

# Supplementary material

## Evaluating the online impact of reporting guidelines for randomised trial reports and protocols: a cross-sectional web-based data analysis of CONSORT and SPIRIT initiatives

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## Appendix A

### Dataset of guidelines and article guidelines

	<b>Reporting guideline</b>	<b>Number of articles</b>
<b>G1</b>	CONSORT 2010	11
<b>G2</b>	STRICTA	4
<b>G3</b>	CONSORT-AI	3
<b>G4</b>	CONSORT 2001	3
<b>G5</b>	SPIRIT-AI	3
<b>G6</b>	CONSORT-Pilot and Feasibility	2
<b>G7</b>	SPIRIT 2013	2
<b>G8</b>	CONSORT-SPI	2
<b>G9</b>	CONSORT-Abstracts	2
<b>G10</b>	CONSORT-Non-pharmacologic treatment 2008	2
<b>G11</b>	ACE	2
<b>G12</b>	CONSORT-CENT	2
<b>G13</b>	CONSORT-Herbal	2
<b>G14</b>	Simulation Research	1
<b>G15</b>	TIDieR-PHP	1
<b>G16</b>	SPIRIT-PRO	1
<b>G17</b>	CONSORT-Cluster	1
<b>G18</b>	CONSORT 1996	1
<b>G19</b>	CONSORT-EHEALTH	1
<b>G20</b>	CENT for TCM	1
<b>G21</b>	CONSORT-Equity	1
<b>G22</b>	CONSERVE	1
<b>G23</b>	CONSORT-Harms	1
<b>G24</b>	CONSORT-CHM 2017	1
<b>G25</b>	CONSORT crossover	1
<b>G26</b>	CONSORT-Within person	1
<b>G27</b>	CONSORT-Non-inferiority	1
<b>G28</b>	SPENT	1
<b>G29</b>	CONSORT multi-arm	1
<b>G30</b>	CONSORT-C	1
<b>G31</b>	CONSORT-Non-pharmacologic treatment 2017	1
<b>G32</b>	SPIRIT-TCM	1
<b>G33</b>	CONSORT SW-CRT	1
<b>G34</b>	TIDieR	1
<b>G35</b>	CONSORT-Pragmatic Trials	1
<b>G36</b>	TIDieR-Placebo	1
<b>G37</b>	CONSORT-PRO	1
<b>G38</b>	CONSORT-ROUTINE	1
	<b>TOTAL</b>	<b>65</b>

## Appendix B

Number of URL citations received by articles according to each URL ID

Publication	Journal	URL IDs					Years
		DOI	Journal	PMC	PubMed	ALL	
G01-p1	British medical journal	36	17		2	55	3
G02-p1	Jama	61	64		2	127	3
G03-p1	British medical journal	19	15			34	4
G04-p1	British medical journal	45	5	3	1	54	4
G05-p1	Annals of internal medicine	29			1	30	4
G06-p1	Annals of internal medicine	441	12		3	456	11
G06-p2	BMC medicine	682	48	3	5	738	11
G06-p3	British medical journal	1,218	50	200	113	1,581	11
G06-p4	Journal of clinical epidemiology	154	1			155	11
G06-p5	Obstetrics and gynecology	60	1		1	62	11
G06-p6	PLoS Medicine	424	6	3		433	11
G06-p7	Trials	272	57	4	1	334	11
G06-p8	Lancet	14				14	11
G06-p9	British medical journal	970	38	134	69	1,211	11
G06-p10	Journal of clinical epidemiology	339			5	344	11
G07-p1	Annals of internal medicine	1,181	19	5	9	1,214	8
G07-p2	British medical journal	924	24	18	10	976	8
G08-p1	Pilot and feasibility studies	187	37		7	231	5
G08-p2	British medical journal	206	40		3	249	5
G09-p1	Journal of the society for simulation in healthcare	10	1		2	13	5
G10-p1	British medical journal	16	8			24	6
G10-p2	British medical journal	13				13	6
G11-p1	British medical journal	862	64		9	935	7
G12-p1	Annals of internal medicine	259	16		44	319	17
G13-p1	Journal of medical internet research	143	51	5	2	201	10
G14-p1	Jama	130	12		1	143	8
G15-p1	Lancet	3				3	11
G16-p1	British medical journal	467	13	52	27	559	13
G17-p1	Lancet	87	5		3	95	13
G17-p2	PLoS Medicine	184	8	45	29	266	13
G18-p1	Annals of internal medicine	87	3		2	92	4
G19-p1	Annals of internal medicine	98	6		5	109	15
G19-p2	Journal of clinical epidemiology	27			2	29	15
G20-p1	British medical journal	474	6		23	503	9
G21-p1	Jama	299	5		1	305	9
G22-p1	PLoS Medicine	183	2	8	2	195	11
G22-p2	Journal of alternative and complementary medicine	23				23	11
G22-p3	Journal of evidence-based medicine	129			1	130	11
G22-p4	Acupuncture in medicine	65		1	1	67	11
G23-p1	Trials	31	34	1	2	68	3
G23-p2	Trials	35	23	2	5	65	3
G24-p1	Chinese journal of integrative medicine	15				15	2
G25-p1	British medical journal	7			3	10	1
G26-p1	Complementary therapies in medicine	4			1	5	2
G27-p1	British medical journal	33	35	1	1	70	2
G28-p1	Jama	18	35			53	2
G29-p1	British medical journal	85	60	3	1	149	3
G30-p1	British medical journal	29	68	5	28	130	1
G30-p2	Trials	21	5	4	26	56	1
G31-p1	British medical journal	21	50	1	8	80	1
G31-p2	Nature medicine	28	42		9	79	1
G31-p3	Lancet digital health	14	85		5	104	1
G32-p1	Nature medicine	28	246		31	305	1
G32-p2	British medical journal	18	50		29	97	1

<b>G32-p3</b>	Lancet digital health	14	45		26	85	1
<b>G33-p1</b>	Jama	89			19	108	25
<b>G34-p1</b>	Annals of internal medicine	134	1		2	137	20
<b>G34-p2</b>	Jama	272	3			275	20
<b>G34-p3</b>	Lancet	554			5	559	20
<b>G35-p1</b>	Annals of internal medicine	56			19	75	13
<b>G35-p2</b>	Annals of internal medicine	568	9		21	598	13
<b>G36-p1</b>	PLoS Medicine	21	14	1	2	38	1
<b>G37-p1</b>	British medical journal	8	14	9	27	58	0
<b>G38-p1</b>	Jama	1	41		2	44	0

Years: number of years since the publication of the article. The value 0 corresponds to 2021.

