 1 in 20 is not exact and is itself an estimate.

The committee noted evidence that bar charts were found to be worse than icon arrays and thus were not mentioned in the recommendation alongside other formats.

Appendices

Appendix A – Review protocols

Review protocol for methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options

Field	Content
PROSPERO registration number	CRD42020171512
Review title	What methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options?
Review question	What methods of presenting information improve a patient's understanding of the risks and benefits associated with their treatment options?
Objective	To update the review of reviews undertaken for the shared decision making section of the NICE patient experience guideline (CG138)
Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Database of Abstracts of Reviews of Effect (DARE) Embase (Ovid)

	 MEDLINE (Ovid) MEDLINE In-Process (Ovid) MEDLINE Epub Ahead of Print PsycINFO (Ovid)
	The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.
	The full search strategies for MEDLINE database will be published in the final review.
Condition or domain being studied	Shared decision making is a collaborative process through which a healthcare professional supports a person to reach a decision about their care, now or in the future (for example, through advance care planning).
Population	 Inclusion: Adults using healthcare services (and their families, carers and advocates) and healthcare providers?
	Exclusion: • People under the age of 18

Intervention	 Unexpected life-threatening emergency needing immediate life-saving care. Situations in which people lack mental capacity to make their own decisions about healthcare at that time. Methods of presenting information intended to improve a patient's understanding of the risks and benefits associated with their treatment options. For example: Types of statistical presentation or formats for standard information (relative risk vs
	 absolute risk, NNT etc) "Framing" effects – comparing negative framing (for example: chance of death) to positive framing (for example: change of survival) Individualised compared to general information
Comparator/Reference standard/Confounding factors	 Each other No intervention/normal care
Types of study to be included	Systematic reviews and meta-analyses of primary controlled studies
Other exclusion criteria	 Non-English language papers Theses, dissertations and conference abstracts Editorials, opinion pieces and letters Surveys

Context	This review is for part of a new NICE guideline for shared decision making.
Primary outcomes (critical outcomes)	Accuracy of risk perception (Relative or absolute)
Secondary outcomes (important outcomes)	 Knowledge Anxiety, decisional regret, time taken or other unintended consequences Quality of life
Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.
	The full text of potentially eligible reviews will be retrieved and will be assessed in line with the criteria outlined above. Data will be extracted from the included studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control conditions; study methodology; recruitment and study completion rates; outcomes and times of measurement and information for assessment of the risk of bias.
	Study investigators may be contacted for missing data where time and resources allow.
Risk of bias (quality) assessment	Risk of bias for systematic reviews will be assessed using the ROBIS checklist as described in Developing NICE guidelines: the manual.

Strategy for data synthesis

Meta-analyses of interventional data from primary studies included in the SRs will be conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2019).

Fixed- and random-effects models (der Simonian and Laird) will be fitted for all syntheses, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models will be the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model is clearly not met, even after appropriate pre-specified subgroup analyses is conducted, random-effects results are presented. Fixed-effects models are deemed to be inappropriate if one or both of the following conditions was met:

- Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis.
- The presence of significant statistical heterogeneity in the meta-analysis, defined as I2≥50%.

Meta-analyses will be performed in Cochrane Review Manager V5.3

If heterogeneity of studies and outcomes renders meta-analysis unachievable then results will be reported narratively, split by type of communication with extracts from relevant SRs reported under each heading.

Analysis of sub-groups	 Age Gender Family origin Care setting Immediate vs f 	ty in the meta-analysis, and where data allow disambiguation, subgroup particularly with reference to future care ported in included systematic reviews will be reported.
Type and method of review	\boxtimes	Intervention
		Diagnostic
		Prognostic
		Qualitative
		Epidemiologic
		Service Delivery
		Other (please specify)
Language	Faciliak	
Language	English	
Country	England	

Anticipated or actual start date			
Anticipated completion date			
Stage of review at time of this submission	Review stage	Started	Completed
	Preliminary searches		
	Piloting of the study selection process		
	Formal screening of search results against eligibility criteria		
	Data extraction		
	Risk of bias (quality) assessment		

	Data analysis		
Named contact	5a. Named contact Guidelines Updates Team		
	5b Named contact e-mail GUTprospero@nice.org.uk		
	5e Organisational affiliation of the National Institute for Health and Ca		Ξ)
Review team members	From the Guideline Updates Team:Mr. Chris Carmona		
	Mr. Joseph Crutwell Ms. Amy Finnegen		
	Ms. Amy FinneganMr. Gabriel Rogers		
Funding sources/sponsor	This systematic review is being compl part of NICE.	eted by the Guideline	e Updates Team, which is
Conflicts of interest	All guideline committee members and any (including the evidence review team and of interest in line with NICE's code of practing interest. Any relevant interests, or change start of each guideline committee meeting	expert witnesses) must ctice for declaring and o es to interests, will also	t declare any potential conflicts dealing with conflicts of be declared publicly at the

Collaborators	interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline. Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are
	available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/
Other registration details	None.
Reference/URL for published protocol	None.
Dissemination plans	 NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the
	NICE website, using social media channels, and publicising the guideline within NICE.
Keywords	Shared decision making, patient engagement, patient activation
Details of existing review of same topic by same authors	

Current review status		Ongoing
		Completed but not published
		Completed and published
		Completed, published and being updated
		Discontinued
Additional information		
/ taditional information	None.	
Details of final publication	www.nice.org.uk	

Appendix B- Methods

Methods for combining intervention evidence

This method was used for this evidence review, the systematic reviews included will have used their own methods and processes that are explored in the risk of bias analysis in Appendix E.

Meta-analyses of interventional data were conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2011).

Where different studies presented continuous data measuring the same outcome but using different numerical scales (e.g. a 0-10 and a 0-100 visual analogue scale), these outcomes were all converted to the same scale before meta-analysis was conducted on the mean differences. Where outcomes measured the same underlying construct but used different instruments/metrics, data were analysed using standardised mean differences (Hedges' g).

A pooled relative risk was calculated for dichotomous outcomes (using the Mantel–Haenszel method) reporting numbers of people having an event, and a pooled incidence rate ratio was calculated for dichotomous outcomes reporting total numbers of events. Both relative and absolute risks were presented, with absolute risks calculated by applying the relative risk to the risk in the comparator arm of the meta-analysis (calculated as the total number events in the comparator arms of studies in the meta-analysis divided by the total number of participants in the comparator arms of studies in the meta-analysis).

Fixed- and random-effects models (der Simonian and Laird) were fitted for all syntheses, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models were the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model were clearly not met, even after appropriate pre-specified subgroup analyses were conducted, random-effects results are presented. Fixed-effects models were deemed to be inappropriate if one or both of the following conditions was met:

- Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. This decision was made and recorded before any data analysis was undertaken.
- The presence of significant statistical heterogeneity in the meta-analysis, defined as l²≥50%.

However, in cases where the results from individual pre-specified subgroup analyses are less heterogeneous (with $I^2 < 50\%$) the results from these subgroups will be reported using fixed effects models. This may lead to situations where pooled results are reported from random-effects models and subgroup results are reported from fixed-effects models.

In situations where subgroup analyses were conducted, pooled results and results for the individual subgroups are reported when there was evidence of between group heterogeneity, defined as a statistically significant test for subgroup interactions (at the 95% confidence level). Where no such evidence as identified, only pooled results are presented.

In any meta-analyses where some (but not all) of the data came from studies at high risk of bias, a sensitivity analysis was conducted, excluding those studies from the analysis. Results from both the full and restricted meta-analyses are reported. Similarly, in any meta-analyses where some (but not all) of the data came from indirect studies, a sensitivity analysis was conducted, excluding those studies from the analysis.

Meta-analyses were performed in Cochrane Review Manager V5.3, with the exception of incidence rate ratio analyses which were carried out in R version 3.3.4.

Minimal clinically important differences (MIDs)

No MIDs were identified for this review, and thus the committee agreed to use the default MIDs as outlined below.

For continuous outcomes expressed as a mean difference where no other MID was available, an MID of 0.5 of the median standard deviations of the comparison group arms was used (Norman et al. 2003). For continuous outcomes expressed as a standardised mean difference where no other MID was available, an MID of 0.5 was used. For relative risks where no other MID was available, a default MID interval for dichotomous outcomes of 0.8 to 1.25 was used.

When decisions were made in situations where MIDs were not available, 'the committee's discussion of the evidence' section of that review makes explicit the committee's view of the expected clinical importance and relevance of the findings. In particular, this includes consideration of whether the whole effect of a treatment (which may be felt across multiple independent outcome domains) would be likely to be clinically meaningful, rather than simply whether each individual sub outcome might be meaningful in isolation.

GRADE for pairwise meta-analyses of interventional evidence

GRADE was used to assess the quality of evidence for the selected outcomes as specified in 'Developing NICE guidelines: the manual (2014)'. Data from all randomised controlled trials was initially rated as high quality and data from observations studies were originally rated as low quality. The quality of the evidence for each outcome was downgraded or not from this initial point, based on the criteria given in **Table 3**.

Table 3: Rationale for downgrading quality of evidence for intervention studies

GRADE criteria	Reasons for downgrading quality
Risk of bias	Not serious: If less than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the overall outcome was not downgraded.
	Serious: If greater than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the outcome was downgraded one level.
	Very serious: If greater than 33.3% of the weight in a meta-analysis came from studies at high risk of bias, the outcome was downgraded two levels.
	Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies at high and low risk of bias.
Indirectness	Not serious: If less than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the overall outcome was not downgraded. Serious: If greater than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from indirect studies, the outcome was downgraded two levels.
	Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between direct and indirect studies.
Inconsistency	Concerns about inconsistency of effects across studies, occurring when there is unexplained variability in the treatment effect demonstrated across studies (heterogeneity), after appropriate pre-specified subgroup analyses have been conducted. This was assessed using the I ² statistic.

GRADE criteria	Reasons for downgrading quality
	N/A: Inconsistency was marked as not applicable if data on the outcome was only available from one study.
	Not serious: If the I ² was less than 33.3%, the outcome was not downgraded.
	Serious: If the I ² was between 33.3% and 66.7%, the outcome was downgraded one level.
	Very serious: If the I^2 was greater than 66.7%, the outcome was downgraded two levels.
	Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies with the smallest and largest effect sizes.
Imprecision	If an MID other than the line of no effect was defined for the outcome, the outcome was downgraded once if the 95% confidence interval for the effect size crossed one line of the MID, and twice if it crosses both lines of the MID. If the line of no effect was defined as an MID for the outcome, it was downgraded once if the 95% confidence interval for the effect size crossed the line of no effect (i.e. the outcome was not statistically significant), and twice if the sample size of the study was sufficiently small that it is not plausible any realistic effect size could have been detected. Outcomes meeting the criteria for downgrading above were not downgraded if the confidence interval was sufficiently narrow that the upper and lower bounds would correspond to clinically equivalent scenarios.

The quality of evidence for each outcome was upgraded if any of the following three conditions were met:

- Data from non-randomised studies showing an effect size sufficiently large that it cannot be explained by confounding alone.
- Data showing a dose-response gradient.
- Data where all plausible residual confounding is likely to increase our confidence in the effect estimate.

Publication bias

Publication bias was assessed in two ways. First, if evidence of conducted but unpublished studies was identified during the review (e.g. conference abstracts, trial protocols or trial records without accompanying published data), available information on these unpublished studies was reported as part of the review. Secondly, where 10 or more studies were included as part of a single meta-analysis, a funnel plot was produced to graphically assess the potential for publication bias.

Evidence statements

Evidence statements for pairwise intervention data are classified in to one of four categories:

- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), and the magnitude of that effect is most likely to meet or exceed the MID (i.e. the point estimate is not in the zone of equivalence). In such cases, we state that the evidence showed that there is an effect.
- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), but the magnitude of that effect is most likely to be less than the MID (i.e. the point estimate is in the zone of equivalence). In such cases, we state that the evidence could not demonstrate a meaningful difference.
- Situations where the confidence limits are smaller than the MIDs in both directions. In such cases, we state that the evidence demonstrates that there is no meaningful difference.

 In all other cases, we state that the evidence could not differentiate between the comparators.

For outcomes without a defined MID or where the MID is set as the line of no effect (for example, in the case of mortality), evidence statements are divided into 2 groups as follows:

- We state that the evidence showed that there is an effect if the 95% CI does not cross the line of no effect.
- The evidence could not differentiate between comparators if the 95% CI crosses the line of no effect.

