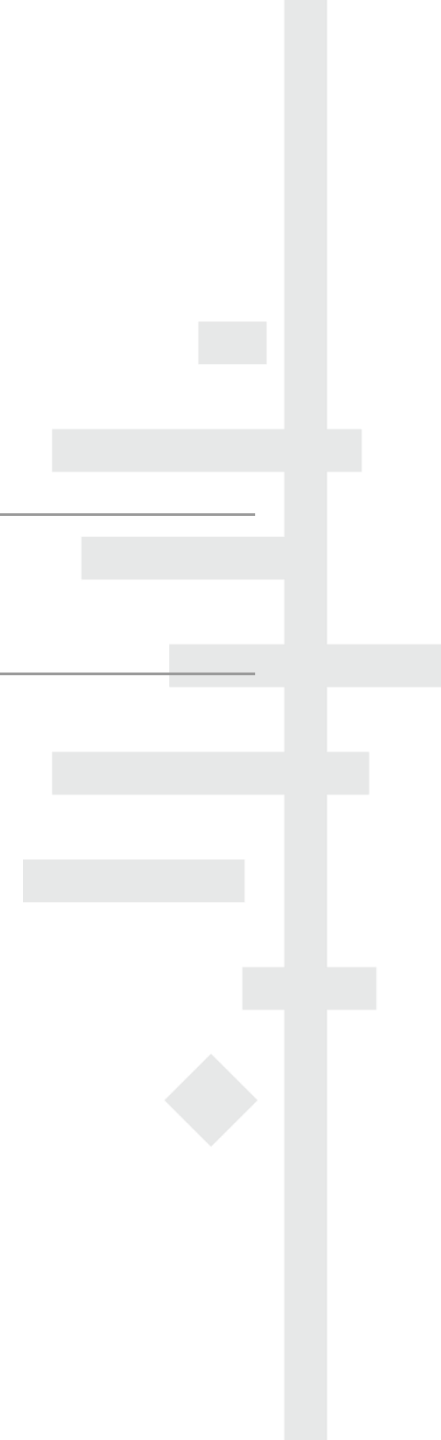


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## Common errors in RoB 2

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**Tess Moore,**  
Systematic Review Methodological Editor, Cochrane  
Methods Support Unit.



# Common errors for RoB 2 in Cochrane reviews

Where are we seeing common errors?

In the RoB 2 data file

Answers to signalling questions

Rationale for judgement

Use of algorithm

In the review

Text of the review

Interactive, results-level tables

Rationale for judgement

Use of algorithm

# The bias assessments in Excel

RoB 2 assessment for individual randomized, parallel group trials

Unique ID (e.g. A1 or 1)  Assessor  20/11/25

Study ID  Ref. or label

Experimental  Comparator

Specify which outcome  Specify the numerical result

Is the review team's aim for this results to assess...?  Weight for analysis

If the aim is to assess the effect of adhering to intervention...(select one at least)

NA

Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

### Randomisation process

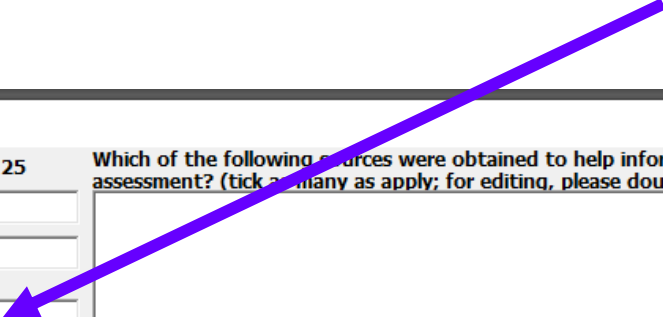
Signalling	Response	Description
1.1 Was the allocation sequence random?	<input type="text" value="Y"/>	
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	<input type="text" value="Y"/>	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	<input type="text" value="N"/>	

### Risk of bias judgement

Algorithm result  Assessor's judgement

Optional: What is the predicted direction of bias arising from

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply; for editing, please double-click the list)





# The bias assessments in Excel



Basic information					
Study ID	Reference	Experimental	Comparator	Outcome	Results
Axiom 2016		12 week supervised	usual care	CRF	
Drees 2014		12 week supervised	usual care	HRQoL	SF-36 and TACQOF-CF
Drees 2014		12 week supervised	usual care	Physical activity	
Dulverton 2015		12 week supervised	usual care	CRF	
Fretof 2020		Inspiratory retraining	no exercise control	CRF	
Klein 2016		Text intervention	no exercise	CRF	
Klein 2016		Text based intervention	no exercise	Physical activity	
Madabar 2011		Hospital Exercise	Usual care	CRF	
Meerain 2012		Exercise	No exercise	Strength	MVC
Meerain 2012		Exercise	No exercise control	CRF	

Numerical result empty  
Incorrect data



Basic information					
Study ID	Reference	Experimental	Comparator	Outcome	Results
Amore Coff	Headache	Caffeine	Decaffeinated	Headache at 30 minutes	Mean Diff 0.22
Deliciozza 2	Headache	Caffeinated	Decaffeinated	Headache at 30 minutes	Mean diff 1.11
Kahave Par	Headache	Caffeinated	Decaffeinated	Headache at 30 minutes	0.55 (0.13 to 2.36)
Mama-Kaff	Headache	Caffeinated	Decaffeinate	Headache at 30 minutes	OR 1.53 [0.7-3.35]
Morrocona	Headache	Caffeine	Decaffeinated	Headache at 30 minutes	3.40 [0.39-29.31]
Oohlalazza	Headache	Caffeine	Decaffeinated	Headach up to 1 hour	2.11 [0.41]
Norscafe	Headache	Caffeine	Decaffeinated	Headach up to 1 hour	OR 1.21 (1.14-1.24)
Piazza Alert	Headache	Caffeine	Decaffeinated	Headach up to 1 hour	OR 0.98 (0.93 - 1.11)