G6-P11 is excluded because this article doesn't have a URL-based DOI.

## Appendix C

Altmetric data (PlumX)

PUBLICATION	ABSTRACT VIEWS	CITATIONS	CLINICAL CITATIONS	EXPORTS SAVES	FACEBOOK COUNT	POLICY CITATIONS	READER COUNT	TWEET COUNT	URL CITATIONS
G1-P01	0	55	0	0	8	2	105	127	55
G2-P01	301	242	1	54	55	1	325	120	127
G3-P01	0	47	0	0	0	3	93	193	34
G4-P01	0	90	0	0	129	1	157	101	54
G5-P01	8	90	2	4	2	1	52	4	30
G6-P01	2,152	2,033	16	163	0	64	615	0	456
G6-P02	216	1,942	2	37	3	25	529	6	738
G6-P03	326	3,729	15	37	10	97	2,583	7	1,581
G6-P04	377	551	1	21	0	19	292	0	155
G6-P05	1	210	1	0	0	2	300	0	62
G6-P06	272	785	3	34	0	37	539	2	433
G6-P07	127	568	0	15	48	8	239	1	334
G6-P08	1	81	0	0	0	3	104	2	14
G6-P09	126	2,974	14	17	64	60	2,852	31	1,211
G6-P10	1,275	1,202	3	32	1	14	815	2	344
G7-P01	1,846	2,261	3	58	715	62	1,228	7	1,214
G7-P02	110	1,628	5	15	29	36	1,577	93	976
G8-P01	24	366	0	7	65	1	552	58	231
G8-P02	0	587	1	0	247	2	620	107	249
G9-P01	0	115	0	2	0	1	69	6	13
G10-P01	21	95	2	1	0	4	124	37	24
G10-P02	16	NA	1	1	123	2	105	32	13
G11-P01	227	2,964	9	29	136	92	2,567	311	935
G12-P01	767	1,005	27	48	0	61	571	4	319
G13-P01	1,015	853	0	242	27	3	968	39	201
G14-P01	297	618	4	69	0	12	528	83	143
G15-P01	1	18	0	0	0	0	92	0	3
G16-P01	78	1,043	15	22	0	31	904	2	559
G17-P01	11	284	13	0	0	10	408	1	95
G17-P02	452	395	16	29	2	19	392	20	266
G18-P01	6	387	2	0	8	7	509	2	92
G19-P01	427	410	21	31	0	17	226	0	109
G19-P02	145	142	0	7	0	6	158	0	29
G20-P01	123	971	3	9	0	32	921	19	503
G21-P01	409	674	4	32	0	8	727	20	305
G22-P01	86	430	5	7	17	10	231	2	195
G22-P02	3,236	55	0	106	0	1	44	0	23
G22-P03	58	236	1	5	0	3	286	0	130
G22-P04	1,660	118	0	62	0	1	59	1	67
G23-P01	82	74	0	19	30	1	144	180	68
G23-P02	83	61	0	23	36	1	151	201	65
G24-P01	31	24	1	5	0	1	25	1	15
G25-P01	0	10	0	0	2	0	42	14	10
G26-P01	20	4	0	1	0	0	21	0	5
G27-P01	0	84	0	0	137	2	205	98	70
G28-P01	89	50	0	3	154	0	150	62	53
G29-P01	0	94	1	0	38	0	141	242	149
G30-P01	2	15	0	0	163	0	62	237	130
G30-P02	0	5	0	0	0	0	29	62	56
G31-P01	0	29	0	0	39	1	78	92	80
G31-P02	0	61	0	0	0	1	130	1	79
G31-P03	0	18	0	0	22	0	105	120	104

<b>G32-P01</b>	0	85	0	0	89	1	159	3	305
<b>G32-P02</b>	0	33	0	0	235	1	89	98	97
<b>G32-P03</b>	0	9	0	0	12	0	101	45	85
<b>G33-P01</b>	145	2,930	32	25	0	105	631	2	108
<b>G34-P01</b>	724	913	13	43	0	22	205	0	137
<b>G34-P02</b>	224	1,887	32	28	0	94	171	0	275
<b>G34-P03</b>	3	2,906	0	0	0	108	308	0	559
<b>G35-P01</b>	1,951	363	5	75	0	12	368	0	75
<b>G35-P02</b>	3,697	1,586	13	136	1	42	1,012	0	598
<b>G36-P01</b>	0	8	0	0	9	0	25	37	38
<b>G37-P01</b>	0	3	0	0	78	0	20	207	58
<b>G38-P01</b>	0	1	0	0	0	0	61	357	44

NA: Not Available.

Note: The article G10-P02 was not found in Scopus. PlumX does not provided citation data from Scopus as well.