Appendix C – Literature search strategies

Search strategies

Database: Medline exp *risk/ or uncertainty/ (43755) (risk* or benefi* or uncertain*).ti,ab. (2236149) 3 or/1-2 (2246826) exp Communication/ or Audiovisual Aids/ or Data Interpretation, Statistical/ (285492) 1 and 4 (2710) 5 ((fram\$ or information*) adj2 (effect\$ or positiv\$ or negativ\$ or consequen* or messag* or prevent* or promo* or neutral* or display*)).ti,ab. (11986) ((graph* or visual* or statistic*) adj3 (present* or format*)).ti,ab. (17599) framing.ti. (1075) 8 9 or/6-8 (30206) 10 3 and 9 (5763) 11 (risk* adj2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)).ti,ab. (24823) 12 or/5,10-11 (32299) 13 (MEDLINE or pubmed).tw. (154842) 14 systematic review.tw. (114422) 15 systematic review.pt. (123063) 16 meta-analysis.pt. (110080) 17 intervention\$.ti. (105633) 18 or/13-17 (347570) 19 12 and 18 (2480)

- 20 limit 19 to ed=20110501-20201231 (1751)
- 21 limit 20 to english language (1711)
- 22 animals/ not humans/ (2464052)
- 23 21 not 22 (1703)
- 24 limit 23 to (letter or historical article or comment or editorial or news or case reports) (26)
- 25 23 not 24 (1677)

Database: MIP

- 1 exp *risk/ or uncertainty/ (0)
- 2 (risk* or benefi* or uncertain*).ti,ab. (381224)
- 3 or/1-2 (381224)
- 4 exp Communication/ or Audiovisual Aids/ or Data Interpretation, Statistical/ (0)
- 5 1 and 4 (0)
- 6 ((fram\$ or information*) adj2 (effect\$ or positiv\$ or negativ\$ or consequen* or messag* or prevent* or promo* or neutral* or display*)).ti,ab. (2707)
- 7 ((graph* or visual* or statistic*) adj3 (present* or format*)).ti,ab. (4958)
- 8 framing.ti. (249)
- 9 or/6-8 (7811)
- 10 3 and 9 (1138)
- 11 (risk* adj2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)).ti,ab. (4145)
- 12 or/5,10-11 (5204)
- 13 (MEDLINE or pubmed).tw. (34279)
- 14 systematic review.tw. (28123)
- 15 systematic review.pt. (732)
- 16 meta-analysis.pt. (40)
- 17 intervention\$.ti. (20667)
- 18 or/13-17 (65732)
- 19 12 and 18 (464)

- 20 limit 19 to dt=20110501-20201231 (446)
- 21 limit 20 to english language (442)
- 22 animals/ not humans/ (0)
- 23 21 not 22 (442)
- 24 limit 23 to (letter or historical article or comment or editorial or news or case reports) (3)
- 25 23 not 24 (439)

Database: MEP

- 1 exp *risk/ or uncertainty/ (0)
- 2 (risk* or benefi* or uncertain*).ti,ab. (65408)
- 3 or/1-2 (65408)
- 4 exp Communication/ or Audiovisual Aids/ or Data Interpretation, Statistical/ or Teaching Materials/ (0)
- 5 1 and 4 (0)
- 6 ((fram\$ or information*) adj2 (effect\$ or positiv\$ or negativ\$ or consequen* or messag* or prevent* or promo* or neutral* or display*)).ti,ab. (436)
- 7 ((graph* or visual* or statistic*) adj3 (present* or format*)).ti,ab. (749)
- 8 framing.ti. (60)
- 9 or/6-8 (1222)
- 10 3 and 9 (225)
- 11 (risk* adj2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)).ti,ab. (879)
- 12 or/5,10-11 (1079)
- 13 (MEDLINE or pubmed).tw. (6851)
- 14 systematic review.tw. (6629)
- 15 systematic review.pt. (32)
- 16 meta-analysis.pt. (27)
- 17 intervention\$.ti. (3940)
- 18 or/13-17 (13391)
- 19 12 and 18 (140)

- 20 limit 19 to dt=20110501-20201231 (134)
- 21 limit 20 to english language (133)
- 22 animals/ not humans/ (0)
- 23 21 not 22 (133)
- 24 limit 23 to (letter or historical article or comment or editorial or news or case reports) (0)
- 25 23 not 24 (133)

Database: Embase

- 1 exp *risk/ or uncertainty/ (326721)
- 2 (risk* or benefi* or uncertain*).ti,ab. (4229024)
- 3 or/1-2 (4260078)
- 4 interpersonal communication/ or audiovisual aid/ or statistical analysis/ (407619)
- 5 1 and 4 (9601)
- 6 ((fram\$ or information*) adj2 (effect\$ or positiv\$ or negativ\$ or consequen* or messag* or prevent* or promo* or neutral* or display*)).ti,ab. (20340)
- 7 ((graph* or visual* or statistic*) adj3 (present* or format*)).ti,ab. (45258)
- 8 framing.ti. (1536)
- 9 or/6-8 (66489)
- 10 3 and 9 (14425)
- 11 (risk* adj2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)).ti,ab. (43658)
- 12 or/5,10-11 (65958)
- 13 (MEDLINE or pubmed).tw. (248153)
- 14 exp systematic review/ or systematic review.tw. (285062)
- 15 meta-analysis/ (182515)
- 16 intervention\$.ti. (193827)
- 17 or/13-16 (632707)

- 18 12 and 17 (4720)
- 19 limit 18 to dc=20110501-20201231 (3612)
- 20 limit 19 to english language (3575)
- 21 nonhuman/ not human/ (4589954)
- 22 20 not 21 (3560)
- 23 22 not (conference abstract or conference paper or conference proceeding or "conference review").pt. (2415)
- 24 23 not (letter or editorial).pt. (2407)
- 25 limit 24 to medline (598)
- 26 24 not 25 (1809)

Database: APA PsycInfo

- 1 exp *risk/ or uncertainty/ (8032)
- 2 (risk* or benefi* or uncertain*).ti,ab. (595972)
- 3 or/1-2 (596625)
- 4 exp Communication/ or Audiovisual Aids/ or Data Interpretation, Statistical/ or Teaching Materials/ (290685)
- 5 1 and 4 (674)
- 6 ((fram\$ or information*) adj2 (effect\$ or positiv\$ or negativ\$ or consequen* or messag* or prevent* or promo* or neutral* or display*)).ti,ab. (14047)
- 7 ((graph* or visual* or statistic*) adj3 (present* or format*)).ti,ab. (12855)
- 8 framing.ti. (2836)
- 9 or/6-8 (28462)
- 10 3 and 9 (4367)
- 11 (risk* adj2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)).ti,ab. (13755)
- 12 or/5,10-11 (18264)
- 13 (MEDLINE or pubmed).tw. (22104)
- 14 systematic review.tw. (26728)

```
15 systematic review.pt. (0)
16 meta-analysis.pt. (0)
17 intervention$\text{$\frac{1}{2}}$. (69376)
18 or/13-17 (104792)
19 12 and 18 (782)
20 limit 19 to up=20110501-20201231 (497)
21 limit 20 to english language (459)
22 animals/ not humans/ (6438)
23 21 not 22 (459)
24 dissertation*.pt,jn. (479843)
25 23 not 24 (413)
26 limit 25 to conference proceedings (0)
27 25 not 26 (413)
```

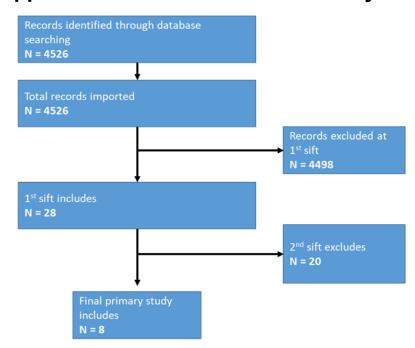
Database: Cochrane – CDSR/CENTRAL			
#1	MeSH descriptor: [Risk] explode all trees 35939		
#2	MeSH descriptor: [Uncertainty] this term only 131		
#3	(risk* or benefi* or uncertain):ti,ab 315866		
#4	#1 or #2 or #3 327132		
#5	MeSH descriptor: [Communication] explode all trees 7970		
#6	MeSH descriptor: [Audiovisual Aids] this term only 368		
#7	MeSH descriptor: [Data Interpretation, Statistical] this term only 1620		
#8	#5 or #6 or #7 9882		
#9	#4 and #8 2595		
#10 ((fram* or information*) near/2 (effect* or positiv* or negativ* or consequen* or messag* or prevent* or promo* or neutral* or display*)):ti,ab 2746			
#11	((graph* or visual* or statistic*) near/3 (present* or format*)):ti,ab 2090		
#12	framing:ti 236		

#13	#10 or #11 or #12	4860			
#14	#4 and #13 1725				
	#15 (risk* near/2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*)):ti,ab 4100				
#16	#9 or #14 or #15	7948			
#17	"clinicaltrials.gov":so	189166			
#18	"www.who.int":so	133989			
#19	(clinicaltrials or trialsearch):so 323326				
#20	"conference":pt158103				
#21	{or #17-#20} 48143	1			
#22 #16 not #21 with Cochrane Library publication date Between May 2011 and Mar 2020, in Cochrane Reviews 334					
#23	#16 not #21 with Publi	cation Year from 2011 to 2020, in Trials 3144			

Databas	Database: CRD – DARE			
1	MeSH DESCRIPTOR Risk EXPLODE ALL TREES	6687		
2	MeSH DESCRIPTOR uncertainty	32		
3	(risk* or benefi* or uncertain*)	39733		
4	#1 OR #2 OR #3	39798		
5	MeSH DESCRIPTOR Communication EXPLODE ALL TREES	750		
6	MeSH DESCRIPTOR audiovisual aids	13		
7	MeSH DESCRIPTOR Data Interpretation, Statistical	281		
8	#5 OR #6 OR #7	1037		
9	#4 AND #8	462		
10	((fram* or information*) near2 (effect* or positiv* or negativ* or consequen* or messag* or prevent* or promo* or neutral* or display*))	288		
11	((graph* or visual* or statistic*) near3 (present* or format*))	400		
12	(framing):TI	1		
13	#10 OR #11 OR #12	684		
14	#4 AND #13	552		
15	(risk* near2 (language* or communicat* or presentation* or presenting* or inform* or tailor* or individuali?e* or personal* or rate* or reference class* or talk* or speech* or percept* or explain*))	1071		
16	(#9 or #14 or #15) IN DARE WHERE LPD FROM 01/05/2011 TO 18/03/2020	688		

FINAL Embedding shared decision making in healthcare systematics.	ems	

Appendix D - Clinical evidence study selection



Appendix E – systematic review evidence tables

Akl Elie A, 2011

Bibliographic Reference

Akl Elie A, Oxman Andrew D, Herrin Jeph, Vist Gunn E, Terrenato Irene, Sperati Francesca, Costiniuk Cecilia, Blank Diana, Schünemann Holger; Using alternative statistical formats for presenting risks and risk reductions; Cochrane Database of Systematic Reviews: Reviews; 2011; vol. issue3

Study design	Systematic review
Study details	Dates searched 1966 to October 2007 1980 to October 2007 1887 to October 2007 Databases searched Ovid Medline EMBASE PsycLIT Cochrane Central Register of Controlled Trials Sources of funding State University of New York at Buffalo, NY, USA. Salary support, infrastructure, Italian National Cancer Institute, Regina Elena, Rome, Italy. Salary support Norwegian Research Council, Norway: Salary support HJS is funded by a european commission: The human factor, mobility and Marie Curie Actions. Scientist Reintegration Grant: IGR 42194 - GRADE., Not specified. Salary support
Study and participant inclusion criteria	Participants Participants Participants of interest included health professionals, policy makers, and consumers. Consumers included patients, the general public, and students. Because of their lack of clinical exposure, we considered students of health professions as consumers Study type randomized and non-randomized controlled parallel and cross-over studies
Study and participant exclusion criteria	Participants NR

	Study type NR
Intervention(s)	Int 1 comparison of statistical presentations of a risk (eg frequencies versus percentages) Int 2 relative risk reduction (RRR) versus absolute risk reduction (ARR) Int 3 RRR versus number needed to treat (NNT), Int 4 ARR versus NNT.
Outcome(s)	outcome 1 actual decisions or behaviours. outcome 2 Understanding: objective only (correctly stating which treatment is more effective after being presented with data) outcome 3 Perception (how effective an intervention is perceived to be) eg. the rating of the perceived effectiveness of vaccination outcome 4 Persuasiveness (how likely participants are to make a hypothetical decision in favour of an intervention) outcome 5 Other: Studies meeting other inclusion criteria did not have to present above outcomes.
Number of studies included in the systematic review	35
Studies from the systematic review that are relevant for use in the current review	Adily 2004 Bobbio 1994 Bramwell 2006a Bramwell 2006c

Bramwell 2006d

Brotons 2002

Bucher 1994

Carling 2008

Carling 2009

Chao 2003

Cranney 1996

Damur 2000

Davey 2005

Fahey 1995

Forrow 1992a

Forrow 1992b

Gigerenzer 1996

Heller 2004

Hux 1995

Kurzenhauser 2002

Lacy 2001

Loewen 1999

Malenka 1993

Mellers 1999

Misselbrook 2001

	Natter 2005a
	Natter 2005b
	Naylor 1992
	Nexoe 2002a
	Nexoe 2002b
	Nikolajevic-S 1999
	Sarfati 1998
	Schwartz 1997a
	Schwartz 1997b
	SedImeir 2001
	Sheridan 2003
	Straus 2002
	Ward 1999
	Wolf 2000 Young 2003
Studies from the systematic review that are not relevant for use in the current review	Study name and date 1 Bramwell 2006b

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low
Synthesis and findings	Concerns regarding the synthesis and findings	Low
Overall study ratings	Overall risk of bias	Low
	Applicability as a source of data	Fully applicable

Bayne, 2020

Bibliographic Reference

Bayne, M.; Fairey, M.; Silarova, B.; Griffin, S.J.; Sharp, S.J.; Klein, W.M.P.; Sutton, S.; Usher-Smith, J.A.; Effect of interventions including provision of personalised cancer risk information on accuracy of risk perception and psychological responses: A systematic review and meta-analysis; Patient Education and Counseling; 2020; vol. 103 (no. 1); 83-95

Study design	Systematic review
Study details	Dates searched 1st January 2000 until 1st July 2017

	Databases searched MEDLINE CINAHL EMBASE PsychINFO Sources of funding JUS is funded by a Cancer Research UK Cancer Prevention Fellowship (C55650/A21464). BS was supported by the Medical Research Council [MC_UU_12015/4]. SJS is supported by the Medical Research Council www.mrc.ac.uk [Unit Programme number MC_UU_12015/1]. The University of Cambridge has received salary support in respect of SJG from the NHS in the East of England through the Clinical Academic Reserve.
Study and participant inclusion criteria	Participants adults with no previous history of cancer Study type were published as a primary research paper in a peer-reviewed journal Outcomes data on either accuracy of risk recall or risk perception at the level of the individual or psychological measures (including cancer worry, anxiety, depression, affect and quality of life).
Study and participant exclusion criteria	Participants patients with a history of cancer Study type vignette studies, qualitative studies, conference abstracts, editorials, commentaries and letters
Intervention(s)	Int 1 provision to individuals of a personal estimate of future cancer risk based on two or more non-genetic variables, either alone or as part of a larger intervention
Outcome(s)	outcome 1 Recall of risk information outcome 2 Accuracy of risk perception outcome 3 Cancer specific worry, anxiety or fear outcome 4 General anxiety outcome 5 depression outcome 6

	affect
	outcome 7: health-related quality of life
Number of studies included in the systematic review	23 (22 papers)
Studies from the systematic review that are relevant for use in the current review	Emmons 2004 Timmermans 2012 Weinstein 2004

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	High (Concern over data extraction checking.)
Synthesis and findings	Concerns regarding the synthesis and findings	High (Lack of robustness around data used and risk of bias)
Overall study ratings	Overall risk of bias	High (Lack of robustness around data used in synthesis and addressing risk of bias in synthesis)
	Applicability as a source of data	Fully applicable

Buchter, 2014

Bibliographic Reference

Buchter, Roland Brian; Fechtelpeter, Dennis; Knelangen, Marco; Ehrlich, Martina; Waltering, Andreas; Words or numbers? Communicating risk of adverse effects in written consumer health information: a systematic review and meta-analysis.; BMC medical informatics and decision making; 2014; vol. 14; 76

Study design	Systematic review
Study details	Dates searched up to November 2012 Databases searched MEDLINE, EMbase, PsychINFO, CINAHL, ERIC, DARE, CDSR, CENTRAL, Campbell library. Sources of funding None
Study and participant inclusion criteria	Participants None Study type randomized controlled trials Outcomes interpretation of probability, comprehension, recall, satisfaction, impact on decision, likelihood of treatment utilization, adherence and psychological outcomes (e.g. anxiety);
Study and participant exclusion criteria	Study type Not in English or German

Intervention(s)	Int 1 Treatment effects communicated through health information
Outcome(s)	outcome 1 estimation of probabilities (in percentages) outcome 2 likelihood of occurrence outcome 3 satisfaction outcome 4 intention to take or continue to take the medicine outcome 5 the impact of the information on the decision
Number of studies included in the systematic review	10 (7 papers)
Studies from the systematic review that are relevant for use in the current review	Berry 2002 Study 1 Berry 2003 Study 2 Berry 2003 Study 1 Berry 2003 study 2 Berry 2004 Berry 2006 Knapp 2009b Study 1 Knapp 2009a Knapp 2009b Study 2

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	High (No protocol provided)

Section	Question	Answer
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	High (No clarity on error checking in risk of bias assessment.)
Synthesis and findings	Concerns regarding the synthesis and findings	High (Risk of bias assessment made many assumptions about missing data in provided studies, assuming unclear was low risk.)
Overall study ratings	Overall risk of bias	High (Risk of bias assessment made many assumptions about missing data in provided studies, assuming unclear was low risk.)
	Applicability as a source of data	Fully applicable

Dieng, 2014

Bibliographic Reference

Dieng, Mbathio; Watts, Caroline G; Kasparian, Nadine A; Morton, Rachael L; Mann, Graham J; Cust, Anne E; Improving subjective perception of personal cancer risk: systematic review and meta-analysis of educational interventions for people with cancer or at high risk of cancer.; Psycho-oncology; 2014; vol. 23 (no. 6); 613-25

Olday Ollaracteristics	
Study design	Systematic review
Study details	Dates searched 1950 - January 2013 1806 - January 2013 1985 - January 2013 1982 - January 2013 1966 - January 2013 Databases searched MEDLINE PsycINFO Allied and Complementary Medicine (AMED) Cumulative Index to Nursing and Allied Health Literature (CINAHL) Sources of funding Not recorded
Study and participant inclusion criteria	Participants People affected by cancer (cancer patients, cancer survivors) or at moderate or high or risk of cancer Study type RCTs, Non randomised trials, prospective studies
Study and participant exclusion criteria	Participants Involved only caregivers Were conducted only among the general population (not targeted at risk groups) Study type Case studies, conference abstracts, systematic review or meta-analyses
Intervention(s)	Int 1 Educational interventions aiming to increase cancer risk understanding among people affected by cancer or at moderate or high or risk of cancer. Included if: - The study evaluated the impact of an educational intervention on cancer risk perception; - The intervention was an educational intervention of any form including genetic counselling; - The intervention targeted people affected by cancer (cancer patients, cancer survivors), people who were at high or moderate risk of developing cancer, or who were referred to genetic counselling because of a personal or family history of cancer.
Outcome(s)	outcome 1 Personal cancer risk perception (Inc criteria) (mean perceived risk, risk accuracy, risk rating)
Number of studies included in the systematic review	40 (13 RCT)
Studies from the systematic review	Albada 2012 Bowen 2004

that are relevant for use in the current review	Brain 2000 Braithwaite 2005
	Lerman 1995
	Roshanai 2009

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low (PROSPERO uploaded late but no evidence)
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low
Synthesis and findings	Concerns regarding the synthesis and findings	High (Risk of Bias high and not incorporated into meta-analysis with any sort of sensitivity analysis Lots of unvalidated measures used.)
Overall study ratings	Overall risk of bias	High
	Applicability as a source of data	Fully applicable

Edwards Adrian GK, 2013

Bibliographic Reference

Edwards Adrian GK, Naik Gurudutt, Ahmed Harry, Elwyn Glyn J, Pickles Timothy, Hood Kerry, Playle Rebecca; Personalised risk communication for informed decision making about taking screening tests; Cochrane Database of Systematic Reviews: Reviews; 2013; vol. issue2

Study design	Systematic review
Study details	Dates searched 2005 - March 2012 Databases searched CENTRAL MEDLINE EMBASE CINAHL PsyINFO Sources of funding Internal sources Welsh Assembly Government, UK: GN's post as an 'Associate Academic Fellow' in Cardiff University was funded by the Welsh Assembly Government External sources: No sources of support supplied
Study and participant inclusion criteria	Participants Participants were people facing real life decisions (not hypothetical exercises) about whether to undergo screening. They were individuals making decisions alone or on another's behalf (for example, for a young child), or couples making decisions together. The screening activities involved an investigation performed by a health professional. Examples of these include: - mammography; - cervical 'Papanicolaou' smears; - colorectal cancer screening; - prostatic cancer screening (PSA test); - antenatal screening (including Down's syndrome, neural tube defects and other fetal anomalies); - genetic screening (including breast cancer gene testing) - high cholesterol/cardiovascular risk screening; - neonatal screening (including cystic fibrosis and Duchenne testing) - skin cancer screening; - lung cancer screening. Study type RCTs
Study and participant exclusion criteria	Participants We excluded studies if they described only: - mass communication; or - military or school or prison-based interventions (where people are less free to choose than in other healthcare settings).

	Study type Not RCT
Intervention(s)	Int 1 Individualised risk score or individual actual risk information (ie. absoloute or relative risk information) Int 2 categorisations of risk status based on individualised risk estimates(for example, high, medium or low risk status); Int 3 discussion of personal risk factors relevant to the screening decision (that is, the individual's own characteristics are taken into account in assessing their actual risk or elevated risk status relative to others).
Outcome(s)	outcome 1 Informed decision outcome 2 Uptake of screening test outcome 3 Cognitive outcomes (Knowledge of risk, accurate risk perception) outcome 4 Affective outcomes: Anxiety/emotional well-being, satisfaction with decision made, decisional conflict, anxiety, intention to take up screening outcome 5 behavioural outcomes: uptake of tests, adherence to choice regarding screening test, 'appropriate' uptake outcome 6 behavioural outcomes: uptake of tests, adherence to choice regarding screening test, 'appropriate' uptake; outcome 7: health status outcomes: specific status measures or quality of life measures such as SF-36 outcome 8 economic outcomes: cost of intervention.
Number of studies included in the systematic review	41 narrative synthesis 38 quantitative synthesis

	Bastani 1999
	Bloom 2006
	Bodurtha 2009
	Bowen 2002
	Bowen 2006
	Bowen 2010
	Campbell 1997
	Champion 1994
	Champion 1995
Studies from the systematic review	Champion 2000A
that are relevant for	Champion 2002
use in the current review	Champion 2003
	Champion 2007
	Curry 1993
	Geller 2006
	Glanz 2007
	glazebrook 2006
	Helmes 2006
	hutchinson 1998
	Jibaja-Weiss 2003
	Kreuter 1996

Lee 1991 Lerman 1995 Lerman 1997 Lipkus 2005b Lipkus 2007b Manne 2009 Manne 2010 Marcus 2005 Myers 1999 Nagle 2008 Rawl 2008 Rimer 2002 Saywell 1999 Schwartz 1999 Sequist 2011 Skinner 1994 Skinner 2002 Smith 2010 Steckelberg 2011 Trevena 2008

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low
Synthesis and findings	Concerns regarding the synthesis and findings	Low
Overall study ratings	Overall risk of bias	Low
	Applicability as a source of data	Fully applicable

Harris, 2020

Bibliographic Reference Harris, Rebecca; Vernazza, Christopher; Laverty, Louise; Lowers, Victoria; Burnside, Girvan; Brown, Stephen; Higham, Susan; Ternent,

