Cochrane Methods

ROBINS-I tool
Resources and reporting guidance

Risk **O**f **B**ias **I**n **N**on-randomised **S**tudies - of **I**nterventions (ROBINS-I)

April 2023

Theresa H Moore, Senior Research Associate, Bristol Medical School (PHS)
Kerry Dwan, Senior Research Fellow in Evidence Synthesis and HTA, Centre for Reviews and Dissemination, University of York
Ella Flemyng, Editorial Product Lead, Evidence Production and Methods Directorate, Cochrane

Contents

About ROBINS-I 3

What guidance is available? 3

Riskofbias.info website 3

Cochrane Handbook 3

MECIR 3

Using RevMan 4

What training is available? 4

What tools are available? 4

Tools for managing your ROBINS-I assessments 4

Tools for creating figures 4

Table 1: ROBINS-I considerations for protocol development 4

Table 2: ROBINS-I considerations for reporting the full review 7

Example: ROBINS-I assessments for Intervention A versus Intervention B condition X-: Outcome y at z months follow up 9

Robvis traffic light plot figure 9

Format for Excel file uploaded to create the above *robvis* traffic light plot figure 9

Example outcome-level table with risk of bias assessments for ROBINS-I – including judgements 10

Example narrative synthesis (also known as synthesis without meta-analysis) with ROBINS-I 13

What support is available? 14

Protocol and Review development support from the Methods Support Unit 14

Questions via email 14

Questions about the ROBINS-I riskofbias.info site 14

Other ROBINS-I tips from review teams 14

Common errors in the application of ROBINS-I 15

About ROBINS-I

Up-to-date information from the developers on the ROBINS-I (**R**isk **O**f **B**ias **I**n **N**on-randomised **S**tudies - of **I**nterventions) tool is available via the Risk of Bias tools website.

The table below gives an overview of key ROBINS-I features.

Focus of assessment	Outcome data with a numerical result– if there is **no numerical result** for an outcome from a specific study, then no risk of bias assessment is needed as it will not be contributing to the review. It is recommended that authors focus on results that will be included in summary of findings tables.
Structure	Pre-specification of some information at the protocol stage. The tool uses signalling questions to reach risk of bias judgements for each domain. The tool has seven domains leading to overall risk of bias for each result.
Domains	-Bias due to confounding -Bias in the selection of participants into the study -Bias in classification of the intervention -Bias due to deviations from intended interventions -Bias due to missing outcome data -Bias in measurement of the outcome -Bias in selection of the reported result Plus 'Overall risk of bias'
Basis of judgement	Signalling questions answered: Yes; probably yes; probably no; no; or no information.
Judgement options	Low, moderate, serious, critical.
Analysis	Authors are advised not to use data from studies at overall critical risk of bias in any analyses. This applies to all synthesis methods (meta-analysis and other). These data could be included in a separate table for completeness.
Presentation	Present risk of bias for each key outcome assessed in the review for which numerical result data were available. These key outcomes are presented at protocol stage.

What guidance is available?

Riskofbias.info website

Detailed and comprehensive guidance on ROBINS-I can be found via the Risk of Bias tools website.

Cochrane Handbook

The relevant chapter in the *Cochrane Handbook for Systematic Reviews of Interventions (Version 6.3)* is Chapter 25, assessing risk of bias in a non-randomised study. Review teams should ensure they are familiar with the contents of this chapter.

MECIR

The Methodological Expectations for Cochrane Intervention Reviews (MECIR) Conduct Standards include nine standards for assessing risk of bias in included studies here (C52-60). Review teams are expected to follow the MECIR standards.

Using RevMan

The ROBINS-I tool has not yet been built directly into RevMan as a default assessment tool, but it can be incorporated into Cochrane Reviews in RevMan with some manual changes required.

What training is available?

At the moment there is no training available on using ROBINS-I. We advise authors check the Cochrane training website to see if new training is added.

What tools are available?

Tools for managing your ROBINS-I assessments

1. ROBINS-I Word template (available here)
2. A browser-based, online tool is under development. Check the riskofbias.info website for updates. If you want to pilot test the new tool contact risk-of-bias@bristol.ac.uk.

Tools for creating figures

To create figures for ROBINS-I we advise authors to use the *robvis* tool. Traffic light plots can be created very easily using this app. These figures can be uploaded into RevMan as additional figures. Easy-to-follow instructions are available within the app. If you use *robvis*, please ensure you cite it in your review.

Table 1: ROBINS-I considerations for protocol development

There are 20 key items to consider when using the ROBINS-I tool.
Authors must make a case for including NRSI in their review and should consult with their Cochrane editorial team.
Editors may use this table to check if authors are planning to apply the tool appropriately.

What to report	Further details
Background section - 'Why it is important to do this review'	
1. State a rationale for including NRSI	**Guidance**: Section 24.1.1 *Cochrane Handbook*. If the rationale is to either evaluate weaknesses of NRSIs or to provide justification of the need for evidence from RCTs, this is insufficient for a Cochrane systematic review.
Methods section - 'Criteria for considering studies for this review' 'Types of studies'	
2. List the study design features that would make a NRSI eligible for your review	Do not use labels to describe the NRSIs, e.g., 'controlled before and after studies', and instead highlight study design features, e.g., 'must have comparative data'. **Guidance** (checklist of study design features): Section 24.2.1.3. and Section 24.2.2, *Cochrane Handbook;* Reeves 2017* **Guidance** (reasons to carefully describe these for your risk of bias assessment): Section 25.4, Section 25.5 and Section 25.6, *Cochrane Handbook*. *Reeves BC, Wells GA, Waddington H. Quasi-experimental study designs series-paper 5: a checklist for classifying studies evaluating the effects on health interventions-a taxonomy without labels. *Journal of Clinical Epidemiology* 2017; **89**: 30-42.
Methods section - '**Assessment of risk of bias in included studies**'	
3. State that ROBINS-I tool will be used and reference it	**Reference:** Sterne JAC, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR,

	Chan AW, Churchill R, Deeks JJ, Hróbjartsson A, Kirkham J, Jüni P, Loke YK, Pigott TD, Ramsay CR, Regidor D, Rothstein HR, Sandhu L, Santaguida PL, Schünemann HJ, Shea B, Shrier I, Tugwell P, Turner L, Valentine JC, Waddington H, Waters E, Wells GA, Whiting PF, Higgins JPT. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. BMJ 2016; 355; i4919; doi: 10.1136/bmj.i4919 (available here) **Guidance**: MECIR C20
4. State who will assess bias (initials), how many and whether independently and duplicate	**Guidance**: MECIR C53; Section 7.3.2 *Cochrane Handbook*.
5. State your effect of interest - effect of assignment (ITT) or effect of adherence (per protocol)	**Guidance**: Section 2.5 and 3.2.2 of the detailed guidance (riskofbias.info); Section 25.3.3 *Cochrane Handbook*.
6. List or refer to the outcomes that will be assessed using ROBINS-I, include: outcome(s), outcome measure(s) and timepoint(s)	**Guidance**: Section 3.6 of the detailed guidance (riskofbias.info); Section 7.3.2, Section 8.2.1 and Section 8.7 *Cochrane Handbook*. **Authors are not expected to assess risk of bias for all results from all included studies: Please see *Other ROBINS-I tips* below.**
7. List the confounders that you would expect to be controlled for each type of outcome	**Guidance**: Section 2.5 and 3.2.2 of the detailed guidance (riskofbias.info); Section 25.3.1 *Cochrane Handbook*.
8. List possible cointerventions that could differ between intervention groups and have an impact on outcomes	**Guidance**: Section 3.1.3 of the detailed guidance (riskofbias.info); Section 25.3.1 *Cochrane Handbook*.
9. List the bias domains of the tool	**Guidance**: Section 2.5 and 3.2.2 of the detailed guidance (riskofbias.info); Section 25.3.4 *Cochrane Handbook*.
10. State you will assess bias in NRSIs with different features	**Guidance**: Section 25.4, Section 25.5 and Section 25.6 *Cochrane Handbook.*
11. List the judgment options (low, moderate, serious, critical) and how overall risk of bias is reached, e.g., using the signalling questions	**Guidance**: Section 2.5 and 3.2.2 of the detailed guidance (riskofbias.info); Section 25.3.4 and Section 25.3.5 *Cochrane Handbook*. Please be aware that it is recommended to exclude from any analysis any studies judged to be at critical risk of bias. **Guidance:** Section 24.6.1 and Section 24.6.2.1 *Cochrane Handbook.*
12. State how you will reach an overall risk of bias judgement for each synthesis, which will involve consideration of the individual risk of bias judgements from each result. This will also feed into GRADE assessments for summary of findings tables (see below)	**Guidance:** Section 7.5 *Cochrane Handbook*
13. State how you will manage ROBINS-I in terms of software. If your review will also include study designs that cannot be assessed with ROBINS-I (e.g. randomised trials, modelling studies, qualitative studies), state how risk of bias will be assessed in these studies.	**No guidance yet.**
Methods section - '**Data synthesis**'	
14. State that you will not pool data from RCTs and NRSI together	**Guidance:** Section 24.6.2.1 *Cochrane Handbook*.
15. Consider stating contingencies for narrative synthesis	Detail planned synthesis methods as well as contingencies for when planned synthesis methods are appropriate but not possible (e.g. necessary data such as variance data are not available), as well as contingency

