

Appendix 2. GRIPP2 reporting checklist development methods for Patient and Public Involvement in research

Section and topic	Item	Reported on page No
Aim	Report the aim of patient and public involvement in the study	10
Methods	Provide a clear description of the methods used for patient and public involvement in the study. Please state if there was no patient and public involvement.	10
Study results	Outcomes—Report the results of patient and public involvement in the study, including both positive and negative outcomes	10
Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	14
Reflections/critical perspective	Comment critically on the study, reflecting on the things concerning patient public involvement that went well and those that did not, so others can learn from this experience	10,14

Appendix 3. List of references included in Table 3.

Nº	Citation
1	Djurisic S, Rath A, Gaber S, et al. Barriers to the conduct of randomised clinical trials within all disease areas. <i>Trials</i> . 2017;18(1):1-11. doi:10.1186/s13063-017-2099-9
2	Awasthi S. Plagiarism and academic misconduct: A systematic review. <i>DESIDOC Journal of Library and Information Technology</i> . 2019;39(2):94-100. doi:10.14429/djlit.39.2.13622
3	Guraya SY, Norman RI, Khoshhal KI, Guraya SS, Forgione A. Publish or perish mantra in the medical field: A systematic review of the reasons, consequences and remedies. <i>Pakistan Journal of Medical Sciences</i> . 2016;32(6):1562-1567. doi:10.12669/pjms.326.10490
4	Guraya SY, Guraya SS. The confounding factors leading to plagiarism in academic writing and some suggested remedies: A systematic review. Published online 2017.
5	Yi N, Nemery B, Dierickx K. Integrity in Biomedical Research: A Systematic Review of Studies in China. <i>Science and Engineering Ethics</i> . 2019;25(4):1271-1301. doi:10.1007/s11948-018-0057-x
6	Stavale R, Ferreira GI, Galvão JAM, et al. Research misconduct in health and life sciences research: A systematic review of retracted literature from Brazilian institutions. <i>PloS one</i> . 2019;14(4):e0214272.
7	Wang J, Ku JC, Alotaibi NM, Rutka JT. Retraction of Neurosurgical Publications: A Systematic Review. <i>World Neurosurgery</i> . 2017;103:809--814.e1. doi:10.1016/j.wneu.2017.04.014
8	Maccaro A, Piaggio D, Pagliara S, Pecchia L. The role of ethics in science: a systematic literature review from the first wave of COVID-19. <i>Health and Technology</i> . 2021;11(5):1063-1071. doi:10.1007/s12553-021-00570-6
9	Nicholls SG, Hayes TP, Brehaut JC, et al. A scoping review of empirical research relating to quality and effectiveness of research ethics review. <i>PLoS ONE</i> . 2015;10(7):1-18. doi:10.1371/journal.pone.0133639
10	Goldstein CE, Weijer C, Brehaut JC, et al. Ethical issues in pragmatic randomized controlled trials: A review of the recent literature identifies gaps in ethical argumentation. <i>BMC Medical Ethics</i> . 2018;19(1):1-10. doi:10.1186/s12910-018-0253-x
11	Phillips A, Borry P, Shabani M. Research ethics review for the use of anonymized samples and data: A systematic review of normative documents. <i>Accountability in Research</i> . 2017;24(8):483-496. doi:10.1080/08989621.2017.1396896
12	Paramasivan S, Davies P, Richards A, et al. What empirical research has been undertaken on the ethics of clinical research in India? A systematic scoping review and narrative synthesis. <i>BMJ Global Health</i> . 2021;6(5):1-19. doi:10.1136/bmjgh-2020-004729
13	Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension—systematic review. <i>Trials</i> . 2021;22(1):1-8. doi:10.1186/s13063-020-04969-w
14	Schellings R, Kessels AG, ter Riet G, Knottnerus JA, Sturmans F. Randomized consent designs in randomized controlled trials: Systematic literature search. <i>Contemporary Clinical Trials</i> . 2006;27(4):320-332. doi:10.1016/j.cct.2005.11.009
15	Natale P, Saglimbene V, Ruospo M, et al. Transparency, trust and minimizing burden to increase recruitment and recruitment in trials: A

