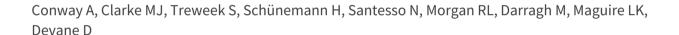


Cochrane Database of Systematic Reviews

Summary of findings tables for communicating key findings of systematic reviews (Protocol)



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[Methodology Protocol]

Summary of findings tables for communicating key findings of systematic reviews

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ABSTRACT

This is a protocol for a Cochrane Review (Methodology). The objectives are as follows:

To assess the effects of 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions.

This will be achieved by:

- assessing the effects of 'Summary of findings' tables versus full versions of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
 - assessing the effects of 'Summary of findings' tables plus full review versus full review (no 'Summary of findings' tables);
- assessing the effects of 'Summary of findings' tables versus other summaries of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing the effects of interactive 'Summary of findings' tables versus static 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing the effects of 'Summary of findings' tables versus other formats of 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing how particular participant groups e.g. patients, healthcare providers, policy makers, understand and apply the information from the 'Summary of findings' tables.

BACKGROUND

Description of the problem or issue

Systematic reviews of randomised trials of the effects of healthcare interventions are important sources of evidence to inform healthcare decisions (Manheimer 2012). Grimshaw 2012 suggests that systematic reviews and other research syntheses should be the basic unit of knowledge translation. Elsewhere, they have been described as one of the most important tools for getting evidence into practice (Carrasco-Labra 2015). Well-conducted systematic reviews contain the depth of information and optimal methodology to best inform users for the decision-making process (Ganann 2010). The number of available systematic reviews is growing rapidly (Bastian 2010). By October 2016, there were 7066 full Cochrane reviews published in the Cochrane Database of Systematic Reviews (Cochrane 2016). Moher 2007 found superior reporting standards in Cochrane reviews compared with non-Cochrane reviews and Lundh 2009 found that Cochrane reviews were of a higher methodological quality than non-Cochrane reviews. However, despite the quality of evidence offered by systematic reviews, uptake of the main findings can be slow or may not happen (Murthy 2012). Waddell 2001 explored dissemination and uptake problems associated with research evidence, one of which was the increasing volume of available evidence. The overload of information available in print and electronic formats can make it difficult to find answers to healthcare questions about the effectiveness of healthcare interventions. Bastian 2010 counted the publication of 75 trials and 11 systematic reviews of trials daily and highlighted that this number is growing. In a more recent cross-sectional study, Page 2016 counted 682 systematic reviews indexed in MEDLINE in February 2014. This is equivalent to more than 8000 each year, or 22 per day. The authors calculated that this represents a threefold increase on 2004 figures.

In a systematic review, Wallace 2012 explored barriers to the use of systematic reviews including; time required to read, the complex nature of their methods and statistics, and lack of user access, perceived usefulness, awareness and training. They identified 28 barriers to the use of research evidence from systematic reviews by decision makers. They divided these barriers into three broad categories: knowledge, attitudinal and behavioural. These factors can have a negative impact on the ability and willingness of potential review users to engage with full versions of systematic reviews. Previous studies exploring information seeking behaviour of physicians revealed the lack of use of current evidence from electronic sources (Dawes 2003; Coumou 2006; Hider 2009). In the systematic review by Dawes 2003, of the 19 included studies, the primary information source for physicians was text sources (textbooks, papers or desk reference) in 13 studies, consultations with colleagues in four studies and electronic sources in one study. It has been recommended that three interventions will improve uptake of systematic reviews: targeted messaging, educational visits and systematic review summaries.

In this review, we will focus on systematic review summaries (Wallace 2014). There are several types of summaries of systematic reviews including plain language summaries (clear, concise and jargon-free summaries of the key question and findings of a systematic review (Chandler 2013), GRADE evidence profiles (similar to 'Summary of findings' tables but also featuring a rationale for the quality of evidence rating (Guyatt 2011)), and 'Summary of findings' tables (Guyatt 2008; Manheimer 2012; Carrasco-Labra 2015). 'Summary of findings' tables are a widely-recognised summarisation method. According to the updated Methodological Expectations of Cochrane Intervention Reviews standards, they are recommended as "highly desirable" for inclusion in new Cochrane reviews and in the protocol it is mandatory for authors to put a plan in place for their inclusion (Higgins 2016). Chapter 11 of the Cochrane Handbook for Systematic Reviews of Interventions details how to produce and present 'Summary of findings' tables. They are also increasingly featured in non-Cochrane systematic reviews (Langendam 2013). One mixed-methods study, incorporating a randomised trial and follow-up participant interviews, compared providing participants with systematic reviews with and without a 'Summary of findings' table, and 'graded-entry' formats (a 'frontend' summary and a contextually framed narrative report plus the review). There were no differences between groups for the primary outcome of correct responses to a test of key clinical questions on specific topics (adjusted odds ratios (ORs): systematic review with 'Summary of findings' table versus systematic review alone 0.59, 95% confidence interval (CI) 0.32 to 1.07; 'graded-entry format versus systematic review alone 0.66, 95% CI 0.36 to 1.21). However, graded-entry formats received a higher composite score than systematic reviews alone for their clarity and ease of use (adjusted mean difference (MD) 0.52, 95% CI 0.06 to 0.99). Findings were conflicting with some users finding 'Summary of findings' tables useful for "rapid consultation", while others reported that they were difficult to understand without supplementary information (Opiyo 2013).

Description of the methods being investigated

'Summary of findings' tables are designed to present key findings of systematic reviews in a clear and concise format. The main elements of a 'Summary of findings' table are:

- a description of patient/population/problem, intervention and comparator(s) and all desirable and undesirable outcomes (PICO);
 - a description of the study setting;
 - the number of participants;
 - the number of studies addressing each outcome;

- a measure of the assumed risk in the control group and the corresponding risk in the intervention group;
 - the relative effect (risk ratio) or other measures of effect;
- the mean difference or standardised mean difference and confidence interval;
- the certainty of the evidence according to the GRADE classification terms listed in the section 'Summarising and interpreting results';
 - a comments section.

In this Cochrane review, we will include studies assessing the effects of interactive or static 'Summary of findings' tables as an intervention to communicate key findings of systematic reviews of the effects of healthcare interventions. The interactive format has additional functionality compared to the traditional static version by providing users with an option to view varying depths of information and complexity (DECIDE 2014). We will also include narrative 'Summary of findings' tables where results have not been pooled in a meta-analysis or when units of analysis cannot be compared. These are 'Summary of findings' tables where authors enter a narrative description of the effect of the outcome. The 'Summary of findings' table is evolving in accordance with feedback from users. The GRADEpro Guideline Development Tool (now also called GRADEpro GDT app) is an online software which enables authors of reviews and guideline developers to create their own 'Summary of findings' tables (Treweek 2013). 'Summary of findings' tables can also be created on the Epistemonikos website. More recently, summary of qualitative findings tables have been introduced to summarise the key findings from qualitative evidence syntheses. These involve using the GRADE-CERQual approach to assess the confidence in the evidence for each finding (Lewin 2015).

How these methods might work

The 'Summary of findings' table may have an impact by communicating key findings of systematic reviews of healthcare interventions to patients, healthcare staff, policy makers and other stakeholders by providing a summary with clear information presented in a user-friendly format (Glenton 2006). A recent study found that it is possible for users to understand key findings of Cochrane systematic reviews using summary formats (Maguire 2014). Rosenbaum 2010 conducted a study to design a 'Summary of findings' table for Cochrane reviews that would be useful to stakeholders. They used an iterative process of brainstorming workshops, advisory group feedback and user testing to develop a 'Summary of findings' table. Participants included attendees of a workshop for beginners to evidence-based practice in Norway and, clinicians and research-related professionals from the UK. Most of the changes to the table addressed the issues of usability and usefulness. The aim is to resolve "the tension between achieving table precision and table simplicity" (Rosenbaum 2010).

In an unpublished study reported by Langendam 2013, researchers found that the layout of a 'Summary of findings' table for a Cochrane systematic review was clear, helpful for presenting results and increased accessibility of the systematic review. However, these findings related to a very specific participant group made up of members of Cochrane review groups and cannot be assumed to be widely transferable.

