ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

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Entity: government agency, foundation, commercial sponsor, academic institution, etc.
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Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting , lectures, speakers bureaus, expert testimony, employment, or other affiliations
Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.
Other: Anything not covered under the previous three boxes
Pending: The patent has been filed but not issued
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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Frank
2. Surname (Last Name): Waldron-Lynch
3. Date: 16-July-2018

4. Are you the corresponding author? ☑ Yes ☐ No

5. Manuscript Title
DILfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes

6. Manuscript Identifying Number (if you know it)
99306-INS-CMED-RV-3_mstext_304730

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Sir Jules Thorn Trust	☑	☐	☐	☐	
Swiss National Science Foundation (SNSF)	☑	☐	☐	☐	
Wellcome	☑	☐	☐	☐	
JDRF	☑	☐	☐	☐	
NIHR Cambridge Biomedical Research Centre	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication.**

Are there any relevant conflicts of interest? ☑ Yes ☐ No

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Epidarex Capital	☐	☑	☐	☐	
GlaxoSmithKline	☑	☑	☐	☐	
Novo Nordisk	☐	☑	☐	☐	
Eli Lilly	☐	☑	☐	☐	
Hoffmann-La Roche	☑	☑	☐	☐	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☑ Yes, the following relationships/conditions/circumstances are present (explain below):

☐ No other relationships/conditions/circumstances that present a potential conflict of interest

FWL is currently employed by Novartis AG.

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Waldron-Lynch reports grants from Sir Jules Thorn Trust, grants from Swiss National Science Foundation (SNSF), grants from Wellcome, grants from JDRF, grants from NIHR Cambridge Biomedical Research Centre, during the conduct of the study; personal fees from Epidarex Capital, grants and personal fees from GlaxoSmithKine, personal fees from Novo Nordisk, personal fees from Eli Lilly, grants and personal fees from Hoffmann-La Roche, outside the submitted work; and FWL is currently employed by Novartis AG..

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Adrian
2. Surname (Last Name): Mander
3. Date: 07-September-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Frank Waldron-lynch

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)
99306-INS-CMED-TR-2

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Dr. Mander has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name): James
2. Surname (Last Name): Howlett
3. Date: 10-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Dr Frank Waldron-Lynch

5. Manuscript Title: DILfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Section 4. Intellectual Property -- Patents & Copyrights

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Mr. Howlett has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Simon
2. Surname (Last Name): Bond
3. Date: 09-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Frank Waldron-Lynch

5. Manuscript Title
DILfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☑ Yes ☐ No

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Sir Jules Thorn Charitable Trust	☑	☐	☐	☐	

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Dr. Bond reports grants from Sir Jules Thorn Charitable Trust, during the conduct of the study; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Ravinder
2. Surname (Last Name): Atkar
3. Date: 07-September-2018

4. Are you the corresponding author? ☐ Yes ☑ No
   Corresponding Author's Name: Frank

5. Manuscript Title:

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

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Dr. Atkar has nothing to disclose.

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This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

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Section 1. Identifying Information

1. Given Name (First Name): James
2. Surname (Last Name): Heywood
3. Date: 06-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Dr. Frank Waldron-Lynch

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)
99306-INS-CMED-TR-2)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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Section 1. Identifying Information

1. Given Name (First Name): Eleonora
2. Surname (Last Name): Seelig
3. Date: 04-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No Corresponding Author's Name

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)
99306-INS-CMED-RV-3

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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Section 1. Identifying Information

1. Given Name (First Name): Ed
2. Surname (Last Name): Rytina
3. Date: 05-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Dr Frank Waldron-Lynch

5. Manuscript Title
DILfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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Dr. Rytina has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Marcin Lukasz
2. Surname (Last Name): Pekalski
3. Date: 09-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Frank Waldron-Lynch

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)
99306-INS-CMED-TR-2

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Dr. Marcin Pekalski has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Mark
2. Surname (Last Name): Evans
3. Date: 06-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Seelig

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (If you know it)

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Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Sir Jules Thorne Trust	☑	☐	☐	☐	
UK NIHR	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Evans reports grants from Sir Jules Thorne Trust, grants from UK NIHR , during the conduct of the study; .

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Jane
2. Surname (Last Name): Kennet
3. Date: 05-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Dr Frank Waldron-Lynch

5. Manuscript Title: DILfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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Ms. Kennet has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): John
2. Surname (Last Name): Todd
3. Date: 06-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: F Waldron-Lynch

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Section 6. Disclosure Statement

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Dr. Todd has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Linda
2. Surname (Last Name): Wicker
3. Date: 05-July-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Frank Waldron-Lynch

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Roche Pharmaceutical	☑	☐	☑	☐	IL-2 fusion proteins received for research use

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Interleukin-2 fusion proteins and uses thereof US20140044675A1	☑	☐	☐	☐		Assigned to Roche Glycart--no financial interest
Interleukin-2 fusion proteins and uses thereof US20150218260A1	☑	☐	☐	☐		Assigned to Roche Glycart--no financial interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☐ Yes, the following relationships/conditions/circumstances are present (explain below):

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Dr. Wicker reports grants and non-financial support from Roche Pharmaceutical , outside the submitted work; In addition, Dr. Wicker has a patent Interleukin-2 fusion proteins and uses thereof US20140044675A1 pending, and a patent Interleukin-2 fusion proteins and uses thereof US20150218260A1 pending.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Lucy
2. Surname (Last Name): Truman
3. Date: 07-June-2018

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Eleonora Seelig

5. Manuscript Title
Targeting regulatory T cells with Interleukin-2 treatment in type 1 diabetes: a response-adaptive, non-randomised, open-label trial of repeat doses of Aldesleukin (DILfrequency)

6. Manuscript Identifying Number (if you know it)
(our reference 99306-INS-CMED-TR-2)

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Dr. Truman has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Emma
2. Surname (Last Name): Arbon
3. Date: 09 July 2018

4. Are you the corresponding author? ☐ Yes ☑ No

5. Manuscript Title: DiLfrequency: an adaptive trial to identify optimal interleukin-2 dosing in patients with type 1 diabetes.

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants/data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☑ No

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	No (adaptive trial design)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	9
	4b	Settings and locations where the data were collected	9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9, 10, Appendix
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	None
Sample size	7a	How sample size was determined	Not applicable
	7b	When applicable, explanation of any interim analyses and stopping guidelines	9
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Not applicable
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Not applicable
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	Not applicable
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not applicable

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not applicable
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tab. 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Fig. 1, Appendix
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5-7, Appendix
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5, Tab 2
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8, 9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8, 9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7-9
Other information			
Registration	23	Registration number and name of trial registry	11
Protocol	24	Where the full trial protocol can be accessed, if available	11
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.