	systematic review. <i>Journal of Clinical Epidemiology</i> . 2021;134:35-51. doi:10.1016/j.jclinepi.2021.01.014
16	Dupont JCK, Pritchard-Jones K, Doz F. Ethical issues of clinical trials in paediatric oncology from 2003 to 2013: A systematic review. <i>The Lancet Oncology</i> . 2016;17(5):e187--e197. doi:10.1016/S1470-2045(16)00142-X
17	Hutchings E, Loomes M, Butow P, Boyle FM. A Systematic Literature Review of Attitudes towards Secondary Use and Sharing of Health Administrative and Clinical Trial Data: A Focus on Consent. Vol 10. <i>Systematic Reviews</i> ; 2021. doi:10.1186/s13643-021-01663-z
18	Alemayehu C, Mitchell G, Nikles J. Barriers for conducting clinical trials in developing countries- a systematic review. <i>International Journal for Equity in Health</i> . 2018;17(1):1-11. doi:10.1186/s12939-018-0748-6
19	Slade AL, Retzer A, Ahmed K, et al. Systematic review of the use of translated patient-reported outcome measures in cancer trials. <i>Trials</i> . 2021;22(1):1-17. doi:10.1186/s13063-021-05255-z
20	Maher NA, Senders JT, Hulsbergen AFC, et al. Passive data collection and use in healthcare: A systematic review of ethical issues. <i>International Journal of Medical Informatics</i> . 2019;129:242-247. doi:10.1016/j.ijmedinf.2019.06.015
21	Mirchev M, Mircheva I, Kerekovska A. The academic viewpoint on patient data ownership in the context of big data: Scoping review. <i>Journal of Medical Internet Research</i> . 2020;22(8). doi:10.2196/22214
22	Dulhunty JM, Boots RJ, Paratz JD, Lipman J. Determining authorship in multicenter trials: A systematic review. <i>Acta Anaesthesiologica Scandinavica</i> . 2011;55(9):1037-1043. doi:10.1111/j.1399-6576.2011.02477.x
23	Hunsinger M, Smith SM, McKeown A, et al. Disclosure of authorship contributions in analgesic clinical trials and related publications: ACTION systematic review and recommendations. <i>Pain</i> . 2014;155(6):1059-1063. doi:10.1016/J.PAIN.2013.12.011
24	McKeown A, Gewandter JS, McDermott MP, et al. Reporting of sample size calculations in analgesic clinical trials: ACTION systematic review. <i>Journal of Pain</i> . 2015;16(3):199--206.e7. doi:10.1016/j.jpain.2014.11.010
25	Treweek S, Lockhart P, Pitkethly M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. <i>BMJ Open</i> . 2013;3(2). doi:10.1136/bmjopen-2012-002360
26	Houghton C, Dowling M, Meskell P, et al. Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis. Published online 2020. doi:10.1002/14651858.MR000045.pub2.www.cochranelibrary.com
27	Karanatsios B, Prang KH, et al. Defining key design elements of registry-based randomised controlled trials: A scoping review. <i>Trials</i> . 2020;21(1). doi:10.1186/s13063-020-04459-z
28	Gewandter JS, Kitt RA, Hunsinger MR, et al. Reporting of data monitoring boards in publications of randomized clinical trials is often deficient: ACTION systematic review. <i>Journal of Clinical Epidemiology</i> . 2017;83:101-107. doi:10.1016/j.jclinepi.2016.12.018
29	Olsen R, Bihlet AR, Kalakou F, Andersen JR. The impact of clinical trial monitoring approaches on data integrity and cost - A review of current literature. <i>European Journal of Clinical Pharmacology</i> . 2016;72(4):399-412. doi:10.1007/s00228-015-2004-y
30	Hayden JA, Ellis J, Ogilvie R, Boulos L, Stanojevic S. Meta-epidemiological study of publication integrity, and quality of conduct and reporting of randomized trials included in a systematic review of low back pain. <i>Journal of Clinical Epidemiology</i> . Published online 2021.
31	Malički M, Jerončić A, Aalbersberg IJ, Bouter L, ter Riet G. Systematic review and meta-analyses of studies analysing instructions to