Column is filled in

# The bias assessments in Excel



RoB 2 assessment for individual randomized, parallel group trials

Unique ID (e.g. A1 or 1) 1601 Assessor CW 20/11/25

Study ID Axiom 2016 Ref. or label

Experimental 12 week supervised exercise Comparator usual care

Specify which outcome Specify the numerical result

CRF

Is the review team's aim for this results to assess...? Weight for analysis

assignment to intervention (the 'intention-to-treat' effect) 1

If the aim is to assess the effect of adhering to intervention...(select one at least)

NA

Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

**Randomisation process**

Signalling	Response	Description
1.1 Was the allocation sequence random?	Y	
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	

**Risk of bias judgement**

Algorithm result: Low Assessor's judgement: Low

Optional: What is the predicted direction of bias arising from

No rationale given for Answers to SQs

No rationale given for DOMAIN-level judgement

# The bias assessments in Excel



RoB 2 assessment for individual randomized, parallel group trials

Assessment ID **1** Assessor **TM** **2021/01/07**

Study ID **Amore Coffea 200** Ref. or label **Headache**

Experimental **Caffeine** Comparator **Decaffeinated**

Specify which outcome **Headache at 30 minutes** Specify the numerical result **Mean Diff 0.22**

Is the review team's aim for this result to assess...? **assignment to intervention (the 'intention-to-treat' effect)** Weight for analysis **1**

If the aim is to assess the effect of adhering to intervention...(select one at least)

- occurrence of non-protocol interventions
- failures in implementing the intervention that could have affected the outcome
- non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s)
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER, Research Councils UK Gateway to R)
- Personal communication with trialist

Domain 1 | **Domain 2** | Domain 3 | Domain 4 | Domain 5 | Overall bias

**Randomisation process**

Signalling	Respons	Description
1.1 Was the allocation sequence random?	<b>PY</b>	Quote: "...randomized to two groups." Comments: method of random sequence generation was not described. Comment: allocation concealment was not described.
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	<b>NI</b>	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	<b>PN</b>	Baseline values did not indicate a problem with randomisation, either the method of generating the randomisation sequence, or allocation concealment were described.

**Risk of bias judgement**

Algorithm result **Some concerns** Assessor's judgement **Some concerns**

Double click on this column to create the support for judgement for this risk of bias domain from descriptions

# The bias assessments in Excel



RoB 2 assessment for individual randomized, parallel group trials

Assessment ID: 1 | Assessor: TM | 2021/01/07

Study ID: Amore Coffea 200 | Ref. or label: Headache

Experimental: Caffeine | Comparator: Decaffeinated

Specify which outcome: Headache at 30 minutes | Specify the numerical result: Mean Diff 0.22

Is the review team's aim for this result to assess...? | Weight for analysis: 1

If the aim is to assess the effect of adhering to intervention... (select one at least)

- occurrence of non-protocol interventions
- failures in implementing the intervention that could have affected the outcome
- non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s)
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER, Research Councils UK Gateway to Research)
- Personal communication with trialist

Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

### Randomisation process

Signalling	Respons	Description
1.1 Was the allocation sequence random?	PY	Quote: "...randomized to two groups." Comments: method of random sequence generation was not described. Comment: allocation concealment was not described.
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	NI	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	DN	Baseline values did not indicate a problem with randomisationNeither the method of generating the randomisation sequence, or allocation concealment were described.

### Risk of bias judgement

Algorithm result: Some concerns | Assessor's judgement: Some concerns

Comments: method of random sequence generation was not described.  
Comment: allocation concealment was not described.  
Baseline values did not indicate a problem with randomisationNeither the method of generating the randomisation sequence, or allocation concealment were described.

# The bias assessments in Excel



4.1	Note for 4.1	4.2	Note for 4.2	4.3	Note for 4.3	4.4	Note for 4.4	4.5	4.0 Algorithm	4.0 Assessor's Judgment
N		N		NI		PY	If the person	PN	Some concerns	Some concerns
N	Validated question	N		Y		PY	Can't blind exper	PY	High	Some concerns
PN	Leisure-Time Sp	N		Y		PY	Cannot blind	PY	High	Some concerns
N		N		NI		PY		PN	Some concerns	Some concerns
N		PN		PY		PY		PN	Some concerns	Some concerns
N		PN		PN	Finally, the bl	NA		NA	Low	Low
N		PN		PN	... statistician	NA		NA	Low	Low
PY	YMCA cycle test	PN		NA		NA		NA	High	High
N		N		NI		PN	MVC is obje	NA	Low	Low
N		PN		NI		PY		PN	Some concerns	Some concerns
PN	Not direct gas an	PN		NI		PY	If the person	PN	Some concerns	Some concerns
N	Measuring activi	PN		NI		PN	Both groups r	NA	Low	Low
N		N		NI		PY	If the person	PN	Some concerns	Some concerns
N		N		NI		PY		PY	High	High
N		PN		NI		PY	If the person	PN	Some concerns	Some concerns
N		PN		NI		NI		PN	Some concerns	Some concerns
N		N		Y		PY	Self reported	PY	High	High

Empty cells for many Signalling questions



Domain 4. Measurement of the outcome										
4.1	Note for 4.1	4.2	Note for 4.2	4.3	Note for 4.3	4.4	Note for 4.4&4.5	4.5	4.0 Algorithm result	4.0 Assessor's Judgment
N	Headache diary	N	Headache diaries	PN	Outcome asse	NA		NA	Low	Low
N	Headache was	N	All participants wei	NI	The outcome v	PY	Assessment o	NI	High	High
N	Headache was	N	Measurement was	N	Outcome asse	NA		NA	Low	Low
N	Headache mea	N	Measurement was	PN	Quote: "Caffeir	NA		NA	Low	Low
N	The outcome	N	The outcome was	PN	Headache is s	NA		NA	Low	Low
N	The outcome w	N	The outcome was	PN	Headache is s	NA		NA	Low	Low
N	The outcome	N	The outcome was	PN	Headache is s	NA		NA	Low	Low
N	The outcome	N	The outcome was	PN	Headache is s	NA		NA	Low	Low

