Supplementary table 1: CONSORT-AI checklist**

Section	Item	CONSORT 2010 item	CONSORT-AI item		Addressed on page no.*
Title and abstract					
Title and abstract	1a	Identification as a randomized trial in the title	CONSORT-AI a,b Elaboration	(i) Indicate that the intervention involves artificial intelligence/machine learning in the title and/or abstract and specify the type of model.	**Title and abstract p1**
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		(ii) State the intended use of the AI intervention within the trial in the title and/or abstract.	**Title and abstract p1**
Introduction					
Background and objectives	2a	Scientific background and explanation of rationale	CONSORT-AI a (i) Extension	Explain the intended use of the AI intervention in the context of the clinical pathway, including its purpose and its intended users (e.g. healthcare	**95-111**

				professionals, patients, public).	
	2b	Specific objectives or hypotheses			**112-114**
Methods					
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio			**118-124**
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons			**NA**
Participants	4a	Eligibility criteria for participants	CONSORT-AI a (i) Elaboration	State the inclusion and exclusion criteria at the level of participants.	**125-129**
			CONSORT-AI a (ii) Extension	State the inclusion and exclusion criteria at the level of the input data.	**125-129**
	4b	Settings and locations where the data were collected	CONSORT-AI b Extension	Describe how the AI intervention was integrated into the trial setting, including any onsite or on site requirements.	**137-143**

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	CONSORT-AI (i) Extension	State which version of the AI algorithm was used.	**137-143**
			CONSORT-AI (ii) Extension	Describe how the input data were acquired and selected for the AI intervention.	**137-143**
			CONSORT-AI (iii) Extension	Describe how poor quality or unavailable input data were assessed and handled.	**137-143**
			CONSORT-AI (iv) Extension.	Specify whether there was human-AI interaction in the handling of the input data, and what level of expertise was required of users.	**137-143**
			CONSORT-AI (v) Extension	Specify the output of the AI intervention	**137-143**
			CONSORT-AI (vi) Extension	Explain how the AI intervention's outputs contributed to decision-making or other elements of clinical practice.	**137-143**
Outcomes	6a	Completely defined pre-specified primary and secondary outcome			**166-177**

		measures, including how and when they were assessed			
	6b	Any changes to trial outcomes after the trial commenced, with reasons			**NA**
Sample size	7a	How sample size was determined			**204-205 supp**
	7b	When applicable, explanation of any interim analyses and stopping guidelines			**NA**
Sequence generation	8a	Method used to generate the random allocation sequence			**130-134**
	8b	Type of randomization; details of any restriction (such as blocking and block size)			**130-136**
Randomization					
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the			**130-136**

		sequence until interventions were assigned			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions			**130-136**
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how			**130-136**
	11b	If relevant, description of the similarity of interventions			**NA**
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes			**191-216**
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses			**191-216**
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 analyzed for the primary outcome			**220-242**
	13b	For each group, losses and exclusions after randomization, together with reasons			**220-240**
Recruitment	14a	Dates defining the periods of recruitment and follow-up			**118-120**
	14b	Why the trial ended or was stopped			**NA**
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group			**Table 1 465**
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups			**244-292**
Outcomes and estimation	17a	For each primary and secondary outcome,			**244-292**

		results for each group, and the estimated effect size and its precision (such as % confidence interval)			
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended			**244-292**
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory			**278-292**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	CONSORT-AI Extension	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.	**254**
Discussion					
Limitations	20	Trial limitations, addressing sources of potential bias,			**323-348**

		imprecision, and, if relevant, multiplicity of analyses			
Generalizability	21	Generalizability (external validity, applicability) of the trial findings			**368-374**
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence			**354-367**
Other information					
Registration	23	Registration number and name of trial registry			**70**
Protocol	24	Where the full trial protocol can be accessed, if available			**NA**
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	CONSORT-AI Extension.	State whether and how the AI intervention and/or its code can be accessed, including any restrictions to access or re-use.	**41-43**

*Indicates page numbers to be completed by authors during protocol development

** 22. Liu X, Rivera SC, Moher D, et al. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI Extension. BMJ 2020;370:m3164.