

# 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

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### Study details

#### Reference

McGregor AH et al. ISSLS Prize Winner: Function After Spinal Treatment, Exercise, and Rehabilitation (FASTER) - A Factorial Randomized Trial to Determine Whether the Functional Outcome of Spinal Surgery Can Be Improved. SPINE Volume 36, Number 21, pp 1711–1720

### Study design

- 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:

(1) 6wk formal rehabilitation (2) booklet-only (3) 6wk formal rehabilitation + booklet

Comparator:

Usual care

### Specify which outcome is being assessed for risk of bias

VAS, 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.

MEAN (SD)

### Is the review team's aim for this result...?

- 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 obtained 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:

*McGregor AH et al. Function after spinal treatment, exercise and rehabilitation (FASTER): improving the functional outcome of spinal surgery. BMC Musculoskeletal Disorders 2010, 11:17*

X Statistical analysis plan (SAP)

*McGregor AH et al. Function after spinal treatment, exercise and rehabilitation (FASTER): improving the functional outcome of spinal surgery. BMC Musculoskeletal Disorders 2010, 11:17*

- 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
<b>1.1 Was the allocation sequence random?</b>	1.1 <u>Y</u> Quote: "Allocation to a study group was by central telephone randomization stratified by surgeon and surgical procedure using random permuted blocks to ensure that each participating surgeon and each surgical procedure had approximately equal numbers of patients allocated to each group" (p. 1712).	<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
<b>1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?</b>	1.2 <u>Y</u> Quote: "Treatment allocation was concealed prior to surgery to avoid selection bias during recruitment" (p. 1712).	<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
<b>1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?</b>	1.3 <b>N</b> Quote: "The four groups were similar at baseline". Quote: "... a descriptive comparison of the trial groups before surgery was done to confirm that randomization had produced balanced groups with respect to known predictors of outcome such as age, sex, type of surgery, ethnic background, marital status, body mass index, occupation type, work status, and smoking status" (p. 1713). Comment: The baseline characteristics are summarized in Table 1.	<b>Y</b> / <b>PY</b> / <u>PN</u> / <u>N</u> / NI
<b>Risk-of-bias judgement</b>	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
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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. <b>Y</b> Quote: "Patients were notified of their randomization after their surgery and those patients allocated to either the booklet-only group or the rehabilitation-plusbooklet group received the booklet entitled "Your Back operation" on discharge" (p. 1712).	<b>Y / PY / <u>PN / N</u> / NI</b>
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	2.2. <b>Y</b> Comment: It is not possible to blind the patients or the carers for the intervention.	<b>Y / PY / <u>PN / N</u> / NI</b>
2.3. If <b>Y/PY/NI</b> to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	2.3. <b>PN</b> Comment: The intervention in the four groups appears to be well separated	<b>NA / Y / PY / <u>PN / N</u> / NI</b>
2.4. If <b>Y/PY</b> to 2.3: Were these deviations likely to have affected the outcome?		<b>NA / Y / PY / <u>PN / N</u> / NI</b>
2.5. If <b>Y/PY/NI</b> to 2.4: Were these deviations from intended intervention balanced between groups?		<b>NA / <u>Y / PY</u> / <b>PN / N</b> / NI</b>
2.6. Was an appropriate analysis used to estimate the effect of assignment to intervention?	2.6. <b>Y</b> Quote: "Baseline characteristics are summarized across the four groups as number (%) for categorical variables or mean (SD) for continuous variables. Baseline values of outcome scores, including ODI, average back pain, average leg pain, FABQ, HADS, and VAS health summary, were summarized as mean (SD) if approximately normal. The primary outcome was the between-group difference in score on the ODI at 1-year follow-up, based on intention-to treat. Secondary outcomes included average back and leg pain, FABQ, HADS anxiety and depression scores and VAS for overall health (all measured at one-year follow-up). Groups were compared using analysis of covariance adjusting for baseline value of outcome and stratifying factors: surgery type as a fixed effect and surgeons as random effects, to increase efficiency in estimating the effect of	<b><u>Y / PY</u> / <b>PN / N</b> / NI</b>