	methods for when planned synthesis methods are possible but not appropriate (e.g. critical risk of bias, high levels of missing data/studies, or heterogeneity that cannot be addressed) **Guidance:** Section 9.3.2, Section 24.6.2.3 and Chapter 12 of the *Cochrane Handbook.*
16. State whether the primary analysis will include results with either low, moderate and serious, or only low and moderate risk of bias	This may depend on the number of studies with each risk of bias rating as you'll need sufficient numbers for the analyses. It could also be appropriate to pool data from studies at "serious" risk of bias and use a sensitivity analysis to assess the effects of restricting the analysis to NRSIs with overall moderate and low risk of bias. It is unlikely that you will identify any studies of low risk of bias as these will equate to a well-run RCT. **Guidance**: MECIR C21, Section 7.6.2 and Section 24.6.1, *Cochrane Handbook*.
17. State that you will exclude data from studies at critical risk of bias from your analyses	**Guidance:** Section 24.6.1 *Cochrane Handbook*
Methods section - '**Subgroup analysis and investigation of heterogeneity'**	
18. (If applicable) Specify if subgroup analysis is planned based on risk of bias	Consider whether overall risk of bias should be used as the basis for any subgroup analysis. Subgroup analyses may be done as a means of investigating heterogeneous results, or to answer specific questions about particular patient groups, types of intervention or types of study (as well as clinical heterogeneity there is methodological heterogeneity). If you would like to perform subgroup analyses using risk of bias, please discuss with your Cochrane editor during protocol development. **Guidance**: MECIR C22; Section 10.11.2 and Section 7.6.2 *Cochrane Handbook.*
Methods section - '**Sensitivity analysis'**	
19. (If applicable) Specify if sensitivity analysis is planned based on risk of bias	Consider whether overall risk of bias should be used as the basis for any sensitivity analysis. A sensitivity analysis is a repeat of the primary analysis or meta-analysis in which alternative decisions or ranges of values are substituted for decisions that were arbitrary or unclear. In respect to risk of bias, review authors may perform sensitivity analyses to show how conclusions might be affected if studies at a serious risk of bias were included. **Guidance**: MECIR C71; Section 10.14 and Section 7.6.2 *Cochrane Handbook*.
Methods section - '**Summary of findings and assessment of the certainty of the evidence'**	
20. State how the ROBINS-I assessment will be used to assess the certainty of the evidence/ GRADE/ summary of findings	State that the *overall* ROBINS-I judgement for each outcome will be used to feed into the GRADE risk of bias assessment. **Guidance**: MECIR C54; Section 7.3.2 *Cochrane Handbook*.
Other considerations	Authors should not adapt the ROBINS-I tool. State how you will store and present your detailed ROBINS-I data. The ROBINS-I tool may generate a large amount of data. We recommend that the consensus decisions for the signalling questions are available to your readers in the full review so your rational for judgements is transparent. This can be stored as supplemental data or files (see the Editorial and Publishing Policy for full details). **Guidance**: MECIR C54; Section 7.3.2 *Cochrane Handbook*. See these published examples: Maisch P, Hwang EC, Narayan V, Bakker CJ, Kunath F, Dahm P. Immunotherapy for advanced or metastatic urothelial carcinoma. Cochrane Database of Systematic Reviews 2020, Issue 11. Art. No.: CD013774. DOI: 10.1002/14651858.CD013774. Accessed 15 February 2023. N.B. This example

	does not tick every box (for example, it does not include the list of outcomes and timepoints to be assessed using ROBINS-I)

Table 2: ROBINS-I considerations for reporting the full review

There are eight key items to consider when reporting ROBINS-I in the full review.
Please note, this checklist ONLY highlights ROBINS-I considerations for review reporting.

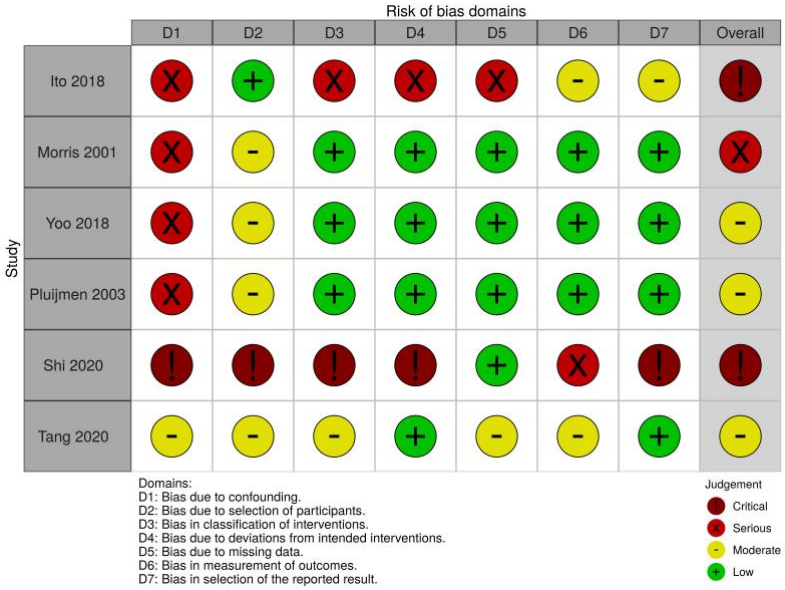
What to report	Further details
Methods - '**Assessment of risk of bias in included studies'**	
1. Include all the ROBINS-I considerations from the Protocol	Compare the Review to the Protocol to ensure they are consistent and use the protocol checklist to ensure everything needed is included. If there were any deviations from the Protocol, these should be detailed in the 'Differences between protocol and review' section.
2.State the version of the ROBINS-I tool that was used	See the riskofbias.info website and ensure you state which version of the tool you used. This can be done by referring to the date the guidance was drafted.
Results - '**Risk of bias in included studies'**	
3. Provide a brief overview of the risk of bias assessments	Describe risk of bias assessments at the outcome level (this differs considerably from risk of bias assessments at the study level which authors may have previously used). You **do not** need to describe all the bias domains for all outcomes for all studies. Instead present a summary paragraph and link to your additional risk of bias outcome-level tables. Please note that if you are including RCTs in your review, you will need to request that RoB2 settings are enabled for your review. If you have not enabled RoB 2 you will still see the RoB 1 headings in this section. If these are not needed, the sections can be left blank and will not be shown in the published review. Contact your editorial team for further advice on this, if needed. Describe your thoughts on the risk of bias as it presents overall for your research question. Focus on ***key aspects*** of the risk of bias assessments, e.g., the adjustment of confounders, selection of participants into the study or extent to which blinding was implemented. Consider whether there are ***important differences*** in risk of bias by outcome. If ***risk-of- bias assessments are very similar*** (or identical) for certain outcomes in the review, a summary of the assessments across outcomes should be presented here. If ***risk-of-bias assessments are very different*** for different outcomes, this section should be very brief, and summaries of the assessments across outcomes should be included within the 'effects of intervention' section (see below).
4.Refer to the outcome-level ROBINS-I tables, which includes the support for judgement for each domain assessment. You can also refer to any traffic light plot figures in additional figures or the appendices	Outcome-level ROBINS-I tables can be added as additional tables. Create a table for each outcome, this should contain your risk of bias judgements (critical, serious, moderate or low) for each domain and the overall risk of bias. Ensure there is a rationale/support for each domain judgement and for the overall risk of bias. Please make sure that the appropriate rationale is entered into the correct domain, but is briefly stated. More detailed information can be saved as supplemental files. ****Guidance on how to draft these tables is below****

5. Figures: Outcome-level traffic light plots	Present traffic light plots for each outcome. Authors will need to use software such as *robviz* to create these figures and add them as additional figures in RevMan. ***Guidance on how to draft these figures is below***
6. State how to access detailed risk of bias assessments data (with consensus responses to the signalling questions)	We suggest authors store their detailed assessments in an online repository. Then they can be cited in the main text as supplemental data or files (they should not be included within the Review itself). These can include the agreed responses to the signalling questions. **Guidance**: Supplemental data and files in the Editorial and Publishing Policy Resource.
Results - '**Effects of intervention'**	
7. Refer to visual representations of the risk of bias assessments in relation to each result.	Authors will not need to give detailed information about risk of bias in this section, but can add links to your outcome-level traffic light plots that are stored as additional figures. It may be very helpful to stratify forest plots according to overall risk of bias. For synthesis without meta-analysis or structured summaries of the results of individual studies, we recommend that a column is added to any visual representation of the data that highlights the overall risk of bias associated with each of the results in the table. ****Guidance on how to draft these tables is below**** **Guidance**: Section 7.6 *Cochrane Handbook*
OPTIONAL- advanced: Include forest plots with risk of bias	Authors can edit the risk of bias headings so that they can enter their ROBINS-I judgements alongside information about each study. Judgements will then appear in the forest plots ***OPTIONAL - advanced:*** For authors familiar with R there are some researchers developing code in R to produce forest plots with traffic lights to indicate bias. The forum discussion and code can be viewed here. At the moment it requires users to code in R and might only be available for RoB 2. Which is why we do not ask authors to do this unless they are very keen. Some developers are working to produce a single R function to make the process much easier and when this becomes available, we will add it here to this optional section.
Results - '**Subgroup analysis'**	
8. (If applicable) Discuss any subgroup analysis conducted that relates to the risk of bias judgments	
Results - '**Sensitivity analysis'**	
9. (If applicable) Discuss any sensitivity analysis conducted that relates to the risk of bias judgments	
Discussion -**'Certainty of the evidence'** (previously the 'Quality of the evidence' section	
10. Discuss any risk of bias judgements that affect the	Along with the other GRADE considerations, ***highlight any important implications*** from the risk of bias assessments. Authors should cover issues that are relevant across all outcome assessments. **Guidance**: Section 7.5 and Section 14.2.2 *Cochrane Handbook*

certainty of the evidence along with all other GRADE considerations	
History – **'Differences between protocol and review'**	
11. (If applicable) State if there were any deviations from the Protocol	
Other considerations	See these published examples: - **Examples to be added when available – in the meantime, email support@cochrane.org and flag it for the Methods Support Unit team.**

Example: ROBINS-I assessments for Intervention A versus Intervention B with condition X: Outcome y at z months follow up

Robvis traffic light plot figure



Format for Excel file uploaded to create the above *robvis* traffic light plot figure

