Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.
eAppendix 1: Search Strategies

Ovid Embase

1 exp artificial intelligence/
2 exp natural language processing/
3 deep learning/
4 ((artificial or computat* or computer* or machine or deep or transfer or hierarchical) adj1 (intelligence* or learning* or reasoning*)).tw,kw.
5 (neural network* or random forest* or decision tree* or knowledge representation* or computer vision system* or computer reasoning* or natural language processing or perceptron* or connectionist model* or expert system*).tw,kw.
6 AI.tw,kw.
7 or/1-6
8 exp diagnosis/
9 exp prediction/
10 exp clinical decision making/
11 exp computer assisted diagnosis/
12 (prognos* or predict* or diagnos*).tw,kw.
13 (decision making* or decision-making* or decision aid* or decision support* or clinical decision*).tw,kw.
14 diagnosis.fs.
15 8 or 9 or 10 or 11 or 12 or 13 or 14
16 7 and 15
17 limit 16 to (randomized controlled trial or controlled clinical trial)
18 exp clinical trial/
19 exp randomized controlled trial/
20 exp randomization/
21 exp single blind procedure/
22 exp double blind procedure/
23 exp crossover procedure/
24 exp placebo/
25 exp prospective study/
26 (randomi#ed controlled or rct or randomly allocated or allocated randomly or random allocation).ti,ab.
27 ((singl* or double or triple) adj1 (blind* or placebo*)).ti,ab.
28 (cross adj1 over).ti,ab.
29 or/18-28
30 16 and 29
31 exp animal/
32 exp animal/ and exp human/
33 31 not 32
34 30 not 33

Ovid MEDLINE(R) ALL
1 exp Artificial Intelligence/
We conducted a systematic search for studies that included artificial intelligence (AI) or machine learning (ML) techniques in clinical decision-making. The search strategy was as follows:

**Title/Abstract:**
- (artificial or computat* or computer* or machine or deep or transfer or hierarchical) adj1 (intelligence* or learning* or reasoning*).tw,kf.
- (neural network* or random forest* or decision tree* or knowledge representation* or computer vision system* or computer reasoning* or natural language processing* or perceptron* or connectionist model* or expert system*).tw,kf.
- AI.tw,kf.
- 1 or 2 or 3 or 4
- exp Diagnosis/
- exp Clinical Decision-Making/
- (prognos* or predict* or diagnos*).tw,kf.
- (decision making* or decision-making* or decision aid* or decision support* or clinical decision*).tw,kf.
- diagnosis.fs.
- 6 or 7 or 8 or 9 or 10
- 5 and 11
- limit 12 to randomized controlled trial
- exp clinical trial/
- exp Randomized Controlled Trial/
- Random Allocation/
- single-blind method/
- Double-Blind Method/
- cross-over studies/
- Prospective Studies/
- (randomi#ed controlled or rct or randomly allocated or allocated randomly or random allocation).ti,ab.
- ((singl* or double or triple) adj1 (blind* or placebo*)).ti,ab.
- (cross adj1 over).ti,ab.
- 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
- 12 and 24
- exp animals/
- exp animals/ and exp humans/
- 26 not 27
- 25 not 28

**Scopus**
- (TITLE-ABS-KEY (( artificial OR computat* OR computer* OR machine OR deep OR transfer OR hierarchical ) W/1 ( intelligence* OR learning* OR reasoning* ))) OR TITLE-ABS-KEY ( "neural network" OR "random forest" OR "decision tree" OR "knowledge representation" OR "computer vision system" OR "computer reasoning" OR "natural language processing" OR "perceptron" OR "connectionist model" OR "expert system" ) AND ( TITLE-ABS-KEY ( prognos* OR predict* OR diagnos* ) OR TITLE-ABS-KEY ( "decision making" OR "decision-making" OR "decision aid" OR "decision support" OR "clinical decision" ) ) AND ( TITLE-ABS-KEY ( randomized OR randomised OR rct OR randomly AND allocated OR allocated randomly OR random AND allocation ) OR TITLE-ABS-KEY ( ( singl* OR double OR triple ) W/1 ( blind* OR placebo* ) ) OR TITLE-ABS-KEY ( cross W/1 over ))

**Web of Science Core Collection**

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#1 TS=((artificial or computat* or computer* or machine or deep or transfer or hierarchical) near/1 (intelligence* or learning* or reasoning*)) OR TS=("neural network*" or "random forest*" or "decision tree*" or "knowledge representation*" or "computer vision system*" or "computer reasoning*" or "natural language processing*" or perceptron* or "connectionist model*" or "expert system*")
#2 TS=(prognos* or predict* or diagnos*) OR TS=("decision making*" or "decision-making*" or "decision aid*" or "decision support*" or "clinical decision")
#3 TS=(randomized or randomised or rct or randomly allocated or allocated randomly or random allocation) OR TS=((singl* or double or triple) near/1 (blind* or placebo*)) or TS=(cross near/1 over)
#4 #1 and #2 and #3

PubMed

(((randomized[Title/Abstract] OR randomised[Title/Abstract] OR rct[Title/Abstract] OR randomly allocated[Title/Abstract] OR allocated randomly[Title/Abstract] OR random allocation[Title/Abstract] OR cross over[Title/Abstract] OR placebo*[Title/Abstract] OR single blind*[Title/Abstract] OR double blind*[Title/Abstract] OR triple blind*[Title/Abstract]) AND ((("neural network*"[Title/Abstract] OR "random forest*"[Title/Abstract] OR "decision tree*"[Title/Abstract] OR "knowledge representation*"[Title/Abstract] OR "computer vision system*"[Title/Abstract] OR "computer reasoning*"[Title/Abstract] OR "natural language processing*"[Title/Abstract] OR perceptron*[Title/Abstract] OR "connectionist model*"[Title/Abstract] OR "expert system*"))[Title/Abstract]) OR (artificial intelligence*[Title/Abstract] OR computat* intelligence*[Title/Abstract] OR computer* intelligence*[Title/Abstract] OR machine intelligence*[Title/Abstract] OR deep intelligence*[Title/Abstract] OR transfer intelligence*[Title/Abstract] OR hierarchical intelligence*[Title/Abstract] OR artificial learning*[Title/Abstract] OR computat* learning*[Title/Abstract] OR computer* learning*[Title/Abstract] OR machine learning*[Title/Abstract] OR deep learning*[Title/Abstract] OR transfer learning*[Title/Abstract] OR hierarchical learning*[Title/Abstract] OR artificial reasoning*[Title/Abstract] OR computat* reasoning*[Title/Abstract] OR computer* reasoning*[Title/Abstract] OR machine reasoning*[Title/Abstract] OR deep reasoning*[Title/Abstract] OR transfer reasoning* or hierarchical reasoning*[Title/Abstract])) AND (prognos*[Title/Abstract] OR predict*[Title/Abstract] OR diagnos*[Title/Abstract] OR "decision making*"[Title/Abstract] OR "decision-making*"[Title/Abstract] OR "decision aid*"[Title/Abstract] OR "decision support*"[Title/Abstract] OR "clinical decision*"[Title/Abstract]) OR ((("neural network*"[Title/Abstract] OR "random forest*"[Title/Abstract] OR "decision tree*"[Title/Abstract] OR "knowledge representation*"[Title/Abstract] OR "computer vision system*"[Title/Abstract] OR "computer reasoning*"[Title/Abstract] OR "natural language processing*"[Title/Abstract] OR perceptron*[Title/Abstract] OR "connectionist model*"[Title/Abstract] OR "expert system*"))[Title/Abstract]) OR (artificial intelligence*[Title/Abstract] OR computat* intelligence*[Title/Abstract] OR computer* intelligence*[Title/Abstract] OR machine intelligence*[Title/Abstract] OR deep intelligence*[Title/Abstract] OR transfer intelligence*[Title/Abstract] OR hierarchical intelligence*[Title/Abstract] OR artificial learning*[Title/Abstract] OR computat* learning*[Title/Abstract] OR computer* learning*[Title/Abstract] OR machine learning*[Title/Abstract] OR deep learning*[Title/Abstract] OR transfer learning*[Title/Abstract] OR hierarchical learning*[Title/Abstract] OR artificial reasoning*[Title/Abstract] OR computat* reasoning*[Title/Abstract] OR computer* reasoning*[Title/Abstract] OR machine reasoning*[Title/Abstract] OR deep reasoning*[Title/Abstract] OR transfer reasoning* or hierarchical reasoning*[Title/Abstract])
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reasoning*[Title/Abstract] OR machine reasoning*[Title/Abstract] OR deep reasoning*[Title/Abstract] OR transfer reasoning* or hierarchical reasoning*[Title/Abstract])
AND (prognos*[Title/Abstract] OR predict*[Title/Abstract] OR diagnos*[Title/Abstract] OR "decision making**"[Title/Abstract] OR "decision-making**"[Title/Abstract] OR "decision aid**"[Title/Abstract] OR "decision support**"[Title/Abstract] OR "clinical decision**"[Title/Abstract])
AND (randomizedcontrolledtrial[Filter]))

**Cochrane Library**

#1 ((artificial or computat* or computer* or machine or deep or transfer or hierarchical) near/1 (intelligence* or learning* or reasoning*)):ti,ab OR ("neural network**" or "random forest**" or "decision tree**" or "knowledge representation**" or "computer vision system**" or "computer reasoning**" or "natural language processing**" or perceptron* or "connectionist model**" or "expert system**"):ti,ab
#2 (prognos* or predict* or diagnos*):ti,ab OR ("decision making**" or "decision-making**" or "decision aid**" or "decision support**" or "clinical decision**"):ti,ab
#3 #1 and #2

**Google Scholar**

machine learning diagnosis randomized controlled trial
## eAppendix 2: Excluded studies

| First Authors Last Name | Year | Title                                                                                                                                                                                                 | Journal                                                                 | Reason for Exclusion                  |
|-------------------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------|
| Abbas                   | 2018 | Machine learning approach for early detection of autism by combining questionnaire and home video screening                                                                                          | J Am Med Inform Assoc                                                  | Wrong study design                    |
| Auloge                  | 2019 | Augmented reality and artificial intelligence-based navigation during percutaneous vertebroplasty: A pilot prospective clinical study                                                            | CardioVascular and Interventional Radiology                           | Duplicate study data                  |
| Avari                   | 2020 | Efficacy and safety of the patient empowerment through predictive personalised decision support (PEPPER) system: an open-label randomised controlled trial                   | Diabetes Technology & Therapeutics                                    | Duplicate study data                  |
| Avari                   | 2020 | Establishment and real-world validation of a computer-assisted polyp identification and localization system based on deep learning                                                                  | Journal of Digestive Diseases                                         | Wrong study design                    |
| Bai                     | 2019 | Effect of a machine learning-based severe sepsis prediction algorithm on patient survival                                                                                                             | Critical Care Medicine                                                | No AI or machine learning             |
| Ben-Yacov               | 2020 | Personalized nutrition for prediabetes by prediction of glycemic responses                                                                                                                          | Diabetes. Conference: 80th Scientific Sessions of the American Diabetes Association, ADA | Conference abstract                   |
| Betancur                | 2018 | Externally validated deep learning improves per-vessel prediction of obstructive coronary artery disease from upright and supine spect MPI: A multicenter study                                          | Journal of Nuclear Cardiology                                        | Wrong study design                    |
| Biester                 | 2019 | DREAM5: An open-label, randomized, cross-over study to evaluate the safety and efficacy of day and night closed-loop control by comparing the MD-Logic automated insulin delivery system to sensor augmented pump therapy in patients with type 1 diabetes at h | Diabetes, Obesity & Metabolism                                       | Wrong intervention                    |
| Blomberg                | 2021 | Effect of Machine Learning on Dispatcher Recognition of Out-of-Hospital Cardiac Arrest during Calls to Emergency Medical Services: A Randomized Clinical Trial                                             | JAMA Network Open                                                    | Duplicate study data                  |
| Browning                | 2020 | Results of the PReDicT Study: A Randomised Controlled Trial of Using the PReDicT Test to Guide Antidepressant Treatment in Depression                                                             | Biological Psychiatry                                                | Conference abstract                   |
| Cai                     | 2021 | Improving Ki67 assessment concordance by the use of an artificial intelligence-empowered microscope: a multi-institutional ring study                                                              | Histopathology                                                       | Wrong study design                    |
| Chae                    | 2020 | Development and Clinical Evaluation of a Web-Based Upper Limb Home Rehabilitation System Using a Smartwatch and Machine Learning Model for Chronic Stroke Survivors: Prospective Comparative Study | JMIR Mhealth Uhealth                                                 | Wrong study design                    |
| Author | Year | Title | Journal/Conference | Notes |
|--------|------|-------|--------------------|-------|
| Chiang | 2021 | Using Wearables and Machine Learning to Enable Personalized Lifestyle Recommendations to Improve Blood Pressure | IEEE Journal of Translational Engineering in Health and Medicine-JTEHM | Wrong study design |
| Chiang | 2020 | Physician Usage and Acceptance of a Machine Learning Recommender System for Simulated Clinical Order Entry | AMIA Summits on Translational Science Proceedings | No clinical decision making |
| Doupis | 2018 | Mobile-based artificial intelligence significantly improves type 1 diabetes management | Diabetes | Wrong study design |
| Dreisheitl | 2009 | Computer versus human diagnosis of melanoma: evaluation of the feasibility of an automated diagnostic system in a prospective clinical trial | Melanoma Research | Wrong study design |
| Elliott | 2017 | Clinical impact of pharmacogenetic profiling with a clinical decision support tool in polypharmacy home health patients: A prospective pilot randomized controlled trial | PLoS ONE | No AI or machine learning |
| Emura | 2021 | Id: 3526254 a Novel Deep Learning Model to Facilitate Complete Systematic Photodocumentation during Upper Gi Endoscopy | Gastrointestinal Endoscopy Conference abstract | |
| Gu | 2021 | Follow-up of atrial fibrillation recurrence after ablation with a BigThumb<sup>®</sup> electrocardiogram monitor. [Chinese] | Academic Journal of Second Military Medical University | Foreign language |
| Harada | 2021 | Efficacy of artificial-intelligence-driven differential-diagnosis list on the diagnostic accuracy of physicians: An open-label randomized controlled study | International Journal of Environmental Research and Public Health | No clinical decision making |
| Ishiyama | 2021 | Impact of the clinical use of artificial intelligence-assisted neoplasia detection for colonoscopy: a large-scale prospective, propensity score-matched study (with video) | Gastrointestinal Endoscopy | Wrong study design |
| Jaroszewski | 2019 | Randomized controlled trial of an online machine learning-driven risk assessment and intervention platform for increasing the use of crisis services | Journal of Consulting & Clinical Psychology | Wrong setting |
| Kamba | 2021 | Id: 3519580 a Multicentre Randomized Controlled Trial to Verify the Reducibility of Adenoma Miss Rate of Colonoscopy Assisted with Artificial Intelligence Based Software | Gastrointestinal Endoscopy Conference abstract | |
| Koons | 2020 | Combat medic testing of a novel monitoring capability for early detection of hemorrhage | The Journal of Trauma and Acute Care Surgery | Wrong study design |
| Kumar | 2020 | OrderRex clinical user testing: a randomized trial of recommender system decision support on simulated cases | J Am Med Inform Assoc | Wrong intervention |
| Labovitz | 2017 | Using Artificial Intelligence to Reduce the Risk of Nonadherence in Patients on Anticoagulation Therapy | Stroke | Wrong intervention |
| Lam | 2021 | Artificial intelligence-assisted colonoscopy improves adenoma detection in screening colonoscopy. A large-scale multi-center randomized controlled study | Journal of Gastroenterology and Hepatology Conference abstract | |
