Common errors in RoB 2

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Common errors for RoB 2 in Cochrane reviews

Where are we seeing common errors?

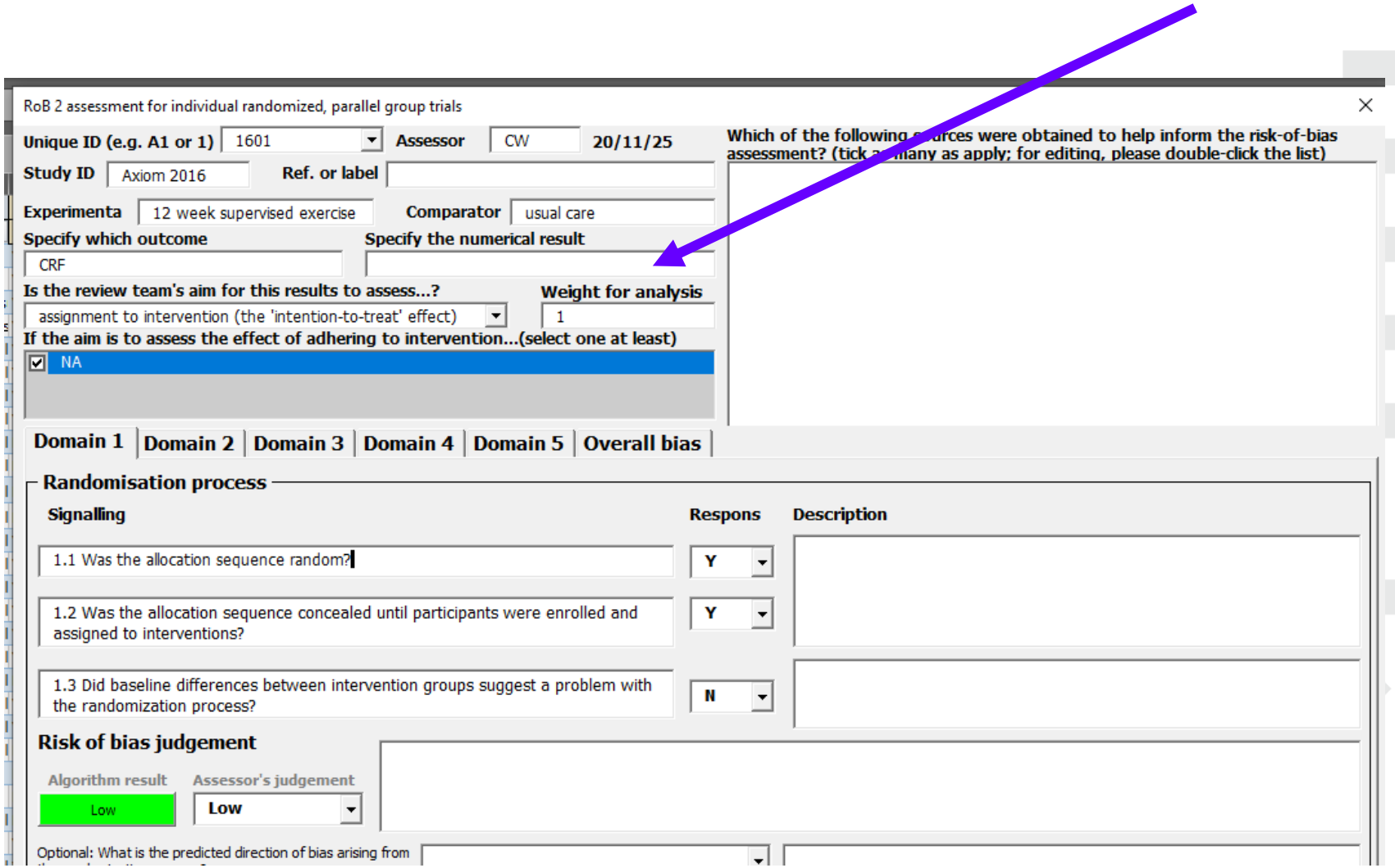
In the RoB 2 data file

- 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



The bias assessments in Excel

Basic information					
Study ID	Refe	Experime	Comparat	Outcome	Results
Axiom 2016		12 week sup	usual care	CRF	
Drees 2014		12 week sup	usual care	HRQofL	SF-36 and TACQOF-CF
Drees 2014		12 week sup	usual care	Physical activity	
Dulverton 2015		12 week sup	usual care	CRF	
Fretof 2020		Inspiratory r	no exercise c	CRF	
Klein 2016		Text interven	no exercise	CRF	
Klein 2016		Text based ir	no exercise	Physical activity	
Madabar 2011		Hospital Exe	Usual care	CRF	
Meerain 2012		Exercise	No exercise	Strength	MVC
Meerain 2012		Exercise	No exercise	CRF	