Laura; No title provided; 2020

Study design	Systematic review
Study details	Databases searched MEDLINE (via Ovid MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations) Web of Science: Social Sciences Citation Index Web of Science: Conference Proceedings Citation Index – Social Science & Humanities PsycINFO PsycArticle Communication & Mass Media Complete ProQuest Dissertations & Theses The Cochrane Library – Cochrane Reviews (reviews and protocols) OpenGrey Health Informatics Journal Patient Preference and Adherence Patient Education and Counselling Health Communication Journal of the American Medical Informatics Association Preventive Medicine Journal of Health Communication BMC Medical Informatics and Decision Making
Study and participant inclusion criteria	Participants Adults aged ≥ 18 years. Study type All study designs. Studies concerned with information aimed at increasing patients' perception of health risk. These include studies involving tailored information about an individual's level of health with reference to likely negative consequences, as well as those involving risk terminology or health outcome probabilities. Studies reporting delivery of information in a certain form (e.g. written, video, online, photographic) versus no intervention/usual care controls, or comparing information in different forms. In the control group, 'usual care' information may or may not be tailored. Studies involving multicomponent interventions that had control group components, such as motivational interviewing, or education that was also part of the intervention group, were included. Outcomes Outcome measures including one or more behaviour mediators, including risk perception, health behaviour and health outcomes
Study and participant exclusion criteria	Study type Studies concerned with giving information in a verbal form compared with a control. Outcomes Outcomes concerned with decision-making in relation to treatment options only.
Intervention(s)	Int 1 Personalised (tailored) information given to patients that is reliant on a pre-assessment of the patient, rather than information that is targeted according to population characteristics, such as age and gender.
Outcome(s)	outcome 1 Adherence to treatment outcome 2 Preferences outcome 3 patient self-efficacy outcome 4 risk perception

	outcome 5 communication satisfaction
	outcome 6 health outcomes
	outcome 7: perceived susceptibility
	outcome 8 perceived seriousness
	outcome 9 stress
Studies from the systematic review that are relevant for use in the current review	Shahab 2007
	Ahmed 2011
	Dapp 2011
	Harari 2008
	Hess 2014
Studies from the systematic review	Kreuter & Strecher 1995
that are not relevant for use in the current review	Mauriello 2016
	Neuner-Jehle 2013
	Saver 2014
	Welschen 2012
	Weymann 2013 Zullig 2014

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low
Synthesis and findings	Concerns regarding the synthesis and findings	High
Overall study ratings	Overall risk of bias	High – no proper synthesis, vague inclusion criteria and high included study risk of bias not addressed in synthesis
	Applicability as a source of data	Directly applicable

Stellamanns, 2017

Bibliographic Reference

Stellamanns, Jan; Ruetters, Dana; Dahal, Keshav; Schillmoeller, Zita; Huebner, Jutta; Visualizing risks in cancer communication: A systematic review of computer-supported visual aids.; Patient education and counseling; 2017; vol. 100 (no. 8); 1421-1431

Study design	Systematic review
Study details	Dates searched August 2015 Databases searched EBSCO: Nursing/Academic edition, Library, Information Science & Technology Abstracts, MEDLINE, Psychology and Behavioural Sciences Collection, PsyINFO, CINAHL and ERIC. OVID: Embase IEEE Xplore Digital Library Included studies references Sources of funding This research did not receive any specific grant from public or commercial funding agencies or from non-profitable sectors.
Study and participant inclusion criteria	Participants patients or lay people Study type Peer reviewed journals with controlled study design and any kind of quantitative evaluation. Intervention computer-supported visual aid or visualization presenting quantitative cancer data for cancer communication or decision support.
Intervention(s)	Int 1 computer-supported visual aid or visualization presenting quantitative cancer data for cancer communication or decision support.
Outcome(s)	outcome 1 Behavioural choice/intention outcome 2 Walker 20145 comprehension outcome 3 efficacy beliefs outcome 4 perceived risk outcome 5 Risk accuracy

	outcome 6 risk-related worries outcome 7: perceived credibility outcome 8 dispositional optimism outcome 9 numeracy
	Outcome 10 knowledge outcome 11 Cognitive effort
Number of studies included in the systematic review	13 (narrative synthesis)
Studies from the systematic review that are relevant for use in the current review	Cameron 2012 Cox 2010 Cox 2014 Feldman-stewart 2000 Han 2011 Han 2012 Waters 2007a Waters 2007b Zikmund-Fisher 2008b Zikmund-Fisher 2010 Zikmund-Fisher 2011 Zikmund-Fisher 2012

Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	Low
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	High (lack of solid baseline numeric characteristics makes judgement of results difficult)
Synthesis and findings	Concerns regarding the synthesis and findings	High (Narrative synthesis does not compare enough baseline criteria or examine numeric results of individual papers robustly enough.)
Overall study ratings	Overall risk of bias	High (Narrative synthesis does not compare enough baseline criteria or examine numeric results of individual papers robustly enough.)
	Applicability as a source of data	Fully applicable

Walker, 2015

Bibliographic Reference

Walker, J G; Licqurish, S; Chiang, P P C; Pirotta, M; Emery, J D; Cancer risk assessment tools in primary care: a systematic review of randomized controlled trials.; Annals of family medicine; 2015; vol. 13 (no. 5); 480-9

Study Characteristics	
Study design	Systematic review
Study details	Dates searched Up to December 2013 Databases searched EMBASE, PubMed, The Cochrane Library Sources of funding This work was supported by funding from the Victorian Comprehensive Cancer Centre, and the National Health and Medical Research Council of Australia (APP1042021).
Study and participant inclusion criteria	Participants Primary care practitioners, primary care patients Study type randomised trials and systematic reviews
Study and participant exclusion criteria	Participants Patients in specialist care, specialist clinicians
Intervention(s)	Int 1 Risk assessment tools used in primary care for cancer screening.
Outcome(s)	outcome 1 Accuracy of patient risk perception outcome 2 Patient behaviours outcome 3 Anxiety/Worry outcome 4 Knowledge outcome 5 Satisfaction outcome 6 Clinician confidence

Number of studies included in the systematic review	11 articles
Studies from the systematic review that are relevant for use in the current review	Schroy 2011 Emery 2007 Holloway 2003

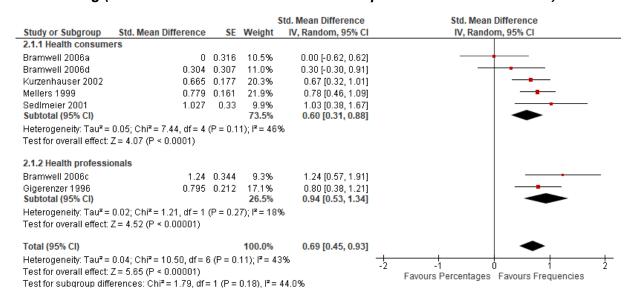
Section	Question	Answer
Study eligibility criteria	Concerns regarding specification of study eligibility criteria	Low
Identification and selection of studies	Concerns regarding methods used to identify and/or select studies	High (No MEDLINE searches suggest key refs may have been missed!)
Data collection and study appraisal	Concerns regarding methods used to collect data and appraise studies	Low
Synthesis and findings	Concerns regarding the synthesis and findings	Low
Overall study ratings	Overall risk of bias	High (Databases searched means many results may have been missed!)
	Applicability as a source of data	Fully applicable

Appendix F – Forest plots

Intervention vs intervention

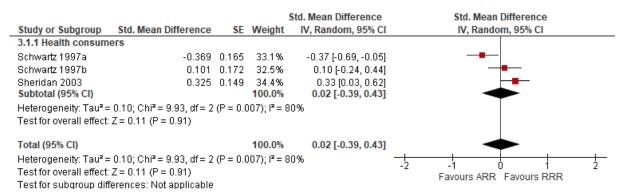
Natural frequencies vs risk percentages

Understanding (measured as correct estimate or interpretation of risk reduction)

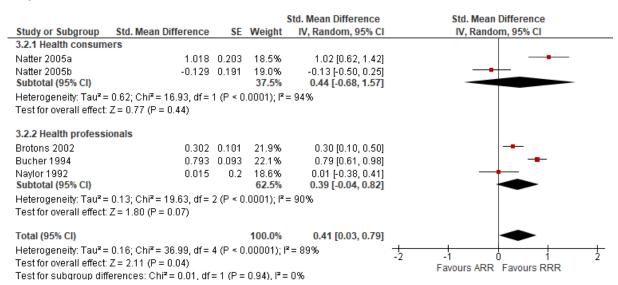


RRR vs ARR

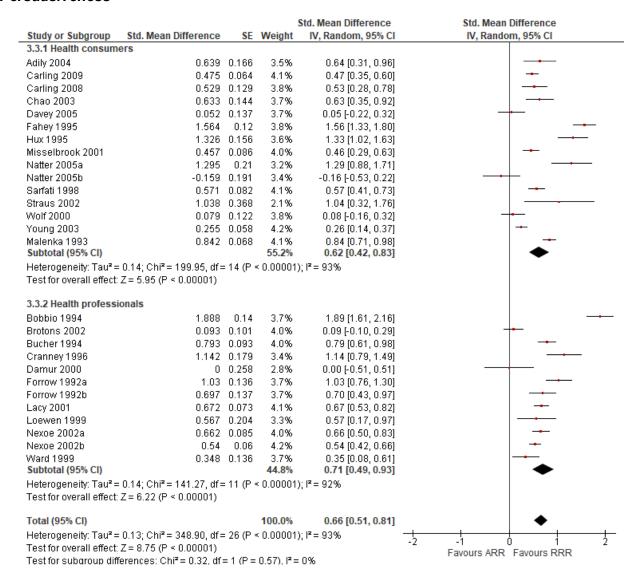
Understanding



Perception



Persuasiveness

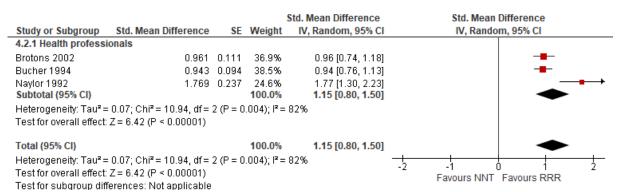


RRR versus NNT

Understanding

				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Std. Mean Difference	SE	Weight	IV, Random, 95% CI	IV, Random, 95% CI
4.1.1 Health consum	ners				
Sheridan 2003	0.734	0.157	100.0%	0.73 [0.43, 1.04]	-
Subtotal (95% CI)			100.0%	0.73 [0.43, 1.04]	•
Heterogeneity: Not ap	pplicable				
Test for overall effect	Z = 4.68 (P < 0.00001)				
Total (95% CI)			100.0%	0.73 [0.43, 1.04]	•
Heterogeneity: Not ap	pplicable			_	-1 -05 0 05 1
Test for overall effect:	Z = 4.68 (P < 0.00001)				Favours NNT Favours RRR
Test for subgroup dif	ferences: Not applicable				Tavouis WWT Pavouis KKK

Perception

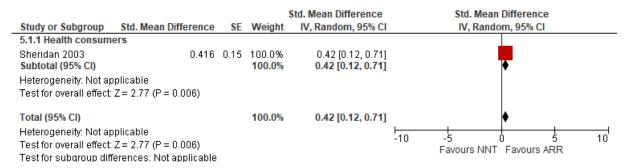


Persuasiveness

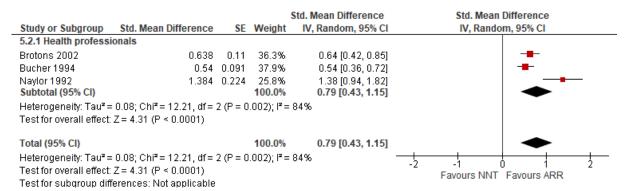
Study or Subarous	Ctd Maan Difference	er.		Std. Mean Difference	Std. Mean Difference
Study or Subgroup 4.3.1 Health consum	Std. Mean Difference	3E	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Adily 2004		0.172	4.3%	0.96 [0.63, 1.30]	
Carling 2008		0.172	4.8%	0.53 [0.28, 0.77]	
Carling 2009		0.064	5.4%	0.40 [0.27, 0.52]	
Chao 2003		0.142	4.7%	0.47 [0.20, 0.75]	
Fahey 1995		0.112	5.0%	1.08 [0.86, 1.30]	
Hux 1995		0.153	4.5%	1.16 [0.86, 1.46]	
Misselbrook 2001	0.599		5.2%	0.60 [0.43, 0.77]	-
Sarfati 1998		0.084	5.2%	0.76 [0.59, 0.92]	
Straus 2002		0.348	2.5%	0.46 [-0.22, 1.14]	
Young 2003		0.058	5.4%	0.23 [0.11, 0.34]	-
Subtotal (95% CI)	0.220	0.000	47.0%	0.66 [0.46, 0.86]	•
	= 0.09; Chi ^z = 86.67, df = 1 : Z = 6.47 (P < 0.00001)	9(P < 0	.00001); I	²= 90%	
4.3.2 Health professi	ionals				
Bobbio 1994	1.377	0.129	4.8%	1.38 [1.12, 1.63]	-
Brotons 2002	0.073	0.105	5.0%	0.07 [-0.13, 0.28]	 -
Bucher 1994	0.943	0.094	5.1%	0.94 [0.76, 1.13]	-
Cranney 1996	1.614	0.191	4.1%	1.61 [1.24, 1.99]	
Damur 2000	0.049	0		Not estimable	
Heller 2004	0.38	0.114	5.0%	0.38 [0.16, 0.60]	
Lacy 2001	0.569	0.072	5.3%	0.57 [0.43, 0.71]	-
Loewen 1999	0.442	0.203	4.0%	0.44 [0.04, 0.84]	
Nexoe 2002a	0.682	0.085	5.2%	0.68 [0.52, 0.85]	-
Nexoe 2002b	0.501		5.4%	0.50 [0.38, 0.62]	-
Nikolajevic-S 1999	0.623		4.3%	0.62 [0.28, 0.96]	
Ward 1999	0.039	0.135	4.7%	0.04 [-0.23, 0.30]	_
Subtotal (95% CI)			53.0%	0.65 [0.42, 0.87]	•
	= 0.13; Chi² = 128.30, df = : Z = 5.67 (P < 0.00001)	: 10 (P ·	< 0.00001); I² = 92%	
Total (95% CI)			100.0%	0.65 [0.51, 0.80]	•
	= 0.10; Chi² = 217.14, df=	: 20 (P <			
	Z = 8.80 (P < 0.00001)	(,	2.00001	71. 2.72	-2 -1 0 1 2
	ferences: Chi² = 0.01, df:	- 4 (D -	0.04\ 12=	0.01	Favours NNT Favours RRR

