Table 1. Comparison of SPIRIT-AI[21] and CONSORT-AI[20] checklists.

	SPIRIT 2013[21]	SPIRIT-AI[21]		CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**		**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.			**Checklist item no.**		
1	Descriptive title identifying the study design, population, interventions and, if applicable, trial acronym	Indicate that the intervention involves artificial intelligence/ machine learning and specify the type of model Specify the intended use of the AI intervention	1	a) Identification as a randomised trial in the title b) Structured summary of trial design, methods, results, and conclusions	a) Indicate that the intervention involves artificial intelligence/ machine learning and specify the type of model b) State the intended use of the AI intervention within the trial in the title and/or abstract
2	Trial registration: a) Trial identifier and registry name. If not yet registered, name of intended registry. b) All items from the World Health Organization Trial Registration Dataset		23	Registration number and name of trial registry	
3	Protocol date and version identifier			-	
4	Funding: sources and types of financial, material and other support			-	
5	a) Names, affiliations and roles of protocol contributors b) Name and contact information for the trial sponsor c) Role of study sponsor and funders d) Composition, roles and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team and other individuals/groups overseeing the trial			-	
6	a) Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	a) Explain the intended use of the AI intervention in the context of the clinical pathway, including its purpose and its intended users Describe any pre-existing evidence for the AI intervention.	2	a) Scientific background and explanation of rationale	Explain the intended use of the AI intervention in the context of the clinical pathway, including its purpose and its intended users
	b) Explanation for choice of comparators			-	
7	Specific objectives or hypotheses			b) Specific objectives or hypotheses	
8	Description of trial design, including type of trial, allocation ratio and framework		3	a) Description of trial design (such as parallel, factorial) including allocation ratio	
	-			b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons	

Table 1. Comparison of SPIRIT-AI[21] and CONSORT-AI[20] checklists. (Cont'd)

	SPIRIT 2013[21]	SPIRIT-AI[21]		CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**		**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.			**Checklist item no.**		
9	Description of study settings and list of countries where data will be collected Reference to where list of study sites can be obtained	Describe the onsite and offsite requirements needed to integrate the AI intervention into the trial setting	4	b) Settings and locations where the data were collected	Describe how the AI intervention was integrated into the trial setting, including any onsite or offsite requirements
10	Inclusion and exclusion criteria for participants If applicable, eligibility criteria for study centres and individuals who will perform the interventions	State the inclusion and exclusion criteria at the (i) level of participants, AND at the (ii) level of input data		A) Eligibility criteria for participants	State the inclusion and exclusion criteria at the (i) level of participants, AND at the (ii) level of input data.
11	a) Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	(i) State version of AI algorithm used (ii) Specify procedure for acquiring and selecting the input data for the AI intervention (iii) Specify the procedure for assessing and handling poor-quality or unavailable input data (iv) Specify whether there is human–AI interaction in the handling of the input data, and what level of expertise is required for users (v) Specify the output of the AI intervention (vi) Explain the procedure for how the AI intervention's output will contribute to decision-making or other elements of clinical practice	5	The interventions for each group with sufficient details to allow replication, including how and when they were administered.	(i) State version of AI algorithm used (ii) Specify procedure for acquiring and selecting the input data for the AI intervention (iii) Specify the procedure for assessing and handling poor-quality or unavailable input data (iv) Specify whether there is human–AI interaction in the handling of the input data, and what level of expertise is required for users (v) Specify the output of the AI intervention (vi) Explain the procedure for how the AI intervention's output will contribute to decision-making or other elements of clinical practice
	b) Criteria for discontinuing or modifying allocated interventions for a given trial participant			-	
	c) Strategies to improve adherence to intervention protocols and any procedures for monitoring adherence			-	
	d) Relevant concomitant care and intervention			-	

