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. | |
| | 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. | |
| **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 | |

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| | | | | professionals, patients, public). | |
| | 2b | Specific objectives or hypotheses | | | |
| **Methods** | | | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | | | |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | | | |
| Participants | 4a | Eligibility criteria for participants | CONSORT-AI a (i) Elaboration | State the inclusion and exclusion criteria at the level of participants. | |
| | | | CONSORT-AI a (ii) Extension | State the inclusion and exclusion criteria at the level of the input data. | |
| | 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. | |

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| 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. | |
| | | | CONSORT-AI (ii) Extension | Describe how the input data were acquired and selected for the AI intervention. | |
| | | | CONSORT-AI (iii) Extension | Describe how poor quality or unavailable input data were assessed and handled. | |
| | | | 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. | |
| | | | CONSORT-AI (v) Extension | Specify the output of the AI intervention | |
| | | | CONSORT-AI (vi) Extension | Explain how the AI intervention's outputs contributed to decision-making or other elements of clinical practice. | |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome | | | |

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| | | measures, including how and when they were assessed | | | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | | | |
| Sample size | 7a | How sample size was determined | | | |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | | | |
| | 8b | Type of randomization; details of any restriction (such as blocking and block size) | | | |
| **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 | | | |

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| | | sequence until interventions were assigned | | | |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | | | |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | | | |
| | 11b | If relevant, description of the similarity of interventions | | | |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | | | |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | | | |
| **Results** | | | | | |

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| 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 | | | |
| | 13b | For each group, losses and exclusions after randomization, together with reasons | | | |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | | | |
| | 14b | Why the trial ended or was stopped | | | |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | | | |
| Numbers analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | | | |
| Outcomes and estimation | 17a | For each primary and secondary outcome, | | | |

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| | | 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 | | | |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | | | |
| 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. | |
| **Discussion** | | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, | | | |

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| | | imprecision, and, if relevant, multiplicity of analyses | | | |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | | | |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | | | |
| **Other information** | | | | | |
| Registration | 23 | Registration number and name of trial registry | | | |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | | | |
| 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. | |

*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.