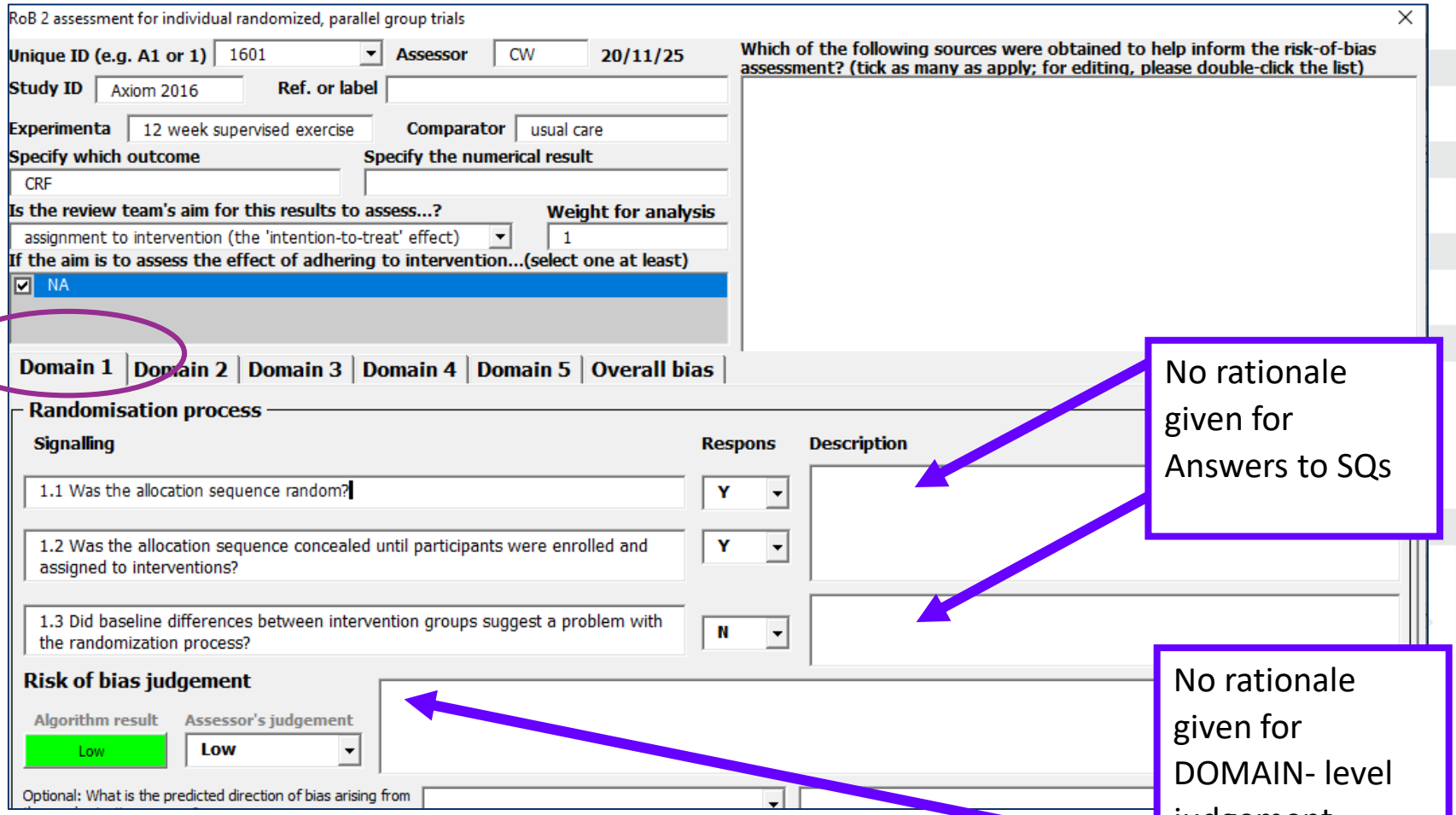
Numerical result empty

Incorrect data

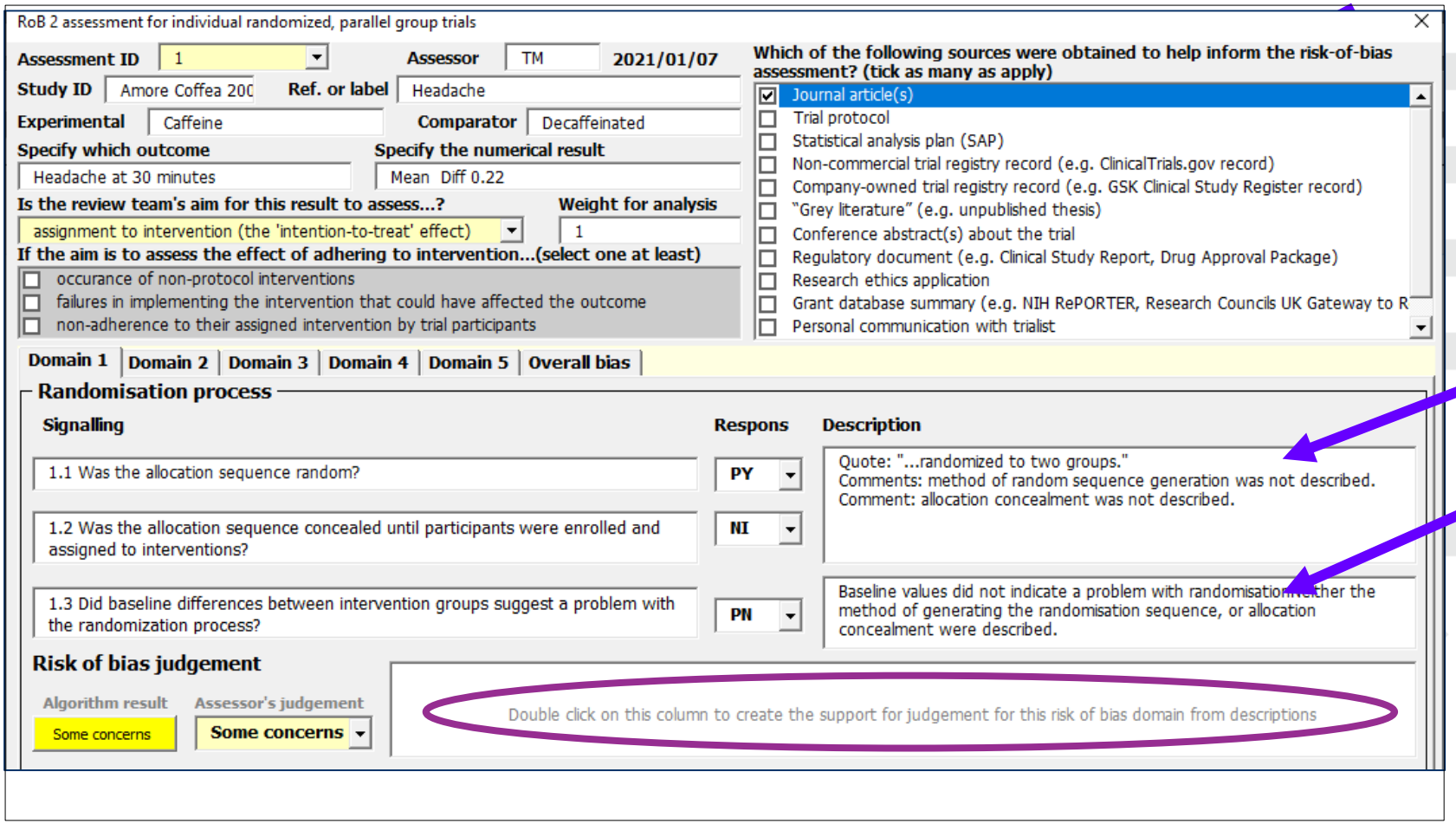
Basic information					
Study ID	Reference	Experimental	Comparator	Outcome	Results
Amore Coff	Headache	Caffeine	Decaffeinated	Headache at 30 minu	Mean Diff 0.22
Deliciozza 2	Headache	Caffeinated	Decaffeinated	Headache at 30 minu	Mean diff 1.11
Kahave Par	Headache	Caffeinated	Decaffeinated	Headache at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