Answers provided



# The bias assessments in Excel



Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

Overall bias

RANDOMISATION process: S  
DEVIATIONS FROM THE INTENDED: L  
MISSING OUTCOMES: L  
MEASUREMENT OF THE: L  
SELECTION OF REPORTED RESULTS: S

Risk of bias judgement

Algorithm result: Some concerns  
Assessor's judgement: Some concerns

Double click on this column to create the support for judgement for this risk of bias domain from descriptions

Optional: What is the overall predicted direction of bias arising for this outcome?



Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

Overall bias

RANDOMISATION process: S  
DEVIATIONS FROM THE INTENDED: I  
MISSING OUTCOMES: I  
MEASUREMENT OF THE: L  
SELECTION OF REPORTED RESULTS: S

Risk of bias judgement

Algorithm result: Some concerns  
Assessor's judgement: Some concerns

Neither the method of generating the randomisation sequence, or allocation concealment were described "...randomized to two groups."  
It is likely that participants were blinded. Blinding of study personnel was not described. Quote: "One group received a café latte with 100 mg of caffeine added, and the other received an identical-tasting decaffeinated latte."  
There were no deviations from the intended intervention.  
Double click on this column to create the support for judgement for this risk of bias domain from descriptions

Most data were available. n=78 participants recruited. Data for the majority of these (n=75, 96%)  
Headache diaries is the usual way to record and report the number of headaches.  
Headache diaries were used for both groups.

Optional: What is the overall predicted direction of bias arising for this outcome?



Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

Overall bias

RANDOMISATION process: S  
DEVIATIONS FROM THE INTENDED: L  
MISSING OUTCOMES: L  
MEASUREMENT OF THE: L  
SELECTION OF REPORTED RESULTS: S

Risk of bias judgement

Algorithm result: Some concerns  
Assessor's judgement: Some concerns

There were issues with two domains. The method of random sequence generation was not described. But there appeared to be no issues with randomisation. Although there was no protocol for this study headache was reported at 24 hours, which is standard for this type of RCT looking at headache following caffeine consumption.

# Bias assessment and judgement

Domain

Signalling questions

Only one (or two) answered

Answered incorrectly (or mis-read)

Domain or overall

Judgement

Does not follow the algorithm

Does not follow the algorithm – and  
no rationale given

## 1. Bias from randomisation process

**Authors' judgement**

**Support for judgement**

High

Baseline imbalance, intervention group were younger at baseline and younger for surgery ( $p < 0.10$ )

Computer based randomisation at the trial centre with allocation centrally and blinded.

SQ 1.1 Was the allocation sequence random?

SQ 1.2 Was allocation concealed until ppts enrolled and assigned?

SQ 1.3 Did baseline differences between intervention groups suggest a problem with randomisation process?

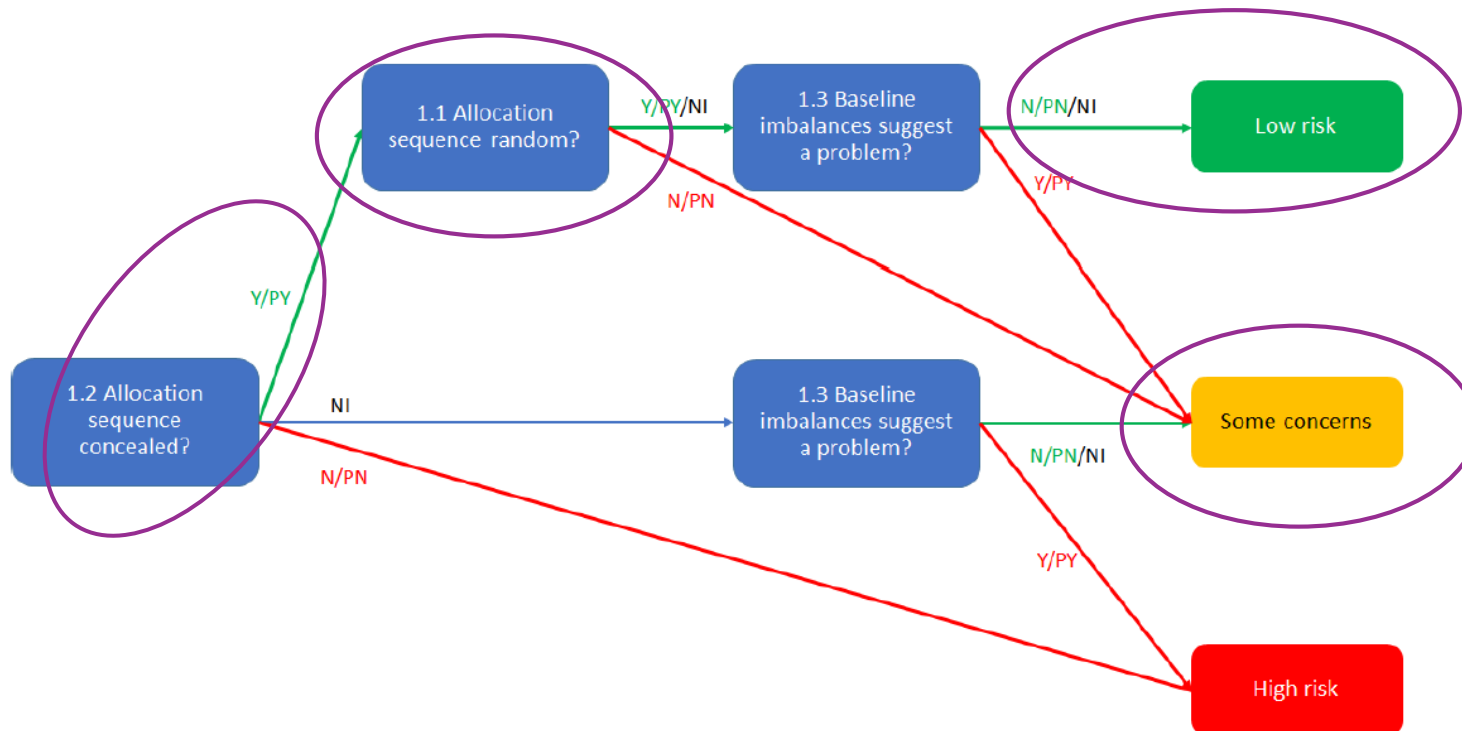
Alternative SQ 1.3 ?

Was there baseline imbalance?



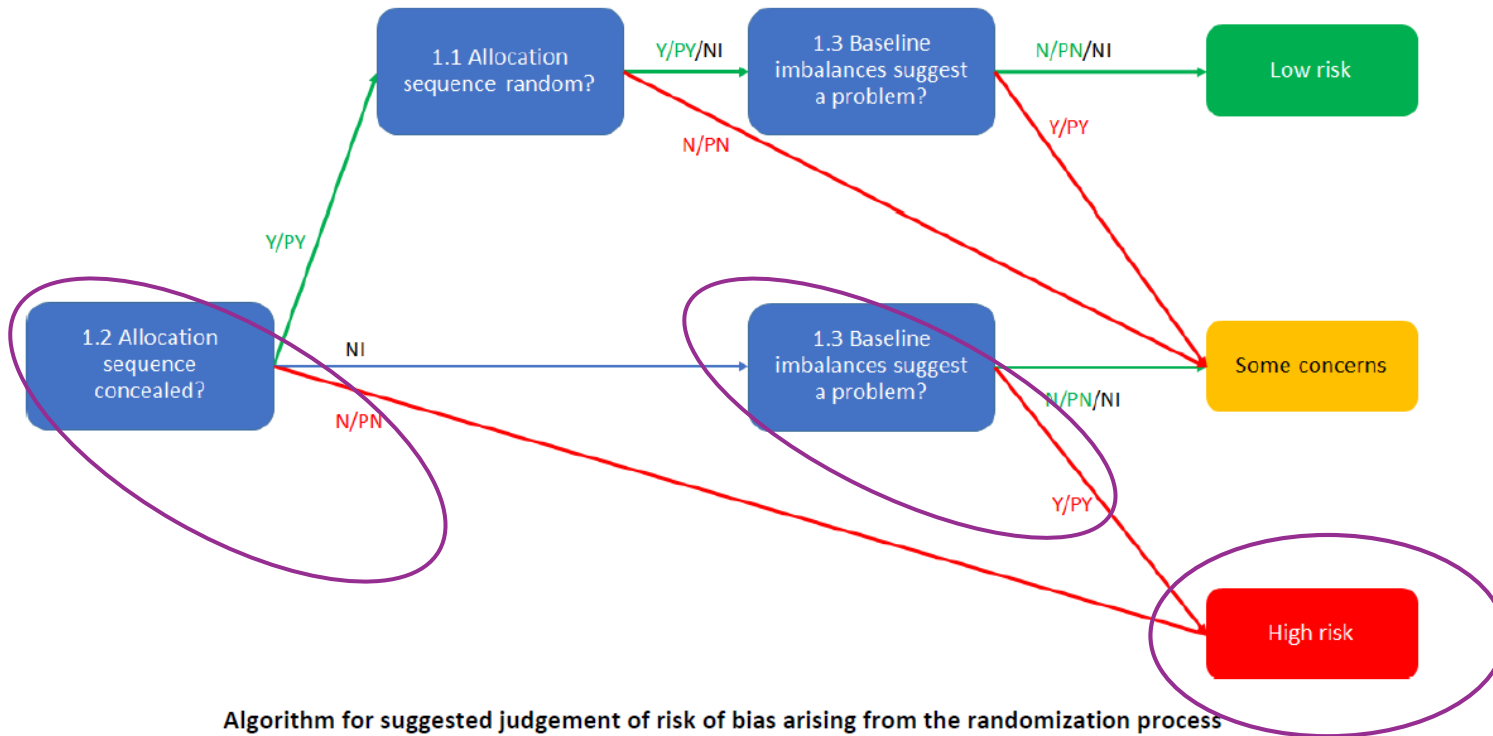
SQ 1.3 Did baseline differences between intervention groups **suggest a problem with randomisation process?**

## 1. Bias from randomisation process



Algorithm for suggested judgement of risk of bias arising from the randomization process

## 1. Bias from randomisation process



## 1. Bias from randomisation process



Domain 2 Simple statement about blinding without describing if result being assessed is likely to be affected by blinding

2. Bias due to deviations from intended interventions	
Authors' judgement	Support for judgement
High	Cannot blind exercise intervention

Authors judge this to be "High" risk of bias  
But algorithm proposed that it could be "Low" or "Some concerns" or "High"



## 2. Bias due to deviations from intended interventions

Authors' judgement	Support for judgement
High	Cannot blind exercise intervention

SQ 2.1 Were participants aware of their assigned intervention during the trial?

SQ 2.2 Were carers or people delivering the intervention aware of the participants assignment during the trial?

SQ 2.3 If **Y/PY** or NI to 2.1 or 2.2 Were there deviations from intended interventions?