Study ID	D1	D2	D3	D4	D5	D6	D7	Overall	Weight
Ito 2018	Serious	Low	Serious	Serious	Serious	Moderate	Moderate	Critical	1
Morris 2001	Serious	Moderate	Low	Low	Low	Low	Low	Serious	1
Yoo 2018	Serious	Moderate	Low	Low	Low	Low	Low	Moderate	1
Pluijmen 2003	Serious	Moderate	Low	Low	Low	Low	Low	Moderate	1
Shi 2020	Critical	Critical	Critical	Critical	Low	Serious	Critical	Critical	1
Tang 2020	Moderate	Moderate	Moderate	Low	Moderate	Moderate	Low	Moderate	1

The final column "weight" is used in creating weighted bar plots and you can enter here weights from the relevant meta-analysis. However, unless you have a specific reason to present weighted bar plots, we suggest you weight all studies as "1" and present only traffic light plots.

Example outcome-level table with risk of bias assessments for ROBINS-I – including judgements

This is an example of the type of table that can be included as an Additional Table in the review. This should be completed for each outcome that is being assessed. More detailed information (i.e. the answers to the signalling questions) can be included in more detailed tables stored in an online repository.

Study	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from the intended intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias
Ito 2018	**Serious**	**Low**	**Serious**	**Serious**	**Serious**	**Moderate**	**Moderate**	**Critical**
Rationale for judgement	They measured confounding variables. But used an analysis (Mann Whitney U) that does not allow for adjustment.	Prospectively recruited study. Consecutive series of participants selected. Later 12 participants were excluded based on outcome. However, we deal with these in Domain 5.	Intervention status is not well defined – 8 participants used both protocols.	There were deviations from usual practice that were unbalanced between the intervention groups and likely to have affected the outcome. We do not know anything about the 8 people that used both protocols (i.e. which groups they were from).	A large proportion 21% of participants were missing because they had no outcome data, we do not know which groups they were in. No analysis was done to assess the effect of missing data.	(i) The methods of outcome assessment were comparable across intervention groups; and (ii) The outcome measure is only minimally influenced by knowledge of the intervention received by study participants; and (iii) Any error in measuring the outcome is only minimally related to intervention status.	There was no a priori protocol. Selection based on outcome could be possible as they have not used Thyroglobulin level (measured at time of whole-body scan) and we would expect that for a study in this time period. There appear to be no issues with, intervention, multiple analyses, or different subgroups.	Four domains at "Serious" risk of bias therefore bias overall judged to be "Critical". Analysis did not adjust for confounding. Intervention status poorly defined. Important deviations from intervention. Over 20% of participants missing.
Morris 2001	**Serious**	**Moderate**	**Low**	**Low**	**Low**	**Low**	**Low**	**Serious**
Rationale for judgement	They measured confounding variables. But used an analysis (Chi square and Mann Whitney U) that does not allow for adjustment.	Selection into the study was based upon the outcome (results of ablation) but this is unlikely to be related to the intervention (advice for low diet).	Intervention status is well defined and based solely on what was collected at the time of intervention.	Any deviations from intended intervention reflected usual practice	Data were complete. But people selected were chosen based on outcome data. Bias for this dealt with in Selection bias (Domain2)	i) The methods of outcome assessment were comparable across intervention groups; and (ii) The outcome measure is unlikely influenced by knowledge of the intervention received by study participants; and (iii) Any error in measuring the outcome is only	There was no a priori protocol however, based on clinical knowledge there appears to be no selection based on outcome, intervention, multiple analyses, or different subgroups.	Analysis did not adjust for confounding. Selection based on results of ablation (outcome).

