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CHECKETTS ET AL.

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

http://dx.doi.org/10.2106/JBJS.17.01039

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Orthopedic Guideline Risk of Bias Evaluations

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

* Required

	s the allocation sequence random? * Mark ne oval.
	Yes
	Probably Yes
	Probably No
	No
	No Information
2. Reaso	ning Sentence (page# if possible) *
	s the allocation sequence concealed until participants were recruited and assigned to entions? * Mark only one oval.
	Yes
	Probably Yes
	Probably No No
	No
	No Information
4. Reaso	ning Sentence (page# if possible) *
	ere there baseline imbalances that suggest a problem with the randomization process? *

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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.

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Page 3		
) Yes	
	Probably Yes	
	Probably No	
) No	
	No Information	
10.		
Reas	oning Sentence (page# if possible)*	
		el aware of participants' assigned
interve	ention during the trial?	
11		
	Yes	
	Probably Yes	
	Probably No	
) No	
	No Information	
	THO IIIIOIIII GUOTI	
12		
12. Reas	oning Sentence (page# if possible)*	

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interver	7/PY/NI to 2.1 or 2.2: Were there deviations from the intended ntion beyond what would be expected in usual practice? A if this question doesn't apply)
13.	
Mark o	nly one oval.
	Not Applicable
	Yes
	Probably Yes
	Probably No
	No
	No Information
14. Reason	ning Sentence (page# if possible)
interver	Y/PY to 2.3: Were these deviations from intended ntion unbalanced between groups and likely to have affected come? (Use NA if this question doesn't apply)

Not Applicable

Probably Yes Probably No

Yes

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O No
No Information
16.
Reasoning Sentence (page# if possible)
2.5 - Were any participants analysed in a group different from the
2.5 - Were any participants analysed in a group different from the one to which they were assigned?
one to which they were assigned?
one to which they were assigned?
one to which they were assigned? 17. *
one to which they were assigned? 17. * Mark only one oval.
17. * Mark only one oval. Yes
17. * Mark only one oval. Yes Probably Yes
17. * Mark only one oval. Yes Probably Yes Probably No
17. * Mark only one oval. Yes Probably Yes Probably No No
17. * Mark only one oval. Yes Probably Yes Probably No No No No Information
17. * Mark only one oval. Yes Probably Yes Probably No No No Information
17. * Mark only one oval. Yes Probably Yes Probably No No No No Information
17. * Mark only one oval. Yes Probably Yes Probably No No No No Information
17. * Mark only one oval. Yes Probably Yes Probably No No No No Information
17. * Mark only one oval. Yes Probably Yes Probably No No No No Information

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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 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?

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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
No Information

25.

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Reaso	oning Sentence (page# if possible)*
2 2 If V	V/DV/NI to 2.1 or 2.2: Word important as interventions
	Y/PY/NI to 2.1 or 2.2: Were important co-interventions ed across intervention groups? (Use NA if the question tapply)
balance doesn't	ed across intervention groups? (Use NA if the question
balance doesn't	ed across intervention groups? (Use NA if the question tapply)
balance doesn't	ed across intervention groups? (Use NA if the question tapply)
26. Mark o	ed across intervention groups? (Use NA if the question tapply) only one oval. Not Applicable
26. Mark o	ed across intervention groups? (Use NA if the question apply) only one oval. Not Applicable Yes
26. Mark o	ed across intervention groups? (Use NA if the question apply) only one oval. Not Applicable Yes Probably Yes

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27 Reasoning Sentence (page# if possible)	
, , , , , , , , , , , , , , , , , , ,	
2.4 - Was the intervention imple	mented successfully?
	-
28.	
Mark only one oval.	
Yes	
Probably Yes	
Probably No	
No	
No Information	
29.	
Reasoning Sentence (page# if possible)*	
O.F. Did atudu partiainanta adh.	one to the engine of intervention
	ere to the assigned intervention
regimen?	
30.	
*	
Mark only one oval.	

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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)
to estimate the effect of starting and adhering to the intervention?
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply)
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply)
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply) 32. * Mark only one oval.
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply) 32. ** ** ** ** ** ** ** ** **
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply) 32. ** ** ** ** ** ** ** ** **
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply) 32. ** ** ** ** ** ** ** ** **
to estimate the effect of starting and adhering to the intervention? (Use NA if this question doesn't apply) 32. ** ** ** ** ** ** ** ** **

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Reasoning Sentence (page# if possible)
34.
What is the final risk of bias? * Mark only one oval.
O 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.

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Reaso	oning Sentence (page# if possible)	
		-
		-
		-
		-
	asons for missing outcome s? (Use NA if this question d	data similar across intervention loesn't apply)
37.		
* Mark o	only one oval.	
	Not Applicable	
	Yes	
	Probably Yes	
	Probably No	
) No	
	No Information	
38.		
	oning Sentence (page# if possible)	
		_
		_
		_
		_
		_

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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		
A0. 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?		

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42. ** Mark only one oval. Yes Probably Yes Probably No No
No Information
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

45.

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Reasoning Sentence (page# if possible)*	
40	
46. What is the final risk of bias? * <i>Mark</i>	
only one oval.	
Low Risk	
Some Concerns	
High Risk	
Box 8	
5.1 - Are the reported outcome data likely to h	ave been selected, on
the basis of the results, from multiple outcom	e measurements (e.g.
scales, definitions, time points) within the out	come domain?
47 * Mark only one oval.	
·	
Yes	
Probably Yes	
Probably No	
No No Information	
No Information	
48.	
Reasoning Sentence (nage# if nossible) *	

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	_
5.2 - Are the reported outcome da the basis of the results, from mult	ta likely to have been selected, on iple analyses of the data?
40	
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	

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