SQ 2.3 Were there deviations from intended interventions?

SQ 2.4 If **Y/PY to 2.3**: Were these deviations likely to have affected the outcome?

SQ 2.5 If **Y/PY** to 2.4: Were these deviations balanced between groups?

SQ 2.6 Was an appropriate analysis used?

SQ 2.7. IF **N/PN** to 2.6: Was there potential for a substantial impact of the failure to analyse participants to the group to which they were randomised?

## 2. Bias due to deviations from intended interventions

Authors' judgement	Support for judgement
Low	Quote: "Treatment coffee was not different from placebo coffee by smell or taste." Comment: It is likely that participants were blinded. Blinding of other study personnel was not described. No deviations from the trial were reported. Analysis was ANOVA. Groups were analysed in the groups they were randomised in.







Domain 3

Despite many missing participants bias judged to be “Low”

Missing outcome data	
Authors' judgement	Support for judgement
Low risk of bias	80% of patients remained at the end of the study. 6 Lost to follow up in each

### 3. Bias due to missing data



## Missing outcome data

**Authors' judgement**

**Support for judgement**

Some concerns

Overall: 16% of people dropped out. Similar numbers from both groups. Reasons for dropping out for some participants were duration of intervention, but some reasons were unrelated. There was no analysis to assess the effect of missing data

**SQ 3.1** Were outcome data available for all or nearly all participants?

**SQ 3.2** If not were there evidence that result is not biased by missing data?

**SQ 3.3** Could missingness in the outcome depend on its true value?

**SQ 3.4** Is it likely that missingness depended on its true value?

**SQ 3.1** 16% of participants lost to follow-up.

**SQ 3.2** No analysis to assess effects of missing data.

**SQ 3.3** Reasons for missing data provided and some were related to the outcome.

**SQ 3.4** It is unlikely that missingness depended on the true value

**Judgement** "Some concerns"



Measurement of the outcome	
Authors' judgement	Support for judgement
High	Outcome assessors were not blinded

Domain 4 Simple statement about blinding without describing if result being assessed is likely to be affected by blinding

Authors judge this to be  
“High” risk of bias  
But it could be “Low”  
or  
“Some concerns”

## 4. Bias due to outcome measurement



Measurement of the outcome	
Authors' judgement	Support for judgement
High	Outcome assessors were not blinded

**SQ 4.1 Was the method of measuring the outcome inappropriate?**

**SQ 4.2 Were measurements similar between groups?**

**SQ 4.3 Were outcome assessors blinded?**

**SQ 4.4 Could the outcome assessment be affected by knowing the assignment?**

**SQ 4.5 Do you the reviewers think this is likely?**

#### **4. Bias due to outcome measurement**



## Measurement of the outcome

### Authors' judgement

### Support for judgement

Some concerns



Measurement was appropriate



Measurements were similar across all intervention groups.



There is no information in whether the outcome assessors were blinded.



Outcome assessors, through encouragement during testing, could affect the outcome, therefore we have some concerns about potential bias.

SQ 4.1 Was the method of measuring the outcome inappropriate?

SQ 4.2 Were measurements similar between groups?

SQ 4.3 Were outcome assessors blinded?

SQ 4.4 Could the outcome assessment be affected by knowing the assignment?

SQ 4.5 Do you the reviewers think this is likely?

Selection of the reported results	
Authors' judgement	Support for judgement
High	No statistical analysis plan

Domain 5 Reliance on availability of *statistical analysis plan*.

- published protocol
- trial register entry
- lists of planned outcomes/ time points
- clinical judgement

SQ 5.1 Data analysed according to statistical analysis plan?

Is the numerical result likely chosen from:

SQ 5.2 multiple eligible outcomes? (scales, timepoints, definitions)

“Q 5.3 multiple eligible analyses of the data

# Disagreeing with the Algorithm

RoB 2 assessment for individual randomized, parallel group trials

Assessment ID  Assessor

Study ID  Ref. or label

Experimental  Comparator

Specify which outcome  Specify the numerical result

Is the review team's aim for this result to assess...?  Weight for analysis

If the aim is to assess the effect of adhering to intervention...(select one at least)

- occurrence of non-protocol interventions
- failures in implementing the intervention that could have affected the outcome
- non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s)
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER, Research Councils UK Gateway to R)
- Personal communication with trialist

Domain 1 | Domain 2 | Domain 3 | Domain 4 | Domain 5 | Overall bias

### Randomisation process

Signalling	Respons	Description
1.1 Was the allocation sequence random?	<input type="text" value="PY"/>	Quote: "...randomized to two groups." Comments: method of random sequence generation was not described. Comment: allocation concealment was not described.
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	<input type="text" value="NI"/>	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	<input type="text" value="PN"/>	Baseline values did not indicate a problem with randomisationNeither the method of generating the randomisation sequence, or allocation concealment were described.

**Risk of bias judgement**

Algorithm result  Assessor's judgement

Quote: "...randomized to two groups."  
Comments: method of random sequence generation was not described.  
Comment: allDouble click on this column to create the support for judgement for this risk of bias domain from descriptions  
Baseline values did not indicate a problem with randomisationNeither the method of generating the randomisation sequence, or allocation concealment were described.

Optional: What is the predicted direction of bias arising from the randomization process?