## Appendix D

### Source entity types

N	Entity type	Scope	Domain names	URL citations
1	<b>Academic database</b>	Website offering access to an online bibliographic database (e.g., dimensions.ai).	52	342
2	<b>App</b>	Website oriented to offering a software to be downloaded or purchased (e.g., issuhub.com)	14	80
3	<b>Blogs provider</b>	Website offering blog services (e.g., wordpress.com)	5	17
4	<b>Clinic</b>	Website representing a clinic (e.g., wellnessdoctorrx.com).	3	12
5	<b>Codes Hub</b>	Website collecting code from different users, offering a search functionality (e.g., sydit.se).	4	7
6	<b>Company</b>	Website representing a private firm (e.g., wire-technology.com). Publishers and media are excluded.	91	629
7	<b>Directory</b>	Website offering a list of URLs pointing to specific thematic websites (e.g., best-university.com).	38	74
8	<b>Encyclopaedia</b>	Website offering one or more encyclopaedias entries (e.g., wikipedia.org).	46	774
9	<b>Event</b>	Website informing about one specific activity (e.g., celebratingbletchleypark.co.uk).	2	6
10	<b>Gambling</b>	Website oriented to online game (e.g., online casinos).	6	11
11	<b>Governmental body</b>	Website representing any official administration or service, not related with health (e.g., csiro.au).	1	3
12	<b>Health government body</b>	Website representing an official health-related government entity, which can include research-related organizations (e.g., nih.gov).	15	107
13	<b>Health information hub</b>	Website including a collection of posts related with health (e.g., outsourcing-pharma.com).	71	335
14	<b>Higher Education Institution</b>	Website representing a university or any other educational body (e.g., columbia.edu).	83	2,326
15	<b>Hospital</b>	Website representing a hospital (e.g., usz.ch).	5	5
16	<b>Images Hub</b>	Website offering a collection of pictures (e.g., nodexlgraphgallery.org).		
17	<b>Library</b>	Website representing a Library, regardless the institution where the library is embedded (e.g., dntb.gov.ua).	2	2
18	<b>News Hub</b>	Website offering a collection of posts and news including a wide variety of topics and themes (e.g., wopular.com).	1	1
19	<b>Non-Academic database</b>	Website offering access to an online database unrelated with scientific and academic literature.	64	142
20	<b>Online Fora</b>	Websites offering forum services to users (e.g., stackexchange.com).	30	75
21	<b>Organization</b>	Websites representing any type of Association, Federation, co-op, excluding research organizations (e.g., equator-network.org).	7	12
22	<b>Other information hubs</b>	Websites or blogs offering a collection of posts in one specific topic, excluding health topics (e.g., ephorie.de).	95	432
23	<b>Parked</b>	Websites whose web domain is registered but no web-content has been included yet.	52	196
24	<b>Personal website</b>	Website representing an individual (e.g., nerler.com).	87	1,559
25	<b>Porn</b>	Websites including adult content and explicit sex.	6	6
26	<b>Promos</b>	Websites including promotional events and coupons.	2	2
27	<b>Publisher</b>	Websites representing a publisher, including books and journals (e.g., springer.com).	222	10,169
28	<b>Research centre</b>	Website representing a research centre, regardless the status (public or private) and the parent institution (e.g., ktdrr.org).	7	11
29	<b>Research group</b>	Website representing a research group, regardless the status (public or private) and the parent institution (e.g., https://www.pocog.org.au).	6	17
30	<b>Research institute</b>	Website representing a research institute, regardless the status (public or private) and the parent institution (e.g., sahmriresearch.org).	3	25
31	<b>Research project</b>	Website representing a research project, regardless the funding body (e.g., humanbehaviourchange.org).	3	4
32	<b>Science Hub</b>	Website including a collection of posts related with scientific content (e.g., the-scientist.com).	8	12
33	<b>Search engine</b>	Website offering a search engine (e.g., zapmeta.ng).	4	14

34	<b>Shopping</b>	Website offering goods and products to be online purchased through an ecommerce functionality (e.g., popflock.com).	10	52
35	<b>Social Networking Site</b>	Website offering a social media functionality, either scientific-related (e.g., figshare.com) or non-scientific (e.g., scwacy.com).	1	1
36	<b>Tourism</b>	Website offering touristic information about a city, region or country (e.g., irvinescotland.info).	4	20
37	<b>Unknown</b>	Websites whose contents have not been possible to be classified, either because its content is not accessible or because it could not be determined with precision.	6,987	66,272
38	<b>Videos Hub</b>	Website offering a collection of videos, including a wide variety of topics and themes (e.g., wikivisually.com).	2	18



## Appendix E

Number of linking domain names per entity type for each article

Publication	Publisher	Organization	Company	Higher Education Institution	Health information hub	News Hub	Other information hubs	Academic database	Encyclopedia	Directory	Other	All
G01-p1	24	6	1	8	1	0	1	2	0	4	8	55
G02-p1	45	21	10	18	21	0	0	3	0	1	8	127
G03-p1	17	1	0	5	0	0	0	0	0	8	3	34
G04-p1	22	0	1	16	7	2	3	2	0	0	1	54
G05-p1	28	0	1	0	0	0	0	0	0	1	0	30
G06-p1	371	2	15	53	2	0	0	9	0	0	4	456
G06-p10	261	0	4	68	0	0	0	8	1	0	2	344
G06-p2	589	7	5	99	15	0	1	12	0	0	10	738
G06-p3	883	18	64	164	64	18	17	24	290	2	37	1,581
G06-p4	128	0	2	17	0	0	0	4	0	0	4	155
G06-p5	51	0	0	4	0	0	0	5	0	0	2	62
G06-p6	395	3	1	28	0	0	0	1	0	0	5	433
G06-p7	209	10	1	83	2	0	1	10	0	0	18	334
G06-p8	9	2	2	1	0	0	0	0	0	0	0	14
G06-p9	706	11	43	144	37	17	10	18	188	5	32	1211
G07-p1	983	6	9	201	2	0	0	5	1	2	5	1,,214
G07-p2	723	3	8	183	8	2	0	12	18	12	7	976
G08-p1	174	1	6	32	2	0	0	10	0	1	5	231
G08-p2	179	0	9	37	0	0	4	8	7	0	5	249
G09-p1	7	0	0	1	0	0	0	1	0	2	2	13
G10-p1	12	1	1	2	1	2	0	0	0	0	5	24
G10-p2	12	0	0	1	0	0	0	0	0	0	0	13
G11-p1	711	19	20	121	2	3	0	31	1	9	18	935
G12-p1	171	8	18	29	0	8	9	3	55	0	18	319
G13-p1	157	0	2	32	0	0	0	3	0	2	5	201
G14-p1	119	4	3	11	1	0	0	0	0	0	5	143
G15-p1	2	0	0	0	0	0	0	0	0	0	1	3
G16-p1	334	9	22	87	15	3	5	4	68	0	12	559
G17-p1	79	0	2	11	0	0	0	0	0	0	3	95
G17-p2	110	7	26	22	7	3	21	1	49	0	20	266
G18-p1	72	4	5	6	0	0	0	4	0	0	1	92
G19-p1	85	4	1	16	0	0	0	2	0	0	1	109

