The Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) assessment tool

(version for cohort-type studies)

Version 19 September 2016

ROBINS-I tool (Stage I): At protocol stage

Commented [AC1]: For assignment 3 – this would be your PICO. For the group presentation, this would simply be the PICO outlined in the paper.

Specify the review question

Participants	Senior nurses in ICU conducting shift handover
Experimental intervention	Relocating handover to bedside and printed version of minimum data set. Supported by education, champions, reminders and audit with feedback.
Comparator	Pre-intervention usual practice
Outcomes	Number of interruptions in total and proportion of handovers that were interrupted (split by reason)

List the confounding domains relevant to all or most studies

Nurse

1. Nurses' experience with handover
2. Nurses' general work experience
3. Nurses' team leader experience
4. Nurses' communication style
5. Amount of information needed to be passed on

Environment

6. Workload at the time of handover
7. Patient complexity

List co-interventions that could be different between intervention groups and that could impact on outcomes

Better staffing mix

Other interventions to decrease interruptions in other aspects of work (i.e. medication administration)

ROBINS-I tool (Stage II): For each study

Specify a target randomized trial specific to the study

Design	Individually randomized / Cluster randomized / Matched (e.g. cross-over)
Participants	Senior nurses in ICU conducting shift handover
Experimental intervention	Relocating handover to bedside and printed version of minimum data set. Supported by education, champions, reminders and audit with feedback.
Comparator	Usual practice

Commented [AC2]: ICUs randomized to receive the intervention or not

Is your aim for this study…?

- ☐ to assess the effect of *assignment to* intervention
- ☐ to assess the effect of *starting and adhering to* intervention

Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

Number of interruptions

Specify the numerical result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Proportion of handovers interrupted (Table 1). RR calculated using this tool: https://www.medcalc.org/calc/relative_risk.php

Relative risk calculator

Exposed group

Number with positive (bad) outcome: 30 *a*

Number with negative (good) outcome: 40 *b*

Control group

Number with positive (bad) outcome: 28 *c*

Number with negative (good) outcome: 49 *d*

Results

Relative risk	1.1786
95% CI	0.7895 to 1.7593
z statistic	0.804
Significance level	P = 0.4215
NNT (Harm)	15.400
95% CI	4.489 (Harm) to ∞ to 10.762 (Benefit)

Preliminary consideration of confounders

Complete a row for each important confounding domain (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as potentially important.

"Important" confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the confounding variable or variables fully measure the domain, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

(i) Confounding domains listed in the review protocol				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information
Nurses' handover experience	Number of years receiving handover	No	No	No information
Workload on the unit	Complexity rating for each patient within the unit	No	No	No information

(ii) Additional confounding domains relevant to the setting of this particular study, or which the study authors identified as important				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information

* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that "no statistically significant association" is not the same as "not predictive".

Commented [AC3]: Confounding was not addressed by the authors

Preliminary consideration of co-interventions

Complete a row for each important co-intervention (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as important.

"Important" co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention.

(i) Co-interventions listed in the review protocol		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
Other interventions to reduce interruptions during other aspects of nursing work	No	No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

(ii) Additional co-interventions relevant to the setting of this particular study, or which the study authors identified as important		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

Commented [AC4]: None identified

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Signalling questions	Description	Response options
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	Although a 'random' selection of nurses were observed at each time-point, there was no information provided to assess the differences in participant characteristics between intervention and control periods.	Y / PY / PN / N
If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, go to question 1.3.	Design involved only two periods – control and intervention	NA / Y / PY / PN / N / NI
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)	N/A	NA / Y / PY / PN / N / NI

Questions relating to baseline confounding only		
1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	Analysis did not account for potential confounding. For example, the authors could have measured a 'experience' variable by asking participants how many years they had been performing the role of team leader and included that as a predictor variable in the analysis.	NA / Y / PY / PN / N / NI
1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	N/A	NA / Y / PY / PN / N / NI
1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	This would be variables influenced by the intervention itself – so maybe things like nurses' knowledge of the SBAR handover tool (because part of the intervention was education). Note: answering Yes to this question *increases* risk of bias.	NA / Y / PY / PN / N / NI
Questions relating to baseline and time-varying confounding		
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding?	N/A	NA / Y / PY / PN / N / NI
1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	N/A	NA / Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to confounding?	I recommend against these sorts of judgement calls. I think it's better (and simpler) to assess RoB as a whole, downgrade according to GRADE and make recommendation based on quality of evidence.	Favours experimental / Favours comparator / Unpredictable

Commented [AC5]: Table 5 in guidance document

Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **If N/PN to 2.1:** go to 2.4 2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention? 2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?	Random selection of participants	Y / PY / PN / N / NI NA / Y / PY / PN / N / NI NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?	Data collection started 3 months after start of intervention period	Y / PY / PN / N / NI
2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?	Although data collection didn't start at the exact time-point at which the intervention started, in my opinion this strategy is ok because with these sorts of intervention it takes time for all components of the bundle to be implemented. Starting data collection right from intervention commencement would likely provide an effect estimate favouring control.	NA / Y / PY / PN / N / NI
Risk of bias judgement	I would judge this as low because 'all participants who would have been eligible for the hypothetical 'target' trial were included in the study. In the 'target' trial data collection for 'intervention' wards would not start for a time after intervention commencement.	Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to selection of participants into the study?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Commented [AC6]: Table 6 in guidance document

Bias in classification of interventions		
3.1 Were intervention groups clearly defined?	Pre and post intervention periods	Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	This was similar to a 'cluster' trial because all nurses within the unit were allocated to the intervention. This field is not all that relevant to the quite simple 'before-after' design scenario because all those before a time-point were in one group and all those after a time-point were a different group. In other NRSI it may be the case that 'intervention' status is measured from, for example, medical records where there is perhaps a greater risk for misclassification.	Y / PY / PN / N / NI
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	Again – not so relevant to the type of design used in the study we are assessing.	Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to classification of interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias due to deviations from intended interventions		
If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	We really don't have a lot of information to go on here. For example, detail about how many of the nurses received the education sessions were not provided. However, due to the pragmatic nature of the study design, in my opinion, it is safe to say that there were no major issues with deviations. If this were a multi-site study where it may have been more likely for there to be differences in intervention implementation *across* sites, then the lack of information provided I think would become a bigger problem.	Y / PY / PN / N / NI
4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?		NA / Y / PY / PN / N / NI
If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
4.3. Were important co-interventions balanced across intervention groups?		Y / PY / PN / N / NI
4.4. Was the intervention implemented successfully for most participants?		Y / PY / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		Y / PY / PN / N / NI
4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk of bias judgement		Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to deviations from the intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?	As essentially all nurses within the unit were *allocated* to the intervention, then we can't say that we have outcome data for all/nearly all participants.	Y / PY / PN / N / NI
5.2 Were participants excluded due to missing data on intervention status?	The process by which data were collected (random sample) did not seem to differ according to the intervention/control periods.	Y / PY / PN / N / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?		Y / PY / PN / N / NI
5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions?	More participants in intervention period.	NA / Y / PY / PN / N / NI
5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data?	No info	NA / Y / PY / PN / N / NI
Risk of bias judgement	The analysis is unlikely to have removed the risk of bias arising from the missing data.	Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to missing data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	Not a completely objective outcome measure	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?	Definitely in the intervention period	Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment comparable across intervention groups?	Direct observation for intervention period versus tape-recorded out of view for baseline control period	Y / PY / PN / N / NI
6.4 Were any systematic errors in measurement of the outcome related to intervention received?		Y / PY / PN / N / NI
Risk of bias judgement	The outcome measure was subjective (i.e. vulnerable to influence by knowledge of the intervention received by study participants); and The outcome was assessed by assessors aware of the intervention received by study participants;	Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to measurement of outcomes?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Bias in selection of the reported result		
Is the reported effect estimate likely to be selected, on the basis of the results, from... 7.1. ... multiple outcome *measurements* within the outcome domain?	Interruptions were measured only one way in the study	Y / PY / PN / N / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?	The comparison reported in the text is not consistent with Table 1. In methods it says t-test, but the comparison seems to be for a comparison of the proportion of interruptions at each handover.	Y / PY / PN / N / NI
7.3 ... different *subgroups*?		Y / PY / PN / N / NI
Risk of bias judgement	Outcomes are defined in different ways in the methods and results sections.	Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall bias		
Risk of bias judgement	On balance, there is serious risk of bias due to uncontrolled confounding, bias in measurement of outcomes, bias in selection of the reported result and bias due to missing data.	Low / Moderate / Serious / Critical / NI
Optional: What is the overall predicted direction of bias for this outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable