Bilaga 3. RoB 2.0 template

Myalgisk encefalomyelit och
kroniskt trötthetssyndrom (ME/CFS)

En systematisk översikt

The RoB 2.0 tool (individually randomized, parallel group trials)

Assessor name/initials	
Study ID and/or reference(s)	

Study design

- ☑ Randomized parallel group trial
- ☐ Cluster-randomized trial
- ☐ Randomized cross-over or other matched design

Specify which outcome is being assessed for risk of bias	
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.	

Is your aim for this study…?

- ☐ to assess the effect of *assignment to intervention*
- ☐ to assess the effect of *starting and adhering to intervention*

Which of the following sources have you <u>obtained</u> to help inform your risk of bias judgements (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- ☐ "Grey literature" (e.g. unpublished thesis)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, Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

Risk of bias assessment for a parallel group trial with interest in the effect of assignment to intervention

Domain	Signalling questions	Response options	Description/Support for judgement
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y / PY / PN / N / NI	
	1.2 Was the allocation sequence concealed until participants were recruited and assigned to interventions?	Y / PY / PN / N / NI	
	1.3 Were there baseline imbalances that suggest a problem with the randomization process?	Y / PY / PN / N / NI	
	Risk of bias judgement	Low / High / Some concerns	
	Optional: What is the predicted direction of bias arising from the randomization process?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	
Bias due to deviations from intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	
	2.2. Were carers and trial personnel 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 beyond what would be expected in usual practice?	NA / Y / PY / PN / N / NI	
	2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?	NA / Y / PY / PN / N / NI	
	2.5 Were any participants analysed in a group different from the one to which they were assigned?	Y / PY / PN / N / NI	
	2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?	NA / Y / PY / PN / N / NI	
	Risk of bias judgement	Low / High / Some concerns	

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	Optional: What is the predicted direction of bias due to deviations from intended interventions?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	
Bias due to missing outcome data	3.1 Were outcome data available for all, or nearly all, participants randomized?	Y / PY / PN / N / NI	
	3.2 If N/PN/NI to 3.1: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?	NA / Y / PY / PN / N / NI	
	3.3 If N/PN/NI to 3.1: Is there evidence that results were robust to the presence of missing outcome data?	NA / Y / PY / PN / N / NI	
	Risk of bias judgement	Low / High / Some concerns	
	Optional: What is the predicted direction of bias due to missing outcome data?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	
Bias in measurement of the outcome	4.1 Were outcome assessors aware of the intervention received by study participants?	Y / PY / PN / N / NI	
	4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	
	Risk of bias judgement	Low / High / Some concerns	
	Optional: What is the predicted direction of bias due to measurement of the outcome?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	
Bias in selection of the reported result	Are the reported outcome data likely to have been selected, on the basis of the results, from...		
	5.1. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Y / PY / PN / N / NI	
	5.2 ... multiple analyses of the data?	Y / PY / PN / N / NI	

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	Risk of bias judgement	Low / High / Some concerns	
	Optional: What is the predicted direction of bias due to selection of the reported result?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	
Overall bias	**Risk of bias judgement**	Low / High / Some concerns	
	Optional: What is the overall predicted direction of bias for this outcome?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	

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