Bilag 2 – Risk of Bias-vurdering med Cochrane Risk of Bias Tool 2.0 af Saaed et al. 2017

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

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	**Outcome of Specific Piriformis Stretching Technique in Females with Piriformis Syndrome** **Authors:** Quratulain Saeed, Arshad Nawaz Malik, Samina Ghulam Foundation University Islamabad, Pakistan

Year published: 2017

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:	External Rotator Self-stretching (ERS): Aktiv, siddende udspænding af hofteudadrotatorer 30 sek. á 10 sæt to gange dagligt i to uger.	Comparator:	Adductor Passive stretching (APS): Passiv, liggende udspænding af hofteadduktorer udført af fysioterapeut i 30 sek. á 10 sæt én gang dagligt i to uger.

Specify which outcome is being assessed for risk of bias	Smerte malt på numerisk rangskala (NRS)
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.	Se tabel 1: ERS-gruppen: Før behandling: 6,13 ± 0,7. Efter: 2,2 ± 1,2 APS-gruppen: Før behandling: 5,13 ± 1,1. Efter:1,4 ± 1,6

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)

Analyse og dropouts ikke angivet.

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)

☒ 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 <u>underlined in green</u> 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?		<u>Y</u> / **<u>PY</u>** / PN / N / NI

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Ja, det er angivet at deltagerne er randomiseret, men metoden er ikke angivet. Ikke angivet i artiklen.	Y / PY / PN / N / **NI**
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Nej.	Y / PY / PN / **N** / NI
Risk-of-bias judgement	Some concerns	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?	Ja. Ja – passiv udspænding af fysioterapeut Adductor Passive Stretch-gruppen.	**Y** / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of		**Y** / PY / PN / N / NI

participants' assigned intervention during the trial?		
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?	Deltagerne kan blive eksponeret af forskellige grader af fysisk aktivitet (og evt. overbelastning, der har medført yderligere hypertoni i hoftemuskulaturen), der kan have påvirket resultatet, men deltagerne får samme behandling/information udover udspændingen – bl.a. øvelser og vejledning, og det har gennemsnitligt smerter sv.t. hhv. 6,13 og 5,11 i interventions- og kontrolgruppen, så det synes usandsynligt, at det har haft en betydelig indvirkning på resultatet. Og som de skriver, er der ikke nogen af deltagerne, der r atleter eller dyrkede nogen form for regelmæssigt fysisk aktivitet: *"In contrast to above study, none of our participants was an athlete or engaged in a regular exercise program."*	NA / Y / PY / **PN** / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	Som ovenstående – sandsynligvis ikke.	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?		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?	Sandsynligvis ikke, da der ikke er frafald af deltagere.	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 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?	Jeps.	**Y** / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Jeps.	**Y** / PY / PN / N / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2:	*"Home plan of bilateral bridging, side leg raise with hip and knee flexion to 45 degrees and feet*	NA / Y / **PY** / PN / N / NI

Were important non-protocol interventions balanced across intervention groups?	*together (without resistance for first 5 days and with resistance of grey theraband for last 5 sessions) was taught to both groups along with avoidance of sacral sitting, changing of posture every 30 minutes, avoidance of lifting heavy objects, avoidance of high heels and flat shoes and recommendation of soles of 1-1.5 inches."* Det er dog uvist, hvor meget, de er blevet belastet hver især. Men som studiet også angiver, er ingen af deltagerne atleter, og ingen af dem dyrker regelmæssig fysisk aktivitet.	
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	Studiet angiver ikke, om der var nogen, der ikke fulgte interventionen, og der er ikke information om supervisionen eller informationen til selv-udspændingsgruppen, men det vurderes usandsynligt, da interventionsperioden kun er to uger, og behandlingen i alt varer ca. 20-30 min. Og desuden fordi de i forvejen behandles med ultralyd, så man må antage, de lavede en del af selvudspændingen under supervision, fordi de var nødt til at møde op på klinikken for ultralydsbehandlingen.	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:		NA / Y / PY / PN / N / **NI**

Was an appropriate analysis used to estimate the effect of adhering to the intervention?		
Risk-of-bias judgement	Low	**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?		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?	Nej – utænkeligt at udspænding kan forvolde så stor skade, at deltagerne trækker sig fra studiet.	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?		Y / PY / PN / **N** / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		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?		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?	De fleste folk med erfaring med fysisk aktivitet ved, hvordan en udspænding føles, og om den føles det sted, de har smerter. Begge grupper modtog dog en masse anden behandling i form af ultralyd, varme, øvelser og vejledning. Derfor vurderes APS-gruppens mistanke om at være kommet i kontrolgruppen som lille.	NA / Y / PY / **PN** / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of		NA / Y / PY / PN / N / NI

the outcome was influenced by knowledge of intervention received?		
Risk-of-bias judgement	Low	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 analyzed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		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		Y / PY / **PN** / N / NI

points) within the outcome domain?		
5.3 ... multiple eligible analyses of the data?		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	Some concerns	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