Why it is important to do this review

'Summary of findings' tables offer users a reduced volume of information when compared to full systematic reviews based on the same high-quality methodology of the systematic review to support the content. Lavis 2009 highlighted the need for summaries of systematic reviews featuring decision-relevant information. This review will provide a single source of evidence for effectiveness of 'Summary of findings' tables when compared to full versions or summaries of systematic reviews.

The potential beneficiaries of this review are systematic review authors because it may provide them with evidence to support the inclusion or exclusion of 'Summary of findings' tables in their reviews. If 'Summary of findings' tables support communication, then this review will also benefit potential users of systematic reviews such as clinicians, guideline developers, healthcare users, policy makers and other stakeholders e.g. charitable organisations, the patient population, the public and individuals or groups who inform them, by providing evidence in a form which allows them to quickly access and understand key findings of future reviews. It may also support these users in making decisions about whether to create 'Summary of findings' tables to disseminate review findings (and potentially other research findings) within their own organisations.

The inclusion of 'Summary of findings' tables in systematic reviews is recommended in publications such as the Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2011) and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group guidelines (Guyatt 2011; Guyatt 2013a; Guyatt 2013b). This review is timely and important because 'Summary of findings' tables are commonly used to disseminate the key findings of Cochrane systematic reviews yet there is no systematic review to synthesise the evidence of their effectiveness at communicating review results. Although this systematic review asks a focused question about the effectiveness of 'Summary of findings' tables, it relates to larger problems of healthcare information overload, training requirements for stakeholders in (1) the interpretation and use of statistics and (2) critical appraisal, and (3) the lack of time healthcare professionals have to spend reviewing evidence during decision-making and daily patient management.

OBJECTIVES

To assess the effects of 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions.

This will be achieved by:

- assessing the effects of 'Summary of findings' tables versus full versions of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing the effects of 'Summary of findings' tables plus full review versus full review (no 'Summary of findings' tables);
- assessing the effects of 'Summary of findings' tables versus other summaries of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing the effects of interactive 'Summary of findings' tables versus static 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions;
- assessing the effects of 'Summary of findings' tables versus other formats of 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions:
- assessing how particular participant groups e.g. patients, healthcare providers, policy makers, understand and apply the information from the 'Summary of findings' tables.

METHODS

Criteria for considering studies for this review

Types of studies

We will consider three types of study design where effects of exposure to 'Summary of findings' tables of systematic reviews of the effects of healthcare interventions on one or more outcome is measured:

- randomised trials;
- non-randomised trials;
- cross-over trials.

We will follow the Cochrane Effective Practice and Organisation of Care (EPOC) Group definitions of these experimental study types (EPOC 2013a). We will include both published and unpublished studies. We anticipate few randomised trials on this topic because 'Summary of findings' tables are a relatively new intervention. Therefore, we have broadened our inclusion criteria to

include the above-mentioned study types to help us determine the potential of 'Summary of findings' tables to communicate key findings of systematic reviews.

Types of data

We will include data from published, unpublished and grey literature comparing standard/static or interactive 'Summary of findings' (i'Summary of findings') tables or both, as described by GRADE (Guyatt 2011; Guyatt 2013a; Guyatt 2013b; Agoritsas 2015) with other types of summaries of systematic reviews.

We will include studies that recruit any participant type that uses 'Summary of findings' tables of systematic reviews including: patients, families/carers, healthcare professionals, policy makers, health systems managers, systematic review authors or other stakeholders.

Types of methods

We will include studies that compare:

- the effects of 'Summary of findings' tables versus full versions of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
- the effects of 'Summary of findings' tables plus full review versus full review (no 'Summary of findings' tables);
- the effects of 'Summary of findings' tables versus other summaries of systematic reviews on communicating key findings of systematic reviews of the effects of healthcare interventions;
- the effects of interactive 'Summary of findings' tables versus static 'Summary of findings' tables on communicating key findings of systematic reviews of the effects of healthcare interventions.

Types of outcome measures

Primary outcomes

- User understanding of key findings of systematic reviews measured by the ability to correctly answer factual questions about the review
- Self-perceived understanding of key findings of systematic reviews as reported by the user
 - Self-reported influence on decision-making

Secondary outcomes

- Time taken to read summary and extract relevant information
 - Accessibility of the main findings of the review
 - User satisfaction/preferences/attitudes
- Other outcomes not reported in the protocol whose importance is realised after the protocol is written or when the

analysis is done. To address any concerns of bias, a justification of the outcome inclusion will be provided (Kirkham 2010).