G19-p2	24	2	0	3	0	0	0	0	0	0	0	0	29
G20-p1	354	1	12	80	10	2	4	6	26	0	8	503	
G21-p1	140	3	0	155	3	1	0	1	0	0	2	305	
G22-p1	163	1	4	15	4	0	0	6	0	0	2	195	
G22-p2	19	0	0	3	0	0	0	0	0	0	1	23	
G22-p3	110	0	7	7	0	0	0	4	0	0	2	130	
G22-p4	59	1	2	3	0	0	0	2	0	0	0	67	
G23-p1	20	10	15	19	0	0	1	2	0	0	1	68	
G23-p2	11	9	12	22	1	0	1	5	0	0	4	65	
G24-p1	9	0	0	0	0	0	0	5	0	0	1	15	
G25-p1	5	1	0	0	0	0	0	3	0	1	0	10	
G26-p1	3	0	0	0	0	0	0	0	0	1	1	5	
G27-p1	30	1	7	2	0	4	10	3	0	2	11	70	
G28-p1	11	8	2	18	9	2	0	1	0	0	2	53	
G29-p1	40	2	7	63	1	3	5	5	0	0	23	149	
G30-p1	5	31	9	20	0	6	13	17	0	0	29	130	
G30-p2	3	28	0	8	9	0	0	7	0	0	1	56	
G31-p1	17	6	5	6	13	3	6	0	0	5	19	80	
G31-p2	12	10	9	10	5	3	1	15	0	0	14	79	
G31-p3	4	10	17	7	4	16	22	2	0	2	20	104	
G32-p1	19	39	81	6	30	36	51	20	0	3	20	305	
G32-p2	15	28	21	4	14	1	1	0	0	1	12	97	
G32-p3	2	31	24	3	6	3	2	0	0	3	11	85	
G33-p1	76	3	0	0	7	1	0	4	7	0	10	108	
G34-p1	107	3	1	21	0	0	0	3	0	0	2	137	
G34-p2	201	2	2	62	0	0	0	4	0	0	4	275	
G34-p3	425	1	6	107	0	0	0	8	8	0	4	559	
G35-p1	19	0	11	3	6	2	2	1	25	0	6	75	
G35-p2	424	2	16	111	6	2	2	3	26	0	6	598	
G36-p1	2	5	9	13	1	2	0	3	1	0	2	38	
G37-p1	3	27	0	4	1	1	1	16	0	2	3	58	
G38-p1	2	6	1	8	4	2	1	10	0	3	7	44	

## Appendix F

### Object genres

Object genre	Scope
Author guidelines	Publishing recommendations and guidelines for authors.
Bibliographic record	Machine-readable record created by a bibliographic database (e.g., repository) which includes bibliographic metadata. This record usually corresponds to the guideline publication itself.
Comment / Forum	Content published as part of an online forum post.
Data Report / Altmetric data provider	Data sheet automatically created by an altmetrics data provider.
Data report / SEO tool	Data sheet automatically created by SEO tools.
Institutional information	Descriptive content related to institutional information.
News	News published in different website categories (e.g., (media, thematic information, professional blogs)
Not found	Non-accessible webpages
Personal page	Personal webpages including academic CVs, that include in turn bibliographic references.
Post	Periodic publication included in multidisciplinary websites.
Post / Tweet	A micro-post published in the social networking site Twitter.
Publication / Article	Scientific publication (in this case a journal article). The link can be placed in any section of the publication.
Publication / Book	Scientific publication (including a thesis). The link can be placed in any section of the publication.
Publication / Mirror	Scientific publication hosted in a publisher's mirror.
Publication / Summary	A summary of one publication (necessarily not the abstract) published in an academic website.
References list	Set of references gathered by bibliographic databases, repositories, wikis or institutional websites (e.g., research centers, research groups).
Resource list	Directory of thematic web resources.
Teaching material	Contents created to support teaching (e.g., syllabi, notes)
Undetermined	Accessible webpages without links
Void	Non-accessible webpages.
Wiki entry	Articles published in a collaboratively developed website (e.g., Wikipedia).

## Author guidelines

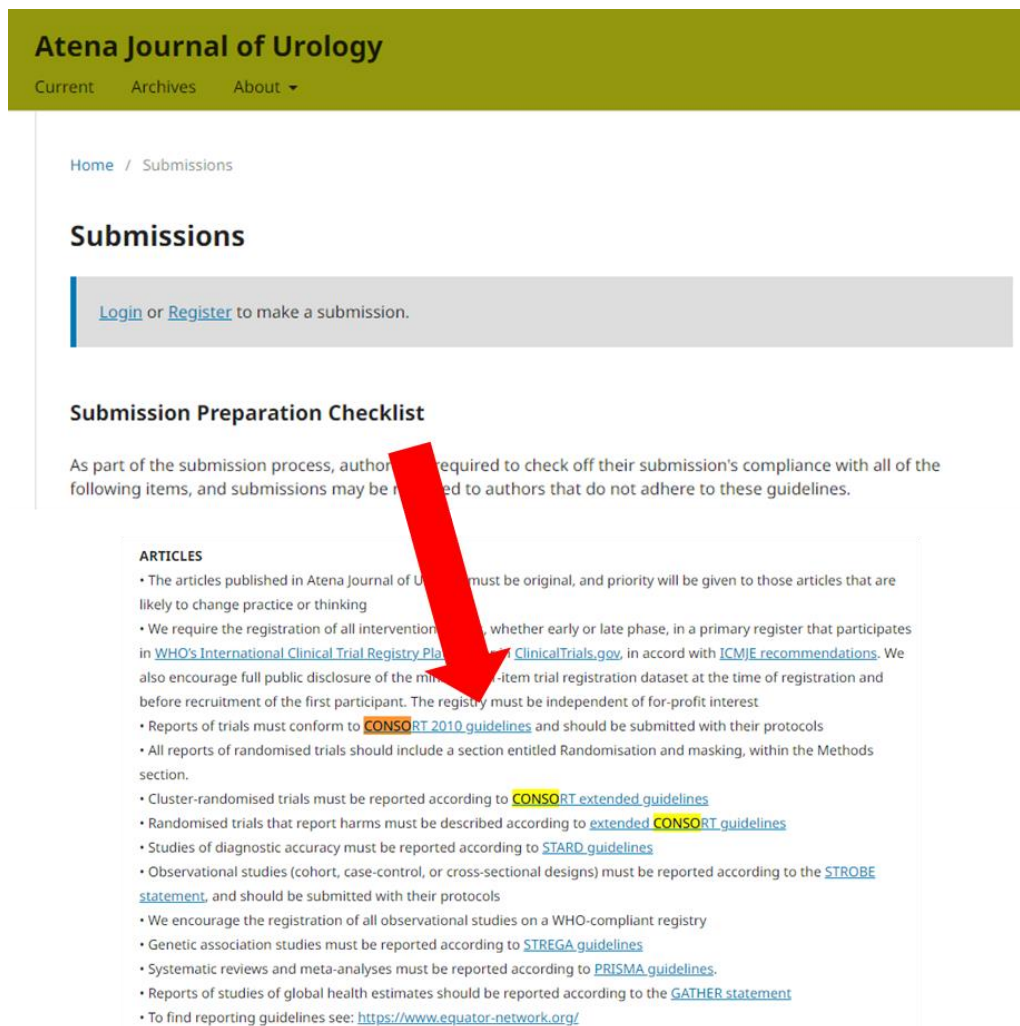
Reporting publication cited: G17-P01

Source URL

<https://www.elsevier.com/journals/journal-of-emergency-nursing/0099-1767/guide-for-authors>