Study	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from the intended intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias
						minimally related to intervention status		
Yoo 2018	**Serious**	**Moderate**	**Low**	**Low**	**Low**	**Low**	**Low**	**Moderate**
Rationale for judgement	They measured confounding variables. But used an analysis (Chi square) that does not allow for adjustment.	Selection into the study was based upon the outcome (results of ablation) but this is unlikely to be related to the intervention (advice for low diet).	Intervention status is well defined and based solely on what was collected at the time of intervention.	Any deviations from intended intervention reflected usual practice	Data were complete. But people selected were chosen based on outcome data. Bias for this dealt with in selection bias (Domain2)	i)The methods of outcome assessment were comparable across intervention groups; and (ii) The outcome measure is unlikely influenced by knowledge of the intervention received by study participants; and (iii) Any error in measuring the outcome is only minimally related to intervention status	There was no a priori protocol however, based on clinical knowledge there appears to be no selection based on outcome, intervention, multiple analyses, or different subgroups.	Analysis did not adjust for confounding. Important deviations from intervention. Over 20% of participants missing.
Pluijmen 2003	**Serious**	**Critical**	**Low**	**Low**	**Low**	**Low**	**Low**	**Critical**
Rationale for judgement	They measured confounding variables. But used an analysis (Chi Square) that does not allow for adjustment.	They only select people that successfully adhered to LID. LID is the intervention and is likely to be related to the outcome. There was no analysis looking at the effect of this selection bias.	Intervention status is well defined and based solely on what was collected at the time of intervention.	Any deviations from intended intervention reflected usual practice	No missing data for this study. But participants were exclude based on intervention and outcome and this is dealt with in Domain 2.	i) The methods of outcome assessment were comparable across intervention groups; and (ii) The outcome measure is unlikely influenced by knowledge of the intervention received by study participants; and (iii) Any error in measuring the outcome is only minimally related to intervention status	There was no a priori protocol however, based on clinical knowledge there appears to be no selection based on outcome, intervention, multiple analyses, or different subgroups.	Analysis did not adjust for confounding. Selection based on success of implementation of the intervention.

Example of a structured summary of the results of individual studies with ROBINS-I judgements

From the Healthy Neighbourhoods review https://doi.org/10.1016/j.healthplace.2018.07.012

Intervention type	Study name	Outcome measure	Timepoint	N Intervention/ Control	Statistics as presented in the papers	Risk-of-bias Overall assessment	Direction of effect favours intervention control?	Re-analysis using summary data from studies Standardised difference in difference (95% Confidence intervals)
Improving green infrastructure	Green storm water Philadelphia	Single item question Stress	2 years	N/A	Adjusted difference in difference estimate for stress (SE)= -0.01 (0.05) p=ns	Moderate	No effect	Not able to calculate
	Greening vacant lots	Single item question Stress	7 years	4436/13308	Adjusted difference in difference estimate for Stress *(SE)*=-0.02 SE=0.12 R^2=0.68 p=ns	Moderate	No effect	Not able to calculate
Urban regeneration	Neighbourhoods Law	GHQ-12	Baseline	274/504	Intervention Proportion poor MH=0.180 SD=0.38 Control Proportion poor MH=0.138 SD=0.345	Critical	Favours intervention	-0.11 (95% CI -0.22 to 0.01)
		GHQ-12	11 years	398/823	Intervention Proportion poor MH=0.176 SD=0.38 Control Proportion poor MH=0.173 SD=0.378			
	Wythenshawe regeneration	GHQ-12	22 months	Total=1344	MD 0.273 (95% CI -0.134 to 0.481) p=0.27	Critical	No effect	0.01 (95% CI -0.06 to 0.09)
	Well London	GHQ-12	4 years	1867/1886	Adjusted MD −0.01 (95% CI −0.15 to 0.12) p=0.4	Low	No effect	-0.01 (95% CI -0.15 to 0.12)
		GHQ-12	4 years	1867/1886	Adjusted risk ratio 1.15 (0.82 to 1.61) p=0.9	Low	No effect	Not applicable
		Single item Feeling anxious or depressed (%)	Baseline	2061/2046	Intervention mean=17.8 (95% CI 13.6 to 22.0) Control mean=18.7 (95% CI 13.6 to 23.8)	Low	No effect	-0.01 (95% CI -0.06 to 0.04)
		Single item question. Feeling anxious or depressed (%)	4 years	1867/1886	Intervention mean= 9.0 (95% CI 6.4 to 11.5) Control mean 8.4 (95% CI 6.4 to 10.4)	Low	No effect	-0.01 (95% CI=-0.06 to 0.04)
	Well London	WEMBS	4 years	Intervention n= 1792 to 1886 Control n=1825 to 1876	Adjusted MD=-1.52 (-3.93 to 0.88) p=0.2 Intervention mean=58.7 (95% CI 56.8 to 60.5) Control mean=60.1 (95% CI 58.3 to 61.9)	Low	No effect	-1.53 (95% CI -3.93 to 0.88)

What support is available?