Search methods for identification of studies

At least one article has reported that the first evaluation of 'Summary of findings' tables occurred in 2005 (Langendam 2013). Nevertheless, we do not know for certain that 'Summary of findings' tables were not mentioned in the literature prior to 2005. Therefore, we will not apply date restrictions on this search. We will not use language restrictions. A search strategy for PubMed is detailed in Appendix 1.

Electronic searches

We will run electronic or manual searches of the following online resources:

- Electronic databases: the Cochrane Library, the Campbell Collaboration, PubMed, CINAHL, LILACS, Web of Science, SCOPUS, Embase, PsycINFO, Epistemonikos.
- International trials registers such as the Cochrane Central Register of Controlled Trials (CENTRAL), PROSPERO, ClinicalTrials.gov, WHO International Clinical Trials Registry Platform (ICTRP) portal.
- Grey literature sources such as reports/dissertations/theses databases and databases of conference abstracts e.g. Cochrane Colloquium abstracts, ETHOS, OpenGrey, ISI Web of Knowledge and websites of key organisations e.g. GRADE, Epistemonikos.

Searching other resources

Reference lists

We will search reference lists of included studies and similar systematic reviews to find additional relevant resources.

Correspondence

If deemed appropriate, we will contact individuals or groups known to have experience or knowledge of 'Summary of findings' tables e.g. researchers, review authors, members of the Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE) collaboration, GRADE Working Group, and the Cochrane Applicability and Recommendations Methods Group to identify and locate additional resources or studies which have not yet been published or are not readily accessible.

Data collection and analysis

The following methods are based on recommendations described in the Cochrane Handbook for Systematic Reviews of Interventions

(Higgins 2011) and the Methodological Expectations for the Conduct of Cochrane Intervention Reviews (Higgins 2016). Randomised trials will be analysed separately from the other types of study design.

Selection of studies

Two review authors (Aislinn Conway (AC)) and (Declan Devane (DD)) will independently screen titles and abstracts of all citations identified by searches against inclusion criteria based on types of studies, types of interventions and participants. The citations will be sorted into the following groups; 'include', 'full-text review' and 'exclude'. Both authors will review full versions of papers where it is unclear whether prespecified eligibility criteria have been met. If, after discussion, there is still disagreement regarding study selection, a third review author (Mike Clarke (MC)) will be provided with a full-text copy of the article for comment and judgement as to whether to include. Reference management software will be used to import all references from databases and other print and electronic sources into a single place accessible to authors.

Data extraction and management

Two review authors (AC and DD) will independently complete tailored data extraction forms for each of the studies. We will discuss discrepancies and if resolution is not reached, we will consult a third author.

Items extracted will include the following.

- Authors
- Year of Publication
- Language
- Setting
- Country
- Study design
- Participants:
 - o Professional or non-professional group e.g. patients
 - Level of experience using 'Summary of findings' tables
- Intervention:
- Characteristics of intervention e.g. format, timing, ting
- Comparison:
 - o Details of comparison intervention
- Outcomes:
- User understanding of key findings of systematic reviews measured by the ability to correctly answer factual questions about the review
- Self-perceived understanding of key findings of systematic reviews as reported by the user
 - o Self-reported influence on decision-making
- o Time taken to read summary and extract relevant information
 - Accessibility of the main findings of the review

- User satisfaction/preferences/attitudes
- o Length of time during which outcomes were measured after initiation of the intervention
- Whether follow-up occurred, if so, length of follow-up and follow-up points
- Data to assess the risk of bias of included studies e.g. sequence generation, allocation concealment, blinding of study participants and personnel, blinding of outcome assessors, withdrawals or incomplete outcome data, selective reporting or other sources of bias
 - Funding sources

Assessment of risk of bias in included studies

Two review authors (AC and DD) will assess the risk of bias for each study independently. We will use the criteria described in the Cochrane 'Risk of bias' criteria (Higgins 2011) and in section 6.4 of the Data Collection Checklist (EPOC 2010) for randomised trials and the Cochrane EPOC Review Group guidance on risk of bias criteria (EPOC 2015) and the Cochrane EPOC Review Group guidance (EPOC 2013b) if our review includes more than one study design. Our inclusion of non-randomised studies brings a greater potential for bias (Higgins 2011). We will contact study authors when information is missing or if clarification is required. Two review authors will apply the 'Risk of bias' criteria to each study independently and differences will be resolved by consulting a third review author (ST).

The following criteria are recommended for randomised trials (RTs), non-randomised trials (NRTs) and cross-over studies.

Selection bias: Random sequence generation

The rules for allocating interventions to participants in the studies will be reported so that we can identify whether there is a risk that 'Summary of findings' tables groups and comparison groups may not have been comparable. We will base our judgements on the following criteria.

- For randomised trials:
- o if sequence generation is truly random (e.g. computer generated random assignment): low risk;
- if sequence generation is not specified and we are unable to obtain relevant information from study authors: unclear risk;
- $\,\circ\,$ if there is a quasi-random sequence generation e.g. alternation: high risk.
 - For non-randomised trials: high risk.

Selection bias: Allocation sequence concealment

Prior to the assignment of interventions to participants, steps should be taken to ensure that knowledge of the allocation sequence is not possible. Studies will be deemed at low risk if they used:

- opaque, sequentially numbered envelopes which were opened sequentially and not re-assigned;
 - central randomisation by a third party.

If the allocation concealment is not specified and we are unable to ascertain whether the allocation concealment was protected before and until assignment, the study will be considered as an unclear risk

Non-randomised trials and studies which have inadequacies in their allocation concealment, e.g. if non-opaque envelopes were used, will be considered at high risk.

Performance Bias: Blinding of participants and personnel

It will not be possible to blind participants or personnel to the intervention to which they have been assigned because of formatting differences between systematic reviews, 'Summary of findings' tables and other summaries. Therefore, risk of bias for performance bias will be judged as high risk. Under certain circumstances, it may be possible to blind for comparisons of different formats of 'Summary of findings' tables. For example if two static 'Summary of findings' tables are being compared. However, without a detailed description of this to allow assessment, risk of bias will be judged as high risk.

Detection Bias: Blinding of outcome assessors

We will judge the risk of detection bias for studies based on whether the assessors have knowledge of the intervention received by participants, using the following criteria:

- if subjective outcomes were not assessed blindly e.g. selfperceived understanding of key findings of systematic reviews (as reported by the user): high risk;
 - if outcomes were assessed blindly: low risk;
- if objectives outcomes were not assessed blindly e.g. openended questions in user understanding of key findings test: low risk;
- if we cannot ascertain whether assessors were blinded and study authors do not provide information to clarify: unclear risk.

Attrition Bias: Incomplete outcome data

We will explore whether withdrawals or incomplete outcome data due to exclusions or attrition may have occurred in randomised and non-randomised studies (including cross-over trials). We will also investigate the spread of missing data across groups. The risk of this bias will be judged using the following criteria:

- if 20% or more of the data are missing or if the missing data are not equally spread across groups: high risk;
- if less than 20% of the data are missing and are spread equally across groups: low risk;

• if the percentage of missing data or the spread of missing data are not clear: unclear risk.

Selective reporting bias

We will investigate whether all outcomes mentioned in methodology sections of randomised and non-randomised studies (including cross-over trials) are reported in results sections. We will assess this using the following criteria:

- if all outcomes in the methodology are not reported in the results or if outcomes reported in the results were not listed in the methodology: high risk;
- if outcomes specified in randomised trial protocols *a priori* are not reported in the results or if outcomes reported in the results are not listed in the protocol: high risk;
- if outcomes are only partly reported in the results or if an obvious outcome is not mentioned in the study: high risk;
- if all outcomes are both listed in the methodology and reported in the results: low risk.

Other potential sources of bias

We will assess the randomised and non-randomised studies for other potential biases (e.g. recruitment bias: imbalance in patient characteristics) using the following criteria:

- If there is one or more important risks of bias e.g. flawed study design: high risk;
 - If there is no evidence of other sources of bias: low risk;
- If there is incomplete information regarding a problem which may lead to bias: unclear risk.