Column is filled in

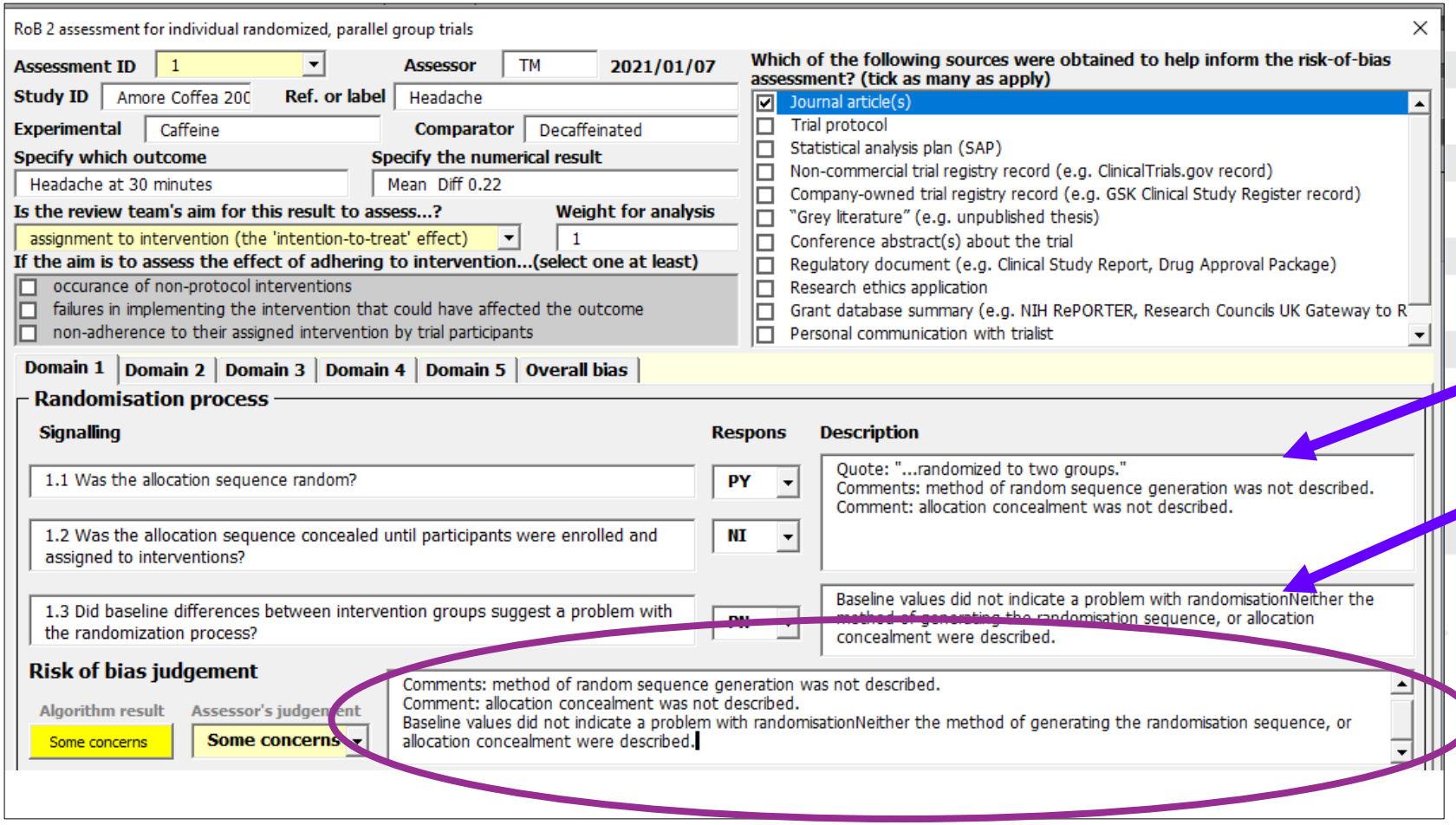
The bias assessments in Excel



The bias assessments in Excel



The bias assessments in Excel



Cochrane Training

The bias assessments in Excel

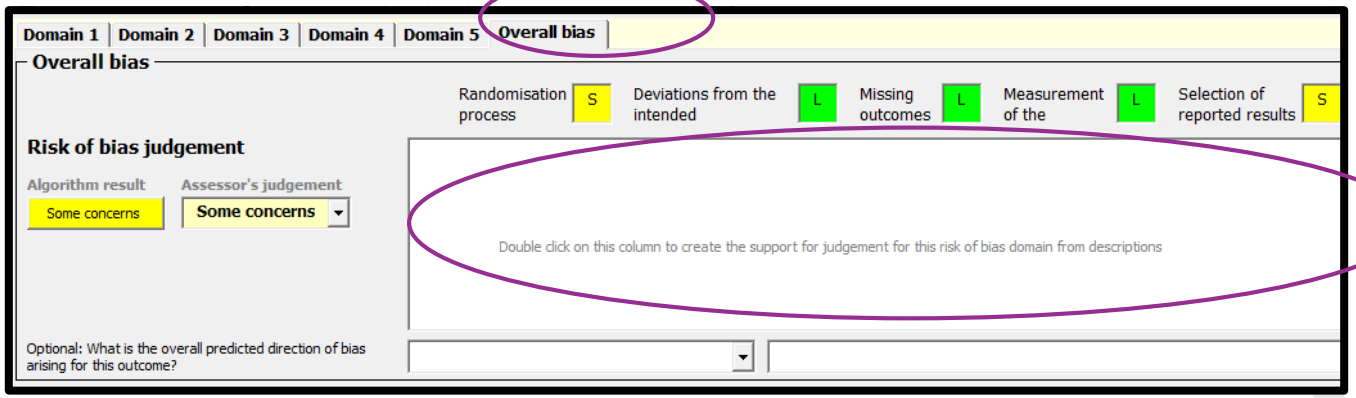
4.1	Note for 4.1	4.2	Note for 4.2	4.3	Note for 4	4.4	Note for 4	4.5	4.0 Algorithm	4.0 Assessor's Jud
N		N		NI		PY	If the person	PN	Some concerns	Some concerns
N	Validated questic	N		Y		PY	Can't blind ex	PY	High	Some concerns
PN	Leisure-Time Spe	N		Y		PY	Cannot blind	PY	High	Some concerns
N		N		NI		PY		PN	Some concerns	Some concerns
N		PN		PY		PY		PN	Some concerns	Some concerns
N		PN		PN	Finally, the bl	NA		NA		Low
N		PN		PN	statistician	NA		NA	Low	
PY	YMCA cycle test. T	PN		NA		NA		NA	High	Hig
N		N		NI		PN	MVC is obje	NA	Low	Low
N		PN		NI		PY		PN	Some concerns	Son
PN	Not direct gas an	PN		NI		PY	If the person	PN	Some concerns	Son
N	Measuring activi	PN		NI		PN	Both groups r	NA	Low	Low
N		N		NI		PY	If the person	PN	Some concerns	Son
N		N		NI		PY		PY	High	Hig
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

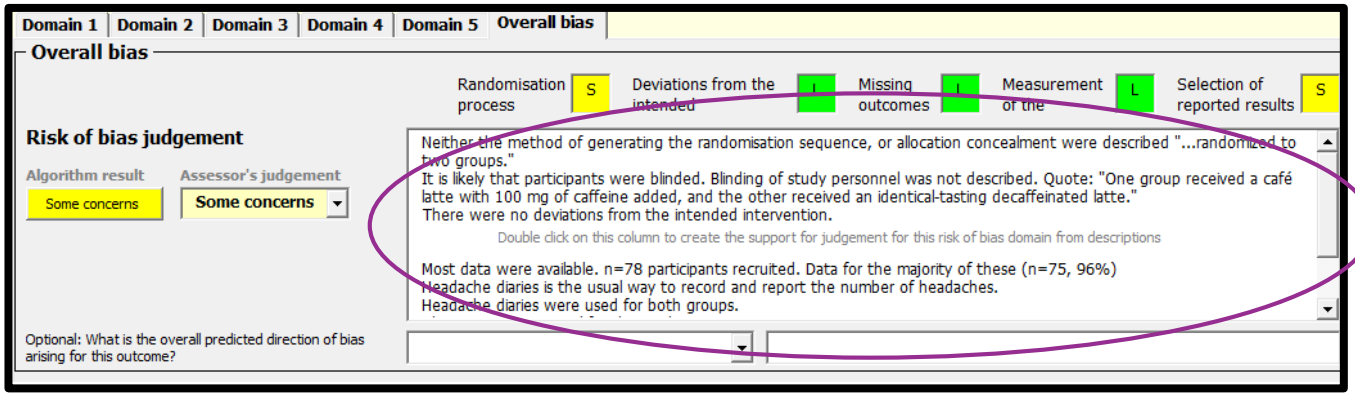
Empty cells for many Signalling questions