Guidance (Internet access)

# Disagreeing with the Algorithm

	1.3	Note for 1.3	1.0 Algorithm result	1.0 Assessor's Judgement	1.0 General note	1.0 Overall
Method of randomization	PN	Baseline values did not differ between groups	Some concerns	Some concerns	"...randomized to two groups."	
Participants were blinded	WY	There were no issues	Low	Low	Quote: "80 participants were blinded."	
Participants were blinded	PN	The allocation ratio was 1:1	High	High	Quote: "Nurses (N=132) were blinded to group allocation."	
Participants were blinded	PN	There were no issues	High	High	Quote: "...participants were blinded to group allocation."	
Participants were blinded	WY	There were no issues	Low	Low	Quote: "... participants were blinded to group allocation."	
Participants were blinded	N	The baseline differed between groups	Low	Low	Quote: "Participants were blinded to group allocation."	
Participant was blinded	N	There were no issues	Some concerns	Some concerns	Quote: "Each participant was blinded to group allocation."	
Randomized controlled trial	N	There were no issues	Low	Low	Quote: "A randomized controlled trial was conducted."	

	Note for 2.6	2.7	Note for 2.7	2.0 Algorithm result	2.0 Assessor's Judgement	2.0 Overall
Blinding of participants and personnel				Low	Low	
Blinding of participants and personnel	NA			Low	Low	
Blinding of participants and personnel	An appropriate randomization sequence was used			High	High	
Blinding of participants and personnel	The analysis was based on the intention-to-treat principle			Low	Low	
Blinding of participants and personnel	The analysis was based on the intention-to-treat principle			Low	Low	
Blinding of participants and personnel	ANOVA was used for continuous data			Low	Low	
Blinding of participants and personnel	ANOVA was used for continuous data			Low	Low	
Blinding of participants and personnel	ANOVA was used for continuous data			Low	Low	
Blinding of participants and personnel	Analysis was based on the intention-to-treat principle			Low	Low	





Study	Bias					Overall
	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	
<b>Subgroup 1.1.1 Exercise training</b>						
Therrien 2003						
<p>No information on method of randomisation and significant baseline imbalance between groups. There is a 8 year age gap – the intervention group are younger and age of repair was younger. Right ventricular outflow tract (11 vs 22 mmhg) were half in the intervention group. Daily activity levels were less in the intervention group. This may suggest a problem with randomisation.</p> <p>Both participants and those delivering the intervention were aware of intervention received but there were no deviations from intended interventions and the analysis was appropriate.</p> <p>17 of 18 participants (95%) were included at follow up. One person lost from the control group due to a lack of interest.</p>						
Moalla 2006						
<p>There was no information on method of randomisation, there was no baseline imbalance that would suggest a problem with randomisation.</p>						
Madhavi 2011						
Winter 2012						
Westhoff-Bleck 2013						

# Results-level tables

Study	Bias											
	Randomisation process		Deviations from intended interventions		Missing outcome data		Measurement of the outcome		Selection of the reported results		Overall	
	Authors' judgement	Support for judgement	Authors' judgement	Support for judgement	Authors' judgement	Support for judgement	Authors' judgement	Support for judgement	Authors' judgement	Support for judgement	Authors' judgement	Support for judgement
Zhōu2003	High risk of bias	Only mentions randomisation with no explanation. Intervention group were younger at baseline and at age of surgery repair, (P<0.1).	High risk of bias	Cannot blind an exercise intervention	Low risk of bias	All outcome data was presented	Some concerns	If the person running the exercise test was not blinded to condition, they could have given more encouragement to the participant in an intervention group. Gas analysis and appropriate protocol on cycle ergometer.	Some concerns		Some-Concerns	
Perera 2006		No information on randomisation. No baseline differences.	High risk of bias	Participants, carers, and			Some concerns	No information on if outcome assessors were aware of assigned intervention, this may bias how the CPET was conducted and/or analysed.	No pre planned statistical plan			Overall due to a lack of detail on randomisation and the blinding outcome assessors
Lambert 2011	High risk of bias	Large baseline differences in peak VO2. Possibly no/no information attempt to conceal randomisation.	Some concerns	group or control group..	Low risk of bias	111 people in an exercise intervention.	High	YMCA cycle test. This is a predictive test not a direct assessment furthermore no description of direct assessment.	Some concerns	No protocol and or statistical plan released prior to study	High risk of bias	Overall due to a lack of blinding outcome assessors, registration, differences at baseline between groups and the high effect size seen.
Gomez 2012	Low risk of bias	Randomisation was performed using sealed envelopes. Each participant chose an opaque envelop from a shuffled stack.	Low risk of bias	You cannot blind an exercise intervention.	Low risk of bias	80% of patients remained at the end of the study. 6 Lost to follow up in each group. Intention to treat analysis	Some concerns	No information on if outcome assessors were blinded to intervention status.	Some concerns	Protocol registered but no statistical plan available.	Some concerns	Overall judged some concerns due to the potential lack of blinding and pre published statist
Touré 2013	Some concerns	No information on method of randomisation other than a 1:1 ratio. Baseline differences are balanced and non-significant (except Creatinine).	Low risk of bias	Cannot blind an exercise intervention	Low risk of bias	16% lost to follow up, intention to treat.	High	Outcome assessors were not blinded	Some concerns	Protocol registered. Not enough information in the protocol on a priori statistical plan and no published statistical plan found.	Some concerns	Overall, some concerns due to the potential lack of blinding, pre published statistical plan and lack of information on randomisation