| Author          | Year | Study Title                                                                 | Journal/Publication                              | Result |
|-----------------|------|------------------------------------------------------------------------------|--------------------------------------------------|--------|
| Lees            | 2003 | Cluster-randomized, controlled trial of computer-based decision support for selecting long-term anti-thrombotic therapy after acute ischaemic stroke | Qjm-an International Journal of Medicine         | Wrong intervention |
| Leng            | 2021 | Assessing rectal cancer treatment response using coregistered endorectal photoacoustic and us imaging paired with deep learning | Radiology                                       | Wrong study design |
| Liu             | 2018 | Evaluating the impact of an integrated computer-based decision support with person-centered analytics for the management of hypertension: A randomized controlled trial | Journal of Hypertension                          | Wrong intervention |
| Liu             | 2020 | Impact of Deep Learning-based Optimization Algorithm on Image Quality of Low-dose Coronary CT Angiography with Noise Reduction: A Prospective Study | Academic Radiology                               | Wrong study design |
| Lugtenberg      | 2015 | Exposure to and experiences with a computerized decision support intervention in primary care: results from a process evaluation | BMC Fam Pract                                    | Wrong intervention |
| Luna            | 2021 | Artificial intelligence application versus physical therapist for squat evaluation: a randomized controlled trial | Scientific reports                               | No clinical decision making |
| McKee           | 2019 | Randomized clinical trial of a just-in-time intervention based on wearable biosensors detecting smoking gestures | Alcoholism: Clinical and Experimental Research    | Wrong intervention |
| Milluzzo        | 2021 | Incremental yield of artificial intelligence in follow-up screening colonoscopies-an interim analysis | Endoscopy                                        | Conference abstract |
| Milluzzo        | 2021 | Id: 3522041 Incremental Yield of Artificial Intelligence in Follow-up Screening Colonoscopies - an Interim Analysis | Gastrointestinal Endoscopy                       | Conference abstract |
| Mirelman        | 2009 | Effects of training with a robot-virtual reality system compared with a robot alone on the gait of individuals after stroke | Stroke                                           | Wrong intervention |
| Nieminen        | 2002 | Prospective and randomised public-health trial on neural network-assisted screening for cervical cancer in Finland: results of the first year | Int J Cancer                                     | No clinical decision making |
| Nieminen        | 2003 | Prospective and randomised public-health trial on neural network-assisted screening for cervical cancer in Finland: Results of the first year | International Journal of Cancer                  | Preliminary results only |
| Noriega         | 2021 | Screening Diabetic Retinopathy Using an Automated Retinal Image Analysis System in Independent and Assistive Use Cases in Mexico: Randomized Controlled Trial | JMIR Formative Research                          | Wrong study design |
| Park            | 2020 | Validation of the effectiveness of a digital integrated healthcare platform utilizing an AI-based dietary management solution and a real-time continuous glucose monitoring system for diabetes management: a randomized controlled trial | BMC Medical Informatics & Decision Making        | Preliminary results only |
| Pelle           | 2020 | Effect of the dr. Bart application on healthcare use and clinical outcomes in people with osteoarthritis of the knee and/or hip in the Netherlands; a randomized controlled trial | Osteoarthritis & Cartilage                       | No AI or machine learning |
| Peyro-Saint-Paul| 2019 | Mobile application for adverse drug reaction reporting by patients with relapsing remitting multiple sclerosis (vigipsep study): a national randomized controlled trial | European Journal of Clinical Pharmacology        | Wrong intervention |
| Author    | Year | Title                                                                 | Journal/Conference                                  | Status                        |
|-----------|------|----------------------------------------------------------------------|-----------------------------------------------------|-------------------------------|
| Raoux     | 2021 | Novel ai-based solution for supporting prostate cancer diagnosis increases the efficiency and accuracy of reporting in clinical routine | Laboratory Investigation                             | Conference abstract           |
| Rapoport  | 2018 | Computer-Based Driving in Dementia Decision Tool With Mail Support: Cluster Randomized Controlled Trial | Journal of Medical Internet Research                 | Wrong intervention            |
| Rein      | 2021 | Personalized diets by prediction of glycemic responses improve glycemic control in subjects with newly diagnosed t2d | Diabetes. Conference: 81st Scientific Sessions of the American Diabetes Association, ADA | Conference abstract           |
| Repici    | 2020 | 876 Real-Time Computer Aided Diagnosis for Detection of Colorectal Neoplasia at Colonoscopy | Gastrointestinal Endoscopy                          | Duplicate study data          |
| Repici    | 2021 | Efficacy of real-time computer-aided detection of colorectal neoplasia in a non-expertsetting: A randomized controlled trial | Endoscopy                                            | Conference abstract           |
| Repici    | 2021 | Id: 3523387 Efficacy of Real-Time Computer Aided Detection of Colorectal Neoplasia in a Non-Expert Setting: A Randomized Controlled Trial | Gastrointestinal Endoscopy                          | Conference abstract           |
| Ringel    | 2012 | Accuracy of robot-assisted placement of lumbar and sacral pedicle screws: a prospective randomized comparison to conventional freehand screw implantation | Spine                                               | Wrong intervention            |
| Sandal    | 2019 | An App-Delivered Self-Management Program for People With Low Back Pain: Protocol for the selfBACK Randomized Controlled Trial | JMIR Research Protocols                             | No original data              |
| Saposnik  | 2020 | Therapeutic decisions in ms care: An international study comparing clinical judgement vs. Information from artificial intelligence-based models | Multiple Sclerosis Journal                          | Conference abstract           |
| Segal     | 2016 | Controlling glucose levels by personalized nutrition tailored to the microbiome | Diabetes Technology and Therapeutics                | Conference abstract           |
| Seok      | 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 | Journal of Personalized Medicine                    | No clinical decision making   |
| Seol      | 2021 | Artificial intelligence-assisted clinical decision support for childhood asthma management: A randomized clinical trial | PLoS ONE                                             | Duplicate study data          |
| Srivannaboon | 1997 | A prospective clinical trial comparing a topographically guided artificial intelligence software system versus clinical expertise for fitting normal and pathologic corneas with contact lenses | IOVS                                                | Conference abstract           |
| Sun       | 2014 | A computer-aided diagnostic algorithm improves the accuracy of transesophageal echocardiography for left atrial thrombi: a single-center prospective study | Journal of ultrasound in medicine: official journal of the American Institute of Ultrasound in Medicine | Wrong study design            |
| Symons    | 2020 | Predicting alcohol dependence treatment outcomes: a prospective comparative study of clinical psychologists versus 'trained' machine learning models | Addiction (Abingdon, England)                       | Wrong study design            |
| Tanaka    | 2012 | Effect of a human-type communication robot on cognitive function in elderly women living alone | Med Sci Monit                                        | Wrong intervention            |