	authors from 1987 to 2017. <i>Nature Communications</i> . 2021;12(1):1-14. doi:10.1038/s41467-021-26027-y
32	Chapman SJ, Shelton B, Mahmood H, Fitzgerald JEF, Harrison E, Bhangu A. Promoting transparency in clinical research: Systematic review of disclosure and data-sharing policies in surgical journals. <i>International Journal of Surgery</i> . 2014;12(2014):S52. doi:10.1016/j.ijso.2014.07.238
33	Liu TY, Cai SY, Nie XL, Lyu YQ, Peng XX, Feng GS. The content of statistical requirements for authors in biomedical research journals. <i>Chinese Medical Journal</i> . 2016;129(20):2491-2496. doi:10.4103/0366-6999.191822
34	Anz HA, Ahmad HA, Kozemchak AM, Rao M, Warth RJ, Harner CD. Funding sources are under-reported in randomised clinical trials of biological treatments in sports medicine: A systematic review. <i>Journal of ISAKOS</i> . 2020;5(6):371-377. doi:10.1136/jisakos-2020-000452
35	Milette K, Roseman M, Thombs BD. Transparency of outcome reporting and trial registration of randomized controlled trials in top psychosomatic and behavioral health journals: a systematic review. <i>Journal of psychosomatic research</i> . 2011;70(3):205-217.
36	Evuvarherhe O, Gattrell W, White R, Winchester CC. Professional medical writing support and the quality, ethics and timeliness of clinical trial reporting: a systematic review. <i>Research Integrity and Peer Review</i> . 2019;4(1):1-8. doi:10.1186/s41073-019-0073-7
37	El-Menyar A, Mekkodathil A, Asim M, et al. Publications and retracted articles of COVID-19 pharmacotherapy-related research: A systematic review. <i>Science Progress</i> . 2021;104(2):1-20. doi:10.1177/00368504211016936
38	Laothavorn J, Wongwai P, Prakash Dumre S, Kongjam P, Na-Bangchang K, Karbwang J. Ethical approval and informed consent reporting in ASEAN journals: a systematic review. <i>Current Medical Research and Opinion</i> . 2019;35(12):2179-2186. doi:10.1080/03007995.2019.1647505
39	di Pietrantonj C D v. Conflict of interest in industry-funded medical research. <i>Epidemiol Prev</i> . 2005;29(2):85-95.
40	Bekelman JE, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: A systematic review. 2003;289(4):454-465.
41	Darmon M, Helms J, de Jong A, et al. Time trends in the reporting of conflicts of interest, funding and affiliation with industry in intensive care research: a systematic review. <i>Intensive Care Medicine</i> . 2018;44(10):1669-1678. doi:10.1007/s00134-018-5350-2
42	Kalil JA, Halperin SA LJM. Human challenge studies: a review of adequacy of reporting methods and results. <i>Future Microbiol</i> . 2012;7(4):481-495. doi:10.2217/fmb.12.1
43	Yiulin W, Fan L, Yuting D, Zhaoxiang B, Chi Z, Yaolong C. Reporting randomised trials of social and psychological interventions: The CONSORT-SPI 2018 Extension. <i>Chinese Journal of Evidence-Based Medicine</i> . 2020;20(12):1449-1457. doi:10.7507/1672-2531.202008180
44	Bordewijk EM, Li W, van Eekelen R, et al. Methods to assess research misconduct in health-related research: A scoping review. <i>Journal of Clinical Epidemiology</i> . 2021;136:189-202. doi:10.1016/j.jclinepi.2021.05.012
45	Adewuyi TE, MacLennan G, Cook JA. Non-compliance with randomised allocation and missing outcome data in randomised controlled trials evaluating surgical interventions: A systematic review. <i>BMC Research Notes</i> . 2015;8(1):1-10. doi:10.1186/s13104-015-1364-9
46	Yelland LN, Kahan BC, Dent E, et al. Prevalence and reporting of recruitment, randomisation and treatment errors in clinical trials: A

	systematic review. <i>Clinical Trials</i> . 2018;15(3):278-285. doi:10.1177/1740774518761627
47	Weissgerber TL, Winham SJ, Heinzen EP, et al. Reveal, Don't Conceal: Transforming Data Visualization to Improve Transparency. <i>Circulation</i> . 2019;140(18):1506-1518. doi:10.1161/CIRCULATIONAHA.118.037777
48	Avenell A, Stewart F, Grey A, Gamble G, Bolland M. An investigation into the impact and implications of published papers from retracted research: systematic search of affected literature. <i>BMJ Open</i> . 2019;9(10). doi:10.1136/bmjopen-2019-031909
49	Kalkman S, van Thiel GJM, Grobbee DE, van Delden JJM. Pragmatic randomized trials in drug development pose new ethical questions: a systematic review. <i>Drug Discovery Today</i> . 2015;20(7):856-862. doi:10.1016/j.drudis.2015.03.005
50	Marušić A, Bošnjak L, Jeročić A. A systematic review of research on the meaning, ethics and practices of authorship across scholarly disciplines. <i>Getting to Good: Research Integrity in the Biomedical Sciences</i> . 2018;6(9):191-207. doi:10.1371/journal.pone.0023477
51	Garrison NA, Sathe NA, Antommaria AH, Holm IA, Sanderson SC, Smith ME, McPheeters ML, Clayton EW. A systematic literature review of individuals' perspectives on broad consent and data sharing in the United States. <i>Genet Med</i> . 2016 Jul;18(7):663-71. doi: 10.1038/gim.2015.138. Epub 2015 Nov 19. PMID: 26583683; PMCID: PMC4873460.
52	Pavlenko E, Strech D, Langhof H. Implementation of data access and use procedures in clinical data warehouses. A systematic review of literature and publicly available policies. <i>BMC Medical Informatics and Decision Making</i> . 2020;20(1):1-13. doi:10.1186/s12911-020-01177-z
53	Marusic A, Wager E, Utrobicic A, Sambunjak D, Anderson MS, Rothstein HR. Interventions to prevent misconduct and promote integrity in research and publication. <i>Cochrane Database of Systematic Reviews</i> . 2013;2013(2). doi:10.1002/14651858.MR000038
54	van der Steen JT, van den Bogert CA, van Soest-Poortvliet MC, et al. Determinants of selective reporting: A taxonomy based on content analysis of a random selection of the literature. <i>PLoS ONE</i> . 2018;13(2):1-15. doi:10.1371/journal.pone.0188247
55	Larson BP, Chung KC. A systematic review of peer review for scientific manuscripts. <i>Hand</i> . 2012;7(1):37-44. doi:10.1007/s11552-012-9392-6