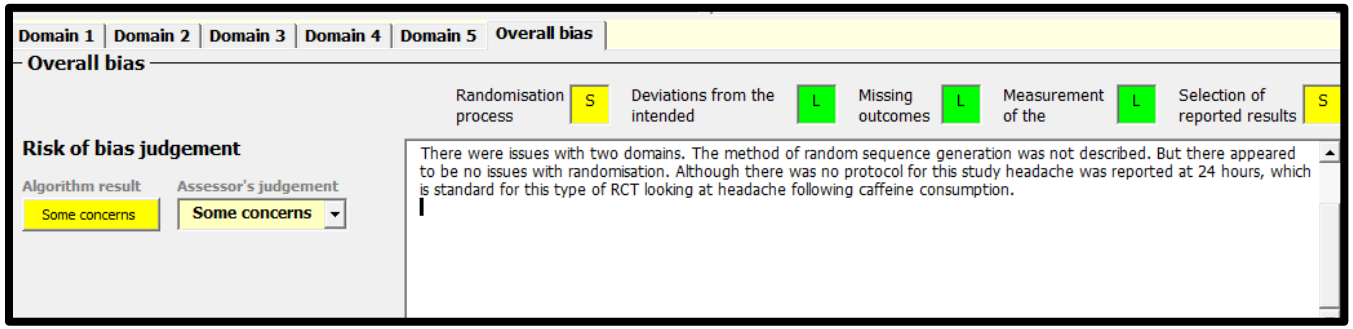
	Domain 4. Measurement of the outcome									
	4.1	Note for 4.1	4.2	Note for 4.2	4.3	Note for 4.3	4.4	Note for 4.4&4.5	4.5	4.0 Algorithm resul	4.0 Assessor
	N	Headache diari	N	Headache diaries	PN	Outcome asse	NA		NA	Low	Low
	N	Headache was	N	All participants wer	NI	The outcome v	PY	Assessment o	NI	High	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 outcomne v	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 outcomne v	N	The outcome	PN	Headache is s	NA		NA	Low	Low
	N	The outcomne v	N	The outcome was	PN	Headache is s	NA		NA	Low	Low

Answers provided

The bias assessments in Excel







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

Domain 1

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?

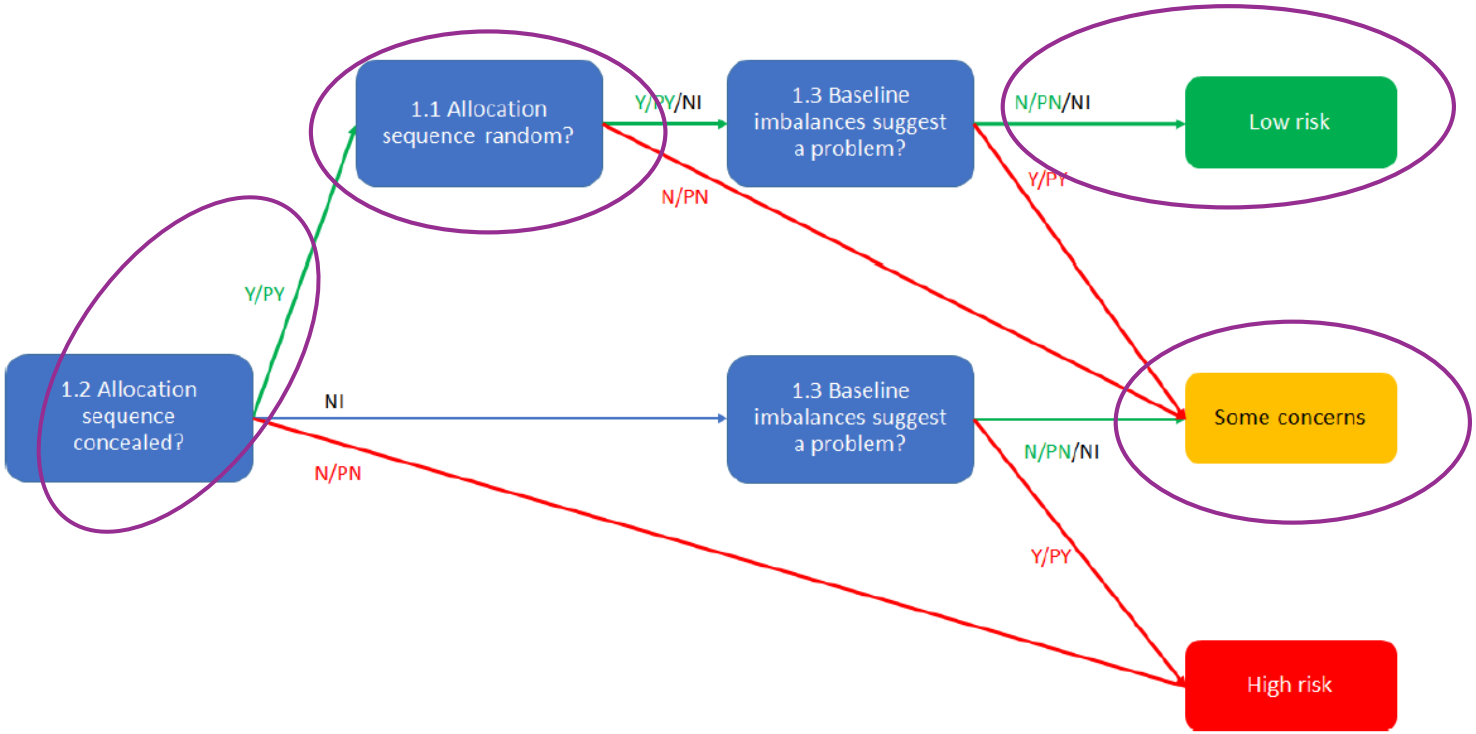
Alternative SQ 1.3 ?

Was there baseline imbalance?

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

1. Bias from randomisation process

Domain 1

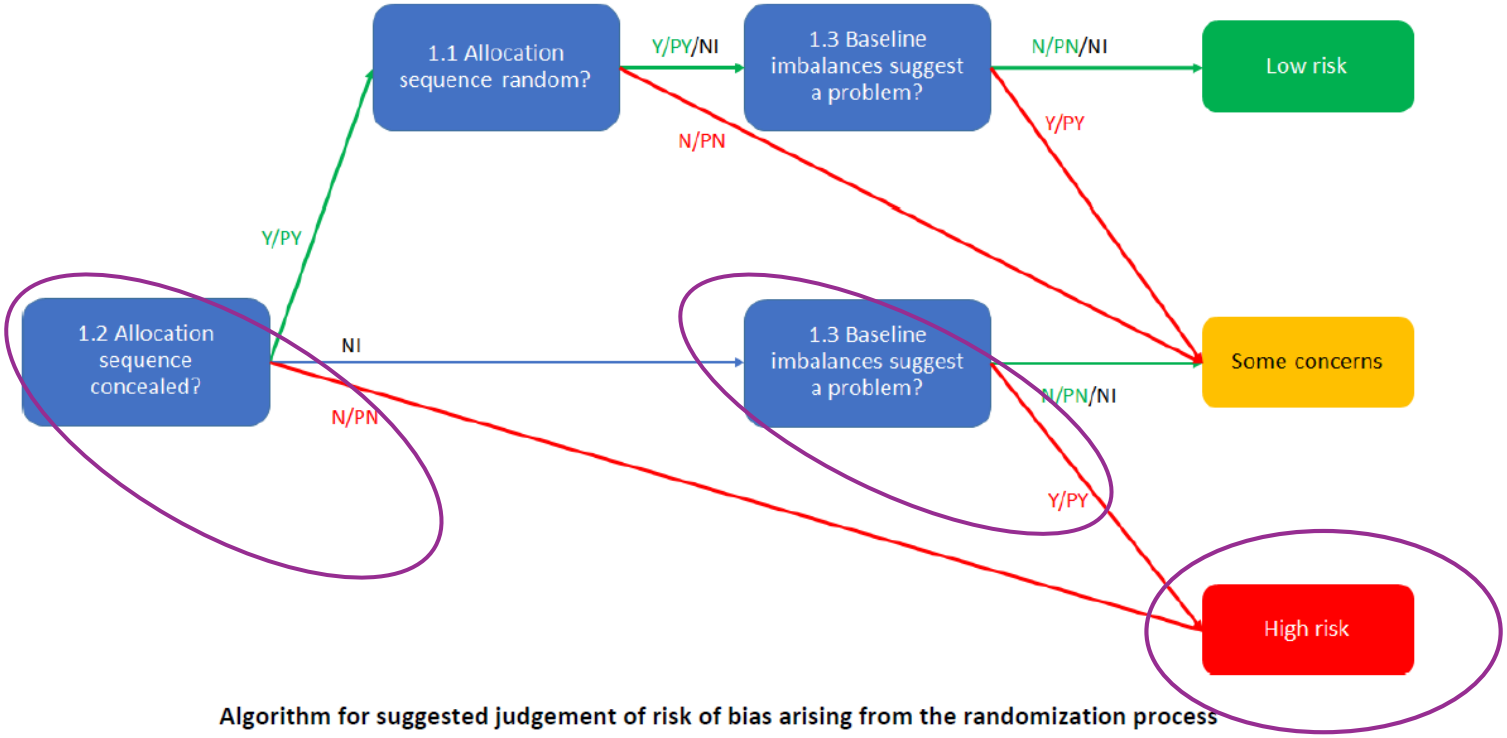


Algorithm for suggested judgement of risk of bias arising from the randomization process

1. Bias from randomisation process

Cochrane Training

Domain 1



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

1. Bias from randomisation process

Domain 2

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

Domain 2 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 algorithm proposed that it could be "Low" or "Some concerns" or "High"

2. Bias from deviation from intended intervention

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Domain 2

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 from deviation from intended intervention

Domain 2

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.

2. Bias from deviation from intended intervention

Domain 3

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

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Domain 3

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 missing ness depended on the true value

Judgement "Some concerns"

Domain 4

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

Domain 4

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

Domain 4

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?

From Williams & Wadey et al 2020

Domain 5

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

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

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

SQ 5.1 Data analysed according to statistical analysis plan?

Is the numerical result likely chosen from:

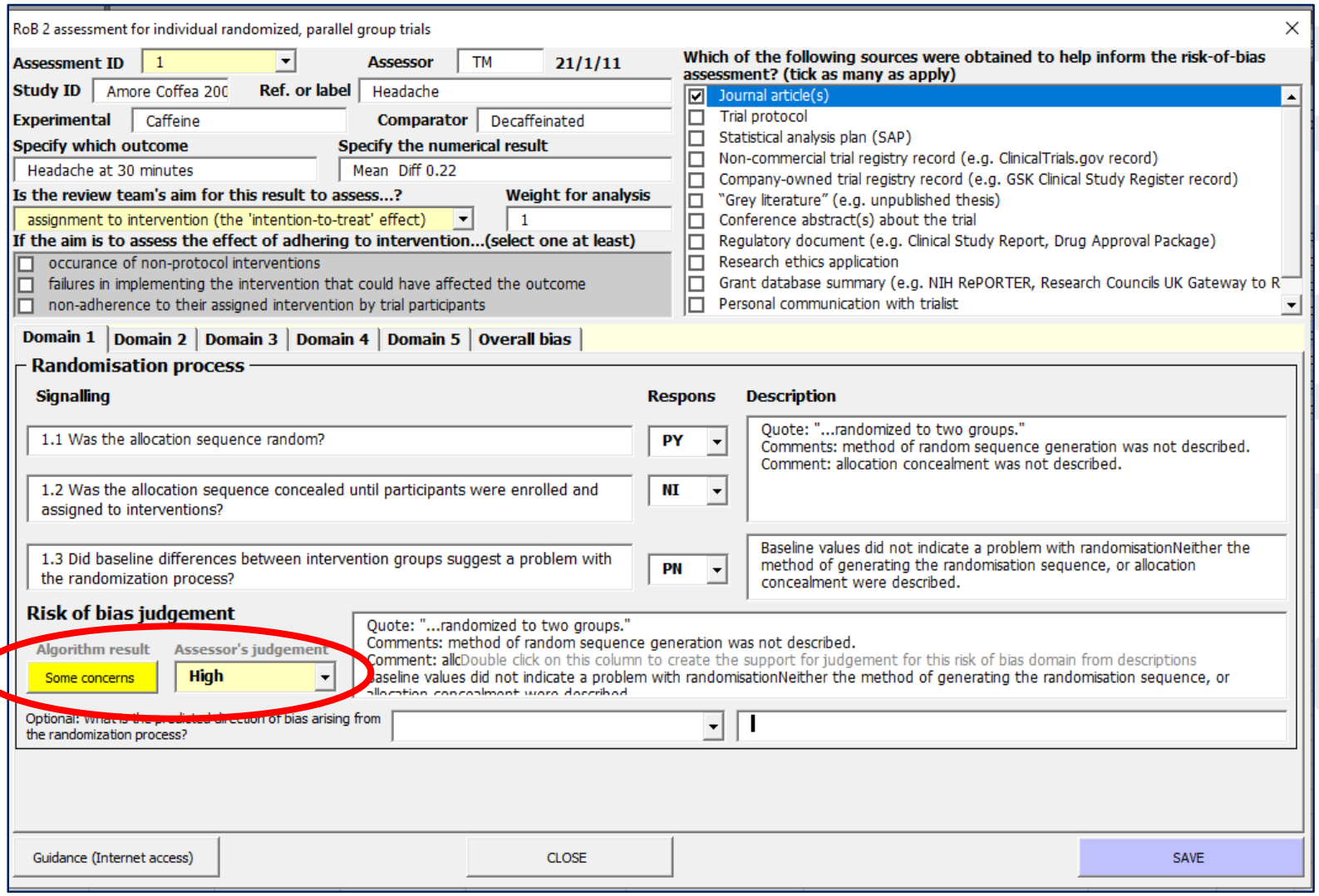
SQ 5.2 multiple eligible outcomes? (scales, timepoints, definitions)