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| Last Name  | Year | Title                                                                                               | Journal/Conference/Abstract | Notes                      |
|-----------|------|-----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------|
| Vennalaganti | 2015 | Increased detection of barrett's esophagus (BE)-associated Neoplasia using wide-area trans-epithelial sampling in conjunction with 4-quadrant biopsies: interim results from a multi-center, prospective, randomized trial | Gastroenterology             | Duplicate study data       |
| Walter     | 2012 | Effect of adding a diagnostic aid to best practice to manage suspicious pigmented lesions in primary care: randomised controlled trial | BMJ (Clinical research ed.) | Wrong intervention         |
| Walter     | 2012 | Effect of adding a diagnostic aid to best practice to manage suspicious pigmented lesions in primary care: randomised controlled trial | Bmj-British Medical Journal  | Wrong intervention         |
| Wang       | 2020 | 859 Computer-Aided-Detection Embedded Colonoscopy Versus Routine Colonoscopy: A Prospective, Randomized Tandem Trial | Gastroenterology             | Duplicate study data       |
| Wang       | 2019 | Colonoscopy with embedded deep learning computer-aided detection system improves adenoma detection without increasing physician fatigue: a prospective randomized study | United European Gastroenterology Journal | Conference abstract         |
| Wang       | 2018 | Assistance of a real-time automatic colon polyp detection system increases polyp and adenoma detection during colonoscopy: A prospective randomized controlled study | United European Gastroenterology Journal | Conference abstract         |
| Wang       | 2018 | Automatic polyp detection during colonoscopy increases adenoma detection: An interim analysis of a prospective randomized control study | Gastrointestinal Endoscopy | Wrong setting               |
| Wang       | 2019 | Application of Artificial Intelligence-based Image Optimization for Computed Tomography Angiography of the Aorta With Low Tube Voltage and Reduced Contrast Medium Volume | J Thorac Imaging            | No clinical outcome        |
| Wismuller  | 2020 | A Prospective Randomized Clinical Trial for Measuring Radiology Study Reporting Time on Artificial Intelligence-Based Detection of Intracranial Hemorrhage in Emergent Care Head CT | SPIE Medical Imaging Conference - Biomedical Applications in Molecular, Structural, and Functional Imaging | No clinical decision making |
| Wu         | 2021 | Evaluating the Effects of An Artificial Intelligence System on Endoscopy Quality and Preliminarily Testing its Performance on Detecting Early Gastric Cancer: a Randomized Controlled Trial | Endoscopy                   | Duplicate study data       |
| Yu         | 2019 | 378 Randomized Controlled Trial of Wisense, a Real-Time Quality Improving System for Monitoring Blind Spots during Esophagogastroduodenoscopy | Gastrointestinal Endoscopy | Duplicate study data       |
| Yu         | 2019 | Improved adenoma detection with ENDOANGEL: A randomized controlled trial | United European Gastroenterology Journal | Duplicate study data       |
| Yu         | 2021 | 1136P A clinically applicable cervical cancer artificial intelligence screening system for accurate cytopathological diagnosis: A multicenter population-based study and randomized controlled trial | Annals of Oncology          | Conference abstract         |
| Zamora     | 2015 | A clinical decision support system can improves the quality of lipid-lowering therapy in coronary patients | European heart journal.     | Conference abstract         |
| Zhou       | 2019 | A real-time automatic deep learning polyp detection system increases polyp and adenoma detection during colonoscopy: a prospective double-blind randomized study | Gastroenterology             | Conference abstract         |
eAppendix 3: Included trial characteristics

| Study Aim                                      | Primary Outcome                                      | ML technology data type | ML technology model type | Primary outcome clinical | Primary outcome thresholded | Tool tested at multiple sites | Overall Risk of Bias |
|-----------------------------------------------|------------------------------------------------------|-------------------------|--------------------------|----------------------------|------------------------------|------------------------------|----------------------|
| Detect neonatal seizures<sup>36</sup>         | Diagnostic accuracy                                  | EEG                     | Not Reported             | Yes                        | Yes                          | Yes                          | Some concerns         |
| Detect colorectal adenomas<sup>37</sup>       | Adenoma miss rate                                    | Imaging                 | Deep learning            | Yes                        | Yes                          | No                           | High                 |
| Premature infant physiological response<sup>38</sup> | Respiratory rate, systolic and diastolic blood pressure, and heart rate | Music                   | Not Reported             | No                         | No                           | Yes                          | Some concerns         |
| Optimize insulin-dose<sup>39</sup>            | Percentage of time glucose in target range           | Glucose levels, insulin delivery history and meal consumption, as reported through the insulin pump's bolus calculator | Artificial intelligence   | Yes                        | Yes                          | Yes                          | Low                  |
| Detect Barrett’s esophagus–associated neoplasia<sup>40</sup> | Rate of detection of high-grade dysplasia/esophageal adenocarcinoma | Histology               | Neural network analysis  | Yes                        | Yes                          | Yes                          | Low                  |
| Improve Socialization in Children With Autism Spectrum Disorder<sup>41</sup> | Four socialization measures                          | 3D images               | Computer vision          | Yes                        | No                           | No                           | Some concerns         |
| Increase Serious Illness Conversations         | Percentage of patient encounters with an SIC         | Structured EHR data     | Not Reported             | Yes                        | No                           | Yes                          | Some concerns         |

