

Improving the Usability of Randomized, Controlled Trials of Artificial Intelligence-based Chatbots in Healthcare: Results of a Systematic Literature Review

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*Abstract: Artificial Intelligence (AI)-powered chatbots and virtual assistants (VAs) have gained importance in healthcare to support communication and decision-making. The value of **Randomized Controlled Trials (RCTs)** providing evidence on their effectiveness and safety depends on the quality of their design, conducting and reporting. The **CONSORT-AI** guideline has been developed to guide researchers in designing, conducting and reporting RCTs for AI interventions. The aim of this research is to identify and analyze RCTs on AI-based chatbots in healthcare, with a special focus on their compliance with the AI-extension part of the **CONSORT-AI**. A **Systematic Literature Review (SLR)** was conducted and identified 28 relevant RCTs. Most AI-chatbot application studies were performed in mental health, public health and cancer care. An increase in the number of RCTs, by time, was observed, however, none of the RCTs fully adhered to the **CONSORT-AI** guideline. Weak reporting quality on input data, inclusion criteria, AI versioning, performance errors and human-AI interactions were common.*

Our study highlights that, in parallel with the development of AI-chatbots, from simple statistical models, to advanced neural network architectures like transformers, more emphasis is needed on standardizing their clinical research and reporting to ensure more robust, transparent and ethical evidence for their application in healthcare.

Keywords: artificial intelligence; natural language processing; chatbot; randomized controlled trial; health; reporting guideline

1 Introduction

Computer technology has realized rapid growth over the last three decades, with Artificial Intelligence (AI) emerging as a key area of innovation [1]. AI-based communication tools like chatbots and virtual assistants (VAs) are becoming increasingly important, evolving from simple statistical models to transformer-based models. Bidirectional Encoder Representations from Transformers (BERT), Generative Pre-trained Transformer (GPT), and T5 have revolutionized natural language processing (NLP), enabling tasks such as translation, sentiment analysis, and text generation. Despite these advances, statistical models like FastText still contribute to linguistic research and problem-solving [2-4]. Another task of the NLP is the language recognition in the online communication [5].

The use of chatbots has grown exponentially in healthcare, particularly during the COVID-19 pandemic. Organizations like WHO and CDC utilized chatbots to provide timely information, while tools like IBM Watson supported government and healthcare institutions [6] [7]. OpenAI's ChatGPT, introduced in 2022, showcases advanced transformer architecture, facilitating human-like conversations, detecting fake news, and toxicity in communication [8-11]. It has been proved to be valuable in enhancing patient communication and supporting clinical decision-making in the medical field [12] [13].

The chatbots' ability to understand and generate human-like responses relies on NLP [14]. However, the "black box" nature of AI models raises concerns about transparency, as the internal workings of these algorithms remain challenging to interpret [15].

Transparency is critical in the use of AI-based chatbots in medical decision-making and healthcare, where decisions must be grounded in scientific evidence. Randomized controlled trials (RCTs), regarded as the gold standard for clinical evidence, compare outcomes between randomized test and control groups. The test group receives the treatment under study, while the control group receives a standard or placebo treatment, allowing evaluation of treatment efficacy and safety through comparative analysis [16].

To minimize bias, RCT design and reporting should adhere to specific guidelines. Standardized reporting tools, such as narratives or checklists, enhance experiment reproducibility [17] [18]. By directing attention to critical factors and ensuring consistency, checklists have demonstrated effectiveness in various fields, notably reducing perioperative morbidity and mortality in surgery [19] [20]. The CONSORT statement is a reporting guideline for assessing RCTs, shown to improve trial outcomes when properly applied [21]. With the growth of AI applications in healthcare, the need for standardized reporting has emerged. While several checklists for AI-based medical solutions exist, their adoption remains limited [17] [22]. These include standalone AI guidelines (e.g., MI-CLAIM) and AI-specific extensions to existing clinical trial guidelines [19, 21, 22]. The CONSORT-AI extension, designed for AI interventions in clinical trials, promotes transparency, reduces bias and aids in evaluating AI's impact on patient outcomes [23].

Literature evidence regarding the effectiveness of chatbots in healthcare have been collected and analyzed by Milne-Ives et al. and Laranjo et al [24] [25]. Authors highlighted methodological weaknesses of the studies and thus their limited usability for health care. However, the reviews did not analyze specifically the AI aspects of the trials. Moreover, the field of AI-based chatbots for health purposes is rapidly evolving. Therefore, the aim of our study is to update and systematically review the literature for RCTs on AI-based chatbots in healthcare and to analyze the quality of the studies in terms AI reporting and compliance with the CONSORT-AI guideline [23].

2 Methods

2.1 Literature Search: Data Sources and Search Terms

We rely on previous SLRs by Milne-Ives et al. [24] and Laranjo et al. [25] that searched PubMed, Medline (Ovid), EMBASE (Excerpta Medica dataBASE), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Web of Science, PsycInfo, and the Association for Computing Machinery Digital Library databases. Based on our prior experience and research, we hypothesized that the IEEE Xplore database would provide valuable, additional information in the topic. To this end, our search strategy was designed to query six key databases: PubMed, EMBASE, ACM Digital Library, Web of Science, