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

(version for cohort-type studies)

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

## 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

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| --- |
| **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**   1. Workload at the time of handover 2. Patient complexity |

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

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| 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

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| --- | --- |
| 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 |

## Is your aim for this study…?

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| □ | 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.

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| 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.

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| Proportion of handovers interrupted (Table 1). RR calculated using this tool: <https://www.medcalc.org/calc/relative_risk.php>    Table  Description automatically generatedGraphical user interface, application  Description automatically generated |

## 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).

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| **(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 |
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| **(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 |
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\* 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”.

## 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.

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| **(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 |

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| **(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 |
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|  |  | Favour experimental / Favour comparator / No information |
|  |  | Favour experimental / Favour comparator / No information |

## 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.

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|  | **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 |

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|  | **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 |

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| **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 |  | Y / PY / PN / N / NI |
| 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 | 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 – potentially the number of interruptions were higher/lower in this period, we don’t know. | 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 |

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| **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.  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 |

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| **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 |

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| **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? | As the design had clearly defined pre-intervention and post-intervention periods, there is no concern that some nurses could have been observed where it was not known whether they were in the intervention group or control group | Y / PY / PN / N / NI |
| 5.3 Were participants excluded due to missing data on other variables needed for the analysis? | This study did not control for other variables so no participants were excluded from the analysis. This may come up in other NRSI. Say for example, researchers conducting a NRSI decided that age was an important confounder and so they planned to undertake an ‘adjusted’ analysis where the age variable was included in the model. If age was unknown for some of the participants included in the study, then those participants wouldn’t be able to be included in 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 |

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| **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 - the observers knowing details of the intervention could potentially have influenced their measurement of the outcome. | Y / PY / PN / N / NI |
| 6.2 Were outcome assessors aware of the intervention received by study participants? | Definitely in the intervention period – not in the control period as the pre-intervention data was probably collected just as part of some sort of quality assurance process. This wasn’t explicitly stated but considering the large difference in time between the control and intervention periods, I would be surprised if the plans to implement the intervention were known at the time of baseline data collection. | Y / PY / PN / N / NI |
| 6.3 Were the methods of outcome assessment comparable across intervention groups? | No - 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;  and  Assessed in a different way – direct observation versus taped | 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 |

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| **Bias in selection of the reported result** | | | |
|  | Is the reported effect estimate likely to be selected, on the basis of the results, from... | The outcome ‘domain’ would be defined as interruptions during handover. The effect estimate reported was the number of handovers that were interrupted. Based on the information provided, they could have ‘cherry-picked’ this particular measurement to report. Because there is no published study protocol or entry in a trial registry, we cannot confirm that this was the planned primary outcome. Could have instead used the outcome, number of interruptions per handover or total interruptions (reported in table 2). |  |
| 7.1. ... multiple outcome *measurements* within the outcome domain? |  | 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 – raises my suspicion that other analyses were planned/undertaken but not reported. | 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 |

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| **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 |



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