

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? * *Mark only one oval.*

- ☐ 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? * *Mark only one oval.*

- ☐ 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.*

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

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.

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

10.

Reasoning Sentence (page# if possible)

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)

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)

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

- ☐ No
- ☐ No Information

16.

Reasoning Sentence (page# if possible)

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) *

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.

Reasoning Sentence (page# if possible)

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

27 Reasoning Sentence (page# if possible)

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.

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

31 Reasoning Sentence (page# if possible) *

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)

32.

*

Mark only one oval.

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

33.

Reasoning Sentence (page# if possible)

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.

Reasoning Sentence (page# if possible)

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.

Reasoning Sentence (page# if possible)*

46.

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?

47 *

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

CHECKETTS ET AL.

THE ROBUSTNESS OF TRIALS THAT GUIDE EVIDENCE-BASED ORTHOPAEDIC SURGERY?

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