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	SPIRIT 2013[21]	SPIRIT-AI[21]		CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**		**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.			**Checklist item no.**		
12	Primary, secondary and other outcomes, including the specific measurement variable, analysis metric, method of aggregation, and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended		6	a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments and visits for participants. A schematic diagram is highly recommended			b) Any changes to trial outcomes after the trial commenced, with reasons	
14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations		7	a) How sample size was determined	
15	Strategies for achieving adequate participant enrolment to reach target sample size			b) When applicable, explanation of any interim analyses and stopping guidelines	
16	a) Method of generating the allocation sequence and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction should be provided in a separate document that is unavailable to those who enrol participants or assign interventions		8	a) Method used to generate the random allocation sequence b) Type of randomisation; details of any restriction (such as blocking and block size)	
	b) Mechanism of implementing the allocation sequence (e.g. central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned		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	
	c) Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions		10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
17	a) Who will be blinded after assignment to interventions and how		11	a) Blinding: If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	
	b) If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial			b) If relevant, description of the similarity of interventions	
18	a) Plans for assessment and collection of outcome, baseline and other trial data, including any related processes to promote data quality and a description of study instruments along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol			-	
	b) Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols			-	
19	Plans for data entry, coding, security and storage, including any related processes to promote data quality. Reference to where details of data management procedures can be found, if not in the protocol			-	

Table 1. Comparison of SPIRIT-AI[21] and CONSORT-AI[20] checklists. (Cont'd)

	SPIRIT 2013[21]	SPIRIT-AI[21]		CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**		**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.			**Checklist item no.**		
20	a) Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol		12	a) Statistical methods used to compare groups for primary and secondary outcomes	
	b) Methods for any additional analyses			b) Methods for additional analyses, such as subgroup analyses and adjusted analyses	
	c) Definition of analysis population relating to protocol non-adherence (e.g. as randomised analysis) and any statistical methods to handle missing data (e.g. multiple imputation)			-	
	-		13	a) For each group, the numbers of participants who were randomly assigned, received intended treatment and were analysed for the primary outcome	
	-			b) For each group, losses and exclusions after randomisation, together with reasons	
	-		14	a) Dates defining the periods of recruitment and follow-up	
	-			b) Why the trial ended or was stopped	
	-		15	A table showing baseline demographic and clinical characteristics for each group	
	-		16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
	-		17	a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	-			b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
	-		18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
21	a) Composition of data monitoring committee; summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a data monitoring committee is not needed			-	
	b) Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial			-	

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	SPIRIT 2013[21]	SPIRIT-AI[21]		CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**		**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.			**Checklist item no.**		
22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Specify any plans to identify and analyse performance errors. If there are no plans for this, justify why not	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Describe results of any analysis of performance errors and how errors were identified, where applicable. If no such analysis was planned or done, justify why not
23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor			-	
24	Plans for seeking research ethics committee/ institutional review board approval			-	
25	Plans for communicating important protocol to relevant parties			-	
26	a) Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see item no. 32)			-	
	b) Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable			-	
27	How personal information about potential and enrolled participants will be collected, shared and maintained in order to protect confidentiality before, during and after the trial			-	
28	Financial and other competing interests for principal investigators for the overall trial and each study site			-	
			20	Trial limitations, addressing sources of potential bias, imprecision and, if relevant, multiplicity of analyses	
			21	Generalisability (external validity)	
			22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
			24	Where the full trial protocol can be accessed, if available	
29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	State whether and how the AI intervention and/or its code can be accessed, including any restrictions to access or reuse	25	Sources of funding and other support (such as supply of drugs), role of funders	State whether and how the AI intervention and/or its code can be accessed, including any restrictions to access or reuse
30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation			-	

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	SPIRIT 2013[21]	SPIRIT-AI[21]	CONSORT 2010[20]	CONSORT-AI[20]
Intended use	**Clinical trial protocol**	**AI-clinical trial protocol**	**Randomised controlled trial**	**AI-randomised controlled trial**
Checklist item no.		**Checklist item no.**		
31	a) Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public and other relevant groups (e.g. via publication, reporting in results databases or other data sharing arrangements), including any publication restrictions		-	
	b) Authorship eligibility guidelines and any intended use of professional writers		-	
	c) Plans, if any, for granting public access to the full protocol, participant-level dataset and statistical code		-	
32	Model consent form and other related documentation given to participants and authorised surrogates		-	
33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable		-	

CONSORT: Consolidated Standards of Reporting Trials; CONSORT-AI: Consolidated Standards of Reporting Trials–Artificial Intelligence; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; SPIRIT-AI: Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence

Superscript numbers: Refer to REFERENCES