ARR versus NNT

Understanding



Perception



Persuasiveness

				Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Std. Mean Difference	SE	Weight	IV, Random, 95% CI	IV, Random, 95% CI
5.3.1 Health consum	iers				
Adily 2004	0.077	0.162	4.0%	0.08 [-0.24, 0.39]	-
Carling 2008	0	0.126	4.9%	0.00 [-0.25, 0.25]	-
Carling 2009	0.08	0.064	6.7%	0.08 [-0.05, 0.21]	+
Chao 2003	-0.166	0.14	4.6%	-0.17 [-0.44, 0.11]	
Fahey 1995	-0.036	0.105	5.6%	-0.04 [-0.24, 0.17]	
Hux 1995	0.321	0.201	3.2%	0.32 [-0.07, 0.71]	+
Misselbrook 2001	0.155	0.085	6.1%	0.15 [-0.01, 0.32]	
Sarfati 1998	0.2	0.081	6.3%	0.20 [0.04, 0.36]	
Straus 2002	-0.616	0.352	1.4%	-0.62 [-1.31, 0.07]	
Young 2003	-0.028	0.061	6.8%	-0.03 [-0.15, 0.09]	-
Subtotal (95% CI)			49.7%	0.05 [-0.04, 0.14]	•
5.3.2 Health profess	ionals				
Bobbio 1994	-0.32	0.117	5.2%	-0.32 [-0.55, -0.09]	
Brotons 2002	-0.022	0.107	5.5%	-0.02 [-0.23, 0.19]	+
Bucher 1994	0.54	0.091	6.0%	0.54 [0.36, 0.72]	-
Cranney 1996	0.646	0.17	3.8%	0.65 [0.31, 0.98]	
Damur 2000	0.049	0.258	2.3%	0.05 [-0.46, 0.55]	
Lacy 2001	-0.071	0.071	6.5%	-0.07 [-0.21, 0.07]	
Loewen 1999	0.151	0.2	3.2%	0.15 [-0.24, 0.54]	
Nexoe 2002a	0.021	0.082	6.2%	0.02 [-0.14, 0.18]	+
Nexoe 2002b	-0.053	0.059	6.9%	-0.05 [-0.17, 0.06]	- +
Ward 1999	-0.112	0.135	4.7%	-0.11 [-0.38, 0.15]	-
Subtotal (95% CI)			50.3%	0.07 [-0.10, 0.24]	•
	= 0.06; Chi² = 59.21, df =	9(P < 0	.00001); P	²= 85%	
Test for overall effect	: Z = 0.83 (P = 0.41)				
Total (95% CI)			100.0%	0.05 [-0.04, 0.15]	+
	= 0.03; Chi² = 74.87, df =	19 (P <	0.00001);	I ² = 75%	-2 -1 1
Test for overall effect	: Z = 1.13 (P = 0.26)				Favours NNT Favours ARR
Test for subgroup dif	ferences: Chi ^z = 0.05, df	= 1 (P =	0.83), $I^2 =$: 0%	. 470410 1411 1 470410 / 1411

Verbal risk information vs Numerical risk information

Perceived likelihood of adverse event occurrence

FINAL Embedding shared decision making in healthcare systems

	٧	erbal		Nur	nerica	al		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
9.1.1 Very common side eff	ect (15%	o)							
Berry 2002	4.4	1.1	56	2.5	1	56	20.0%	1.90 [1.51, 2.29]	-
Knapp 2009a part 1	4.3	1.4	34	4.3	1.4	66	9.0%	0.00 [-0.58, 0.58]	
Knapp 2009a part 2	4.3	1.4	35	3.6	1.2	52	9.4%	0.70 [0.13, 1.27]	
Knapp 2009b part1 study1	3.48	1.51	25	2.43	1.21	46	6.4%	1.05 [0.36, 1.74]	_
Knapp 2009b part1 study2	4.59	1.35	23	4.3	1.17	54	7.6%	0.29 [-0.34, 0.92]	
Knapp 2009b part2 study1	3.48	1.51	25	2.44	1.33	41	5.9%	1.04 [0.32, 1.76]	
Knapp 2009b part2 study2	4.59	1.35	23	4.04	1.14	48	7.4%	0.55 [-0.09, 1.19]	
Subtotal (95% CI)			221			363	65.8%	0.97 [0.75, 1.18]	◆
Heterogeneity: Chi ² = 39.73,	df = 6 (P	< 0.00	0001); I	²= 85%					
Test for overall effect: $Z = 8.8$	5 (P < 0.	00001)						
9.1.2 Common side effect (2	2%)								
Berry 2004	3.97	1.37	94	2.61	1.22	94	22.1%	1.36 [0.99, 1.73]	
Knapp 2004	4.2	1.78	30	2.6	1.78	30	3.7%	1.60 [0.70, 2.50]	
Subtotal (95% CI)			124			124	25.8%	1.39 [1.05, 1.74]	•
Heterogeneity: Chi² = 0.23, d	lf=1 (P=	0.63)	$; I^2 = 09$	Х.					
Test for overall effect: $Z = 7.9$	17 (P ≤ 0.	00001)						
9.1.3 Rare side effect (0.029	%)								
Knapp 2004	•	1.19	30	2.4	1.19	30	8.4%	0.90 [0.30, 1.50]	
Subtotal (95% CI)			30			30	8.4%	0.90 [0.30, 1.50]	•
Heterogeneity: Not applicable	е								
Test for overall effect: Z = 2.9		003)							
Total (95% CI)			375			517	100.0%	1.07 [0.90, 1.25]	_
	df = 0 /D	~ 0.00		z _ 000		317	100.070	1.07 [0.30, 1.23]	
Heterogeneity: Chi ² = 44.55, Test for overall effect: Z = 12	•			- 00%					-2 -1 0 1 2
Test for overall ellect, Z= 12. Test for subgroup difference				D = 0.40	N 12 _	EC EO.			Higher numerical Higher verbal
restrot subdroup dilletetice	s. cm²=	4.09,	ui = 2 (r = 0.1t	n, r=	JO.576			

Risk tools vs other risk tools

Patient knowledge

	Decisio	n aid al	lone	Decision aid	d + RiskAs	sess		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Schroy 2011	3.2	2.6	212	3	2.5	223	100.0%	0.20 [-0.28, 0.68]	
Total (95% CI)			212			223	100.0%	0.20 [-0.28, 0.68]	
Heterogeneity: Not ap Test for overall effect:	•	P = 0.41	1)					•	-1 -0.5 0 0.5 1 Favours Decision aid alone Favours Decision aid + RiskAssess

Patient satisfaction

	Decisio	n aid a	lone	Decision aid	d + RiskAs	sess		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Schroy 2011	50.7	6.2	212	50.5	6.2	223	100.0%	0.20 [-0.97, 1.37]	
Total (95% CI)			212			223	100.0%	0.20 [-0.97, 1.37]	
Heterogeneity: Not ap Test for overall effect:		P = 0.74	4)					-	-2 -1 0 1 2 Favours Decision aid alone Favours Decision aid + RiskAssess

Intervention vs control

Personalised risk communication versus general information

Informed decision

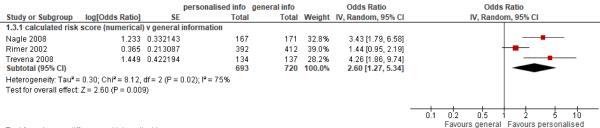
			onalised info ger			Odds Ratio		Odds Ratio
Study or Subgroup	log[Odds Ratio]	SE	Total	Total	Weight	IV, Random, 95% CI	IV, I	Random, 95% CI
1.1.1 calculated risk	score (numerical) v general inf	ormation					
Nagle 2008	0.7324	0.3088	167	171	28.2%	2.08 [1.14, 3.81]		
Subtotal (95% CI)			167	171	28.2%	2.08 [1.14, 3.81]		
Heterogeneity: Not ap	oplicable							
Test for overall effect:	Z = 2.37 (P = 0.02))						
1.1.2 personal risk fa	actor list v genera	l information						
Smith 2010	1.3047	0.2583	357	172	31.6%	3.69 [2.22, 6.12]		
Steckelberg 2011	1.6798	0.1285	785	792	40.2%	5.36 [4.17, 6.90]		-
Subtotal (95% CI)			1142	964	71.8%	4.75 [3.37, 6.70]		•
Heterogeneity: Tau2=	0.03; Chi ² = 1.69,	df = 1 (P = 0.1)	9); I² = 41%					
Test for overall effect:	Z = 8.90 (P < 0.00)	001)						
Total (95% CI)			1309	1135	100.0%	3.65 [2.13, 6.23]		•
Heterogeneity: Tau ² =	0.17; Chi ² = 8.71,	df = 2 (P = 0.0)	1); I²= 77%					-
Test for overall effect:	Z = 4.73 (P < 0.00	001)	**				0.1 0.2 0.	5 1 2 5 10 neral Favours personalised
Test for subgroup diff	*		0.02), I ² = 81.6%				ravours ge	merar ravours personalised

Knowledge regarding screening test/condition concerned

			personalised info	general info		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Std. Mean Difference	SE	Total	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
1.2.1 calculated risk	score (numerical) v ge	neral inf	ormation				
Glazebrook 2006 Subtotal (95% CI)	0.395	0.083	259 259		100.0% 100.0 %		•
Heterogeneity: Not ap	pplicable						
Test for overall effect	Z = 4.76 (P < 0.00001)						
1.2.2 calculated risk	score (categorised) v g	jeneral i	information				_
Skinner 2002	0.57	0.128	130		100.0%		
Subtotal (95% CI)			130	130	100.0%	0.57 [0.32, 0.82]	▼
Heterogeneity: Not a							
Test for overall effect	: Z= 4.45 (P < 0.00001)						
1.2.3 personal risk f	actor list v general infor	mation					
Lerman 1997	1.02	0.122	128	180	37.3%	1.02 [0.78, 1.26]	• • • • • • • • • • • • • • • • • • •
Smith 2010	0.82	0.094	357	173	62.7%	0.82 [0.64, 1.00]	■
Subtotal (95% CI)			485	353	100.0%	0.89 [0.75, 1.04]	♦
Heterogeneity: Chi ² =	: 1.69, df = 1 (P = 0.19); P	²= 41%					
Test for overall effect	Z = 12.01 (P < 0.00001)						
							-4 -2 0 2 4
							Favours general Favours personalised

Test for subgroup differences: $Chi^2 = 20.60$, df = 2 (P < 0.0001), $I^2 = 90.3\%$

Knowledge regarding screening test/condition concerned – proportion with good knowledge