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- We require the registration of all interventional trials, whether early or late phase, in a primary register that participates in [WHO's International Clinical Trial Registry Platform](#) or [ClinicalTrials.gov](#), in accord with [ICMJE recommendations](#). We also encourage full public disclosure of the minimum 5-item trial registration dataset at the time of registration and before recruitment of the first participant. The registry must be independent of for-profit interest
- Reports of trials must conform to [CONSORT 2010 guidelines](#) and should be submitted with their protocols
- All reports of randomised trials should include a section entitled Randomisation and masking, within the Methods section.
- Cluster-randomised trials must be reported according to [CONSORT extended guidelines](#)
- Randomised trials that report harms must be described according to [extended CONSORT guidelines](#)
- Studies of diagnostic accuracy must be reported according to [STARD guidelines](#)
- Observational studies (cohort, case-control, or cross-sectional designs) must be reported according to the [STROBE statement](#), and should be submitted with their protocols
- We encourage the registration of all observational studies on a WHO-compliant registry
- Genetic association studies must be reported according to [STREGA guidelines](#)
- Systematic reviews and meta-analyses must be reported according to [PRISMA guidelines](#).
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24/10/2016

**Author**  
[Eldridge, Sandra M.](#)  
[Chan, Claire L.](#)  
[Campbell, Michael J.](#)  
[Bond, Christine M.](#)

**Citation**  
Eldridge, S M, Chan, C L, Campbell, M J, Bond, C M, Hopewell, S, Thabane, L, Lancaster, G A & PAFS consensus group 2016, 'CONSORT 2010 Statement : extension to randomised pilot and feasibility trials', *BMJ*, vol. 355, i5239, pp. 1-29.  
<https://doi.org/10.1136/bmj.i5239>

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### Reference Collection to push back against “Common Statistical ...

■ data analysis journal teaching



- Snapinn SM, Jiang Q. Responder analyses and the assessment of a clinically relevant treatment effect. *Trials* 2007. 38

### Significance testing in pilot studies

**Rationale:** Authors often perform null-hypothesis testing in pilot studies and report p-values. However, the purpose of pilot studies is to identify issues in all aspects of the study ranging from recruitment to data management and analysis. Pilot studies are not usually powered for inferential testing. If testing is done, p-values should not be emphasized and confidence intervals should be reported. Results on potential outcomes should be regarded as descriptive. A CONSORT extension for pilot and feasibility studies exist, and is a useful reference to include in submissions and cover letters. Editors may not be aware of this extension of CONSORT.

- Eldridge SM *et al.* CONSORT 2010 statement: extension to randomised pilot and feasibility trials, *BMJ* 2016 32
- Moore CG *et al.* Recommendations for Planning Pilot Studies in Clinical and Translational Research, *Clin Transl Sci* 2011 25

## Data report / Altmetric bibliographic report

Reporting publication cited: G11-P01

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<https://doi.org/10.1136/bmj.g1687>

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### CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

Home / CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

#### Multilingual Wikipedia

In June 2020 the work **CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials** was on the **3,102<sup>nd</sup> place** in the ranking of the most reliable and popular publications with DOI number in multilingual Wikipedia from readers' point of view (PR-score). If we consider only frequency of appearance of this source in references of Wikipedia articles (F-score), this work was on the **4,367<sup>th</sup> place** in June 2020. From Wikipedians' point of view, "CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials" is the **27,545<sup>th</sup>** most reliable publication with DOI number in different language versions of Wikipedia (AR-score).

PR-score: ▲ 3,102 <sup>nd</sup> place <b>284,143</b> -49,549	AR-score: ▲ 27,545 <sup>th</sup> place <b>5,771</b> +84	F-score: ▼ 4,367 <sup>th</sup> place <b>55</b> 0
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## Outcomes

Theme Leads

[Kerry Avery](#)

[Shelley Potter](#)

### Patient reported outcomes (PROs) and measures (PROMs)

The centre is working with international collaborators to improve measurement and reporting of PROs in surgical trials. This has included work with the [European Organisation for Research and Treatment of Cancer \(EORTC\) Quality of life Group](#) to develop and validate a portfolio of PRO measures (PROMs). Other collaborations have produced the [SPIRIT-PRO extension](#) and the [CONSORT-PRO extension](#) guidelines for incorporating PROs in protocols and trial reports.

We have developed a novel approach to outcome assessment and designed a single questionnaire for completion by patients and/or healthcare professionals; universal-reporter outcome measures ([UROMs](#)). UROMs combine plain language alongside medical terminology in items, and are suitable for use when patient and healthcare views on the same subject are required. The use of plain language alongside medical terminology presents

## News

Reporting publication cited: G32-P03

Source URL :

<https://www.news-medical.net/news/20200910/New-guidelines-can-boost-transparency-of-clinical-trials-evaluating-AI-health-solutions.aspx>

Target URL :

[https://doi.org/10.1016/S2589-7500\(20\)30218-1](https://doi.org/10.1016/S2589-7500(20)30218-1)

The screenshot shows the top portion of a news article on the News Medical Life Sciences website. The main headline is "New guidelines can boost transparency of clinical trials evaluating AI health solutions". Below the headline is a "Download PDF Copy" button and a byline: "Reviewed by Emily Henderson, B.Sc." dated "Sep 10 2020". The article text begins with "Patients could benefit from faster and more effective introduction of artificial intelligence (AI) innovations to diagnose and treat disease - thanks to the first international standards for reporting of clinical trials for AI." and continues with "As evaluation of health interventions involving machine learning or other AI systems moves into clinical trials, an international group has developed guidelines aiming to improve the quality of these studies and ensure that they are reported transparently." To the right of the main text are three featured stories: "A pair of analyses reveals early epicenter of the COVID-19 pandemic", "Three doses of Novavax vaccine effective against Omicron subvariants", and "Researchers report 'hybrid immune damping' following SARS-CoV-2 Omicron infection".

The SPIRIT-AI extension includes 15 new items and the CONSORT-AI extension includes 14 new items - all considered sufficiently important for clinical trial protocols of AI interventions to be routinely reported in addition to core items.

**Source:**

University of Birmingham

**Journal reference:**

Liu, X., *et al.* (2020) Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. *Nature Medicine*. doi.org/10.1016/S2589-7500(20)30218-1.

## Personal page

Reporting publication: G23-P01, G23-P02

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Target URL:

<https://doi.org/10.1186/s13063-018-2733-1>



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# Professor Paul Montgomery

[Department of Social Policy, Sociology and Criminology](#)

Professor of Social Intervention

Director of Postgraduate Research for the School of Social Policy

Cross Whitehall Trials Panel Advisor and Affiliate Professor at the

Department of Family Studies, University of Malta

Research	+
Other activities	+
Publications	—

Foster, J.; Montgomery, P. A Study of Environmentally Friendly Menstrual Absorbents in the Context of Social Change for Adolescent Girls in Low- and Middle-Income Countries. *Int. Environ. Res. Public Health* 2021, 18, 9766.