Protocol and Review development support from the Methods Support Unit

The Methods Support Unit are available to support Cochrane authors and editors with reviews using ROBINS-I. They may ask for hands-on support for their first Protocol and Review using ROBINS-I.

Cochrane authors and Cochrane editors or staff can submit ROBINS-I questions to the **monthly Methods Support Unit Web Clinic** for discussion – read more and submit questions here.

Questions via email

Questions about ROBINS-I assessments, guidance, tools, or other miscellaneous questions can be directed to support@cochrane.org, please flag that it's for the attention of the Methods Support Unit.

Questions about the ROBINS-I riskofbias.info site

Questions about the riskofbias.info site can be emailed to risk-of-bias-info@bristol.ac.uk.

Other ROBINS-I tips from review teams

If you have any tips that would help other authors use and report ROBINS-I, please let support@cochrane.org know so we can add them to this section.

Training course. We will add details here of any training courses for the use of ROBINS-I.

Worked examples are key. Example protocols and reviews using ROBINS-I will be added to this document as they become available.

Don't forget to complete all the boxes! Do remember to fully complete all the boxes providing evidence for your judgements. It is difficult for authors to have meaningful discussions about decisions if boxes are left blank.

Disagreements are no bad thing. Practicing a couple of assessments will always highlight differences that can be ironed out, but inter-rater discrepancies beyond that should be expected and may even improve the review. The signalling questions in ROBINS-I provide a clearer framework for discussing differences in judgements and justifications and the process of doing so is a key part of gaining understanding and interrogating the evidence.

Early investment goes a long way. While ROBINS-I is an outcome-based assessment, considering which domains are expected to be consistent across results within a study and designing the data-collection form accordingly can save a lot of time, e.g. issues in confounding, the type of adjustments made, issues of missing data may differ for outcomes at different time points, and issues of outcome assessment may be different between patient-reported outcomes and outcomes derived from routine data sources. The first few assessments may take some time to get right but once done, subsequent assessments naturally become much easier and faster.

Authors are not expected to assess risk of bias for all results from all included studies: The risk of bias assessment should focus on results of studies that contribute information to outcomes that users of the review will find most useful. This will generally correspond to the results that are used to populate outcomes in 'summary of findings' tables; however, this will depend on your review question and protocol, which may have specified other outcomes for risk of bias assessment.

Common errors in the application of ROBINS-I

Data taken from Methods Support Unit records and paper by Idelstrom 2021 (https://doi.org/10.1016/j.jclinepi.2021.08.022).

Common mistake	Advice
Application of the tool	
Authors apply ROBINS-I to studies not to specific results.	Select the key outcomes of relevance to your review. Apply ROBINS-I to all the results that will contribute to those analyses.
Modification of the tool e.g., removal of a domain or creation of additional domains.	No modifications should be made to the tool.
Overall judgement does not include the worst domain-level judgement.	The overall judgement should be based on an assessment of all domain level biases.
Use of ROBINS-I in the review analysis	
Including data that is at critical risk of bias in analyses	Data from results at critical risk of bias should not be included in meta-analyses or narrative syntheses of reviews.
Sensitivity analyses based on a judgement from a single domain	Sensitivity analyses should be based on the overall judgement from all domains
Reporting of bias as assessed by the tool	
No support for overall judgements in the tables.	Make a summary statement of the reasons for the judgement
No support for domain-level judgements in the tables.	Make a summary statement of the reasons for the judgement
Long description of all aspects of bias in the results text section of the review.	Provide a short summary illustrating the causes of variation in bias across outcomes and by domains. Repetition of t all the domain judgements is not needed as these will be presented in the summary tables.