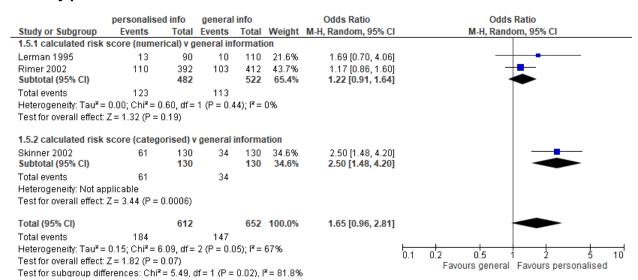


Test for subgroup differences: Not applicable

Knowledge regarding screening test/condition concerned – proportion with good knowledge

		pe	ersonalised info	general info		Odds Ratio	Odds Rati	0
Study or Subgroup	log[Odds Ratio]	SE	Total	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95°	% CI
1.4.1 personal risk f	actor list v genera	linformation						
Smith 2010	1.725	0.222704	357	173	22.8%	5.61 [3.63, 8.68]		-
Steckelberg 2011 Subtotal (95% CI)	2.036	0.121173	785 1142			7.66 [6.04, 9.71] 7.13 [5.79, 8.79]		
Heterogeneity: Chi² = Test for overall effect								
Total (95% CI)			1142	965	100.0%	7.13 [5.79, 8.79]		•
Heterogeneity: Chi ² =	= 1.50, df = 1 (P = 0.	22); I² = 34%					t	10 100
Test for overall effect	: Z=18.46 (P ≤ 0.0	0001)					0.01 0.1 1 Favours general Fav	10 100 ours personalised

Accurately perceived risk



Perceived risk – perceiving self as appropriate candidate for test

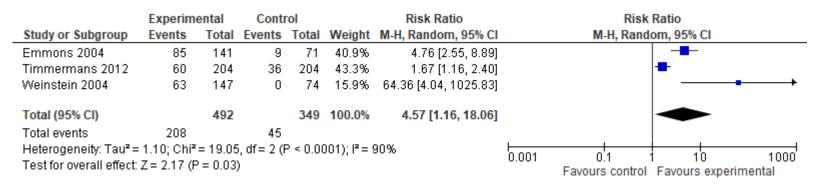
	personalise		general		Odds Ratio				Ratio			
Study or Subgroup	Events	Total	Events	Total	M-H, Fixed, 95% CI			M-H, Fixe	d, 95% (
1.6.1 calculated risk	score (nume	rical) v g	eneral in	formati	on							
Bowen 2002	72	105	84	109	0.65 [0.35, 1.19]				_			
						0.1	0.2	0.5	i :	Ż	5	10
							Fav	ours general	Favour	s personal	ised	

Anxiety (Cancer related anxiety and helplessness scale; IEs breast cancer distress)

		pers	onalised info	general info		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Std. Mean Difference	SE	Total	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.7.1 calculated risk	score (numerical) v ge	neral information					
Bloom 2006	0.19	0.15816326	80	83	13.4%	0.19 [-0.12, 0.50]	
Helmes 2006	-0.40642991	0.118112	209	109	17.1%	-0.41 [-0.64, -0.17]	—
Lerman 1995	-0.3	0.13265306	108	131	15.7%	-0.30 [-0.56, -0.04]	
Nagle 2008	-0.1875	0.116	167	171	17.3%	-0.19 [-0.41, 0.04]	
Subtotal (95% CI)			564	494	63.5%	-0.19 [-0.42, 0.04]	◆
Heterogeneity: Tau ² =	= 0.04; Chi2 = 9.65, df = 3	$(P = 0.02); I^2 = 69\%$)				
Test for overall effect:	: Z = 1.64 (P = 0.10)						
1.7.2 calculated risk	score (categorised) v g	eneral information	ı				
Skinner 2002	0	0.12244898	130	130	16.7%	0.00 [-0.24, 0.24]	
Subtotal (95% CI)			130	130	16.7%	0.00 [-0.24, 0.24]	-
Heterogeneity: Not ap	pplicable						
Test for overall effect:	: Z = 0.00 (P = 1.00)						
1.7.3 personal risk fa	actor list v general infor	mation					
Smith 2010	-0.02	0.09183674	357	173	19.9%	-0.02 [-0.20, 0.16]	
Subtotal (95% CI)			357	173	19.9%	-0.02 [-0.20, 0.16]	•
Heterogeneity: Not ap	pplicable						
Test for overall effect:	Z = 0.22 (P = 0.83)						
Total (95% CI)			1051	797	100.0%	-0.13 [-0.29, 0.03]	•
Heterogeneity: Tau ² =	= 0.03; Chi ² = 14.02, df =	5 (P = 0.02); I ² = 64	%			-	-1 -0.5 0 0.5 1
Test for overall effect		//-					
	ferences: Chi² = 1.69. df	= 2 (P = 0.43) P = 0	96				Favours personalised Favours general

Personalised cancer risk information vs control (Bayne 2020)

Absolute risk accuracy



Comparative risk accuracy

FINAL Embedding shared decision making in healthcare systems

	Experim	ental	Cont	rol		Risk Ratio		Risk	(Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI		M-H, Rand	dom, 95% CI		
Timmermans 2012	89	204	86	204	55.8%	1.03 [0.83, 1.29]			•		
Weinstein 2004	57	146	14	73	44.2%	2.04 [1.22, 3.40]			-		
Total (95% CI)		350		277	100.0%	1.40 [0.71, 2.73]			•		
Total events	146		100								
Heterogeneity: Tau² =	0.20; Chi²	= 5.85,	df=1 (P	= 0.02)	; I² = 83%		0.01		 	10	100
Test for overall effect:	Z = 0.97 (F	P = 0.33)				0.01	Favours control	Favours ex	(perimer	

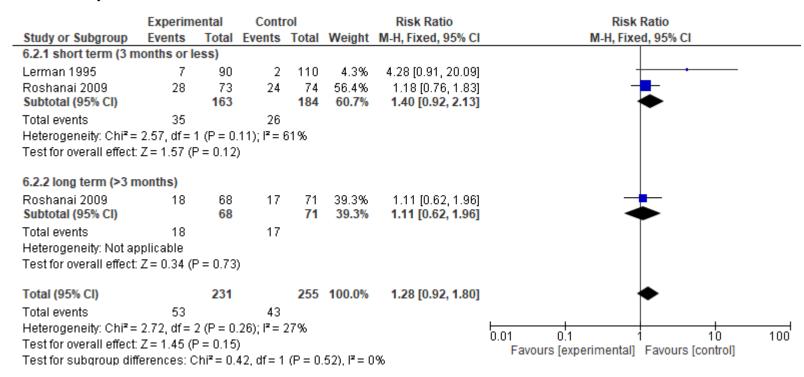
Education intervention (general) vs control (Dieng 2014)

Risk perception

	Expe	eriment	al	(ontrol			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
6.1.1 short term (3 m	onths or	less)							
Albada 2012	-11.02	24.47	103	-8.69	25.63	94	19.8%	-0.09 [-0.37, 0.19]	
Brain 2000	-0.85	1.8	263	-0.71	1.63	282	22.9%	-0.08 [-0.25, 0.09]	
Braithwaite 2005 Subtotal (95% CI)	0.04	1.45	38 404	-0.64	0.99	34 410	14.3% 56.9%	0.54 [0.06, 1.01] 0.05 [-0.24, 0.34]	•
Heterogeneity: Tau ² =	0.04; Ch	i ^z = 6.10	0, df = 2	P = 0.	05); l² =	67%			
Test for overall effect:	Z = 0.33	(P = 0.7)	4)						
6.1.2 long term (>3 m	nonths)								
Bowen 2004	-26.6	30.9	110	-4	33.97	121	20.2%	-0.69 [-0.96, -0.43]	
Brain 2000	-0.55	1.8	263	-0.43	1.71	282	22.9%	-0.07 [-0.24, 0.10]	
Subtotal (95% CI)			373			403	43.1%	-0.37 [-0.98, 0.24]	
Heterogeneity: Tau ² =	0.18; Ch	$i^2 = 15.1$	11, df=	1 (P = 0)	0.0001);	$I^{z} = 93$	%		
Test for overall effect:	Z = 1.19	(P = 0.2)	3)						
Total (95% CI)			777			813	100.0%	-0.12 [-0.39, 0.16]	
Heterogeneity: Tau ² =	0.08; Ch	$i^2 = 25.7$	73, df=	4 (P < 0	0.0001);	$I^2 = 84$	%		-1 -0.5 0 0.5 1
Test for overall effect:	Z = 0.84	(P = 0.4)	0)						Favours [experimental] Favours [control]
Test for subgroup diff	erences:	$Chi^2 = 1$	I.48, df	= 1 (P =	0.22),	l ² = 32.	5%		r avours [experimental] T avours [control]

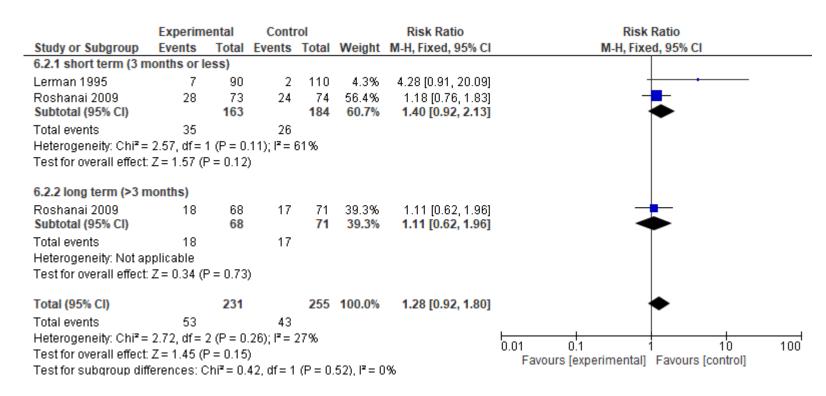
FINAL Embedding shared decision making in healthcare systems

Risk accuracy



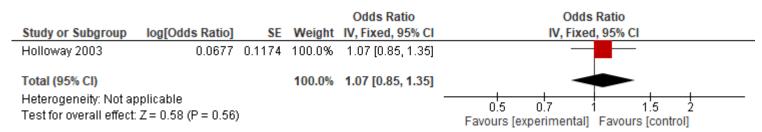
Tailored risk information vs control (Harris 2020)

Risk perception (susceptibility)



Risk tool vs control (Walker 2015)

Risk perception



Patient knowledge

FINAL Embedding shared decision making in healthcare systems

	Exp	eriment	al	(Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Emery 2007	0.11	1.9846	23	0	1.9846	22	19.1%	0.05 [-0.53, 0.64]	
Schroy 2011 (1)	3.2	2.6	212	0.8	2.2	231	40.3%	1.00 [0.80, 1.20]	-
Schroy 2011 (2)	3	2.5	223	0.8	2.2	231	40.6%	0.93 [0.74, 1.13]	-
Total (95% CI)			458			484	100.0%	0.79 [0.46, 1.12]	•
Heterogeneity: Tau²: Test for overall effect			•	(P = 0.0	01); I² = 7	8%		-	-2 -1 0 1 2 Favours [control] Favours [experimental]

Footnotes

- (1) Decision aid alone
- (2) Decision aid plus personalized risk assessment

Patient satisfaction

	Expe	rimen	tal	Co	ontro	I	Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Schroy 2011 (1)	50.7	6.2	212	46.7	7.9	231	49.2%	4.00 [2.68, 5.32]	
Schroy 2011 (2)	50.5	6.2	231	46.7	7.9	231	50.8%	3.80 [2.50, 5.10]	
Total (95% CI)			443			462	100.0%	3.90 [2.97, 4.82]	•
Heterogeneity: Chi ² = 0.05, df = 1 (P = 0.83); I^2 = 0% Test for overall effect: Z = 8.27 (P < 0.00001)								-	-4 -2 0 2 4 Favours [experimental] Favours [control]

Footnotes

- (1) Decision aid alone
- (2) Decision aid plus personalised risk assessment

Anxiety/Worry (Cancer)

FINAL Embedding shared decision making in healthcare systems

	Exp	eriment	al	(Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Emery 2007	0	1.9846	22	-0.11	1.9846	23	100.0%	0.11 [-1.05, 1.27]	
Total (95% CI)			22			23	100.0%	0.11 [-1.05, 1.27]	
Heterogeneity: Not ap Test for overall effect:	•		5)						-4 -2 0 2 4 Favours [experimental] Favours [control]

Appendix G: GRADE Tables

Intervention vs intervention

Pre-existing systematic review analysis

Natural frequencies vs risk percentages (Effect size >1 supports frequencies)

					Absolute risk: intervention (95% CI)					
No. of studies	Study design	Sample size	Effect size (95% CI)	Absolute risk: control		Quality				
Understanding	(measured as o	orrect estimat	e or interpretation of risk	reduction)						
7	RCT	642	SMD 0.69 (0.45 to 0.93)	-	-	Moderate ¹				
1. Outcome is a	. Outcome is a surrogate for health behaviour.									