Bach-Mortensen, A.M and Montgomery, P. (2019) Does sector matter for the quality of care services? A secondary analysis of social care services regulated by the Care Inspectorate in Scotland, Vol 9, 2. *BMJ Open*

Montgomery, P., Grant, S., Mayo-Wilson, E., Macdonald, G., Michie, S., Hopewell, S. and Moher, D. on behalf of the CONSORT-SPI Group (2018) Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension.

Grant, S., Mayo-Wilson, E., Montgomery, P., Macdonald, G., Michie, S., Hopewell, S. and Moher, D. on behalf of the CONSORT-SPI Group (2018). CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials.

## Post

Reporting publications cited: G6-P01, G6-P02, G6-P05, G6-P06, G6-P07, G6-P11

Source URL :

<https://cambridgemedicallibrary.blogspot.com/2010/03/new-consort-guidelines-for-rcts.html>

Target URL :

<http://www.annals.org/content/early/2010/03/18/0003-4819-152-11-201006010-00232.full?aimhp>

<http://www.biomedcentral.com/1741-7015/8/18/abstract>

[http://journals.lww.com/greenjournal/documents/CONSORT2010\\_ObstetGynecol.pdf](http://journals.lww.com/greenjournal/documents/CONSORT2010_ObstetGynecol.pdf)

<http://www.openmedicine.ca/article/view/352/315>

<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000251>

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## New CONSORT guidelines for RCTs



"New guidance to improve the reporting of trial

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**Full and transparent reporting of trials is crucial** to ensure that decisions about health care are based on the best available evidence. "

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[https://doi.org/10.1016/S2589-7500\(20\)30219-3](https://doi.org/10.1016/S2589-7500(20)30219-3)

<http://www.bmj.com/content/370/bmj.m3210>

<https://www.nature.com/articles/s41591-020-1034-x>

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**Pearse Keane** @pearkeane Jan 15th 2021  
"ANNOUNCEMENT" (This time with correct links!) On Feb 17th we'll be releasing a new short course @Moorfields @StudyVisionUCL @UCLeye "An introduction to AI for clinicians" We're excited and proud to tell you all about it... #OnDemand #Virtual #AI  
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**Xiao Liu** @DxvfxLiu Sep 9th 2020  
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Read 11 tweets

**Declan O'Regan** @DeclanORegan Feb 8th 2020  
Having reviewed a bunch of radiology papers lately with the same flaws - some #ML but most not - here are my top 10 tips! #AcademicChatter #radiology #AI  
1/ Start with what is already known, where is the gap in  
Read 11 tweets

**Xiao Liu**  
Follow @DxvfxLiu 1,783 followers  
9 Sep, 11 tweets, 12 min read  
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1/NEW: Today the SPIRIT-AI and CONSORT-AI Working Group have published the first reporting guidelines for clinical trials evaluating AI interventions in @NatureMedicine @LancetDigitalH @bmj\_latest

Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension

CONSENSUS STATEMENT

REPORTING GUIDELINES FOR CLINICAL TRIAL REPORTS FOR INTERVENTIONS INVOLVING ARTIFICIAL INTELLIGENCE: THE CONSORT-AI EXTENSION

2/ Papers here:

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[bmj.com/content/370/bmj.m3210](http://www.bmj.com/content/370/bmj.m3210)

CONSORT-AI [nature.com/articles/s41591-020-1034-x](https://www.nature.com/articles/s41591-020-1034-x); [doi.org/10.1016/S2589-7500\(20\)30218-1](https://doi.org/10.1016/S2589-7500(20)30218-1);

Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension

CONSENSUS STATEMENT

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**Infectious Diseases of Poverty**

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Scoping Review | Open Access | Published: 03 September 2018

**A scoping review on the field validation and implementation of rapid diagnostic tests for vector-borne and other infectious diseases of poverty in urban areas**

Lyda Osorio , Jonny Alejandro Garcia, Luis Gabriel Parra, Victor Garcia, Laura Torres, Stéphanie Degroote & Valéry Ridde



12. Pluye P, Robers E, Cargo M, Bartlett G, O' Cathain A, Griffiths F, et al. Proposal: a mixed methods appraisal tool for systematic mixed studies reviews. Montreal: Department of Family Medicine, McGill University; 2011. Available from: <http://mixedmethodsappraisaltoolpublic.pbworks.com/w/page/24607821/FrontPage>  
[Google Scholar](#)
13. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24609605>  
[Article](#) [PubMed](#) [Google Scholar](#)
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[Article](#) [PubMed](#) [Google Scholar](#)
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## Publication / Book

Reporting publication cited: G17-P02

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<https://deemagclinic.com/2020/12/03/art-of-thesis-writing/>

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<https://doi.org/10.1371/journal.pmed.0050020>



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<https://doi.org/10.1007/978-981-13-0890-1>

Library of Congress Control Number: 2018956493

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8. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals- Updated December 2016. Available from: <http://www.icmje.org/icmje-recommendations.pdf>. Accessed 29 Aug 2017.

9. International Committee of Medical Journal Editors- Manuscript preparation Available from: <http://www.icmje.org/recommendations/browse/manuscript-preparation/>. Accessed 29 Aug 2017.

10. PLOS Medicine Editors. From checklists to tools: lowering the barrier to better research reporting. PLoS Med. 2015;12:e1001910.

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## Publication / Mirror

Reporting publication cited: G9-P01

Source URL:

<https://0-advancesinsimulation-biomedcentral-com.brum.beds.ac.uk/articles/10.1186/s41077-017-0039-0>

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[https://journals.lww.com/simulationinhealthcare/Fulltext/2016/08000/Reporting\\_Guidelines\\_for\\_Health\\_Care\\_Simulation.4.aspx](https://journals.lww.com/simulationinhealthcare/Fulltext/2016/08000/Reporting_Guidelines_for_Health_Care_Simulation.4.aspx)

The screenshot shows a web browser displaying the BMC article page. A red box highlights the URL in the address bar. A red arrow points from the title area down to the citation list. A red box highlights the citation for the current article (47).

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[Adam Cheng](#) ✉, [David Kessler](#), [Ralph Mackinnon](#), [Todd P. Chang](#), [Vinay M. Nadkarni](#), [Elizabeth A. Hunt](#), [Jordan DuBois](#), [Arno Arnold](#), [Yiqun Lin](#), [Martin Pusic](#) & [Marc Auerbach](#)

*Advances in Simulation* 2, Article number: 6 (2017) | [Cite this article](#)

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### Abstract

45. Cheng A, Kessler D, Mackinnon R, et al. Reporting guidelines for health care simulation research: extensions to the CONSORT and STROBE statements. *BMJ Simul Technol Enhanced Learn*. 2016;bmjstel-2016-000124.

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## Publication / Summary

Reporting publication cited: G2-P01

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The screenshot shows the top navigation bar of the University of Birmingham website. On the left is the university's crest and logo. To the right, there are links for 'Teaching excellence', 'Alumni', 'Work here', 'Events', 'Visit', and a location selector set to 'UK Dubai'. Below these are main navigation categories: 'Study', 'Research', 'International', 'Business', 'News', and 'About us'. A search icon is on the far right. Below the navigation bar is a breadcrumb trail: 'Home > Research > Centre for Patient Reported Outcome Research (CPROR) > Research > SPIRIT-PRO Standard Protocol Items: Recommendations for Interventional Trials Patient-Reported Outcome Extension'. A secondary navigation bar contains links for 'Research Spotlights', 'Our Researchers', 'Research Areas', 'PhDs', 'Institutes', 'Research News', and 'Quest'.

# International Consensus Guidance on the Inclusion of Patient-Reported Outcomes (PROs) in Clinical Trial Protocols: The SPIRIT-PRO Extension

## Background

Patient reported outcomes (PRO) including; health-related quality of life, symptoms such as pain or fatigue and health utility are often assessed in clinical trials as a measure of effectiveness. Increasingly PRO data may be used to inform clinical care and decision-making, predict long-term outcomes and inform health policy.

This work has been published in [JAMA](#).

The SPIRIT-PRO guidelines provide recommendations for items that should be addressed and included in clinical trial protocols in which PROs are a primary or key secondary outcome. Improved design of clinical trials including PROs could help ensure high-quality data that may inform patient-centered care.

The use of PRO ensures that the patient perspective is at the heart of health research and clinical decision-making. Therefore, studies with a PRO outcome should strive to maintain the highest standards; in-terms of

The sidebar contains three items: 'In 'Research'' (highlighted), '> Resources / Facilities', and a button with a left-pointing arrow labeled 'Back to 'Centre for Patient Reported Outcome Research (CPROR)''.

## References list

Reporting publication cited: G31-P02 and G32-P01

Source URL:

<https://www.birmingham.ac.uk/research/applied-health/key%20publications.aspx>

Target URL:

<https://pubmed.ncbi.nlm.nih.gov/32908283/>

<https://pubmed.ncbi.nlm.nih.gov/32908284/>

The screenshot shows the 'Key Publications' page on the University of Birmingham website. The page header includes the university logo and navigation links. Below the header, there is a breadcrumb trail: Home > Research > Institute of Applied Health Research > Key Publications. A navigation menu contains links for Research Spotlights, Our Researchers, Research Areas, PhDs, Institutes, Research News, and Quest. The main heading is 'Key Publications'. Below this, a text block states: 'Shown here are some of the recent publications which highlight significant advances made by researchers in the Institute of Applied Health Research.' To the right, there is a sidebar with a search icon and a link to 'Institute of Applied Health Research'. The main content area displays a list of publications. A red box highlights two publications:

- Liu X, Cruz Rivera S, Moher D, Calvert MJ, Denniston AK; SPIRIT-AI and CONSORT-AI Working Group. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. *Nat Med.* 2020 Sep;26(9):1364-1374.
- Cruz Rivera S, Liu X, Chan AW, Denniston AK, Calvert MJ; SPIRIT-AI and CONSORT-AI Working Group; SPIRIT-AI and CONSORT-AI Steering Group; SPIRIT-AI and CONSORT-AI Consensus Group. Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension. *Nat Med.* 2020 Sep;26(9):1351-1363.

Other visible publications include:

- Digoxin vs bisoprolol for Heart Rate Control in Atrial Fibrillation on Patient-Reported Quality of Life: The RATE-AF Randomized Clinical Trial. *JAMA.* 2020 Dec 22;324(24):2497-2508. doi:10.1001/jama.2020.23138.
- Lemp JM, De Neve J, Bussmann H, et al. Lifetime Prevalence of Cervical Cancer Screening in 55 Low- and Middle-Income Countries. *JAMA.* 2020;324(15):1532-1542. doi:10.1001/jama.2020.16244
- Allotey J, Stallings E, Bonet M, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ.* 2020;370:m3320. Published 2020 Sep 1. doi:10.1136/bmj.m3320
- Chu JJ, Devall AJ, Beeson LE, Hardy P, et al. Mifepristone and misoprostol versus misoprostol

## Resource list

Reporting publication cited: G38-P01

Source URL:

<https://ecrin.org/other-covid-19-resources>

Target URL:

<https://jamanetwork.com/journals/jama/fullarticle/2781397>



The screenshot shows the ECRIN website header with the logo and navigation menu. Below the header is a banner image with the text "ECRIN - European Clinical Research Infrastructure Network". Underneath the banner is the section title "OTHER COVID-19 RESOURCES".

- EFGCP (European Forum for Good Clinical Practice)
- Trials: COVID-19 randomised trial protocols
- Risk factors for COVID-19 disease progression
- Guidelines for trials impacted by the COVID-19 pandemic
- The CONSERVE 2021 Statement - Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances**
- COVID-19 Statistics/Epidemiological data
- Worldometers
- WHO (World Health Organization)
- ECDC (European Center for Disease Prevention and Control)
- Global health COVID-19 dataset
- COVID-19 trials reviews/trackers
- COVID-NMA - COVID-19 living mapping of ongoing research and network meta-analysis

