# Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
# TEMPLATE FOR COMPLETION

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on behalf of the RoB2 Development Group

**Version of 22 August 2019**

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**Study details**

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| **Reference** | Rolving N et al. Does a Preoperative Cognitive-Behavioral Intervention Affect Disability, Pain Behavior, Pain, and Return to Work the First Year After Lumbar Spinal Fusion Surgery? |

**Study design**

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

**For the purposes of this assessment, the interventions being compared are defined as**

| | | | |
|---|---|---|---|
| Experimental: | Standard course of treatment and preoperative cognitive-behavioral intervention | Comparator: | Usual care |

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| **Specify which outcome is being assessed for risk of bias** | NRS, ODI |
| **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. | Median (IQR) |

**Is the review team's aim for this result…?**

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

**If the aim is to assess the effect of *adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ 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 <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)**

X Journal article(s) with results of the trial
X Trial protocol: ISRCTN42281022 https://doi.org/10.1186/ISRCTN42281022
☐ 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☐ "Grey literature" (e.g. unpublished thesis)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 or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

## 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.

### Domain 1: Risk of bias arising from the randomization process

| Signalling questions | Comments | Response options |
|---|---|---|
| **1.1 Was the allocation sequence random?** | 1.1. Y<br>1.2. Y | Y / PY / PN / N / NI |
| **1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?** | Quote: "Eligible patients were assigned by computer-generated block-randomization (by hospital) to receive either the standard treatment (control group) or the standard treatment plus a preoperative CBT intervention (CBT group). A 1:2 ratio was applied to enable group sessions in the intervention group" (p. 594). | Y / PY / PN / N / NI |
| **1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?** | 1.3. PN<br>Quote: "The median number of days from baseline measurement to surgery was 42.5 days (range: 26–210 d) for the group as a whole. Table 1 shows the baseline characteristics of the patients. Overall, the 2 groups were comparable at baseline" (p. 596).<br><br>Comment: The use of the word "overall" → PN in stead of N | Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | Low | Low / High / Some concerns |
| Optional: What is the predicted direction of bias arising from the randomization process? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

| Signalling questions | Comments | Response options |
|---|---|---|
| **2.1. Were participants aware of their assigned intervention during the trial?** | 2.1. Y<br>Quote: "Because of the nature of the intervention, the patients could not be blinded to treatment allocation" (p. 594).<br><br>2.2. Y<br>Comment: It is not possible to blind the carer. | Y / PY / PN / N / NI |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | | Y / PY / PN / N / NI |
| **2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?** | 2.3. PY<br>Quote: "Another limitation relates to the lack of control with the postoperative rehabilitation. In Denmark, the municipalities manage the postoperative rehabilitation programs individually. An 8-week exercise program is the minimum standard treatment offered, but some municipalities also offered pain education, potentially influencing the longitudinal findings. However, the randomized study design ensured an even distribution of the various types of rehabilitation in the 2 groups" (p. 599). | NA / Y / PY / PN / N / NI |
| **2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?** | 2.4. PN<br>Quote: "However, the randomized study design ensured an even distribution of the various types of rehabilitation in the 2 groups" (p. 599). | NA / Y / PY / PN / N / NI |
| **2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?** | | NA / Y / PY / PN / N / NI |
| **2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?** | 2.6. Y<br>Quote: "All data were entered twice in EpiData version 3.1, and any divergence was corrected according to original data. STATA version 13.0 (Stata Corp, College Station, TX) was used for statistical evaluation. The data were analyzed according to the intention-to-treat principle. The differences from baseline to each follow-up are presented with medians (with 25th and 75th percentiles). For comparison of differences between the 2 groups, the Wilcoxon rank sum test was used. Nonparametrical statistics was chosen for analysis because of the | Y / PY / PN / N / NI |

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| | ordinal properties of the primary parameter, the ODI, and the same applied to the secondary outcome measures (p. 595-596). | |
| **2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?** | | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | Some concerns | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

## Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

| **Signalling questions** | **Comments** | **Response options** |
|---|---|---|
| **2.1. Were participants aware of their assigned intervention during the trial?** | | Y / PY / PN / N / NI |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | | Y / PY / PN / N / NI |
| **2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?** | | NA / Y / PY / PN / N / NI |
| **2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?** | | NA / Y / PY / PN / N / NI |
| **2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?** | | NA / Y / PY / PN / N / NI |
| **2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?** | | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 3: Missing outcome data

| Signalling questions | Comments | Response options |
|---|---|---|
| **3.1 Were data for this outcome available for all, or nearly all, participants randomized?** | 3.1 PY<br>Comment: Nearly all (93%) | Y / PY / PN / N / NI |
| **3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?** | | NA / Y / PY / PN / N |
| **3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?** | | NA / Y / PY / PN / N / NI |
| **3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?** | | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | Low | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to missing outcome data? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 4: Risk of bias in measurement of the outcome

| Signalling questions | Comments | Response options |
|---|---|---|
| **4.1 Was the method of measuring the outcome inappropriate?** | 4.1 N<br><br>AIM:<br><br>Quote: "We hypothesized that the CBT intervention would outperform usual care without a preoperative CBT intervention in regard to disability, psychological variables, return to work, and back and leg pain" p. 594.<br><br>METHOD OF MEASURING THE OUTCOME:<br><br>Quote: "For each participant, the following baseline data were retrieved from the medical records system: sex, age, diagnosis, surgical information, and previous spine surgery. The primary outcome measure was changed in Oswestry Disability Index (ODI) score from baseline to 1 year after surgery. Secondary outcomes included psychological variables, return to work, and pain. The Fear Avoidance Beliefs Questionnaire was used to quantify fear avoidance beliefs about physical activity. The catastrophizing subscale of the Coping Strategies Questionnaire was used to assess the patients' use of negative thinking in relation to pain. Data on return to work were obtained from the Danish Register for Evaluation of Marginalisation (DREAM), which is managed by the Danish Ministry of Employment. Back and leg pain was measured with the Low Back Pain Rating Scale. All outcomes were measured at baseline, 3 months, 6 months, and 1 year after surgery" p. 594. | Y / PY / PN / N / NI |
| **4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?** | 4.2. PN<br><br>Comment: Comparable methods of outcome measurement and time points. | Y / PY / PN / N / NI |
| **4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the** | 4.3 Y<br><br>Comment: The outcome assessor is the study participant. | NA / Y / PY / PN / N / NI |

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| **intervention received by study participants?** | | |
| **4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?** | 4.4. PY<br><br>Comment: Knowledge of the assignment could influence participant-reported outcomes. | NA / Y / PY / PN / N / NI |
| **4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?** | 4.5 PN<br><br>Comment: There is no reason to believe that knowledge of the intervention status could have influenced outcome. | NA / Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | Some concerns | Low / High / Some concerns |
| Optional: What is the predicted direction of bias in measurement of the outcome? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

Domain 5: Risk of bias in selection of the reported result

| Signalling questions | Comments | Response options |
|---|---|---|
| **5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?** | 5.1 NI<br>Comment: The researchers' pre-specified intentions are not available in sufficient details. | Y / PY / PN / N / NI |
| **Is the numerical result being assessed likely to have been selected, on the basis of the results, from...** | | |
| **5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?** | 5.2 NI<br>Comment: Analysis intentions are not available. | Y / PY / PN / N / NI |
| **5.3 ... multiple eligible analyses of the data?** | 5.3 NI<br>Comment: Analysis intentions are not available. | Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | Some concerns | Low / High / Some concerns |
| Optional: What is the predicted direction of bias due to selection of the reported result? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

## Overall risk of bias

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| **Risk-of-bias judgement** | | Low / High / Some concerns |
| Optional: What is the overall predicted direction of bias for this outcome? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |