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Quality of reporting of randomised controlled trials of artificial intelligence in healthcare: a systematic review

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ABSTRACT

Objectives The aim of this study was to evaluate the quality of reporting of randomised controlled trials (RCTs) of artificial intelligence (AI) in healthcare against Consolidated Standards of Reporting Trials—AI (CONSORT-AI) guidelines.

Design Systematic review.

Data sources We searched PubMed and EMBASE databases for studies reported from January 2015 to December 2021.

Eligibility criteria We included RCTs reported in English that used AI as the intervention. Protocols, conference abstracts, studies on robotics and studies related to medical education were excluded.

Data extraction The included studies were graded using the CONSORT-AI checklist, comprising 43 items, by two independent graders. The results were tabulated and descriptive statistics were reported.

Results We screened 1501 potential abstracts, of which 112 full-text articles were reviewed for eligibility. A total of 42 studies were included. The number of participants ranged from 22 to 2352. Only two items of the CONSORT-AI items were fully reported in all studies. Five items were not applicable in more than 85% of the studies. Nineteen per cent (8/42) of the studies did not report more than 50% (21/43) of the CONSORT-AI checklist items.

Conclusions The quality of reporting of RCTs in AI is suboptimal. As reporting is variable in existing RCTs, caution should be exercised in interpreting the findings of some studies.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This systematic review assesses the reporting of randomised trials of artificial intelligence (AI) interventions across medical fields from 2015 to 2021 against Consolidated Standards of Reporting Trials—AI (CONSORT-AI) guidance, establishing a baseline for future studies.
⇒ We did not separately analyse publications from before and after the publication of the CONSORT-AI guidance in September 2020, so were unable to assess whether there was any change in reporting quality following publication of the guidance.
⇒ Only two databases were searched and only English-language publications were eligible for inclusion.

INTRODUCTION

Artificial intelligence (AI) is finding increased utility in the medical realm, with a special emphasis on deep learning. Medical applications of AI range from screening, diagnosis, prognosis and generation of management plans.[1–5] For example, AI has been extensively studied in ophthalmology for various diseases such as diabetic retinopathy,[6] age-related macular degeneration[7] and glaucoma.[8] However, increased hype associated with AI—without sound evidence base—may result in inappropriate clinical decisions, which can potentially be detrimental to healthcare.[9]

Randomised controlled trials (RCTs) are one of the highest quality of evidence used by clinicians in decision making regarding interventions.[10] RCTs may be susceptible to various forms of biases. Adequate reporting of RCTs is vital to allow results and conclusions derived from a study to be assessed critically by readers.[11 12]

The Consolidated Standards of Reporting Trials (CONSORT) statement was introduced in 1996 to establish guidelines to improve the reporting quality of clinical trials. Additionally, the CONSORT statement is a useful guide that helps readers with the critical appraisal of RCTs to ascertain their reliability and clinical applicability.[13] The most recent update of the CONSORT statement was published in 2010, listing 25 minimum reporting requirements.[14] Several extensions to CONSORT also exist, which cater to certain specific study designs.[15–18]

There has been an exponential increase in AI-based healthcare studies in recent years due to rapid advances in computational power. However, the methodological rigour has not kept pace with the development in technology. For example, the design and quality of reporting in these studies have not always been adequate.[19 20] CONSORT-AI was published on 9 September 2020 as an extension of the CONSORT 2010 statement to evaluate RCTs involving AI. Fourteen new items

were added to the checklist—including 11 extensions and 3 elaborations.[21 22] These items mostly relate to the AI intervention in question and are necessary to independently evaluate and replicate the trial.

The aim of this study was to evaluate the quality of reporting of RCTs of AI intervention for medical conditions, published from 2015 to 2021, based on CONSORT-AI guidelines. While CONSORT-AI did not exist for much of this timeline, this study will serve as a baseline measure of reporting quality for comparison with future studies' adherence to CONSORT-AI guidelines.

METHODS

Search strategy

We performed a systematic review of RCTs of AI for medical conditions published from January 2015 to December 2021. The search date range was initially set as an arbitrary period of 5 years from 2015 to 2020; the literature search was later updated to include publications until December 2021. RCTs of AI in healthcare are a nascent field, and we expected very few RCTs of AI in healthcare prior to 2015. We searched PubMed and EMBASE databases for potential studies. The PubMed search was conducted using the MeSH terms: "artificial intelligence", "machine learning" and "deep learning". The terms "artificial intelligence", "deep learning" and "machine learning" were searched in EMBASE. In both the databases, the search was limited to RCTs, publications in the English language, from the year 2015 to 2021 and human subjects (online supplemental appendix 1).

Screening and study selection

The records were screened by two independent investigators (RS and BA) for potential inclusion. The abstracts of RCTs using AI, deep learning and machine learning were further evaluated for possible inclusion. Protocols, conference abstracts, studies on robotics and post hoc analyses of RCTs were excluded.

Full-text articles of all shortlisted abstracts were then screened for eligibility. Publications were included if AI was used as an intervention for a medical condition, if there was a comparator control group in the study and if there was evidence of randomisation. In case of a disagreement, a senior reviewer assessed the full text and the disagreement was resolved with consensus. The exclusion criteria were non-randomised studies, secondary studies, post hoc analyses, or if the intervention investigated was not AI. Additionally, if the target condition was not a medical disease or if the research pertained to medical education, the study was excluded.

Assessment against CONSORT-AI guidance

The CONSORT-AI checklist of 43 items (online supplemental table 1) was used to grade the included studies. Each item was scored fully, partially or not reported. If an item was irrelevant to a particular study, it was labelled as 'not applicable'. Each publication was scored by two trained graders (RS and BA) independently. Differences were discussed with the senior reviewer (MARS) to reach a consensus.

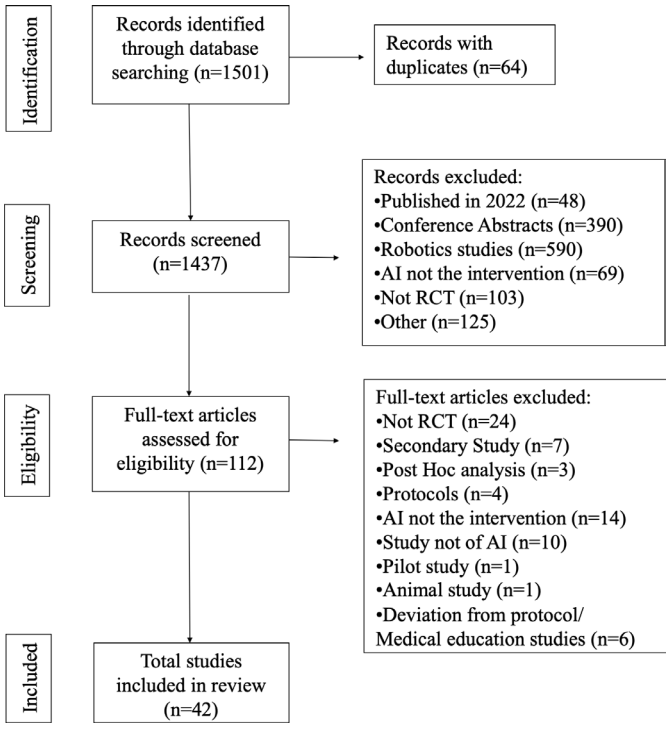

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart. AI, artificial intelligence; RCT, randomised controlled trial.

The results were tabulated by writing all the reported items as the numerator and the total number of applicable items as the denominator. The descriptive statistics for the study population and clinical characteristics are reported. The only deviation from the initial protocol for the review was the extension of the search until December 2021 to keep this review up-to-date.

Patient and public involvement

None.

RESULTS

Study selection

The initial search identified 1501 potential records. One hundred and twelve articles were considered as potentially eligible after screening of abstracts. Following a review of full-text manuscripts, a total of 42 manuscripts were included in the systematic review (figure 1).

General characteristics

The included studies (online supplemental table 2) were from the years 2016 to 2021 (figure 2). The number of participants ranged from 22 to 2352. They pertained to various medical fields, including gastroenterology (n=12), medicine (n=6), cardiology (n=5), psychiatry (n=4), ophthalmology (n=2), endocrinology (n=2), paediatrics (n=2), oncology (n=2), orthopaedics (n=2), surgery (n=1), radiology (n=1), neurology (n=1), pulmonology

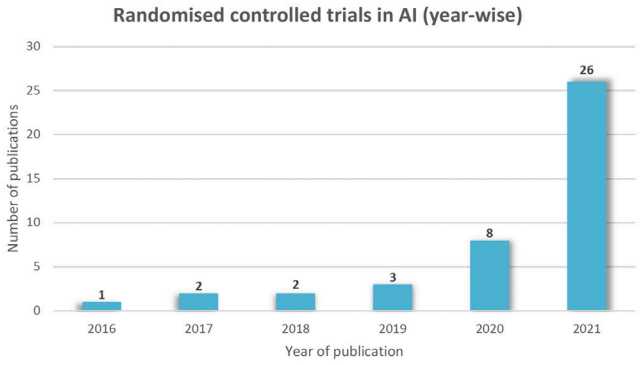

Figure 2 Yearwise distribution of RCTs in AI. AI, artificial intelligence; RCT, randomised controlled trial.

(n=1) and dentistry (n=1). Studies were from different parts of the world, including China (n=16), USA (n=14), Japan (n=3), UK (n=2), Spain (n=2), Netherlands (n=1), Germany (n=1), Korea (n=1), Denmark (n=1) and Israel (n=1). (figure 3)

Adherence to reporting standards

The median number of fully reported CONSORT-AI checklist items in the included studies was 30 (range 7–37) of a possible total of 43. Overall, only 2 (items #1b, and 21) out of possible 43 items were fully reported in all 42 studies. Five items (items #3b, 6b, 7b, 14b and 17b) were deemed not applicable in more than 85% of the included studies. The two least reported items were item #5iii (not reported in 36/42 studies) and item #24 (not reported in 31/42 studies). Nineteen per cent (8/42) of included studies did not report more than 50% (21/43) of the CONSORT-AI checklist items. The reporting of each item is given in table 1.

DISCUSSION

In our review, variable reporting standards of RCTs of AI in healthcare were observed. While some items were reported adequately—for example, those relating to the abstract and introduction of the manuscript—other items particularly in the Methods section, had poor reporting scores.

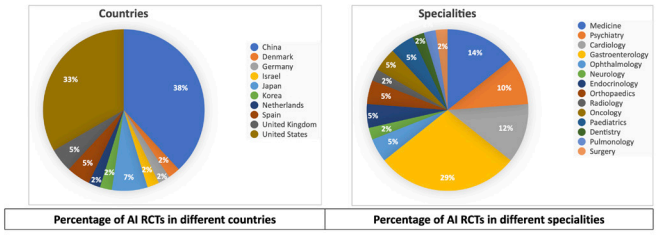

Figure 3 Percentage of AI RCTs in different countries and specialties. AI, artificial intelligence; RCT, randomised controlled trial.

Our results reinforce previously published findings. In a systematic review conducted by Liu *et al*, it was seen that sufficient reporting and external validation were done in less than one-third of the included 82 deep learning studies, thereby limiting their reliability.[23] Similarly, Nagendran *et al* also found deviations from reporting standards, with less than 50% adherence to 12/29 items in the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) guidelines, and high levels of bias in AI studies.[20] Bozkurt *et al* reported that demographic specifics of study populations were poorly reported in studies developing Machine learning (ML) models from electronic health records, and external validation was omitted in 88% of the models.[24] In another systematic review of 28 articles regarding machine learning models for medical diagnosis, Yusuf *et al* discovered that all studies in their systematic review failed to follow reporting guidelines.[25] Our study also revealed variable reporting of CONSORT-AI items in RCTs of AI in healthcare, suggesting there is still room in AI studies for further improving the quality of their reporting.

The CONSORT-AI checklist was developed to encourage transparent reporting of RCTs in AI. The extensions and elaborations added to the original CONSORT guideline largely emphasise the peculiarities related to AI intervention itself and its clinical application. These include details of the interventions, such as algorithm version, input and output data, how the intervention was integrated into the trial and whether there was human and AI interaction. This information is crucial for the critical appraisal of a study and facilitates the replication of clinical trials.[23] These items had variable reporting scores in our study (items 4a to 5vi). Twenty-seven out of 42 (64%) studies did not mention the version of the AI algorithm used. This could confuse the reader regarding which version to apply the study findings to because an AI algorithm is likely to undergo multiple updates.[21] Moreover, information regarding input data were largely missed in the majority of included studies; with only 35% (15/42) of the studies identifying the inclusion and exclusion criteria at the level of the input data, and a mere 14% (6/42) of studies reported how poor quality or unavailable input data was handled and assessed. Such details are essential, as the overall performance of any given AI intervention relies on the quality of input data. Additionally, this information allows an evaluator to distinguish AI platforms that may only work in ideal conditions from those which can be applied to real-world settings.[26 27]

On the other hand, items regarding human–AI interaction and required expertise level, as well as AI output were fully reported by majority of studies (37 and 41/42, respectively). Clarity about the human–AI interface is essential to ensure a standard approach and functional safety, as well as to avoid ethical implications.[28 29] For example, it is essential that qualified experts can interpret dynamically complex variables exhibited by AI interfaces which are related to patients as well as the clinical

Table 1 CONSORT-AI scores of included studies

	Item	Fully reported	Partially reported	Not reported	Not applicable
Title and abstract	1a, 1a(i)	41	1	0	0
	1b, 1b(ii)	42	0	0	0
Introduction					
Background and objectives	2a, 2a(i)	41	1	0	0
	2b	38	0	4	0
Methods					
Trial design	3a	26	6	10	0
	3b	6	0	0	36
Participants	4ai	39	0	3	0
	4aii	15	0	27	0
	4b	40	0	2	0
Intervention	5i	15	0	27	0
	5ii	34	0	8	0
	5iii	6	0	36	0
	5iv	37	0	5	0
	5v	41	0	1	0
	5vi	31	0	11	0
Outcomes	6a	39	0	3	0
	6b	2	0	0	40
Sample size	7a	30	0	11	1
	7b	2	0	0	40
Sequence generation	8a	34	0	8	0
	8b	25	0	17	0
Randomisation					
Allocation concealment mechanism	9	24	0	18	0
Implementation	10	18	3	21	0
Blinding	11a	24	0	18	0
	11b	23	0	17	2
Statistical methods	12a	39	0	3	0
	12b	34	0	8	0
Results					
Participant flow	13a	32	2	8	0
	13b	29	1	12	0
Recruitment	14a	38	0	4	0
	14b	1	0	0	41
Baseline data	15	32	0	10	0
Numbers analysed	16	32	1	9	0
Outcomes and estimation	17a	31	3	8	0
	17b	1	0	0	41
Ancillary analyses	18	33	0	9	0
Harms	19	4	11	27	0
Discussion					
Limitations	20	36	0	6	0
Generalisability	21	42	0	0	0

Continued

Table 1 Continued

	Item	Fully reported	Partially reported	Not reported	Not applicable
Interpretation	22	41	0	1	0
Other information					
Registration	23	35	0	7	0
Protocol	24	11	0	31	0
Funding	25	10	20	12	0

CONSORT-AI, Consolidated Standards of Reporting Trials—artificial intelligence.

context—only then it is possible that AI platforms enable an improvement in clinicians' decision-making process.[30] It is encouraging to see most authors report these items clearly.

Interestingly, although missing out on important information regarding the details of AI intervention, 42/42 of the studies were promising generalisability of their findings in the clinical setting. The generalisability of AI systems may be limited, especially when used in the real-world setting outside of the environment they were developed in.[31 32] Therefore, caution must be employed when evaluating such studies.

An important factor to consider about CONSORT-AI, however, is the applicability of each item to clinical trials. Five items of the CONSORT-AI checklist were deemed to be not applicable in the majority of studies evaluated. Three of these items referred to changes made to methods and outcomes after trial commencement, and why the trial was ended (items 3b, 6b and 14b). These items pertain to modifications made in the protocol, which was not the case in most included studies.

Another item not applicable to most of the included studies was an explanation about any interim analysis and stopping guidelines. Since AI is a relatively recent advance in healthcare, harms and adverse events from AI have not been clearly defined yet. Perhaps this is the reason stopping guidelines were not reported in 40 out of 42 included studies. This ties closely to item 19: which requires reporting of adverse events in AI trials and a description of the analysis of performance errors. AI platforms can make errors that can be difficult to predict and go beyond human judgement, but may have harmful effects if employed on a large scale.[31] Only 4/42 studies fully reported this item, even though it is important to report information about error and outline risk mitigation strategies to decide which settings and populations the AI intervention can be safely employed in.[21] These points emphasise that AI clinical trials in healthcare have not integrated the concept of harm related to AI intervention to determine appropriate stopping guidelines.

Certain general observations were made regarding the included RCTs in our review. There was a large range of sample size (22–2352) in the studies. This wide range suggests that a standard approach to sample size calculation is not practised in RCTs of AI. For example, the diagnostic accuracy of healthcare professionals is often set higher than that of AI while employing sample size estimation, which presumes that AI is inferior to humans.[33] It is recommended that sample size calculations are performed using a non-inferior design by setting a more suitable non-inferiority margin, of diagnostic accuracy, for example, 5%.[34] Similarly, the majority of the studies took place in China, and were focused on gastroenterology, making them less representative of other fields and perhaps other parts of the world.

There are some limitations to our review. Potential eligible studies could have been missed in the inclusion process, as only two databases were searched, and only English-language publications were eligible for inclusion. The majority of the included studies were published before the CONSORT-AI checklist was widely available. As such, most study authors would not have been able to use the guidance to inform their reporting. Furthermore, trial reports from before and after the publication of the CONSORT-AI guidance were not analyses separately, so we were not able to assess whether there was any improvement in reporting quality following publication of the guidance.

In conclusion, the standards of reporting in RCTs of AI were variable. We found certain important information regarding the AI intervention was insufficiently reported in many studies. Therefore, caution should be employed by healthcare service providers and policymakers when using these studies to inform decision making.

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Contributors The idea for the study was conceived and planned by MARS. RS and BA carried out the literature review process including screening of abstracts and review of full-text articles, while MARS acted as a senior reviewer. RS and BA independently scored the included studies using the CONSORT-AI checklist and disagreements were resolved following discussions with MARS. The manuscript was prepared by RS and BA and reviewed by MARS. All authors reviewed and approved the final manuscript. MARS is the gaurantor of the study.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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Search Strategy:

FOR EMBASE:

1) *deep learning/
2) *artificial intelligence/
3) *machine learning/
4) 1 or 2 or 3

For PubMed:

1. Artificial intelligence
2. Machine learning
3. Deep learning
4. 1 OR 2 OR 3

Restricted to:

- Article type: Randomized Control Trial
- Publication Date: 1/01/2015 to 31/12/2021
- Species: Human
- Language: English

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	

				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.	

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			

		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			

		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					

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,			

		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,			

		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.

Supplementary table 2: Included studies

No.	Authors	Year	Title	Country	Specialty	Disease studied	Sample size	Intervention	Control	Blinding	Primary outcome	Trial registration
1.	Sadasivam, et al.	2016	Impact of a Collective Intelligence Tailored Messaging System on Smoking Cessation: The Perspect Randomized Experiment	United States	Medicine	Smoking addiction	120	AI recommended motivational messages	Standard tailored messages	Single (study staff)	Influence of messages	NR
2.	Morrison, et al.	2017	The Effect of Timing and Frequency of Push Notifications on Usage of a Smartphone- Based Stress Management	United States	Psychiatry	Stress	77	Smartphone-based stress management system	Daily/occasional notifications within pre-defined	Not stated	Notification response	ISRCTN67177737

			Intervention: An Exploratory Trial						time frames			
3.	Labovitz, et al.	2017	Using Artificial Intelligence to Reduce the Risk of Nonadherence in Patients on Anticoagulation Therapy	United States	Cardiology	Ischemic stroke	28	AI system monitoring	No daily monitoring	Not stated	Adherence to therapy	NCT02599259
4.	Rostill, et al.	2018	Technology integrated health management for dementia	United Kingdom	Psychiatry	Dementia	408	Technology-integrated health management for dementia	No TIHM	Not stated	Alerts	NR
5.	Wang, et al	2018	Real-time automatic detection system increases colonoscopic polyp and adenoma	China	Gastroenterology	Adenoma	1058	AI-aided colonoscopy	Standard colonoscopy	None	Adenoma detection rate	ChiCTR-DDD-17012221

			detection rates: a prospective randomised controlled study									
6.	Lin, et al.	2019	Diagnostic Efficacy and Therapeutic Decision-making Capacity of an Artificial Intelligence Platform for Childhood Cataracts in Eye Clinics: A Multicentre Randomized Controlled Trial	China	Ophthalmology	Cataract	350	AI-assisted cataract detection	Normal clinic	Double	Diagnostic accuracy for congenital cataracts	NCT03240848

7.	Voss, et al.	2019	Effect of Wearable Digital Intervention for Improving Socialization in Children With Autism Spectrum Disorder A Randomized Clinical Trial	United States	Psychiatry	Autism	474	AI-driven behavioral intervention	Applied behavioral analysis therapy	Single	SRS-II, EGG, VABS-II, NEPSY-II socialization scores	NCT03569176
8.	Wu, et al.	2019	Randomised controlled trial of WISENSE, a real-time quality improving system for monitoring blind spots	China	Gastroenterology	Upper GI lesions	324	AI-aided esophagogastroduodenoscopy	Standard esophagogastroduodenoscopy	Single	Blind spot rate	ChiCTR1800014809

			during esophagogastroduodenoscopy									
9.	Wang, et al.	2020	Effect of a deep-learning computer-aided detection system on adenoma detection during colonoscopy (CADe-DB trial): a double-blind randomised study	China	Gastroenterology	Adenoma	1046	AI-aided colonoscopy	Sham	Double	Adenoma detection rate	ChiCTR1800017675
10.	Persell, et al.	2020	Effect of Home Blood Pressure Monitoring via a Smartphone Hypertension Coaching	United States	Medicine	Hypertension	333	AI-driven coaching app	Blood pressure tracking app	None	Systolic blood pressure at 6 months	NCT03288142

			Application or Tracking Application on Adults With Uncontrolled Hypertension A Randomized Clinical Trial									
11.	Wijnberge, et al.	2020	Effect of a Machine Learning–Derived Early Warning System for Intraoperative Hypotension vs Standard Care on Depth and Duration of Intraoperative Hypotension	Netherlands	Cardiology	Intra-operative hypotension	68	AI-driven early warning system for intraoperative hypotension	Standard care	None	Time-weighted average of intraoperative hypotension	NCT03376347

			During Elective Noncardiac Surgery The HYPE Randomized Clinical Trial									
12.	Pavel, et al.	2020	A machine-learning algorithm for neonatal seizure recognition: a multicentre, randomised, controlled trial	United Kingdom	Neurology	Neonatal seizures	264	Automated seizure detection algorithm	Conventional EEG	Single	Diagnostic accuracy of healthcare professionals with aid of algorithm	NCT02431780
13.	Nimri, et al.	2020	Insulin dose optimization using an automated artificial intelligence-based decision support	Israel	Endocrinology	Diabetes	108	AI-based decision support system	Physician guided care	Single	Time of glucose level within target range	NCT03003806

			system in youths with type 1 diabetes									
14.	Liu, et al.	2020	The single-monitor trial: an embedded CADe system increased adenoma detection during colonoscopy: a prospective randomized study	China	Gastroenterology	Adenoma	790	AI-aided colonoscopy	Routine colonoscopy	None	Adenoma detection rate	ChiCTR1800018058
15.	Gong, et al.	2020	Detection of colorectal adenomas with a real-time computer-aided system (ENDOANGEL): a randomised	China	Gastroenterology	Adenoma	704	AI-aided colonoscopy	Unassisted colonoscopy	Single	Adenoma detection rate	ChiCTR1900021984

			controlled study									
16.	Luo, et al.	2020	Artificial Intelligence-Assisted Colonoscopy for Detection of Colon Polyps: a Prospective, Randomized Cohort Study	China	Gastroenterology	Polyps	150	AI-aided colonoscopy	Unaided colonoscopy	None	Polyp detection rate	NCT04712626265
17.	Anan, at al.	2021	Effects of an Artificial Intelligence-Assisted Health Program on Workers With Neck/Shoulder Pain/Stiffness and Low Back Pain:	Japan	Orthopaedics	Neck/shoulder and back pain	94	AI-assisted health program	Usual care routine	None	Pain level	(UMIN-CTR) 000033894

			Randomized Controlled Trial									
18.	Blomberg, et al.	2021	Effect of Machine Learning on Dispatcher Recognition of Out-of-Hospital Cardiac Arrest During Calls to Emergency Medical Services: A Randomized Clinical Trial	Denmark	Cardiology	Cardiac arrest	654	AI-led alerts	Normal protocol	Double	Recognition of cardiac arrest	NCT04219306
19.	Chen, et al.	2021	The Role of Deep Learning-Based Echocardiography in the Diagnosis and Evaluation of the Effects of Routine Anti-Heart-	China	Cardiology	Heart failure	80	AI-based echocardiography	Routine echocardiography	None	Mortality and rehospitalization rate	NR

			Failure Western Medicines in Elderly Patients with Acute Left Heart Failure									
20.	Eng, et al.	2021	Artificial Intelligence Algorithm Improves Radiologist Performance in Skeletal Age Assessment	United States	Radiology	Skeletal age	1903	AI diagnostic aid	Without aid	None	Mean absolute difference between the skeletal age	NCT03530098
21.	Harada, et al.	2021	Efficacy of artificial-intelligence-driven differential-diagnosis list on the diagnostic accuracy	Japan	Medicine	Various medical conditions	22	AI-assisted differential diagnosis	Without AI assistance	Single	Diagnostic accuracy	UMIN000042881

			of physicians: An open-label randomized controlled study									
22.	Hassoon, et al.	2021	Randomized trial of two artificial intelligence coaching interventions to increase physical activity in cancer survivors	United States	Oncology	Different cancer types	42	AI coaching	Written information	Single	Change in steps per day	NCT03212079
23.	Jayakumar, et al.	2021	Comparison of an Artificial Intelligence-Enabled Patient Decision Aid vs Educational Material on	United States	Orthopaedics	Osteoarthritis	129	AI-enabled patient decision aid	Educational material	None	Knee OA Decision Quality	NCT03956004

			Decision Quality, Shared Decision-Making, Patient Experience, and Functional Outcomes in Adults with Knee Osteoarthritis: A Randomized Clinical Trial									
24.	Kamba, et al.	2021	Reducing adenoma miss rate of colonoscopy assisted by artificial intelligence: a multicenter randomized controlled trial	Japan	Gastroenterology	Adenoma	358	AI-aided colonoscopy	Unaided colonoscopy	None	Adenoma miss rate	jRCTs032190061

25.	Luna, et al.	2021	Artificial intelligence application versus physical therapist for squat evaluation: a randomized controlled trial	United States	Medicine	Physical therapy	30	AI-assisted exercise application	Unassisted exercise	Single	Successful squats	NCT04624594
26.	Medina, et al.	2021	Electrophysiological brain changes associated with cognitive improvement in a pediatric attention deficit hyperactivity disorder digital artificial intelligence-driven intervention:	Spain	Psychiatry	Attention deficit hyperactivity disorder	29	AI-driven cognitive stimulation program	Commerical video games	Single	Conners CPT (CPT-III) score	ISRCTN71041318

			Randomized controlled trial									
27.	Mertens, et al.	2021	Artificial intelligence for caries detection: Randomized trial	Germany	Dentistry	Caries	22	AI-based diagnostic support	Unaided diagnosis	None	Accuracy metrics	DRKS00022357
28.	Prochaska, et al.	2021	A randomized controlled trial of a therapeutic relational agent for reducing substance misuse during the COVID-19 pandemic	United States	Medicine	Substance-related disorders	180	AI relational conversational agent	No intervention during the study	None	Past-month substance use occasions	NCT04096001
29.	Rafferty, et al.	2021	A novel mobile app (heali) for disease treatment in participants with irritable bowel	United States	Gastroenterology	Irritable bowel syndrome	58	AI dietry mobile app	Educational material	None	Quality of life score	NCT04256551

			syndrome: Randomized controlled pilot trial									
30.	Seok, et al.	2021	A personalized 3d-printed model for obtaining informed consent process for thyroid surgery: A randomized clinical study using a deep learning approach with mesh-type 3d modeling	Korea	Endocrinology	Thyroid lesions	53	AI 3D-printed thyroid model	Without model	None	Patient general knowledge and satisfaction	KCT0005069
31.	Seol, et al.	2021	Artificial intelligence-assisted clinical decision support for childhood asthma management: A	United States	Paediatrics	Childhood asthma	184	AI-assisted decision support	Usual asthma care	Single	Asthma exacerbation occurrence within one year	NCT02865967

			randomized clinical trial									
32.	Strombla d, et al.	2021	Effect of a Predictive Model on Planned Surgical Duration Accuracy, Patient Wait Time, and Use of Presurgical Resources: A Randomized Clinical Trial	United States	Surgery	Gynaecol ogical and colorecta l surgery	683	AI-assisted surgical predictions	Standard estimatio n process	None	Accurate surgery duration prediction	NCT0347137 7
33.	Turino, et al.	2021	Management and treatment of patients with obstructive sleep apnea using an intelligent monitoring system	Spain	Pulmonolo gy	Obstructi ve sleep apnea	60	Intelligent monitoring system	Standard manage ment	None	Complianc e to CPAP	NCT0311695 8

			based on machine learning aiming to improve continuous positive airway pressure treatment compliance: Randomized controlled trial									
34.	Wang, et al.	2021	Utilization of Ultrasonic Image Characteristics Combined with Endoscopic Detection on the Basis of Artificial Intelligence Algorithm in Diagnosis of Early Upper	China	Gastroenterology	Early gastric cancer	80	Endoscopy with AI-based ultrasound imaging	Endoscopy alone	None	Detection rate of upper gastric cancer	NR

			Gastrointestinal Cancer									
35.	Wu, et al.	2021	Evaluation of the effects of an artificial intelligence system on endoscopy quality and preliminary testing of its performance in detecting early gastric cancer: a randomized controlled trial	China	Gastroenterology	Early gastric cancer	1050	AI-aided endoscopy	Endoscopy alone	Single	Number of blind spots during endoscopy	ChiCTR1800018403
36.	Wu, et al.	2021	Effect of a deep learning-based system on the miss rate of gastric neoplasms during	China	Gastroenterology	Gastric neoplasm	1886	AI-assisted endoscopy	Unaided endoscopy	Single	Gastric neoplasm miss rate	ChiCTR2000034453

			upper gastrointestinal endoscopy: a single-centre, tandem, randomised controlled trial									
37.	Xu, et al.	2021	The Clinical Value of Explainable Deep Learning for Diagnosing Fungal Keratitis Using in vivo Confocal Microscopy Images	China	Ophthalmology	Fungal keratitis	1089	AI-assisted image reading	Unassisted image reading	None	Accuracy	NR
38.	Xu, et al.	2021	Artificial intelligence-assisted colonoscopy: A prospective, multicenter, randomized	China	Gastroenterology	Polyp	2352	AI-assisted colonoscopy	Conventional colonoscopy	None	Polyp detection rate	ChiCTR1800015607

			controlled trial of polyp detection									
39.	Yao, et al.	2021	Artificial intelligence-enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial	United States	Cardiology	Low ejection fraction	358	AI-enabled electrocardiograms	Usual care	None	New diagnosis of low ejection fraction	NCT04000087
40.	Zeng, et al.	2021	Long-Term Assessment of Rehabilitation Treatment of Sports through Artificial Intelligence Research	China	Medicine	Sports health management	150	AI-based personalized sports management service system	General management	None	Blood glucose, blood pressure, lipids	NR

41.	Zhang, et al.	2021	Artificial Intelligence Algorithm-Based Ultrasound Image Segmentation Technology in the Diagnosis of Breast Cancer Axillary Lymph Node Metastasis	China	Oncology	Breast cancer	90	AI-based ultra sound image segmentation	Routine ultrasound	Double	Accuracy metrics	NR
42.	Zhang, et al.	2021	Value of Rehabilitation Training for Children with Cerebral Palsy Diagnosed and Analyzed by Computed Tomography	China	Paediatrics	Cerebral palsy	73	AI-assisted analysis of brain images	Original images	None	Cerebral artery blood flow velocity (VP) and Vasscular pulse index (PI)	NR

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