We will further assess cross-over trials using the following criteria outlined in Section 16.4.3 of the *Cochrane Handbook for Systematic Reviews of Interventions*:

- suitability of the cross-over design;
- whether there is a carry-over effect;
- whether only first period data are available;
- whether the analysis is correct;
- comparability of results with those from parallel-group trials.

Measures of the effect of the methods

Dichotomous data (correct/incorrect answers on tests of understanding of key findings of systematic reviews) will be determined using a risk ratio (RR) with a 95% confidence interval (CI).

Ordinal scale data outcomes reported in this way will be collapsed into dichotomous outcomes.

Continuous data will be analysed using mean difference (MD) with the 95% CI if the measurement scale is the same. If the scale is different, standardised mean differences (SMD) with 95% CIs will be used.

Unit of analysis issues

Randomised trials will be analysed separately from the other types of study design.

Cluster-randomised trials included in the systematic review will be identified as such. We will report the baseline comparability of clusters and consider statistical adjustment if it may help to reduce an imbalance.

We will estimate the intracluster correlation coefficient (ICC) as described by Higgins 2011 using information from the study if it is available or, from an external estimate obtained from a similar study. If we do this, we will conduct sensitivity analyses to explain variation in ICC values.

Studies with multiple intervention groups we will include and analyse groups which are relevant to our review. However, all intervention groups will be clearly listed in the 'Characteristics of included studies' table. To avoid "double counting" data for studies that could contribute more than one control group, we will combine comparison groups to create a single pair-wise comparison (Higgins 2011).

Dealing with missing data

We will contact authors when a gap is identified in studies. If we decide that there may be reasons to impute missing data e.g. to explore the impact of missing data in the sensitivity analysis, we will discuss the potentials harms and benefits of this. If the missing data are substantial, analysis with imputed data may be futile.

We will narratively explore the potential impact of missing data in the discussion section of the review.

Assessment of heterogeneity

We have specified that we will include non-randomised trials in this review which may lead to increased statistical heterogeneity. We will assess heterogeneity by visually inspecting a forest plot of included studies. The location of point estimates, the degree to which confidence intervals overlap and the presence and results of meta-analysis will be taken into account. Next, we will test for the presence of heterogeneity using the Chi² test. If the P value is low (less than 0.10), the likelihood of heterogeneity will increase.

We will quantify the extent of heterogeneity by calculating an estimation of the I² statistic. We will follow the guidance outlined in Section 9.5.2 of the Higgins 2011:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity*;
- 50% to 90%: may represent substantial heterogeneity*;
- 75% to 100%: considerable heterogeneity*.

*The importance of the observed value of I² depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g. P value from the Chi² test, or a confidence interval for I²). If our I² value indicates that heterogeneity is a possibility and either the Tau² is greater than zero, or the P value

is low (less than 0.10), heterogeneity may be due to a factor other than chance.

If we identify methodological or statistical heterogeneity, we will not pool results into a meta-analysis. Instead we will carry out a narrative synthesis, grouping trials with similar populations and interventions together to attempt to identify reasons for heterogeneity.

Assessment of reporting biases

If 10 or more studies are included in a meta-analysis, we will create a funnel plot to investigate whether bias may exist unless all studies are of a similar size. We will use the funnel plot test proposed by Egger 1997. If we notice asymmetry we cannot conclude that reporting biases exist however, we will consider the sample sizes and presence and possible influence of outliers. We will discuss potential explanations such as publication bias or poor methodological quality of included studies and subsequently perform a sensitivity analysis.

Data synthesis

We will use Review Manager software (RevMan 2014) to conduct our statistical analysis and undertake meta-analysis if it is deemed appropriate. Considering the differences in the participant groups, the comparisons and the outcomes in this review, we will use a random-effects model. The pooled estimate of the effects will estimate the mean effects across the groups, comparisons and methods of outcome evaluation. Both within-study and between study variability will be addressed.

If we do not deem it appropriate to conduct meta-analyses we will present a systematic, narrative summary of the results.