Relative risk reductions vs absolute risk reductions (Effect size >1 supports RRR)

No. of studies	Study design	Sample size	Effect size (95% CI)	Quality				
Understanding (measured as correct estimate or interpretation of	risk reduction)							
			SMD 0.02					
3	RCT	469	(-0.39 to 0.43)	Moderate ^{1,2}				
Perception (measure as rating on a scale of perceived effectiveness)								
			SMD 0.41					
5	RCT	1116	(0.03 to 0.79)	Low ^{2,3}				
Persuasiveness (measured as a hypothetical decision or intention	or willingness	to adopt an in	tervention					
			SMD 0.66					
27	RCT	11221	(0.51 to 0.81)	Moderate ^{2,4}				
1 The results were inconsistent. We did not however downgrade for inconsistent	cy because the S	MD is on the bord	der of no to small effects in either direct	ion.				

² Outcome is a surrogate for health behaviour.

³ The results were inconsistent. In three of the five comparisons RRR was perceived to be larger. Two found little or no difference. The overall estimate was also imprecise with the lower confidence limit bordering on no difference.

⁴ The results were inconsistent. However, the l₂ test is very powerful for SMD. In addition, the robustness of the results with the various analytic methods (fixed or random effects model; risk ratios, risk differences or standardized effects) and the magnitude of the effect (average effect across the included studies was moderate or large) limit our concerns about heterogeneity.

(Relative risk reductions vs number needed to treat) (Effect size >1 supports RRR)

No. of studies	Study design	Sample size	Effect size (95% CI)	Quality
Understanding (measured as correct estimate or interpretation of risk reduction) – health consumers				
			SMD 0.73	
1 (Sheridan 2003)	RCT	182	(0.43 - 1.04)	Moderate ^{1,2}
Perception (measure as rating on a scale of perceived effectiveness) – health professionals				
3	RCT	970	SMD 1.15 (0.8 to 1.5)	Moderate ^{2,3}
Persuasiveness (measured as a hypothetical decision or intention or willingness to adopt an intervention			·	
22	RCT	9582	SMD 0.65 (0.51 to 0.8)	Moderate ^{2,3}

- 1. Only one comparison evaluated this outcome.
- 2. Outcome is a surrogate for health behaviour
- 3. The results were inconsistent. However, the I2 test is very powerful for SMD. In addition, the robustness of the results with the various analytic methods (fixed or random effects model; risk ratios, risk differences or standardized effects) and the magnitude of the effect (average effect across the included studies was moderate or large) limit our concerns about heterogeneity.

(Absolute risk reductions vs number needed to treat) (Effect size >1 supports ARR)

No. of studies	Study design	Sample size	Effect size (95% CI)	Quality
Understanding (measured as correct estimate or interpretation of risk reduction)				
1 (Sheridan 2003)	RCT	182	SMD 0.42 (0.12 to 0.71)	Moderate ^{1,2}
Perception (measure as rating on a scale of perceived effectiveness)				

3	RCT	949	SMD 0.79 (0.43 to 1.15)	Moderate ^{2,3}
Persuasiveness (measured as a hypothetical decision or intention or willingness to adopt an intervention				
20	RCT	9024	SMD 0.05 (-0.04 to 0.15)	Moderate ^{2,4}

- 1. Only one comparison evaluated this outcome.
- 2. Outcome is a surrogate for health behaviour
- 3. The results were inconsistent. However, the I2 test is very powerful for SMD. In addition, the robustness of the results with the various analytic methods (fixed or random effects model; risk ratios, risk differences or standardized effects) and the magnitude of the effect (average effect across the included studies was large) limit our concerns about heterogeneity.
- 4. The results were inconsistent. We did not however downgrade for inconsistency because the SMD is in the borders of no to small effects in either direction.

Novel analysis or analysis adapted to NICE methodology

Verbal risk information vs Numerical risk information (Buchter 2014) (Effect size >1 supports Verbal risk information)

No. of studies	Stud y desi gn	Sam ple size	MIDs	Effect size (95% CI)	Conver ted MD	Absol ute risk: contro	Absolute risk: intervent ion (95% CI)	Risk of bias	Indirectn ess	Inconsiste ncy	Imprecis ion	Qualit y
Perceived likelihood of AE												
occurrence												
6	RCT	892	+/- 0.60	MD 1.07 (0.90, 1.25)	-	-	-	Very serious1	Not serious	Very serious2	Not serious	Very low
1. >33.3% of the weight in a m	eta-ana	lysis cam	ne from s	tudies at hi	gh risk of b	oias						
2. 12 > 66.7%												

Risk tools vs other risk tools (Walker 2015) (Effect size >1 supports risk tools)

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)		Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Patient knowledge										
1 (Schroy 2011)	RCT	435	+/- 1.25	MD 0.20		Very serious1	Not serious	NA2	Not serious	Low

				(-0.28, 0.68)						
Patient satisfaction										
				MD 0.20						
1 (Schroy 2011)	RCT	435	+/- 3.10	(-0.97, 1.37)		Very serious1	Not serious	NA2	Not serious	Low
1. >33.3% of the weig	ht in a m	eta-analysi	s came fro	m studies at high ris	sk of bias					
2. Only one study so	no incons	istency								

Intervention vs Control

Pre-existing systematic review analysis

(personalised risk communication versus general risk information)

No. of studies	Study design	Sample size	Effect size (95% CI)	Quality
Informed decision (Numerical risk and categorised risk combined) Multi-dimensional measure of informed choice				
3	RCT	2444	OR 3.65 (2.13, 6.23)	High
Knowledge regarding screening test/condition concerned – calculated risk score (categorised) versus general information Various continuous scales				
1 (Glazebrook 2006)	RCT	588	SMD 0.40 (0.23 to 0.56)	Moderate ^{1,14}
Knowledge regarding screening test/condition concerned – calculated risk score (categorised) versus general information Various continuous scales				
1 (Skinner 2002)	RCT	260	SMD 0.57 (0.32 to 0.82)	Low ^{2,11,14}
Knowledge regarding screening test/condition concerned – personal risk factor list versus general information				

Various continuous scales				
2	RCT	838	SMD 0.89 (0.75 to 1.04)	High ^{3,14}
Knowledge regarding screening test/condition concerned – calculated risk score (numerical) versus general Information proportion with good knowledge				
3	RCT	1413	OR 2.60 (1.27 to 5.34)	High ^{4,6,13,14}
Knowledge regarding screening test / condition concerned – personal risk factor list versus general information (proportion with good knowledge) Information proportion with good knowledge				Ü
2	RCT	2107	OR 7.13 (5.79 to 8.79)	High ^{6,12,14}
Accurately perceived risk Proportion of participants who perceived risk accurately				
3	RCT	1264	OR 1.65 (0.96 to 2.81)	Low ^{7,8,13,14}
Anxiety – all groups various continuous scales				
6	RCT		SMD -0.13 (-0.29 to 0.03)	Very Low ^{5,8,9,14}

- 1. This study was high risk for reporting bias. Four risk of bias items were low risk and four were unclear risk. Quality downgraded by a point.
- 2. Seven out of nine risk of bias items were unclear. Quality downgraded by a point.
- 3. One out of two studies included in this analysis was of very good quality. The other study had mostly unclear risk of bias. Overall we have not downgraded the quality for this analysis.
- 4. Two out of three studies had more than four risk of bias items assessed as low risk. The other study had most unclear risk of bias items. Overall quality was not downgraded.
- 5. Substantial/ significant heterogeneity of results exists and all studies did not show similar direction of effect. Quality downgraded by a point.
- 6. Consistently large effects favouring personalised risk communication and hence upgraded the quality by one point.
- 7. Most risk of bias items were unclear with some high-risk items. Quality downgraded by one point.
- 8. Pooled estimate includes no effect and hence downgraded by one point.

- 9. Two out of six studies had more than four risk of bias items assessed as low risk. The remaining studies had most risk of bias items assessed as unclear. Quality downgraded by one point.
- 10. Control risk was used as baseline risk due to lack of studies that measure this in detail to be presented as baseline risk for the population.
- 11. Sample size less than the Optimal Information size (OIS). Quality downgraded by one point.
- 12. Both studies were of low risk of bias and hence not downgraded.
- 13. Significant heterogeneity among studies but all studies have same direction of effect and hence quality not downgraded.
- 14. Not downgraded for indirectness of evidence.

Novel analysis or analysis adapted to NICE methodology

Personalised cancer risk vs control (Bayne 2020)

No. of studies	Study design	Sam ple size	MIDs	Effect size (95% CI)	Conve rted MD	Absolut e risk: control	Absolut e risk: interven tion (95% CI)	Risk of bias	Indirect ness	Inconsist ency	Impreci sion	Quali ty
Absolute risk accuracy (Bayne 2020)												
·	2x2 and	841	0.80, 1.25	RR 4.57 (1.16, 18.06)	_	12.9 per 100	58.9 per 100 (14.9, 232.9)	Very serious ¹	Not serious	Very serious ²	Serious ³	Very low
Comparative risk accuracy (Bayne 2020)												
	2x2 and 2 RCT	627	0.80, 1.25	RR 1.40 (0.71, 2.73)	-	36.1 per 100	50.4 per 100 (25.7, 98.7)	Very serious ¹	Not serious	Very serious ²	Very serious ⁴	Very low

- 1. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
- 2. 12 > 66.7%
- 3. 95% confidence intervals cross one end of the defined MIDs
- 4. 95% confidence intervals cross both ends of the defined MIDs

Educational intervention (general) vs control (Dieng)

No. of studies	Study desig n	Sampl e size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectne ss	Inconsisten cy	Imprecisio n	Quality
Risk perception											

5	RCT	1590	+/- 0.50	SMD -0.12 (-0.39, 0.16)	-	-	Very serious ¹	Not serious	Very serious ²	Not serious	Very low
Risk accuracy											
3	-		0.80, 1.25	RR 1.28 (0.92, 1.80)	16.9 per 100	21.7 per 100 (15.4, 30.4)	Very serious ¹	Not serious	Not serious	Serious ³	Very low

^{1. &}gt;33.3% of the weight in a meta-analysis came from studies at high risk of bias

Tailored risk information vs control (Harris 2020)

No. of studies	Stud y desi gn	Samp le size	MIDs	Effect size (95% CI)	Convert ed MD	Absolu te risk: control	Absolute risk: interventi on (95% CI)	Risk of bias	Indirectn ess	Inconsiste ncy	Imprecisi on	Quali ty
Risk perception (susceptibility)												
			+/-	MD 8.04 (5.58,				Very	Not		Not	
1 (Shahab 2007)	RCT	23	1.50	10.50)	-	-	-	serious ¹	serious	NA^2	serious	Low
1. >33.3% of the weight in	a meta	-analysis	came fro	m studies at	high risk of	f bias						

Risk tool vs control (Walker 2015)

No. of studies	Stu dy desi gn	Sam ple size	MID s	Effect size (95% CI)	Risk of bias	Indirect ness	Inconsiste ncy	Impreci sion	Quali ty
Risk perception									

^{2. 12 &}gt; 66.7%

^{3. 95%} confidence intervals cross one end of the defined MIDs

^{2.} Only one study so no inconsistency

1 (Holloway 2003)	RCT	1890	NA	OR 1.07 (0.85, 1.35)	Not serious	Not serious	NA^2	NA*	NA*
Patient knowledge understanding of population cancer risk, causes of cancer, and screening guidelines.									
2	RCT	942	+/- 0.50	SMD 0.79 (0.46, 1.12)	Very serious ¹	Not serious	Very serious ³	Serious ⁴	Very low
Patient satisfaction Patient satisfaction with making screening decisions compared with the control				·					
1 (Schroy 2011)	RCT	905	+/- 3.95	MD 3.90 (2.97, 4.82)	Very serious ¹	Not serious	NA ²	Serious ⁴	Very low
Anxiety/worry (Cancer)									
4 (0 1 2044)	DCT	45	+/-	MD 0.11 (-1.05,	Not		N.A.?	Very	
1 (Schroy 2011)	RCT	45	0.99	1.27)	serious	Not serious	NA ²	serious ⁵	Low

^{*}Imprecision/Quality not calculable with data provided

^{1. &}gt;33.3% of the weight in a meta-analysis came from studies at high risk of bias

