

ICMJE DISCLOSURE FORM

Date: 5/31/2023

Your Name: Hillary Anne Vanderven

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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	society, committee or advocacy group, paid or unpaid		
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

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Date: 5/31/2023

Your Name: Win Min Han

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Date: 5/31/2023

Your Name: Ian Barr

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

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Date: Click or tap to enter a date.

Your Name: Dominic Dwyer

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Date: 5/31/2023

Your Name: Professor Brian Angus

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Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 5/31/2023

Your Name: Richard T. Davey, Jr.

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 5/31/2023

Your Name: John H Beigel

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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ICMJE DISCLOSURE FORM

Date: 5/31/2023

Your Name: James D Neaton

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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ICMJE DISCLOSURE FORM

Date: 6/1/2023

Your Name: Stephen Kent

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

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6	Payment for expert testimony	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/1/2023

Your Name: Heidi Peck

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
Time frame: Since the initial planning of the work								
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> <div style="text-align: right; font-size: small; color: #ccc; margin-top: 5px;">Click the tab key to add additional rows.</div>						
Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

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4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>									
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12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/1/2023

Your Name: Matthew Law

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: past 36 months									
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4	Consulting fees	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							
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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 20px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>							
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11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/1/2023

Your Name: Mamta K. Jain

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 50%;">Janssen Pharmaceuticals</td><td style="width: 50%;">contract with institution</td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>	Janssen Pharmaceuticals	contract with institution				
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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input checked="" type="checkbox"/> None	
		Gilead Sciences	Advisory Board (payment to self)
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		HCPLive	honoraria -self
		ACT HIV	honoraria- self
		The Cooper Clinic	honoraria- self
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
		HIV MA Board of Directors, member	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJJE DISCLOSURE FORM

Date: 6/4/2023

Your Name: Christian T. Brandt

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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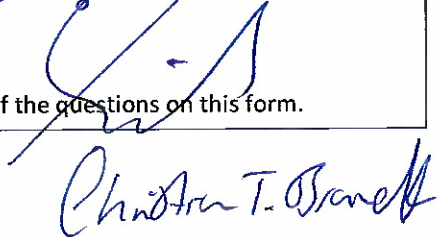
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4	Consulting fees	<input checked="" type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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Copenhagen June 4, 2023

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.



ICMJE DISCLOSURE FORM

Date: 6/5/2023

Your Name: Deborah N Wentworth

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 6/5/2023

Your Name: Analia Mykietiuik

Manuscript Title: Understanding the treatment benefit of hyperimmune anti-influenza intravenous immunoglobulin (Flu-IVIG) for severe human influenza

Manuscript Number (if known): 167464-INS-RG-RV-3

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
Time frame: Since the initial planning of the work								
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> <div style="text-align: right; font-size: small; color: #ccc; margin-top: 5px;">Click the tab key to add additional rows.</div>						
Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; height: 40px; margin-top: 5px;"> <tr><td style="width: 60%;"></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

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I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORT reporting guidelines, and cite them as:

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

		Reporting Item	Page Number
Title and Abstract			
Title	#1a	Identification as a randomized trial in the title.	pg 3 & Ref. 8 (Davey <i>et al.</i> 2019)
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	pg 3
Introduction			
Background and objectives	#2a	Scientific background and explanation of rationale	pg 4-6
Background and objectives	#2b	Specific objectives or hypothesis	pg 6
Methods			
Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	pg 6-8 & Ref. 8 (Davey <i>et al.</i> 2019)
Trial design	#3b	Important changes to methods after trial	Ref. 8 (Davey <i>et al.</i>

		commencement (such as eligibility criteria), with reasons	2019)
Participants	#4a	Eligibility criteria for participants	Ref. 8 (Davey <i>et al.</i> 2019)
Participants	#4b	Settings and locations where the data were collected	Supplemental material pg 2-3 & Ref. 8 (Davey <i>et al.</i> 2019)
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pg 6 & Ref. 8 (Davey <i>et al.</i> 2019)
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	pg 6 & Ref. 8 (Davey <i>et al.</i> 2019)
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	Ref. 8 (Davey <i>et al.</i> 2019)
Sample size	#7a	How sample size was determined.	pg 7 & Ref. 8 (Davey <i>et al.</i> 2019)
Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	Ref. 8 (Davey <i>et al.</i> 2019)
Randomization - Sequence generation	#8a	Method used to generate the random allocation sequence.	Ref. 8 (Davey <i>et al.</i> 2019)
Randomization - Sequence generation	#8b	Type of randomization; details of any restriction (such as blocking and block size)	Ref. 8 (Davey <i>et al.</i> 2019)
Randomization - Allocation concealment mechanism	#9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Ref. 8 (Davey <i>et al.</i> 2019)

Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	Ref. 8 (Davey <i>et al.</i> 2019)
Blinding	#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	Ref. 8 (Davey <i>et al.</i> 2019)
Blinding	#11b	If relevant, description of the similarity of interventions	Ref. 8 (Davey <i>et al.</i> 2019)
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	pg 29-30 & Ref. 8 (Davey <i>et al.</i> 2019)
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	pg 29-30 & Ref. 8 (Davey <i>et al.</i> 2019)
Results			
Participant flow diagram (strongly recommended)	#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 & Ref. 8 (Davey <i>et al.</i> 2019)
Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	Figure 1 & Ref. 8 (Davey <i>et al.</i> 2019)
Recruitment	#14a	Dates defining the periods of recruitment and follow-up	pg 6 & Ref. 8 (Davey <i>et al.</i> 2019)
Recruitment	#14b	Why the trial ended or was stopped	pg 6 & Ref. 8 (Davey <i>et al.</i> 2019)
Baseline data	#15	A table showing baseline demographic and clinical characteristics for each group	Ref. 8 (Davey <i>et al.</i> 2019)
Numbers analysed	#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	pg 7, Figure 1 & Ref. 8 (Davey <i>et al.</i> 2019)
Outcomes and estimation	#17a	For each primary and secondary outcome, results for each group, and the estimated	pg 9-17 & Ref. 8 (Davey <i>et al.</i> 2019)

		effect size and its precision (such as 95% confidence interval)	
Outcomes and estimation	#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	pg 9-17 & Ref. 8 (Davey et al. 2019)
Ancillary analyses	#18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	pg 15-17 & Ref. 8 (Davey et al. 2019)
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	Ref. 8 (Davey et al. 2019)
Discussion			
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	pg 17-24 & Ref. 8 (Davey et al. 2019)
Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	pg 17-24 & Ref. 8 (Davey et al. 2019)
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	pg 17-24 & Ref. 8 (Davey et al. 2019)
Registration	#23	Registration number and name of trial registry	pg 3 & Ref. 8 (Davey et al. 2019)
Other information			
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	pg 17-24 & Ref. 8 (Davey et al. 2019)
Registration	#23	Registration number and name of trial registry	pg 3 & Ref. 8 (Davey et al. 2019)
Protocol	#24	Where the full trial protocol can be accessed, if available	pg 3 & Ref. 8 (Davey et al. 2019)
Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	pg 31 & Ref. 8 (Davey et al. 2019)

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