	<p>intervention. Analyses were performed for booklet versus no-booklet and rehabilitation versus no rehabilitation, simultaneously. Comparisons were followed by a test for interaction of the two interventions” (p. 1713).</p> <p>Comment: Information on software used for data analysis is missing.</p>	
<b>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?</b>		NA / Y / PY / <u>PN</u> / N / NI
<b>Risk-of-bias judgement</b>	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
<b>3.1 Were data for this outcome available for all, or nearly all, participants randomized?</b>	3.1 PY Comment: Nearly all – data was available for 93,4 % of the participants randomized.	<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
<b>3.2 If <u>N/PN/NI</u> to 3.1: Is there evidence that the result was not biased by missing outcome data?</b>		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u>
<b>3.3 If <u>N/PN</u> to 3.2: Could missingness in the outcome depend on its true value?</b>		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
<b>3.4 If <u>Y/PY/NI</u> to 3.3: Is it likely that missingness in the outcome depended on its true value?</b>		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
<b>Risk-of-bias judgement</b>	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
<p><b>4.1 Was the method of measuring the outcome inappropriate?</b></p>	<p>4.1 <b>N</b></p> <p>AIM</p> <p>Quote: “The objective of this factorial randomized controlled trial function after spinal treatment, exercise, and rehabilitation (FASTER) was to evaluate the benefits of a rehabilitation program and an education booklet for the postoperative management of patients undergoing discectomy or lateral nerve root decompression, each compared with “usual care.” Our hypothesis is that a program of postoperative rehabilitation that combines professional support and advice with graded exercise will improve the long-term outcome of surgery, and that appropriate educational information will also improve outcome but to a lesser degree than rehabilitation. We assume that the effect of the combination of the two interventions will be additive; that is, there will be no interaction “ p. 1712.</p> <p>METHOD OF MEASURING THE OUTCOME</p> <p>Quote: “ The Oswestry Disability Index ... was the primary outcome measure ... Secondary outcome measures included 10-cm visual analog scales (VAS), which recorded average back and leg pain... the hospital anxiety and depression (HADS) questionnaire recorded anxiety and depression ... Fear Avoidance Beliefs Questionnaire (FABQ) was used to assess pain behaviors ... the EQ-5D was used to determine health-related quality-of-life ... and return to work” p. 1712-1713.</p>	<p><b>Y / PY / <u>PN / N</u> / NI</b></p>
<p><b>4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?</b></p>	<p>4.2. <b>PN</b></p> <p>Comment: Comparable methods of outcome measurement and time points.</p>	<p><b>Y / PY / <u>PN / N</u> / NI</b></p>
<p><b>4.3 If <u>N/PN/NI</u> to 4.1 and 4.2: Were outcome assessors aware of the</b></p>	<p>4.3 <b>Y</b></p> <p>Comment: The outcome assessor is the study participant.</p>	<p><b>NA / <u>Y / PY</u> / <u>PN / N</u> / NI</b></p>

intervention received by study participants?	Quote: "It was not possible to assess outcome measures blind to the randomized intervention since all outcome measures are patient assessments" p. 1713.	
4.4 If <b>Y/PY/NI</b> to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	4.4. <b>PY</b> Comment: Knowledge of the assignment could influence participant-reported outcomes.	NA / <b>Y / PY</b> / <b>PN / N</b> / NI
4.5 If <b>Y/PY/NI</b> to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	4.5 <b>PN</b> Comment: There is no reason to believe that knowledge of the intervention status could have influenced outcome.	NA / <b>Y / PY</b> / <b>PN / N</b> / 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
<p><b>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?</b></p>	<p>5.1 <span style="color: green;">Y</span></p> <p>Quote: "This was performed according to our protocol*" p. 1713.</p> <p>*McGregor AH, Doré CJ, Morris TP, Morris S, Jamrozik K. Function after spinal treatment, exercise and rehabilitation (FASTER): improving the functional outcome of spinal surgery. BMC Musculoskelet Disord. 2010 Jan 26;11:17. doi: 10.1186/1471-2474-11-17. PMID: 20102625; PMCID: PMC2823667.</p>	<p><span style="color: green;">Y</span> / <span style="color: green;">PY</span> / <span style="color: red;">PN</span> / <span style="color: red;">N</span> / NI</p>
<p><b>Is the numerical result being assessed likely to have been selected, on the basis of the results, from...</b></p>		
<p><b>5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?</b></p>	<p>5.2 <span style="color: green;">N</span></p> <p>Comment: All eligible reported results for the outcome domain correspond to all intended outcome measurements.</p>	<p><span style="color: red;">Y</span> / <span style="color: red;">PY</span> / <span style="color: green;">PN</span> / <span style="color: green;">N</span> / NI</p>
<p><b>5.3 ... multiple eligible analyses of the data?</b></p>	<p>5.3 <span style="color: green;">N</span></p> <p>Comment: All eligible reported results for the outcome domain correspond to all intended outcome measurements.</p>	<p><span style="color: red;">Y</span> / <span style="color: red;">PY</span> / <span style="color: green;">PN</span> / <span style="color: green;">N</span> / NI</p>
<p><b>Risk-of-bias judgement</b></p>	<p>Low</p>	<p>Low / High / Some concerns</p>
<p>Optional: What is the predicted direction of bias due to selection of the reported result?</p>		<p>NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable</p>



Overall risk of bias

<b>Risk-of-bias judgement</b>		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



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