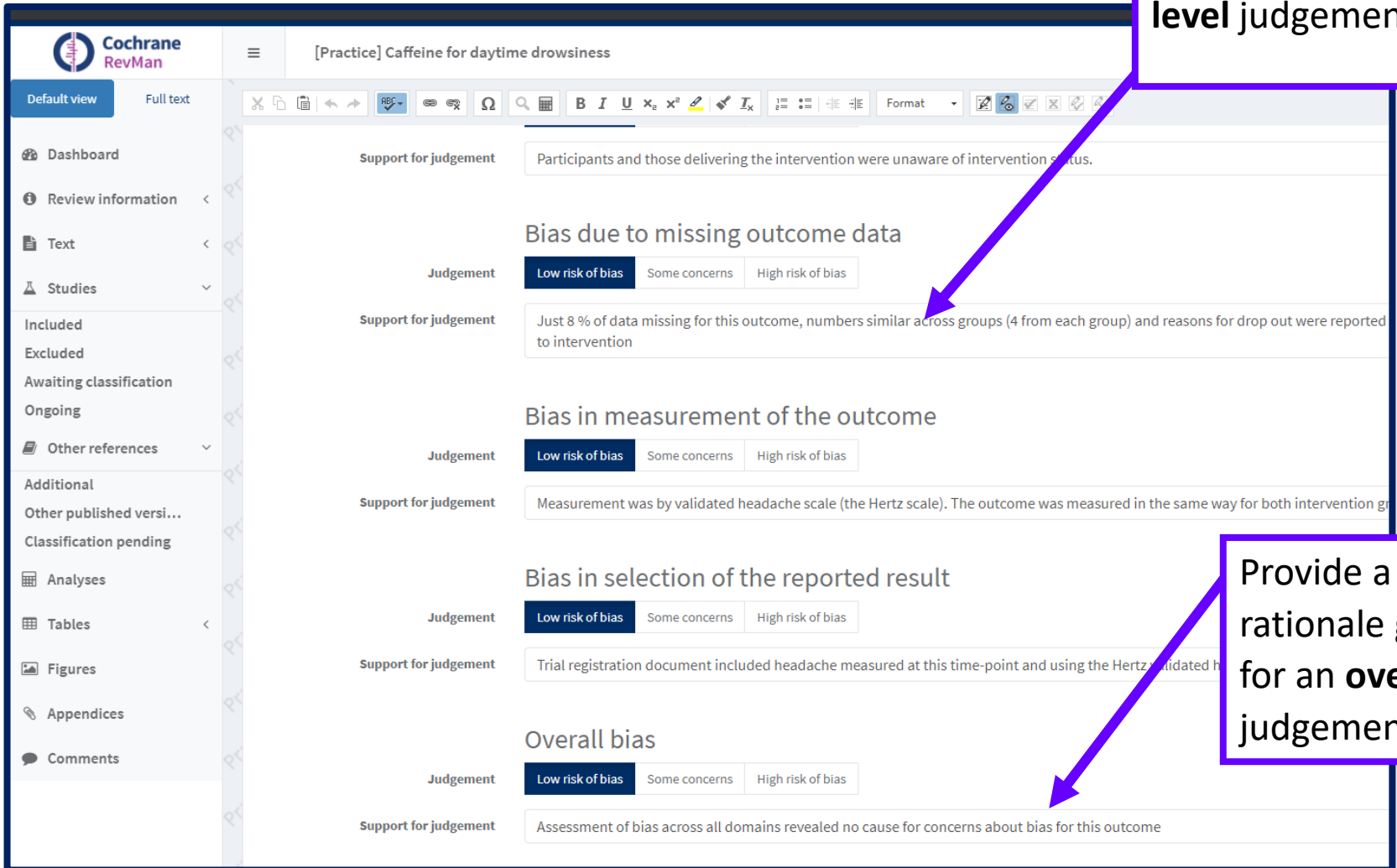
No rationale given for a **domain-level** judgement

No rationale given for an **overall** judgement

No judgement

# Results-level tables

Provide rationale for a **domain-level** judgement



The screenshot displays the Cochrane RevMan interface for a practice review titled "[Practice] Caffeine for daytime drowsiness". The left sidebar shows navigation options: Dashboard, Review information, Text, Studies, Included, Excluded, Awaiting classification, Ongoing, Other references, Additional, Other published versions, Classification pending, Analyses, Tables, Figures, Appendices, and Comments. The main content area shows a table of results-level judgements for various bias domains. Each domain includes a "Support for judgement" text box and a "Judgement" button set with three options: "Low risk of bias", "Some concerns", and "High risk of bias".