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| Among Patients With Cancer<sup>42</sup> | Improve control of blood pressure in outpatients with hypertension<sup>43</sup> | Systolic blood pressure at 6 months | Blood pressure, pulse, user responses to prompts | Artificial intelligence | Yes | No | Yes | Some concerns |
|---|---|---|---|---|---|---|---|---|
| Detect colorectal adenomas<sup>44</sup> | Adenoma detection rate | Imaging | CNN | Yes | No | Yes | Low |
| Detect Intraoperative Hypotension<sup>45</sup> | Time-weighted average of hypotension during surgery | Arterial waveform data | Not Reported | Yes | No | No | Low |
| Predict Outcomes of Patients with Sepsis<sup>46</sup> | Length of stay | Demographic and physiological information | Not Reported | Yes | No | No | High |
| Detect colorectal adenomas<sup>47</sup> | Adenoma detection rate | Imaging | Deep learning | Yes | Yes | No | Low |
| Detect colorectal adenomas<sup>48</sup> | Adenoma detection rate | Imaging | Deep learning | Yes | No | No | Some concerns |
| Diagnose childhood cataracts<sup>49</sup> | Diagnostic performance for childhood cataracts | Ocular images | Collaborative AI cloud platform | Yes | No | Yes | Low |
| Facilitate weight loss through automated personalized feedback for physical activity and diet<sup>50</sup> | Amount of walking | Physical activity and dietary intake data collected solely from a mobile phone | Multi-armed bandit | No | No | No | High |
| Feasibility of AI/AR tool for vertebroplasty<sup>51</sup> | Technical feasibility | Imaging | Not Reported | No | Yes | No | Some concerns |
| Decrease hypoglycemia episodes with personalized bolus advice for people with type 1 diabetes<sup>52</sup> | Percentage time in range | Insulin levels, physical activity before a meal, lifestyle information | Case-based reasoning | Yes | No | Yes | Some concerns |
| Detect colorectal adenomas<sup>53</sup> | Adenoma detection rates | Imaging | Deep learning | Yes | Yes | No | Some concerns |
| Task                                                                 | Outcome Measure                                     | Methodology             | Assessed | Domain | Sawa | Notes |
|----------------------------------------------------------------------|----------------------------------------------------|-------------------------|----------|--------|------|-------|
| Facilitate weight loss by predicting and preventing dietary lapses | Weight-loss and satisfaction                        | Patient-reported survey answers | Not Reported | Yes    | No   | Yes   | Some concerns |
| Reduce rate of blind spots during EGD                               | Blind Spot Rate                                     | Video                   | CNN      | Yes    | Yes  | No    | Some concerns |
| Predict optimal CPAP by neural network to reduce titration failure  | Time to optimal CPAP pressure                       | Polysomnography         | ANN      | Yes    | No   | No    | High         |
| Self-management of Congestive Heart Failure using app and wristband | HRQOL and self-reported improvement in self-care   | Sensing device (wristband) | Not Reported | No    | No   | Yes   | Some concerns |
| AI-based Echocardiogram for diagnosis of acute heart failure        | Rehospitalization rate                              | Echocardiogram          | CNN      | Yes    | No   | No    | High         |
| Management of childhood asthma                                       | Occurrence of asthma exacerbation in 1 year         | Clinician alert         | Not Reported | Yes    | No   | No    | Some concerns |
| Colon adenoma detection of non-expert endoscopists                   | Adenoma detection rate                              | Imaging                 | CNN      | Yes    | No   | Yes   | Low          |
| Decrease colon adenoma miss rate                                     | Adenoma miss rate                                   | Imaging                 | CNN      | Yes    | No   | Yes   | Some concerns |
| Increase polyp and adenoma detection with CADe                       | Adenoma detection rate                              | Imaging                 | Deep-learning | Yes  | No  | No    | Some concerns |
| Emergency Dispatched recognition of cardiac arrest during call       | Rate of dispatcher recognition of subsequently confirmed cardiac arrest | Dispatcher alert | Not Reported | Yes    | No   | No    | Low          |
| Task                                                                 | Method                                                                 | Tool                           | Deep learning | Yes/No | Some concerns |
|----------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------|---------------|--------|---------------|
| Polyp detection of AI-assisted colonoscopy                          | Polyp detection rate                                                   | Imaging                        | Deep learning | Yes    | No            | Yes          | Some concerns |
| AI-enabled patient decision aid on knee OA management               | Decision quality                                                       | PROM scores                    | Not Reported | Yes    | No            | No           | High          |
| Identify blind spots in EGD                                         | Number of blind spots                                                 | Imaging                        | CNN           | No     | No            | Yes          | Some concerns |
| Improve quality of life in patients with lower back pain with app   | RMDQ Score                                                             | User input                     | Not Reported | Yes    | No            | Yes          | Low           |
| Identify follicles in patients with ovarian stimulation             | Number of oocytes retrieved                                           | Sonography                     | Not Reported | Yes    | No            | No           | High          |
| Identify patients with low ejection fraction from EKG data          | Low EF                                                                 | ECG waveforms                  | CNN           | Yes    | Yes           | Yes          | Some concerns |
| Identify gastric neoplasms on EGD                                   | Gastric neoplasia miss rate                                           | Imaging                        | CNN           | Yes    | No            | No           | Low           |
| Predict surgical case durations                                     | Accurate prediction of duration of each scheduled surgery by mean absolute error | EHR data, including patient data, surgeon-associated statistics, procedure groups, operational factors, and clinical note text | Random Forest | No     | No            | No           | Low           |
| Skeletal age assessment                                             | Mean absolute difference between skeletal age dictated into radiologists’ signed report | Images                         | CNN           | No     | No            | Yes          | Low           |
| Computer-aided Polyp Detection                                       | Adenoma miss rate                                                     | Endoscopic videos              | CNN           | Yes    | No            | Yes          | Some concerns |
| Reduces Adenoma Miss Rate\textsuperscript{73} | Reducing pain after surgery\textsuperscript{74} | Postoperative pain assessed in the PACU | Autonomic clinical data | Not Reported | Yes | No | Yes | Low |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Improving the detection rate of polyps and adenomas\textsuperscript{75} | Detection rate of polyps/adenomas in colonoscopy | Imaging | CNN | Yes | No | No | Some concerns |
| Improving the detection rate of polyps and adenomas\textsuperscript{76} | Adenoma detection rate | Imaging | CNN | Yes | No | No | Some concerns |
## Study Adherence to CONSORT-AI Guidelines