## Teaching material

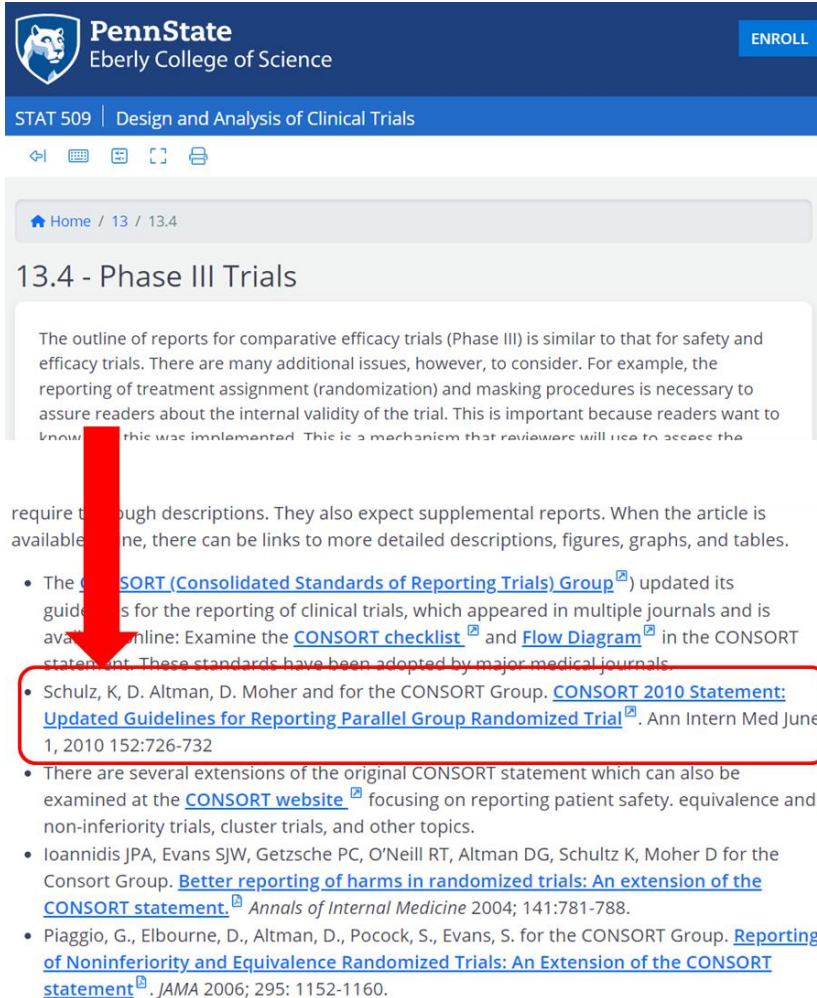
Reporting publication cited: G6-P01

Source URL:

<https://online.stat.psu.edu/stat509/lesson/13/13.4>

Target URL:

<https://www.acpjournals.org/doi/10.7326/0003-4819-152-11-201006010-00232>



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Home / 13 / 13.4

### 13.4 - Phase III Trials

The outline of reports for comparative efficacy trials (Phase III) is similar to that for safety and efficacy trials. There are many additional issues, however, to consider. For example, the reporting of treatment assignment (randomization) and masking procedures is necessary to assure readers about the internal validity of the trial. This is important because readers want to know how this was implemented. This is a mechanism that reviewers will use to assess the

require thorough descriptions. They also expect supplemental reports. When the article is available online, there can be links to more detailed descriptions, figures, graphs, and tables.

- The [CONSORT \(Consolidated Standards of Reporting Trials\) Group](#) updated its guidelines for the reporting of clinical trials, which appeared in multiple journals and is available online: Examine the [CONSORT checklist](#) and [Flow Diagram](#) in the CONSORT statement. These standards have been adopted by major medical journals.
- Schulz, K, D. Altman, D. Moher and for the CONSORT Group. [CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trial](#). *Ann Intern Med* June 1, 2010 152:726-732
- There are several extensions of the original CONSORT statement which can also be examined at the [CONSORT website](#) focusing on reporting patient safety, equivalence and non-inferiority trials, cluster trials, and other topics.
- Ioannidis JPA, Evans SJW, Getzsche PC, O'Neill RT, Altman DG, Schultz K, Moher D for the Consort Group. [Better reporting of harms in randomized trials: An extension of the CONSORT statement](#). *Annals of Internal Medicine* 2004; 141:781-788.
- Piaggio, G., Elbourne, D., Altman, D., Pocock, S., Evans, S. for the CONSORT Group. [Reporting of Noninferiority and Equivalence Randomized Trials: An Extension of the CONSORT statement](#). *JAMA* 2006; 295: 1152-1160.

## Wiki Entry

Reporting publication cited: G6-P03

Source URL:

[https://en.m.wikipedia.org/wiki/Blinded\\_experiment](https://en.m.wikipedia.org/wiki/Blinded_experiment)

Target URL:

<https://doi.org/10.1136%2Fbmj.c332>

WIKIPEDIA Search Wikipedia

## Blinded experiment

Article Talk

Language Download PDF Watch Edit

In a **blind** or **blinded experiment**, information which may influence the participants of the [experiment](#) is withheld until after the experiment is complete. Good blinding can reduce or eliminate experimental [biases](#) that arise from a participants' expectations, [observer's effect on the participants](#), [observer bias](#), [confirmation bias](#), and other sources. A blind can be imposed on any participant of an experiment, including subjects, researchers, technicians, data analysts, and evaluators. In

### References

- <sup>a</sup> <sup>b</sup> <sup>c</sup> Bello, Segun; Moustgaard, Helene; Hróbjartsson, Asbjørn (October 2014). "The risk of unblinding was infrequently and incompletely reported in 300 randomized clinical trial publications". *Journal of Clinical Epidemiology*. **67** (10): 1059–1069. doi:10.1016/j.jclinepi.2014.05.007. ISSN 1878-5921. PMID 24973822.
- <sup>a</sup> "Oxford Centre for Evidence-based Medicine - Levels of Evidence (March 2009) - CEBM". *cebm.net*. 11 June 2009. Archived from the original on 26 October 2017. Retrieved 2 May 2018.
- <sup>a</sup> Fétis F (1868). *Biographie Universelle des Musiciens et Bibliographie Générale de la Musique, Tome 1* (Second ed.). Paris: Firmin Didot Frères, Fils, et Cie. p. 249. Retrieved
- <sup>a</sup> Rees, Judy; Wade, Timothy J.; Levy, Deborah A.; Colford, John M.; Hilt, Susan F. (February 2005). "Changes in beliefs identify unblinding in randomized controlled trials: a method to meet CONSORT guidelines". *Contemporary Clinical Trials*. **26** (1): 25–37. doi:10.1016/j.cct.2004.11.020. PMID 15837.
- <sup>a</sup> Ledford, H. "A question of Control" (PDF). *nature.com*. Nature Magazine. Retrieved 24 April 2019.
- <sup>a</sup> <sup>b</sup> Moher, David; Altman, Douglas G.; Schulz, Kenneth F. (24 March 2010). "CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials". *BMJ*. **340**: c332. doi:10.1136/bmj.c332. ISSN 0959-8138. PMC 2844940. PMID 20332509.