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

Study details

Reference	Saha BS et al. The Effect of Computer-Based Training on Self-care and Daily Living Activities in Patients With Lumbar Discectomy Surgery A Randomized Controlled Study. CIN: Computers, Informatics, Nursing Volume 00	Number 0

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: | Computer-Based training on selfcare and daily living activities   Comparator: | Usual care

Specify which outcome is being assessed for risk of bias   Modified Barthel Index (MBI), and the Exercise of Self-Care Agency (ESCA) Scale

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…?

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
☐   Trial protocol
☐   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☐   "Grey literature" (e.g. unpublished thesis)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	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	1.2. Y Quote: "A randomization method was used to determine the intervention and control groups by the researcher. The patients were divided into groups using a computer-based randomization method (www.random.org). Participants were assigned to the training or control group in the randomization list according to the order of hospitalization" (p. 2)	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	1.3. N Quote: "There was no statistically significant difference between the intervention and control groups regarding individual characteristics (P > .05)" (p. 4).	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 2.2. Y	Y / PY / <u>PN / N</u> / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Comment: It is not possible to blind the patients or the carer for this intervention.	Y / PY / <u>PN / N</u> / 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. NI	NA / Y / PY / <u>PN / N</u> / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / <u>PN / N</u> / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / <u>Y / PY</u> / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	2.6 Y Quote: "Data were analyzed using the Number Cruncher Statistical System 2007 (Kaysville, UT, USA) program. Mean, standard deviation, median, percentage, minimum, and maximum for descriptive variables were used. The Mann-Whitney U test was used to compare variables that did not show normal distribution between two groups. Wilcoxon's signed rank test was used for pre- and post-training comparison of variables that did not show normal distribution. The t test was used to compare descriptive characteristics between the groups. The χ2 test was used to compare categorical variables. Statistical significance was accepted as P < .05" (p. 4).	<u>Y / PY</u> / PN / N / NI
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 / <u>PN / N</u> / 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

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 Y Comment: All (figure 1).	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 AIM Quote: "The aim of this study was to determine the effect of computer-based discharge training on patients with lumbar disc surgery on self-care agency and independence in daily living activities" p. 2. METHOD OF MEASURING THE OUTCOME Quote: "The data were collected using a Patient Information Form, the Modified Barthel Index (MBI), and the Exercise of Self-Care Agency (ESCA) Scale" p. 2.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	4.2. PN 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 intervention received by study participants?	4.3 Y Comment: The outcome assessor is the study participant.	NA / Y / PY / PN / N / NI
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 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 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 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 Comment: Analysis intentions are not available.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	5.3 NI 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

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