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	Aldemir K, Gürkan A. The effect of pedometer-supported walking and telemonitoring after disc hernia surgery on pain and disability levels and quality of life. Int J Nurs Pract. 2021;27:e12917

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:	Pedometer-supported walking exercise and telemonitoring	Comparator:	No walking exercise

Specify which outcome is being assessed for risk of bias	Subjective outcomes: The Short Form McGill Pain Questionnaire, Oswestry Disability Index, Short Form 36.
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☐ "Grey literature" (e.g. unpublished thesis)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 1.2 Y	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Quote: "The randomization of the patients who met inclusion criteria was performed before surgery using a random number generator (random.org)" (p. 3).	Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	1.3 N Quote: "The study was completed with 33 patients in the intervention group and 34 patients in the control group" (p. 3). Quote: "The mean age of the participants in the intervention group was 42.30 (SD = 9.92) (range, 29–65), whereas the mean age of the participants in the control group was 44.88 (SD = 9.25) (range, 31–64)" (p. 5). Quote: "In our study, there was no significant difference between groups with regard to personal characteristics. The only significant difference between the groups was that the patients in the intervention group had occupations that required extended standing/sitting at greater rates (54.5%) compared with the control group (26.5%). This, in turn, is a situation that may increase the risk of relapse with a return to work after surgery" (p. 10).	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 Comment: It is not possible to blind the intervention.	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 NI	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		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 Quote: "Demographic variables were summarized using descriptive statistics (mean and SD values, numbers and percentages). The intergroup comparison of normally distributed parameters was performed using the independent samples t test, whereas the comparison of qualitative data was performed using the chi-squared test. The levels and directions of the relationships between variables were tested through Pearson correlation analysis. The effect of their daily physical activity of the intervention group on pain and disability levels in the second and third months was tested through linear regression analysis. The level of statistical significance was accepted as $p < 0.05$." (p. 5).	Y / PY / 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 / 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 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 PN Comment: Only 82,5 % (33 of 40) in the intervention group and 85 % (34 of 40) in the control group was included for analysis (Figure 1 - Consort diagram).	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?	3.2. PN	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	3.3. PN Comment: Missing outcome data	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 risk	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 Quote: "The Short Form McGill Pain Questionnaire (SF-MPQ) was developed by Melzack (1987) and tested for validity and reliability in Turkish. This form gives information on the sensory– perceptual and severity components of the perception of pain" (p. 3). Quote (The Modified Oswestry Disability Index): "This index, which was developed by Fairbank et al. (1980) and later modified by Hudson-Cook et al. (1989), is suggested as a sensitive scale for the evaluation of the functional insufficiency of patients with back pain because of its validity and reliability. The scale was tested for validity and reliability in Turkish" (p. 4). Quote: "The 36-Item Short Form Survey (SF-36) is a generic scale widely used to evaluate quality of life. The scale was developed by Ware and Sherbourne (1992) and tested for validity and reliability in Turkish by Kocyigit et al. (1999). It is a self-report questionnaire and examines eight subdimensions of health through 36 items. These subdimensions are physical functionality, social functionality, role difficulties (physical and emotional), mental health, vitality, pain and general perception of health" (p. 4).	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	4.2. N Comment: Same measurement methods and thresholds, used at comparable 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: It is not decisive for the statistical calculations	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: It is not reported that a pre-specified analysis plan has been made or used. The study is not registered on ClinicalTrials.gov	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 PN Comment: No indication that particular outcome measures have been selected. Data is reported with details and in monthly intervals. Negative and positive findings are reported.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	5.3 PN Comment: It is not possible to assess with certainty. There is no indication that this is the case.	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	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