Orthopedic Guideline Risk of Bias Evaluations
This form was derived from the Cochrane Risk of Bias Tool 2.0

* Required

1. **1.1 Was the allocation sequence random?** *
   - [ ] Yes
   - [ ] Probably Yes
   - [ ] Probably No
   - [ ] No
   - [ ] No Information

2. **Reasoning Sentence (page# if possible)***

3. **1.2 Was the allocation sequence concealed until participants were recruited and assigned to interventions?** *
   - [ ] Yes
   - [ ] Probably Yes
   - [ ] Probably No
   - [ ] No
   - [ ] No Information

4. **Reasoning Sentence (page# if possible)***

5. **1.3 Were there baseline imbalances that suggest a problem with the randomization process?** *
   - [ ] Mark only one oval.
6. **Reasoning Sentence (page# if possible)** *

7. **What is the final risk of bias?** *Mark only one oval.**
   - Low Risk
   - Some Concern
   - High Risk

8. **Were the number of patients randomized the same number that were analyzed at the end?** *
   *Mark only one oval.*
   - Yes  Skip to question 9.
   - No   Skip to question 22.

**Box 4**

**2.1- Were participants aware of their assigned intervention during the trial?**

9. **Mark only one oval.**
2.2- Were carers and trial personnel aware of participants' assigned intervention during the trial?

11

☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

12.

Reasoning Sentence (page# if possible)*

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*Reasoning sentence (page# if possible)
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? (Use NA if this question doesn't apply)

13. *

Mark only one oval.

☐ Not Applicable
☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

14. Reasoning Sentence (page# if possible)

____________________________________________________________________________
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2.4 - IF Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome? (Use NA if this question doesn't apply)

15

☐ Not Applicable
☐ Yes
☐ Probably Yes
☐ Probably No
2.5 - Were any participants analysed in a group different from the one to which they were assigned?

17. * 
Mark only one oval.

☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

18. 
Reasoning Sentence (page# if possible)*
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? (Use NA if this question doesn't apply)

19

☐ Not Applicable
☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

20.

Reasoning Sentence (page# if possible)

21.

What is the final risk of bias? * Mark only one oval.

☐ Low Risk
☐ Some Concern
☐ High Risk

Skip to question 35.

Box 5

2.1 - Were participants aware of their assigned intervention during the trial?
22. *

Mark only one oval.

☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

23 Reasoning Sentence (page# if possible) *

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________________________________________________________________________

2.2 - Were carers and trial personnel aware of participants' assigned intervention during the trial?

________________________________________________________________________

24. *

Mark only one oval.

☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

25.
2.3 - If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups? (Use NA if the question doesn't apply)

26. *

Mark only one oval.

- Not Applicable
- Yes
- Probably Yes
- Probably No
- No
- No Information
2.4 - Was the intervention implemented successfully?

28.  *

Mark only one oval.

☐ Yes
☐ Probably Yes
☐ Probably No
☐ No
☐ No Information

29.

Reasoning Sentence (page# if possible)

2.5 - Did study participants adhere to the assigned intervention regimen?

30.  *

Mark only one oval.
2.6 - If N/PN/NI to 2.3, 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply)
34. What is the final risk of bias? * Mark only one oval.
   - Low Risk
   - Some Concerns
   - High Risk

Box 6

3.1 - Were outcome data available for all, or nearly all, participants randomized?

35 * Mark only one oval.
   - Yes
   - Probably Yes
   - Probably No
   - No
   - No Information

36.
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? (Use NA if this question doesn't apply)

37. *
   Mark only one oval.
   - Not Applicable
   - Yes
   - Probably Yes
   - Probably No
   - No
   - No Information

38. Reasoning Sentence (page# if possible)
3.3 - If N/PN/NI to 3.1: Is there evidence that results were robust to the presence of missing outcome data? (Use NA if the question doesn't apply)

39 *

Mark only one oval.

- Not Applicable
- Yes
- Probably Yes
- Probably No
- No
- No Information

40.

Reasoning Sentence (page# if possible)

41.

What is the final risk of bias? * Mark only one oval.

- Low Risk
- Some Concerns
- High Risk

Box 7

4.1 - Were outcome assessors aware of the intervention received by study participants?
42. *  

Mark only one oval. 

- [ ] Yes 
- [ ] Probably Yes 
- [ ] Probably No 
- [ ] No 
- [ ] No Information

43. Reasoning Sentence (page# if possible) *

________________________________________________________________________________

4.2 - If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received? (Use NA if this question doesn't apply)

________________________________________________________________________________

44. *  

Mark only one oval. 

- [ ] Not Applicable 
- [ ] Yes 
- [ ] Probably Yes 
- [ ] Probably No 
- [ ] No 
- [ ] No Information 

45.
What is the final risk of bias? * Mark only one oval.

- Low Risk
- Some Concerns
- High Risk

Box 8

5.1 - Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? * Mark only one oval.

- Yes
- Probably Yes
- Probably No
- No
- No Information

48.

Reasoning Sentence (page# if possible) *
5.2 - Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

49. *
   
   Mark only one oval.
   
   ☐ Yes
   ☐ Probably Yes
   ☐ Probably No
   ☐ No
   ☐ No Information

50. 
   Reasoning Sentence (page# if possible)*

51. 
   What is the final risk of bias? * Mark only one oval.
   
   ☐ Low Risk
   ☐ Some Concerns
   ☐ High Risk