'Summary of findings' table

Two review authors (AC, DD) will assess the quality of the evidence. Based on the methods described in Section 8.5 of chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and by GRADE (Guyatt 2013a; Guyatt 2013b), we will create 'Summary of findings' tables for the main comparisons of the review: 'Summary of findings' tables versus full versions of systematic reviews; 'Summary of findings' tables plus full review versus full review (no 'Summary of findings' tables); 'Summary of findings' tables versus other summaries of systematic reviews; and interactive versus static 'Summary of findings' tables. We will present the following primary and secondary outcomes for each comparison: user understanding of key findings of systematic reviews, self-perceived understanding of key findings of systematic and self-reported influence on decision-making, time taken to read summary and extract relevant information, accessibility of the main findings of the review, user satisfaction/preferences/ attitudes and other outcome(s) of main interest, as outlined in the section on Types of outcome measures. We will describe the study settings and number of participants and studies addressing each outcome. For each assumed risk cited in the table(s), we will provide a source and rationale, and the GRADE system will be used to assess the quality of the evidence using GRADEpro software or the GRADEpro GDT app. If meta-analysis is not appropriate or the units of analysis cannot be compared, we will present results in a narrative 'Summary of findings' table format (using Chan 2011 for guidance). If we do this, the imprecision of the evidence will be an issue of concern due to the lack of a quantitative effect measure.

Subgroup analysis and investigation of heterogeneity

If visual inspection of forest plots, Chi² test, I² statistic and Tau² indicate that statistical heterogeneity could be present, a subgroup analysis will be carried out.

A subgroup analysis will be deemed appropriate if included studies satisfy criteria to assess credibility of subgroup analyses (Oxman 1992; Sun 2010).

The following are our *a priori* subgroups:

- different participant groups e.g. patients, policy makers or healthcare professionals;
- intervention characteristics e.g. different formats of 'Summary of findings' tables, different summarisation products;
 - type of study.

Sensitivity analysis

We will use the GRADE approach (Guyatt 2008) to assess the level of quality of the evidence and thereby, interpret the results. This involves the GRADE classification terms: high, moderate, low or very low. GRADE is characterised by eight criteria for authors to consider (Schünemann 2013).

- Risk of bias (potential to reduce level of quality of evidence by one or two levels)
- Inconsistency of results (potential to reduce level of quality of evidence by one or two levels)
- Indirectness of evidence (potential to reduce level of quality of evidence by one or two levels)
- Imprecision of results (potential to reduce level of quality of evidence by one or two levels)
- Risk of publication bias (potential to reduce level of quality of evidence by one or two levels)
- Magnitude of effect (potential to increase level of quality of evidence by one or two levels)
- Dose response gradient (potential to increase level of quality of evidence by one level)
- Influence of residual plausible confounding (potential to increase level of quality of evidence by one level)

We will downgrade randomised trials by one, two or three levels according to the severity of the study limitations (the first five factors listed above). We will upgrade non-randomised trials if their results show large effects and bias is not evident, or we will downgrade them if they demonstrate limitations as listed above.

We will use The GRADEpro Guideline Development Tool to create a 'Summary of findings' table incorporating our results.

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* Indicates the major publication for the study

APPENDICES

Appendix I. PubMed search strategy

Platform: part of the Entrez series of databases provided by the NLM National Center for Biotechnology Information (NCBI) Years of coverage: generally 1946 to the present, with some older material

Date conducted: 13/01/2016

#1 "summary of findings" OR summary-of-findings #2 table OR tables OR tabulate* OR tabular

#3 #1 AND #2 Limits: none No. of hits: 100

CONTRIBUTIONS OF AUTHORS

DD, MC and AC devised the study. AC drafted the protocol and DD, ST, NS, RM and LM reviewed the protocol. AC developed the search strategy and will conduct the search. DD and AC will select the studies, assess risk of bias and certainty of the evidence.

DECLARATIONS OF INTEREST

The authors declare no financial conflict of interest. However, some are members of the GRADE working group (HS, NS, RM) the DECIDE project (ST) and the Cochrane Collaboration. These authors who may be authors of potentially eligible studies will not have any role in study selection, risk of bias and certainty of evidence assessments.

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