"Q 5.3 multiple eligible analyses of the data

4. Bias due to selective outcome reporting

Cochrane Training

Disagreeing with the Algorithm

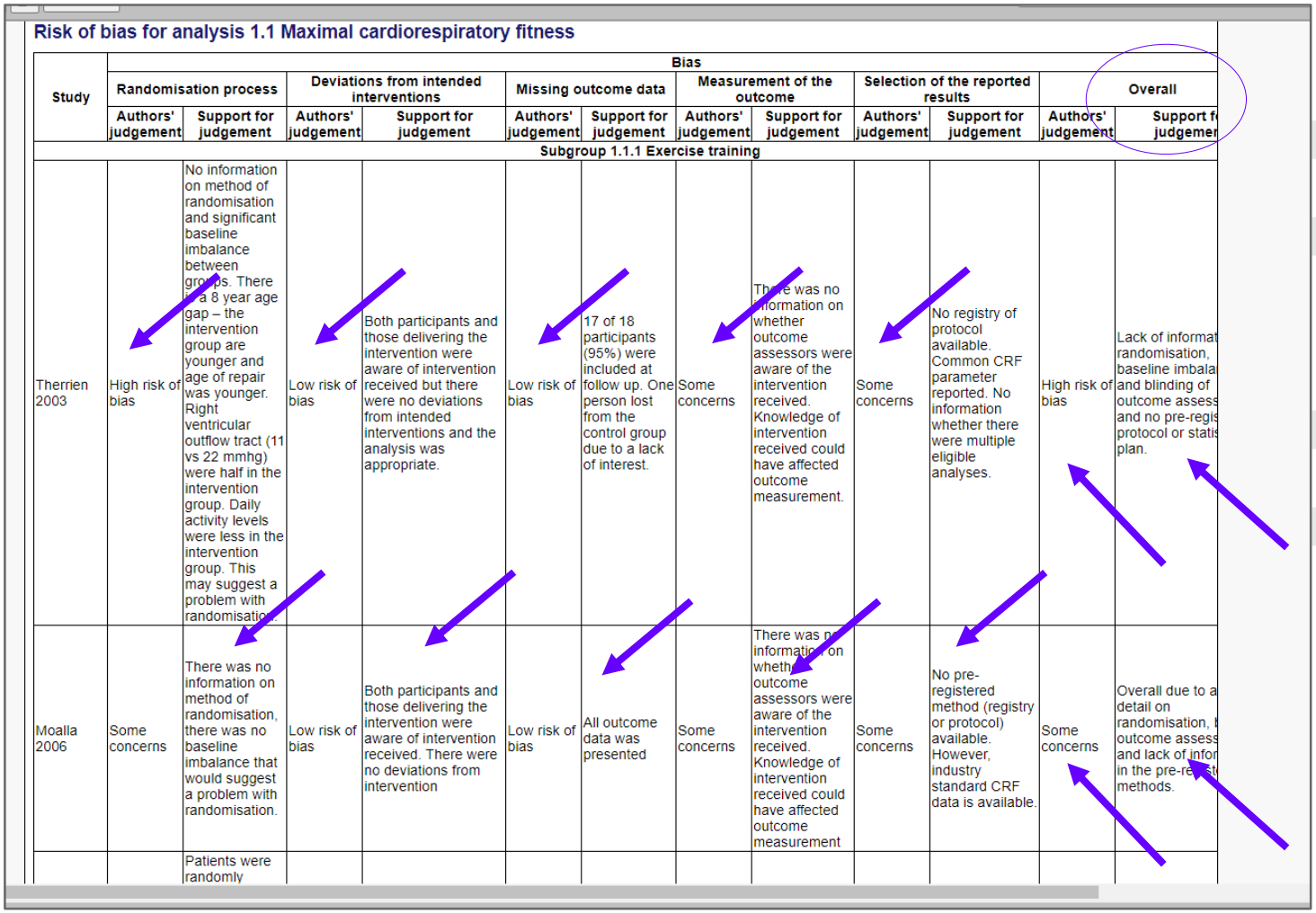


Disagreeing with the Algorithm

	1.3	Note for 1.3	1.0 Algorithm result	1.0 Assessor's Judgeme	1.0 General note	1.0 O
thod of	PN	Baseline values did	Some concerns	Some concerns	"...randomized to two groups."	
cipants we	N	There were no base	Low	Low	Quote: "80 participants	
(N=132) w	Y	The allocation ratio	High	High	Quote: "Nurses (N=132)	
pants borr	PN	Thre were no issues	High	High	Quote: "...participants b	
ipants wei	N	There were no base	Low	Low	Quote: "... participants	
ants were	N	The baseline differe	Low	Low	Quote: "Participants we	
rticipant w	N	There were no issue	Some concerns	Some concerns	Quote: "Each participan	
mized con	N	There were no issue	Low	Low	Quote: "A randomized c	

6	Note for 2.6	2.7	Note for 2.7	2.0 Algorithm result	2.0 Assessor's Judgeme	2.
		NA		Low	Low	th p
	An appropriate an	NA		High	High	B
	The analysis was	NA		Low	Low	O
	The analysis was	NA		Low	Low	O
	ANOVA was usec	NA		Low	Low	O
	ANOVA was usec	NA		Low	Low	O
	ANOVA was usec	NA		Low	Low	O
	Analysis was ANC	NA		Low	Low	O

Results-level tables



Risk of bias for analysis 1.1 Maximal cardiorespiratory fitness

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 f judgemer
Subgroup 1.1.1 Exercise training												
Therrien 2003	High risk of bias	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 randomisatio	Low risk of bias	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.	Low risk of bias	17 of 18 participants (95%) were included at follow up. One person lost from the control group due to a lack of interest.	Some concerns	There was no information on whether outcome assessors were aware of the intervention received. Knowledge of intervention received could have affected outcome measurement.	Some concerns	No registry of protocol available. Common CRF parameter reported. No information whether there were multiple eligible analyses.	High risk of bias	Lack of informat randomisation, baseline imbala and blinding of outcome assess and no pre-regis protocol or statis plan.
Moalla 2006	Some concerns	There was no information on method of randomisation, there was no baseline imbalance that would suggest a problem with randomisation.	Low risk of bias	Both participants and those delivering the intervention were aware of intervention received. There were no deviations from intervention	Low risk of bias	All outcome data was presented	Some concerns	There was n information on wheth outcome assessors were aware of the intervention received. Knowledge of intervention received could have affected outcome measurement	Some concerns	No pre-registered method (registry or protocol) available. However, industry standard CRF data is available.	Some concerns	Overall due to a detail on randomisation, outcome assess and lack of infor in the pre-re methods.
		Patients were randomly										

Results-level table in published review

Risk of bias for analysis 1.1 Maximal cardiorespiratory fitness

	Bias					
Study	**Randomisation process**	**Deviations from intended interventions**	**Missing outcome data**	**Measurement of the outcome**	**Selection of the reported results**	**Overall**
Subgroup 1.1.1 Exercise training						
Therrien 2003	✗	✓	✓	~	~	✗
	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.					
		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.				
			17 of 18 participants (95%) were included at follow up. One person lost from the control group due to a lack of interest.			
Moalla 2006	~	✓	✓	~	~	~
	There was no information on method of randomisation, there was no baseline imbalance that would suggest a problem with randomisation.					
Madhavi 2011	✗	~	✗	✗	~	✗
Winter 2012	~	✓	~	~	~	~
Westhoff-Bleck 2013	~	✓	~	~	~	~

From Williams & Wadey et al 2020

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
Zhõu2003	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			ns	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, re-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

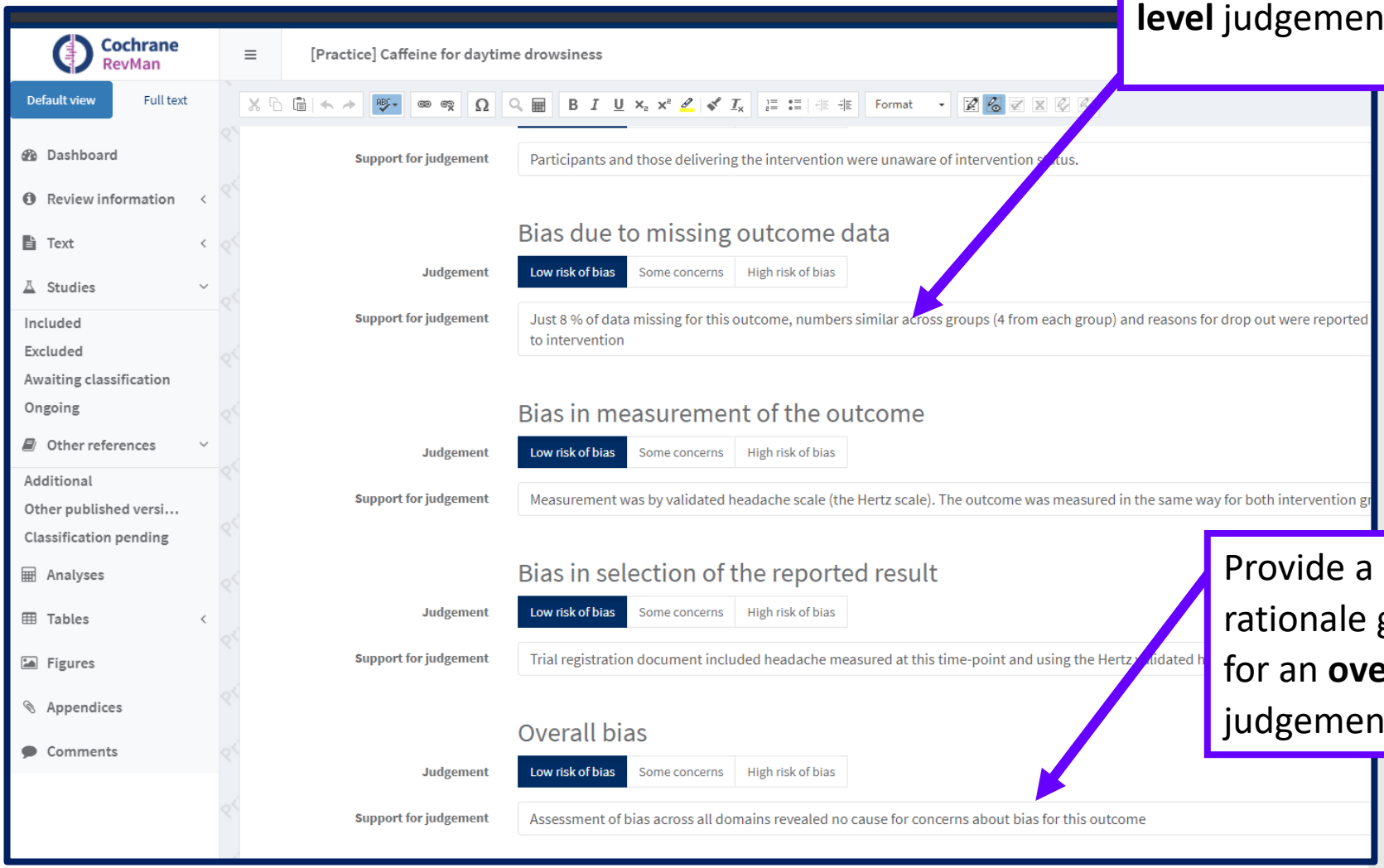
No rationale given for a **domain-level** judgement

No rationale given for an **overall** judgement

No judgement

Results-level tables

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



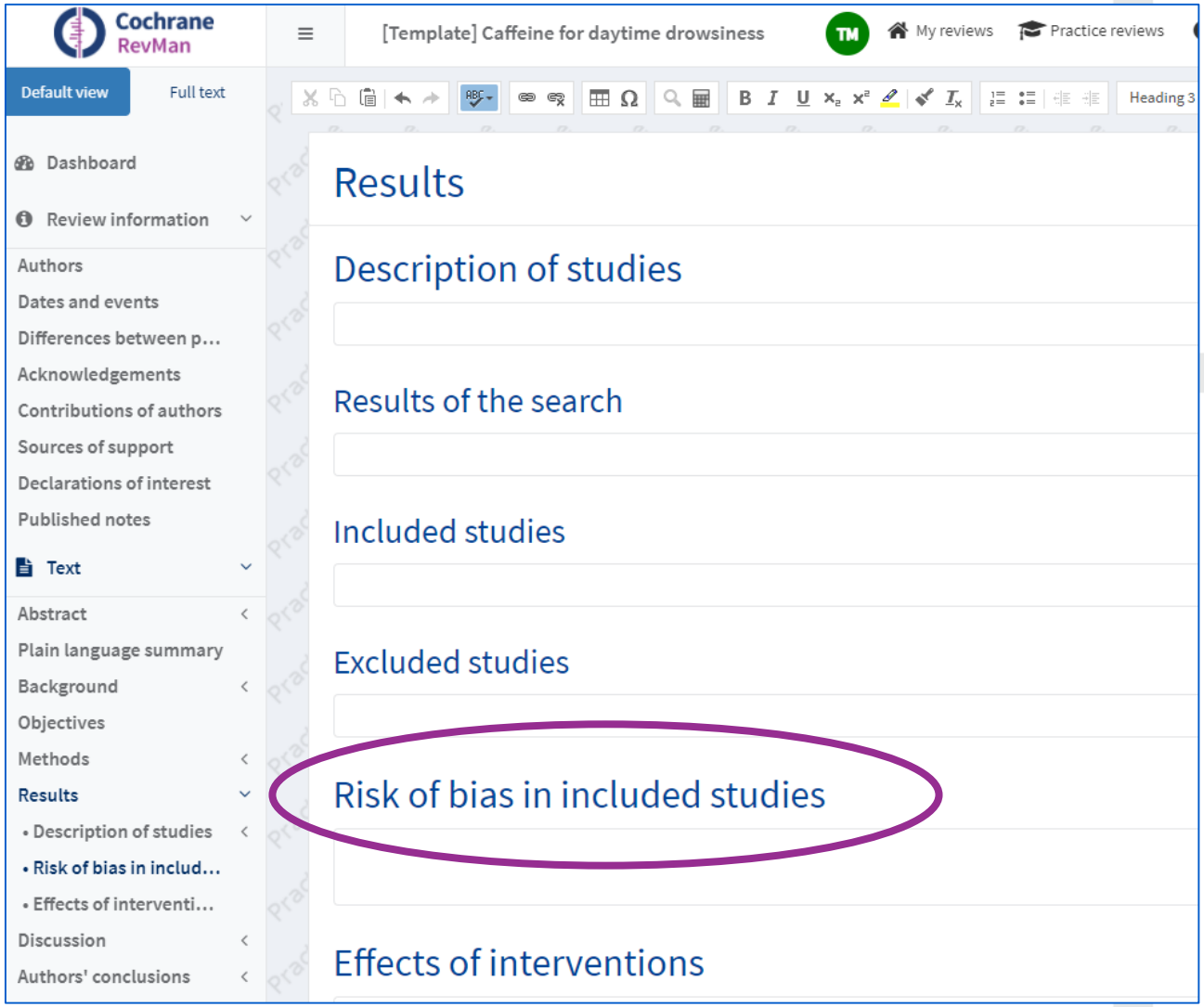
Provide a rationale given for an **overall** judgement

The text

Section: Results

Subsection : Risk of bias

Overview of bias - across the studies – for each outcome



The text

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). ….

The text

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

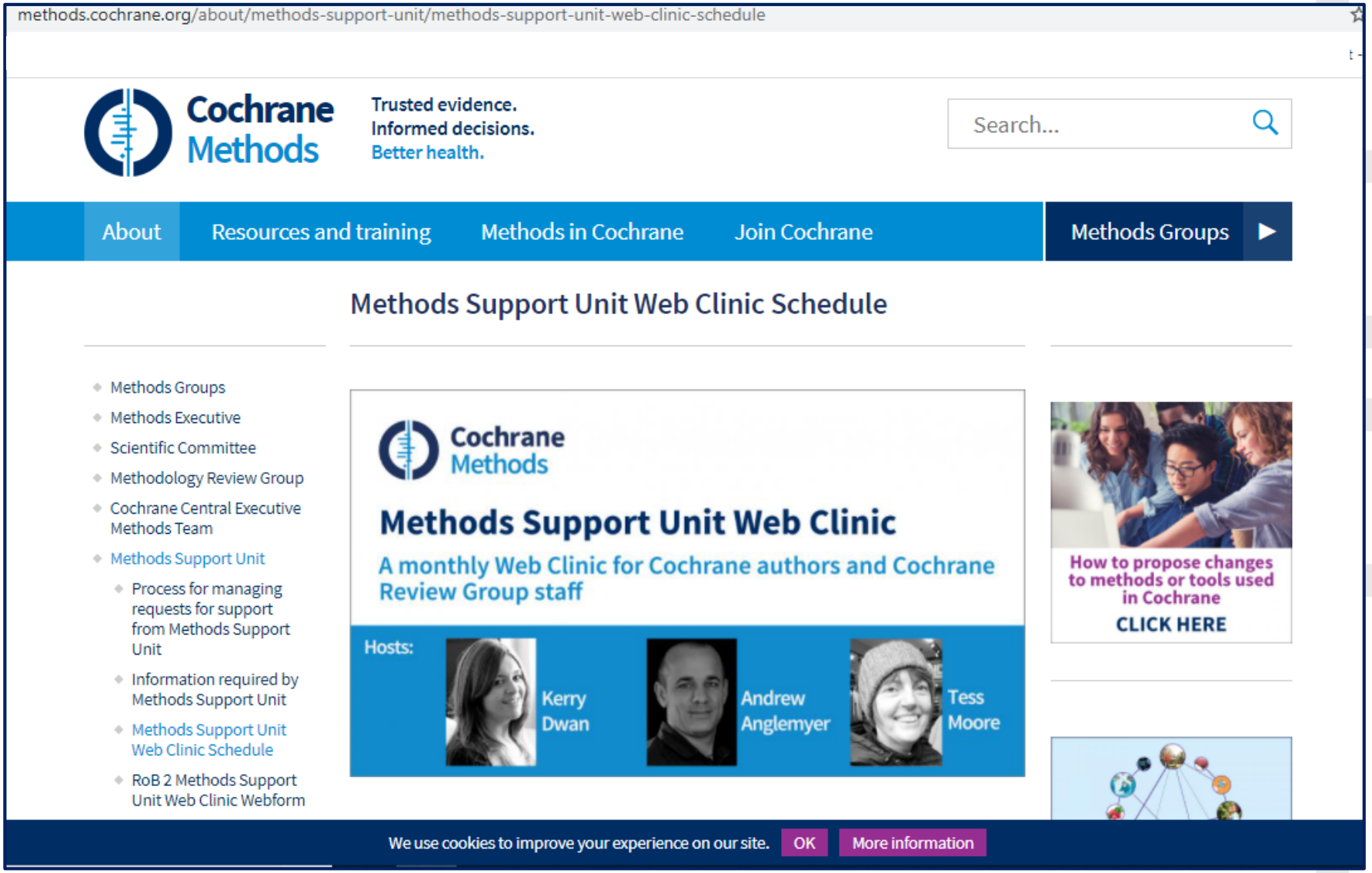
In the summary results level tables (Risk of bias entry for RevMan Web)

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
Cochrane Methods
Trusted evidence.
Informed decisions.
Better health.
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Resources and training
Methods in Cochrane
Join Cochrane
Methods Groups
Methods Support Unit Web Clinic Schedule
Methods Groups
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
Cochrane Methods
Methods Support Unit Web Clinic
A monthly Web Clinic for Cochrane authors and Cochrane Review Group staff
Hosts:
Kerry Dwan
Andrew Anglemyer
Tess Moore
How to propose changes to methods or tools used in Cochrane
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END

Questions