| Ref # | Did the study meet the 11 new extension items in the CONSORT-AI extension reporting guidelines? (yes/no) | 1) Explain the intended use of the AI intervention in the context of the clinical pathway, including its purpose and its intended users (for example, healthcare professionals, patients, public). | 2) State the inclusion and exclusion criteria at the level of the input data. | 3) Describe how the AI intervention was integrated into the trial setting, including any onsite or offsite requirement(s). | 4) State which version of the AI algorithm was used. | 5) Describe how the input data were acquired and selected for the AI intervention. | 6) Describe how poor quality or unavailable input data were assessed and handled. | 7) Specify whether there was human–AI interaction in the handling of the input data, and what level of expertise was required of users. | 8) Specify the output of the AI intervention | 9) Explain how the AI intervention's outputs contributed to decision-making or other elements of clinical practice. | 10) 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. | 11) State whether and how the AI intervention and/or its code can be accessed, including any restrictions to access or re-use. |
|-------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| 36    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 37    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 38    | No                                               | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           |
| 39    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           |
| 40    | No                                               | Yes                                                                                           | No                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 41    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 42    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 43    | No                                               | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 44    | No                                               | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 45    | No                                               | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 46    | No                                               | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 47    | No                                               | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
| 48    | No                                               | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | Yes                                                                                           | No                                                                                           | No                                                                                           | No                                                                                           |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 49 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | No | No |
| 50 | No | Yes | No | Yes | No | Yes | No | Yes | Yes | Yes | No | No |
| 51 | No | Yes | Yes | Yes | No | Yes | No | No | Yes | Yes | No | No |
| 52 | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No | No |
| 53 | No | Yes | No | Yes | No | Yes | No | Yes | Yes | Yes | No | No |
| 54 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | No | No |
| 55 | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No | No |
| 56 | No | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | No | No |
| 57 | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 58 | No | Yes | Yes | Yes | No | Yes | Yes | No | Yes | Yes | Yes | No |
| 59 | No | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | No |
| 60 | No | Yes | Yes | Yes | No | Yes | Yes | No | Yes | Yes | Yes | No | No |
| 61 | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | No |
| 62 | No | Yes | No | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | No |
| 63 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | No |
| 64 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | No |
| 65 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | No | Yes | No |
| 66 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | No | No | No |
| 67 | No | Yes | No | Yes | No | Yes | No | Yes | Yes | Yes | No | No | No |
| 68 | No | Yes | Yes | No | No | Yes | No | Yes | Yes | Yes | Yes | No | No |
| 69 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| 70 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| 71 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| 72 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| 73 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | No | No |
| 74 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | No | No | No |
| 75 | No | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No | No | No | No |
| 76 | No | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | No | No | No | No |
**eAppendix 4:** Study article comparison and contrast with articles included in Zhou, Q., Chen, Zh., Cao, Yh. et al. Clinical impact and quality of randomized controlled trials involving interventions evaluating artificial intelligence prediction tools: a systematic review. NPJ Digit. Med. 4, 154 (2021).

| Included in present study and Zhou et al (n=14)                                                                 | Reason for Exclusion |
|------------------------------------------------------------------------------------------------------------------|----------------------|
| Blomberg SN, Christensen HC, Lippert F, Ersbøll AK, Torp-Petersen C, Sayre MR, et al. Effect of Machine Learning on Dispatcher Recognition of Out-of-Hospital Cardiac Arrest During Calls to Emergency Medical Services: A Randomized Clinical Trial. JAMA network open. 2021;4(1):e2032320 | N/A                  |
| Gong D, Wu L, Zhang J, Mu G, Shen L, Liu J, et al. Detection of colorectal adenomas with a real-time computer-aided system (ENDOANGEL): a randomised controlled study. The Lancet Gastroenterology & Hepatology. 2020;5(4):352-61. | N/A                  |
| Lin H, Li R, Liu Z, Chen J, Yang Y, Chen H, et al. Diagnostic Efficacy and Therapeutic Decision-making Capacity of an Artificial Intelligence Platform for Childhood Cataracts in Eye Clinics: A Multicentre Randomized Controlled Trial. EClinicalMedicine. 2019;9:52-9. | N/A                  |
| Manz CR, Parikh RB, Small DS, Evans CN, Chivers C, Regli SH, et al. Effect of Integrating Machine Learning Mortality Estimates With Behavioral Nudges to Clinicians on Serious Illness Conversations Among Patients With Cancer: A Stepped-Wedge Cluster Randomized Clinical Trial. JAMA oncology. 2020;6(12):e204759. | N/A                  |
| Meijer F, Honing M, Roor T, Toet S, Calis P, Olofsen E, et al. Reduced postoperative pain using Nociception Level-guided fentanyl dosing during sevoflurane anaesthesia: a randomised controlled trial. British journal of anaesthesia. 2020;125(6):1070-8. | N/A |
| --- | --- |
| Pavel AM, Rennie JM, de Vries LS, Blennow M, Foran A, Shah DK, et al. A machine-learning algorithm for neonatal seizure recognition: a multicentre, randomised, controlled trial. The Lancet Child & adolescent health. 2020;4(10):740-9. | N/A |
| Liu WN, Zhang YY, Bian XQ, Wang LJ, Yang Q, Zhang XD, et al. Study on detection rate of polyps and adenomas in artificial intelligence-aided colonoscopy. Saudi J Gastroenterol. 2020;26(1):13-9. | N/A |
| Su JR, Li Z, Shao XJ, Ji CR, Ji R, Zhou RC, et al. Impact of a real-time automatic quality control system on colorectal polyp and Index Articles adenoma detection: a prospective randomized controlled study (with videos). Gastrointestinal endoscopy. 2019;91(2):415-24.e4. | N/A |
| Repici A, Badalamenti M, Maselli R, Correale L, Radaelli F, Rondonotti E, et al. Efficacy of Real-Time Computer-Aided Detection of Colorectal Neoplasia in a Randomized Trial. Gastroenterology. 2020. | N/A |
| Shimabukuro DW, Barton CW, Feldman MD, Mataraso SJ, Das R. Effect of a machine learning-based severe sepsis prediction algorithm on patient survival and hospital length of stay: a randomised clinical trial. BMJ Open Respiratory Research. 2017;4(1). | N/A |
| Wang P, Berzin TM, Glissen Brown JR, Bharadwaj S, Becq A, Xiao X, et al. Real-time automatic detection system increases colonoscopic polyp and adenoma detection rates: a prospective randomised controlled study. Gut. 2019;68(10):1813-9. | N/A |
| Wang P, Liu X, Berzin TM, Glissen Brown JR, Liu P, Zhou C, et al. Effect of a deep-learning computer-aided detection system on adenoma detection during colonoscopy (CADe-DB trial): a double-blind randomised study. The Lancet Gastroenterology & Hepatology. 2020;5(4):343-51. | N/A |
| Study                                                                 | Excluded Reason                                                                 |
|----------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Wijnberge M, Geerts BF, Hol L, Lemmers N, Mulder MP, Berge P, et al. | Effect of a Machine Learning-Derived Early Warning System for Intraoperative Hypotension vs Standard Care on Depth and Duration of Intraoperative Hypotension During Elective Noncardiac Surgery: The HYPE Randomized Clinical Trial. Jama. 2020. |
| Wu L, Zhang J, Zhou W, An P, Shen L, Liu J, et al.                  | Randomised controlled trial of WISENSE, a real-time quality improving system for monitoring blind spots during esophagogastrroduodenoscopy. Gut. 2019;68(12):2161-9 |
| **Excluded in present study via Title/Abstract Screening** (n=10)   |                                                                                  |
| *Based on reviewer consensus*                                       |                                                                                  |
| Bailey TC, Chen Y, Mao Y, Lu C, Hackmann G, Micek ST, et al.        | Did not meet study criteria for machine learning algorithm                      |
| Brier ME, Gaweda AE, Dailey A, Aronoff GR, Jacobs AA.               | Did not meet study criteria for machine learning algorithm                      |
| Caballero-Ruiz E, García-Sáez G, Rigla M, Villaplana M, Pons B,    | Not a clinical intervention                                                     |
| Hernando ME.                                                        |                                                                                  |
| Chen D, Wu L, Li Y, Zhang J, Liu J, Huang L, et al.                 | Not a clinical intervention; use of AI not the primary intervention being compared (secondary outcome) |
| Geersing GJ, Hendriksen JMT, Zuithoff NPA, Roes KC, Oudega R, Takada T, et al. | Did not meet study criteria for machine learning algorithm                      |
| Study Title                                                                 | Machine learning intervention not part of randomization | Machine learning intervention not part of randomization; wrong study design (Community-based cohort study) | Did not meet study criteria for machine learning algorithm | Did not meet study criteria for machine learning algorithm | Not a clinical intervention | Did not meet study criteria for machine learning algorithm | Did not meet study criteria for machine learning algorithm |
|---------------------------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------|--------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| Hong JC, Eclov NCW, Dalal NH, et al. System for High-Intensity Evaluation During Radiation Therapy (SHIELD-RT): A Prospective Randomized Study of Machine Learning-Directed Clinical Evaluations During Radiation and Chemoradiation. J Clin Oncol. 2020;38(31):3652-3661. |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Martin CM, Vogel C, Grady D, Zarabzadeh A, Hederman L, Kellett J, et al. Implementation of complex adaptive chronic care: the Patient Journey Record system (PaJR). Journal of Evaluation in Clinical Practice. 2012;18(6):1226-34 |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Sheridan SL, Draeger LB, Pignone MP, Keyserling TC, Simpson RJ, Jr., Rimer B, et al. A randomized trial of an intervention to improve use and adherence to effective coronary heart disease prevention strategies. BMC health services research. 2011;11:331 |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Zeevi D, Korem T, Zmora N, et al. Personalized Nutrition by Prediction of Glycemic Responses. Cell. 2015;163(5):1079-1094. |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Removed in citation chasing (n=2)                                                                                                           |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Brocklehurst P., Field D., Keith Greene, Ed Juszczak, Robert Keith, Sara Kenyon, et al. Computerised interpretation of fetal heart rate during labour (INFANT): a randomised controlled trial. Lancet. 2017;389(10080):1719-29. |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Kougias P, Tiwari V, Sharath SE, Garcia A, Pathak A, Chen M, et al. A Statistical Model-driven Surgical Case Scheduling System Improves Multiple Measures of Operative Suite Efficiency: Findings From a Single-center, Randomized Controlled Trial. Annals of surgery. 2019;270(6):1000-4. |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Not identified from study search criteria (n=40)                                                                                             |                                                                                                       |                                                                                 |                                                                                                                   |                                                                              |                                                                                                             |                                                                                                                   |
| Luo Y, Zhang Y, Liu M, Lai Y, Liu P, Wang Z, et al. Artificial Intelligence-Assisted Colonoscopy for Detection of Colon Polyps: a Prospective, Randomized Cohort Study. Journal of gastrointestinal surgery : official journal of the Society for Surgery of the Alimentary Tract. 2020. | Not a randomized control trial |
|---|---|
| Allegra A, Marino A, Volpes A, Coffaro F, Scaglione P, Gullo S, et al. A randomized controlled trial investigating the use of a predictive nomogram for the selection of the FSH starting dose in IVF/ICSI cycles. Reproductive biomedicine online. 2017;34(4):429-38 | Not a clinical intervention |
| Clemons M, Bouganim N, Smith S, Mazzarello S, Vandermeer L, Segal R, et al. Risk Model-Guided Antiemetic Prophylaxis vs Physician's Choice in Patients Receiving Chemotherapy for Early-Stage Breast Cancer: A Randomized Clinical Trial. JAMA oncology. 2016;2(2):225-31 | Not a clinical intervention |
| Finkelstein SM, Lindgren BR, Robiner W, Lindquist R, Hertz M, Carlin BP, et al. A randomized controlled trial comparing health and quality of life of lung transplant recipients following nurse and computer-based triage utilizing home spirometry monitoring. Telemedicine journal and e-health : the official journal of the American Telemedicine Association. 2013;19(12):897-903. | Not a clinical intervention |
| Fulmer R, Joerin A, Gentile B, Lakerink L, Rauws M. Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial JMIR Ment Health 2018;5(4):e64 | Not a clinical intervention |
| Gerendas BS, Waldstein SM, Simader C, et al. Three-dimensional automated choroidal volume assessment on standard spectral-domain optical coherence tomography and correlation with the level of diabetic macular edema. Am J Ophthalmol. 2014;158(5):1039-1048. | Not a clinical intervention |
| Study | Title | Intervention | Machine Learning | Randomization |
|-------|-------|--------------|------------------|---------------|
| Guenancia C, Stamboul K, Hachet O, Yameogo V, Garnier F, Gudjoncik A, et al. | Clinical effectiveness of the systematic use of the GRACE scoring system (in addition to clinical assessment) for ischaemic outcomes and bleeding complications in the management of NSTEMI compared with clinical assessment alone: a prospective study. Heart and vessels. 2016;31(6):897-906. | Did not meet study criteria for machine learning algorithm | | |
| Hill JC, Whitehurst DG, Lewis M, Bryan S, Dunn KM, Foster NE, et al. | Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet. 2011;378(9802):1560-71. | Did not meet study criteria for machine learning algorithm | | |
| Hsu JC, Chen YF, Chung WS, Tan TH, Chen T, Chiang JY. | Clinical verification of a clinical decision support system for ventilator weaning. Biomedical engineering online. 2013;12 Suppl 1(Suppl 1):S4 | Not a clinical intervention | | |
| Kappen TH, Moons AH, Wolfsinkel L, Kalkman CJ, Vergouwe Y, van Klei WA. | Impact of Risk Assessments on Prophylactic Antiemetic Prescription and the Incidence of Postoperative Nausea and Vomiting A Cluster-randomized Trial. Anesthesiology. 2014 | Did not meet study criteria for machine learning algorithm | | |
| Lauffenburger JC, Lewey J, Jan S, Makanji S, Ferro CA, Krumme AA, et al. | Effectiveness of Targeted Insulin-Adherence Interventions for Glycemic Control Using Predictive Analytics Among Patients With Type 2 Diabetes: A Randomized Clinical Trial. JAMA network open. 2019;2(3):e190657. | Machine learning intervention not part of randomization | | |
| Mazurek MO, Parker RA, Chan J, Kuhlthau K, Sohl K. | Effectiveness of the Extension for Community Health Outcomes Model as Applied to Primary Care for Autism: A Partial Stepped-Wedge Randomized Clinical Trial. JAMA pediatrics. 2020;174(5):e196306 | Did not meet study criteria for machine learning algorithm | | |
| Nieuwlaat R, Hubers LM, Spyropoulos AC, Eikelboom JW, Connolly BJ, Van Spall HG, et al. | Randomised comparison of a simple warfarin dosing algorithm versus a computerised anticoagulation management system for control of warfarin maintenance therapy. Thrombosis and haemostasis. 2012;108(6):1228-35 | Did not meet study criteria for machine learning algorithm | | |
| Nieuwlaat R, Eikelboom JW, Schulman S, van Spall HG, Schulze KM, Connolly BJ, et al. Cluster randomized controlled trial of a simple warfarin maintenance dosing algorithm versus usual care among primary care practices. Journal of thrombosis and thrombolysis. 2014;37(4):435-42 | Did not meet study criteria for machine learning algorithm |
|---|---|
| Persell SD, Lloyd-Jones DM, Friesema EM, Cooper AJ, Baker DW. Electronic health record-based patient identification and individualized mailed outreach for primary cardiovascular disease prevention: a cluster randomized trial. Journal of general internal medicine. 2013;28(4):554-60. | Not a clinical intervention |
| Pielmeier U, Rousing ML, Andreassen S, Nielsen BS, Haure P. Decision support for optimized blood glucose control and nutrition in a neurotrauma intensive care unit: preliminary results of clinical advice and prediction accuracy of the Glucosafe system. Journal of clinical monitoring and computing. 2012;26(4):319-28 | Did not meet study criteria for machine learning algorithm |
| Plomb-Holmes C, Hilfiker R, Leger B, Luthi F. Impact of a non-return-to-work prognostic model (WORRK) on allocation to rehabilitation clinical pathways: A single centre parallel group randomised trial. PloS one. 2018;13(8):e0201687. | Not a clinical intervention |
| Sadasivam RS, Borglund EM, Adams R, Marlin BM, Houston TK. Impact of a Collective Intelligence Tailored Messaging System on Smoking Cessation: The Perspect Randomized Experiment. Journal of medical Internet research. 2016;18(11). | Not a clinical intervention |
| Sherratt FC, Marcus MW, Robinson J, Field JK. Utilizing Lung Cancer Risk Prediction Models to Promote Smoking Cessation: Two Randomized Controlled Trials. American Journal of Health Promotion. 2016;32(5):1196-205. | Not a clinical intervention |
| Steiner JF, Shainline MR, Bishop MC, Xu S. Reducing Missed Primary Care Appointments in a Learning Health System. Medical care. 2016. | Not a clinical intervention |
| Steiner JF, Shainline MR, Dahlgren JZ, Kroll A, Xu S. Optimizing Number and Timing of Appointment Reminders: A Randomized Trial. Am J Manag Care. 2018. | Not a clinical intervention |
| Reference                                                                 | Note                                                                 |
|--------------------------------------------------------------------------|----------------------------------------------------------------------|
| True MW, Strickland LE, Lewis JE, Sterling LM, Dai H, Haas RW, et al. Impact of a Diabetes Risk Score on Lifestyle Education and Patient Adherence (IDEA) in Prediabetes: A Multisite Randomized Controlled Trial. Military medicine. 2015;180(10):1091-7. | Not a clinical intervention |
| Thurtle DR, Jenkins V, Pharoah PD, Gnanapragasam VJ. Understanding of prognosis in non-metastatic prostate cancer: a randomised comparative study of clinician estimates measured against the PREDICT prostate prognostic model. Br J Cancer. 2019;121(8):715-8 | Not a clinical intervention |
| Cox CE, White DB, Hough CL, Jones DM, Kahn JM, Olsen MK, et al. Effects of a Personalized Web-Based Decision Aid for Surrogate Decision Makers of Patients With Prolonged Mechanical Ventilation. Ann Intern Med. 2019;170(5) | Did not meet study criteria for machine learning algorithm |
| de Vos-Kerkhof E, Nijman RG, Vergouwe Y, Polinder S, Steyerberg EW, van der Lei J, et al. Impact of a clinical decision model for febrile children at risk for serious bacterial infections at the emergency department: a randomized controlled trial. PloS one. 2015;10(5):e0127620. | Did not meet study criteria for machine learning algorithm |
| Mahler SA, Riley RF, Hiestand BC, Russell GB, Hoekstra JW, Lefebvre CW, et al. The HEART Pathway randomized trial: identifying emergency department patients with acute chest pain for early discharge. Circulation Cardiovascular quality and outcomes. 2015;8(2):195-203. | Did not meet study criteria for machine learning algorithm |
| Mán E, Simonka Z, Varga A, Rárosi F, Lázár G. Impact of the Alvarado score on the diagnosis of acute appendicitis: comparing clinical judgment, Alvarado score, and a new modified score in suspected appendicitis: a prospective, randomized clinical trial. Surgical endoscopy. 2014;28(8):2398-405. | Did not meet study criteria for machine learning algorithm |
| Mann D, Hess R, McGinn T, Richardson S, Jones S, Palmisano J, et al. Impact of Clinical Decision Support on Antibiotic Prescribing for Acute Respiratory Infections: a Cluster Randomized Implementation Trial. Journal of general internal medicine. 2020;35(Suppl 2):788-95. | Did not meet study criteria for machine learning algorithm |
| McGinn TG, McCullagh L, Kannry J, Knaus M, Sofianou A, Wisnivesky JP, et al. Efficacy of an evidence-based clinical decision support in primary care practices: a randomized clinical trial. JAMA internal medicine. 2013;173(17):1584-91 | Did not meet study criteria for machine learning algorithm |
| Palen TE, Sharpe RE, Jr., Shetterly SM, Steiner JF. Randomized Clinical Trial of a Clinical Decision Support Tool for Improving the Appropriateness Scores for Ordering Imaging Studies in Primary and Specialty Care Ambulatory Clinics. AJR Am J Roentgenol. 2019;213(5):1015-20. | Did not meet study criteria for machine learning algorithm |
| Poldervaart JM, Reitsma JB, Backus BE, Koffijberg H, Veldkamp RF, Ten Haaf ME, et al. Effect of Using the HEART Score in Patients With Chest Pain in the Emergency Department: A Stepped-Wedge, Cluster Randomized Trial. Ann Intern Med. 2017;166(10):689-97 | Did not meet study criteria for machine learning algorithm |
| Tan WJ, Acharyya S, Chew MH, Foo FJ, Chan WH, Wong WK, et al. Randomized control trial comparing an Alvarado Score-based management algorithm and current best practice in the evaluation of suspected appendicitis. World journal of emergency surgery : WJES. 2020;15(1):30 | Did not meet study criteria for machine learning algorithm |
| Torres FA, Pasarelli I, Cutri A, Ossorio MF, Ferrero F. Impact assessment of a decision rule for using antibiotics in pneumonia: a randomized trial. Pediatric pulmonology. 2014;49(7):701-6. | Did not meet study criteria for machine learning algorithm |
| van de Maat JS, Peeters D, Nieboer D, van Wermeskerken AM, Smit FJ, Noordzij JG, et al. Evaluation of a clinical decision rule to guide antibiotic prescription in children with suspected lower respiratory tract infection in The Netherlands: A stepped-wedge cluster randomised trial. PLoS medicine. 2020;17(1):e1003034. | Did not meet study criteria for machine learning algorithm |
| Van Driest SL, Wang L, McLemore MF, Bridges BC, Fleming GM, McGregor TL, et al. Acute kidney injury risk-based screening in pediatric inpatients: a pragmatic randomized trial. Pediatric research. 2020;87(1):118-24 | Did not meet study criteria for machine learning algorithm |
| K B, A. JH, O. AM. Quality improvement of functional diagnostics in dentistry through computer-aided diagnosis: a randomized controlled trial. International Journal of Computerized Dentistry. 2018 | Machine learning intervention not part of randomization |
| Study                                                                 | Criteria for Machine Learning |
|----------------------------------------------------------------------|--------------------------------|
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