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 II): Skolasky et al. 2018 Telephone-Based Intervention to Improve Rehabilitation Engagement After Spinal Stenosis Surgery: A Prospective Lagged Controlled Trial.

Specify a target randomized trial specific to the study

Design	Prospective lagged controlled trial
Participants	63 + 59
Experimental intervention	Telephone-based health behavior change counseling
Comparator	Usual care

Is your aim for this study…?

X	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.

Brief Pain Inventory, ODI, SF12 – changes over time in pain, disability, and health status

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	1.1 PY Quote: "Without random assignment, however, we could not rule out unobserved confounding" p. 8.	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.	1.2 N Quote: "Pain, disability, and health status were assessed at 3, 6, 12, 24, and 36 months after the surgical procedure" p. 5.	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)		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?	1.4 Y Quote: "Statistical models for each outcome were adjusted by age, sex, education, and baseline measure" (p. 5).	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?	1.5 PY Comment: Table 1, p. 18.	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?	1.6 NI	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?		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?		NA / Y / PY / PN / N / NI
Risk of bias judgement	Moderate	Low / Moderate / Serious / Critical / NI
Optional: What is the predicted direction of bias due to confounding?		Favours experimental / Favours comparator / Unpredictable

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	2.1 N Quote: "We enrolled consecutive patients with lumbar spinal stenosis presenting to our academic spine center from December 2009 through August 2012 for lumbar decompression. Patients with lumbar spondylolisthesis or scoliosis also underwent arthrodesis. Patients were ≥18 years of age, were English-speaking, and were able to provide informed consent. Patients who had undergone a previous lumbar spine surgical procedure were excluded… All participants were enrolled before the surgical procedure, when patients were evaluated" (p. 3-4).	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?		NA / Y / PY / PN / N / NI
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?		NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?	2.4 PY Comment: Comparable methods of outcome measurement and time points.	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?		NA / Y / PY / PN / N / NI
Risk of bias judgement	Low	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

Bias in classification of interventions

3.1 Were intervention groups clearly defined?	3.1 Y Quote: "Sixty patients were assigned usual care and 65 patients were assigned health behavior change counseling" p. 3 Comment: Figure 2, p. 15.	Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	3.2 Y	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?	3.3 PN	Y / PY / PN / N / NI
Risk of bias judgement	Low	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?	4.1 PN	Y / PY / <u>PN / N</u> / 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 / <u>PN / N</u> / 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?		<u>Y / PY</u> / PN / N / NI
4.4. Was the intervention implemented successfully for most participants?		<u>Y / PY</u> / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		<u>Y / PY</u> / 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 / <u>Y / PY</u> / PN / N / NI
Risk of bias judgement	Low	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?	5.1 Y Comment: Nearly all = 97,6 % (fig.2, p. 15).	<u>Y / PY</u> / PN / N / NI
5.2 Were participants excluded due to missing data on intervention status?	5.2 N Comment: Fig. 2, p. 15	Y / PY / <u>PN / N</u> / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?	5.3 N Comment: Fig. 2, p. 15	Y / PY / <u>PN / N</u> / 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?		NA / <u>Y / PY</u> / 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?		NA / <u>Y / PY</u> / PN / N / NI
Risk of bias judgement	Low	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?	6.1 PY Comment: Knowledge of the assignment could influence participant-reported outcomes.	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?	6.2 Y Comment: The outcome assessor is the study participant.	Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment comparable across intervention groups?	6.3 Y Comment: Comparable methods of outcome measurement and time points.	Y / PY / PN / N / NI
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	6.4 PN Comment: Reliable and valid questionnaires are used for data collection	Y / PY / PN / N / NI
Risk of bias judgement	Moderate	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?	7.1 PN Comment: The researchers' pre-specified intentions are available in sufficient details. Skolasky RL, Riley LH 3rd, Maggard AM, Bedi S, Wegener ST. Functional recovery in lumbar spine surgery: a controlled trial of health behavior change counseling to improve outcomes. Contemp Clin Trials. 2013 Sep;36(1):207–17.	Y / PY / <u>PN / N</u> / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?	7.2 PN Comment: Analysis intentions are available.	Y / PY / <u>PN / N</u> / NI
7.3 ... different *subgroups*?	7.3 PN Comment: Analysis intentions are available.	Y / PY / <u>PN / N</u> / NI
Risk of bias judgement	Low	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	Low	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