^{2.} Only one study so no inconsistency

^{3. 12 &}gt; 66.7%

^{4. 95%} confidence intervals cross one end of the defined MIDs

^{5. 95%} confidence intervals cross both ends of the defined MIDs

Appendix H – Excluded studies

Study	Code [Reason]
Albada A, Ausems MG, Bensing JM, van Dulmen S (2009) Tailored information about cancer risk and screening: a systematic review. Patient Education and Counseling 77(2): 155-171	- No extractable data Outcome data for Relevant outcomes is not presented in a way that can be analysed (missing arm data, missing variance)
Albarqouni, Loai; Doust, Jenny; Glasziou, Paul (2017) Patient preferences for cardiovascular preventive medication: a systematic review. Heart (British Cardiac Society) 103(20): 1578-1586	- No relevant outcomes Decision regarding medication only no risk perception
Atkinson, Thomas M, Salz, Talya, Touza, Kaitlin K et al. (2015) Does colorectal cancer risk perception predict screening behavior? A systematic review and meta-analysis. Journal of behavioral medicine 38(6): 837-50	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Exclude: Looking at effect sizes not presentation of information,
Best, Ryan and Charness, Neil (2015) Age differences in the effect of framing on risky choice: A meta-analysis. Psychology and aging 30(3): 688-98	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Related to age not risk framing interventions and not healthcare setting.
Bould, Kathryn, Daly, Blanaid, Dunne, Stephen et al. (2016) A Systematic Review of the Effect of Individualized Risk Communication Strategies on Screening Uptake and Its Psychological Predictors: The Role of Psychology Theory. Health psychology research 4(2): 6157	- Qualitative SLR
de Mik, Sylvana M L, Indrakusuma, Reza, Legemate, Dink A et al. (2019) Reporting of Complications and Mortality in Relation to Risk Communication in Patients with an Abdominal Aortic Aneurysm: A Systematic Review. European journal of vascular and endovascular surgery: the official journal of the European Society for Vascular Surgery 57(6): 796-807	- Qualitative SLR
Edwards, Adrian G K, Naik, Gurudutt, Ahmed, Harry et al. (2013) Personalised risk communication for informed decision making	- Duplicate reference

Study	Code [Reason]
about taking screening tests. The Cochrane database of systematic reviews: cd001865	
French, David P, Cameron, Elaine, Benton, Jack S et al. (2017) Can Communicating Personalised Disease Risk Promote Healthy Behaviour Change? A Systematic Review of Systematic Reviews. Annals of behavioral medicine: a publication of the Society of Behavioral Medicine 51(5): 718-729	- No relevant outcomes Studies in review of reviews no relevant outcomes. more disease based than risk outcomes.
Garcia-Retamero, Rocio and Cokely, Edward T (2017) Designing Visual Aids That Promote Risk Literacy: A Systematic Review of Health Research and Evidence-Based Design Heuristics. Human factors 59(4): 582-627	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options SLR about skills in the use of visual aids as opposed to the aids themselves
Harris, R.; Noble, C.; Lowers, V. (2017) Does information form matter when giving tailored risk information to patients in clinical settings? A review of patients' preferences and responses. Patient Preference and Adherence 11: 389-400	- Duplicate reference All data is present in Harris 2020 with one extra study
Pedrini, L., Prefumo, F., Frusca, T. et al. (2017) Counselling about the Risk of Preterm Delivery: A Systematic Review. BioMed Research International 2017: 7320583	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Talking about a general counselling intervention, not a risk communication method. Not looking at ways to communicate risk.
Portnoy, David B, Ferrer, Rebecca A, Bergman, Hannah E et al. (2014) Changing deliberative and affective responses to health risk: a meta-analysis. Health psychology review 8(3): 296-318	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Looking at responses to presenting information as opposed to the interventions themselves.
Reen, Gurpreet K; Silber, Eli; Langdon, Dawn W (2017) Multiple sclerosis patients' understanding and preferences for risks and benefits of disease-modifying drugs: A systematic review. Journal of the neurological sciences 375: 107-122	- not an SLR of primary controlled studies Most data derived from surveys and questionnaires
Roelsgaard, IK, Esbensen, BA, Østergaard, M et al. (2019) Smoking cessation intervention for reducing disease activity in chronic autoimmune	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options

Study	Code [Reason]
inflammatory joint diseases. Cochrane Database of Systematic Reviews	All smoking cessation interventions not only risk communication
Saleem, Mohammed D; Kesty, Chelsea; Feldman, Steven R (2017) Relative versus absolute risk of comorbidities in patients with psoriasis. Journal of the American Academy of Dermatology 76(3): 531-537	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Not a risk communication intervention
Trifiletti, Daniel M, Sturz, Vanessa N, Showalter, Timothy N et al. (2017) Towards decision-making using individualized risk estimates for personalized medicine: A systematic review of genomic classifiers of solid tumors. PloS one 12(5): e0176388	- Study does not contain a method of presenting information intended to improve patients understanding of risks and benefits of their treatment options Study of clinical utility not study of use in risk communication.
Usher-Smith, Juliet A, Silarova, Barbora, Schuit, Ewoud et al. (2015) Impact of provision of cardiovascular disease risk estimates to healthcare professionals and patients: a systematic review. BMJ open 5(10): e008717	- not an SLR of primary controlled studies Only key outcome data is from before-after studies
Usher-Smith, Juliet A, Silarova, Barbora, Sharp, Stephen J et al. (2018) Effect of interventions incorporating personalised cancer risk information on intentions and behaviour: a systematic review and meta-analysis of randomised controlled trials. BMJ open 8(1): e017717	- No relevant outcomes Only outcome is decision in screening.
Zipkin, Daniella A, Umscheid, Craig A, Keating, Nancy L et al. (2014) Evidence-based risk communication: a systematic review. Annals of internal medicine 161(4): 270-80	- Data not reported in an extractable format No clear indication of arm levels or arm level variance of data and poor reporting.

Appendix I - References to included studies

A.1.1 Systematic reviews

Akl Elie A, Oxman Andrew D, Herrin Jeph, Vist Gunn E, Terrenato Irene, Sperati Francesca, Costiniuk Cecilia, Blank Diana, Schünemann Holger (2011) Using alternative statistical formats for presenting risks and risk reductions. Cochrane Database of Systematic Reviews: Reviews issue3

Bayne, M., Fairey, M., Silarova, B. et al. (2020) Effect of interventions including provision of personalised cancer risk information on accuracy of risk perception and psychological responses: A systematic review and meta-analysis. Patient Education and Counseling 103(1): 83-95

Buchter, Roland Brian, Fechtelpeter, Dennis, Knelangen, Marco et al. (2014) Words or numbers? Communicating risk of adverse effects in written consumer health information: a systematic review and meta-analysis. BMC medical informatics and decision making 14: 76

Dieng, Mbathio, Watts, Caroline G, Kasparian, Nadine A et al. (2014) Improving subjective perception of personal cancer risk: systematic review and meta-analysis of educational interventions for people with cancer or at high risk of cancer. Psycho-oncology 23(6): 613-25

Edwards Adrian GK, Naik Gurudutt, Ahmed Harry, Elwyn Glyn J, Pickles Timothy, Hood Kerry, Playle Rebecca (2013) Personalised risk communication for informed decision making about taking screening tests. Cochrane Database of Systematic Reviews: Reviews issue2

Harris, Rebecca, Vernazza, Christopher, Laverty, Louise et al. (2020) No title provided.

Stellamanns, Jan, Ruetters, Dana, Dahal, Keshav et al. (2017) Visualizing risks in cancer communication: A systematic review of computer-supported visual aids. Patient education and counseling 100(8): 1421-1431

Walker, J G, Licqurish, S, Chiang, P P C et al. (2015) Cancer risk assessment tools in primary care: a systematic review of randomized controlled trials. Annals of family medicine 13(5): 480-9

Individual studies within reviews

Akl 2011

Adily 2004 *{published data only}* Adily A, Ward J. Evidence based practice in population health: a regional survey to inform workforce development of organisational change. *Journal of Epidemiology and Community Health* 2004;**58**:455–60.

Bobbio 1994 *{published data only}* Bobbio M, Demichelis B, Giustetto G. Completeness of reporting trial results: effect on physicians' willingness to prescribe. *Lancet* 1994;**343**(8907):1209–11.

Bramwell 2006a *{published data only}* Bramwell R, West H, Salmon P. Health professionals' and service users' interpretation of screening test results: experimental study. *BMJ* 2006;**333**:284.

Bramwell 2006b *{published data only}* Bramwell R, West H, Salmon P. Health professionals' and service users' interpretation of screening test results: experimental study. *BMJ* 2006;333:284.

Bramwell 2006c *{published data only}* Bramwell R, West H, Salmon P. Health professionals' and service users' interpretation of screening test results: experimental study. *BMJ* 2006;**333**:284.

Bramwell 2006d *{published data only}* Bramwell R, West H, Salmon P. Health professionals' and service users' interpretation of screening test results: experimental study. *BMJ* 2006;**333**:284.

Brotons 2002 *{published data only}* Brotons C, Moral I, Ribera A, Cascant P, Iglesias M, Permanyer-Miralda G, et al.Methods of reporting research-results and their influence on decision-making by cardiologists prescribing drugs for primary and secondary prevention. *Revista Española de Cardiología* 2002;**55**(10): 1042–51.

Bucher 1994 *{published data only}* Bucher HC, Weinbacher M, Gyr K. Influence of method of reporting study results on decision of physicians to prescribe drugs to lower cholesterol concentration. *BMJ* 1994;**309** (6957):761–4.

Carling 2008 {published data only} Carling C, Tove Kristoffersen D, Herrin J, Treweek S, Oxman AD, Schünemann HJ, et al. How should the impact of different presentations of treatment effects on patient choice be evaluated? A pilot randomized trial. *PLoS ONE* 2008;3(11):e3693.

Carling 2009 {published data only} Carling CLL, Kristoffersen DT, Montori VM, Herrin J, Schünemann HJ, Treweek S, et al. The effect of alternative summary statistics for communicating risk reduction on decisions about taking statins: a randomized trial. *PLoS Medicine* 2009;6(8):e1000134.

Chao 2003 *{published data only}* Chao C, Studts JL, Abell T, Hadley T, Roetzer L, Dineen S. Adjuvant chemotherapy for breast cancer: How presentation of recurrence risk influences decision-making. *Journal of Clinical Oncology* 2003;**21**:4299–305.

Cranney 1996 *{published data only}* Cranney M, Walley T. Same information, different decisions: the influence of evidence on the management of hypertension in the elderly. *British Journal of General Practice* 1996;**46**(412):661–3.

Damur 2000 {published data only} Damur JS. Do doctors judge therapy results differently from students? [Beurteilen Arzte Therapieergebnisse anders als Studenten?]. *Schweizerische Medizinische Wochenschrift* 2000;**1**(30):171–6.

Davey 2005 *{published data only}* Davey C, White V, Gattellari M, Ward JE. Reconciling population benefits and women's individual autonomy in mammographic screening: in-depth interviews to explore women's views about 'informed choice'. *Australian and New Zealand Journal of Public Health* 2005;**29**:69–77.

Fahey 1995 *{published data only}* Fahey T, Griffiths S, Peters TJ. Evidence based purchasing: Understanding results of clinical trials and systematic reviews. *BMJ* 1995;**311**(7012):1056.

Forrow 1992a *{published data only}* Forrow L, Taylor WC, Arnold RM. Absolutely relative: how research results are summarized can affect treatment decisions. *American Journal of Medicine* 1992;**92**(2):121–4.

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Loewen 1999 *{published data only}* Loewen PS, Marra CA, Marrra F. Influence of presentation of clinical trial data on pharmacists willingness to recommend drug therapy. *Canadian Journal of Hospital Pharmacy* 1999;**52**:145–9.

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Misselbrook 2001 *{published data only}* Misselbrook D, Armstrong D. Patients' responses to risk information about the benefits of treating hypertension. *British Journal of General Practice* 2001;**51**:276–9.

Natter 2005a *{published data only}* Natter HM, Berry DC. Effects of presenting the baseline risk when communicating absolute and relative risk reductions. *Psychology, Health & Medicine* 2005;**10**(4): 326–34.

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Nexoe 2002a *{published data only}* Nexoe J, Gyrd-Hansen D, Kragstrup J, Kristiansen IS, Nielsen JB. Danish GPs' perception of disease risk and benefit of prevention. *Family Practice* 2002;**19**(1):3–6.

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