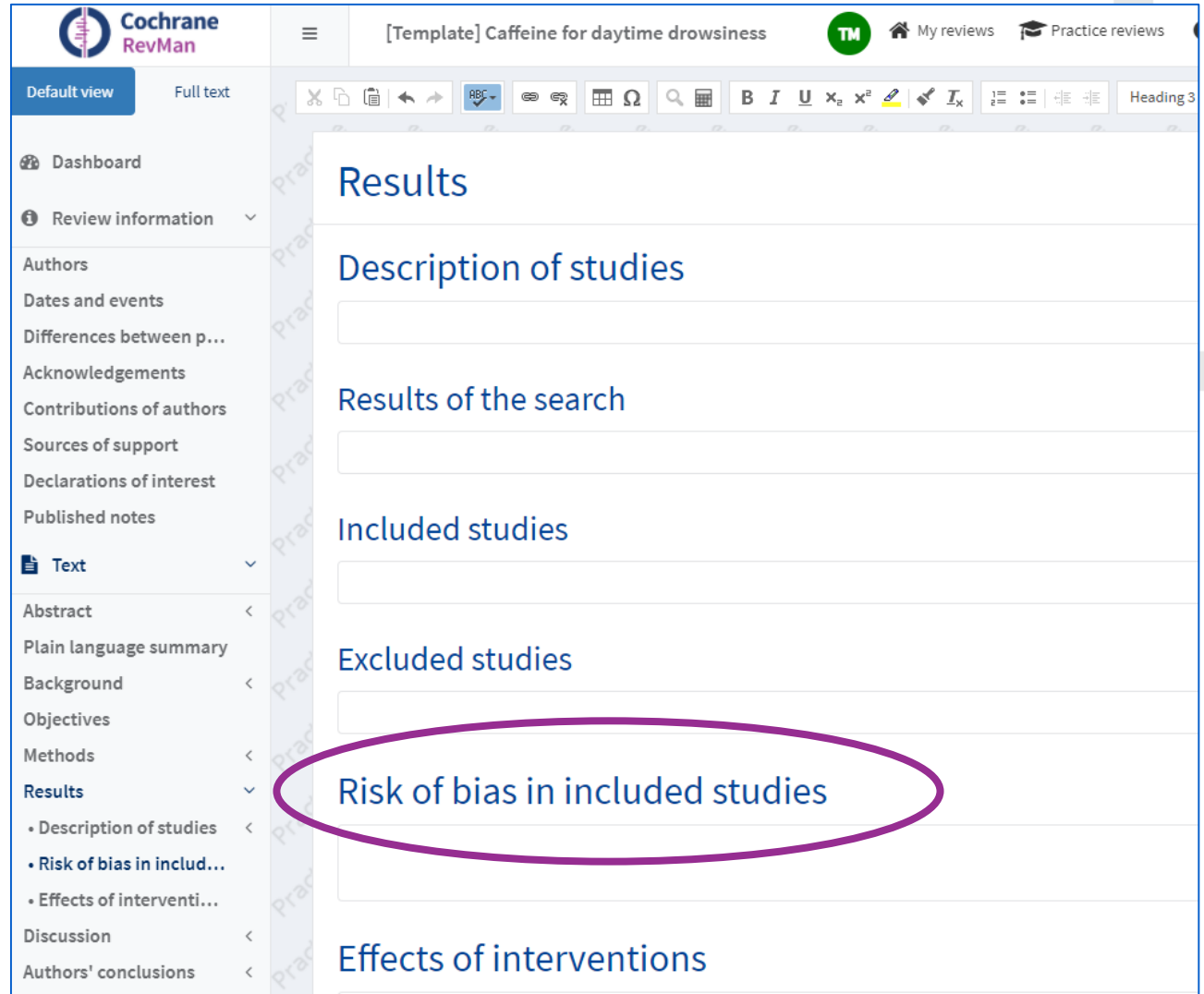
Bias Domain	Support for judgement	Judgement
Support for judgement	Participants and those delivering the intervention were unaware of intervention status.	Low risk of bias
Bias due to missing outcome data	Just 8 % of data missing for this outcome, numbers similar across groups (4 from each group) and reasons for drop out were reported to intervention	Low risk of bias
Bias in measurement of the outcome	Measurement was by validated headache scale (the Hertz scale). The outcome was measured in the same way for both intervention groups	Low risk of bias
Bias in selection of the reported result	Trial registration document included headache measured at this time-point and using the Hertz validated headache scale	Low risk of bias
Overall bias	Assessment of bias across all domains revealed no cause for concerns about bias for this outcome	Low risk of bias

Provide a rationale given for an **overall** judgement

Section: Results

Subsection : Risk  
of bias

Overview of bias -  
across the studies –  
for each outcome



The screenshot displays the Cochrane RevMan interface for a review titled "[Template] Caffeine for daytime drowsiness". The left sidebar shows a navigation menu with the following items: Dashboard, Review information, Authors, Dates and events, Differences between p..., Acknowledgements, Contributions of authors, Sources of support, Declarations of interest, Published notes, Text (selected), Abstract, Plain language summary, Background, Objectives, Methods, Results (expanded), Discussion, and Authors' conclusions. The main content area shows a list of sections for the 'Results' section: Results, Description of studies, Results of the search, Included studies, Excluded studies, Risk of bias in included studies (circled in purple), and Effects of interventions. The 'Risk of bias in included studies' section is highlighted with a purple oval.



## Study level / Outcome level

### Risk of bias

Some concerns in relation to selection bias were identified in all five studies (Adeley 2016, Garcia 2020, Meaden 2012, Osborne 2018, Victor 2019). Although all five **studies** reported that the interventions were 'randomly' allocated, the methods for generating the randomisation sequence was missing from four **studies** (Adeley 2016, Garcia 2020, Meaden 2012, Osborne 2018). ....



## Study level / Outcome level

### Risk of bias

The results for all **studies** were mostly assessed at “Low” risk of bias for the domain “Bias in relation to measurement of the outcome” except for the **outcomes : HRqoL** where five of the seven studies (Axiom 2016, Fretof 2020, Meerain 2012, Orford 2018, van Dieter 2019), and **Pain** (the same five **studies**) were judged to be at “some concerns” for bias because the intervention could not be blinded and the **outcome measures** were subjective and may have been affected by knowledge of the outcome.

Wadey ey al 2020

<https://doi.org/10.1002/14651858.CD013400.pub2>

# Common errors list 1

**Assessment of bias - In the Excel, word or online tool:**

1. State the result
2. For each domain:
  - a) Answer all SQs
  - b) Provide a rationale for all answers to all SQ
  - c) Use the algorithm for deciding your judgement
  - d) Provide a support for DOMAIN-level judgement - based on SQ answers
3. Overall:
  - a) Provide support for the OVERALL- bias

**In the summary results level tables (Risk of bias entry for RevMan Web)**

4. Complete all cells of the tables (all support for judgement statements)

**Text in the review**

8. Report at the results-level rather than at the study-level
9. Provide a broad summary of the patterns of bias you see across the results, rather than an exhaustive list.



# Webclinics

methods.cochrane.org/about/methods-support-unit/methods-support-unit-web-clinic-schedule



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## Methods Support Unit Web Clinic Schedule

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- ◆ Methods Executive
- ◆ Scientific Committee
- ◆ Methodology Review Group
- ◆ Cochrane Central Executive Methods Team
- ◆ Methods Support Unit
  - ◆ Process for managing requests for support from Methods Support Unit
  - ◆ Information required by Methods Support Unit
  - ◆ Methods Support Unit Web Clinic Schedule
  - ◆ RoB 2 Methods Support Unit Web Clinic Webform



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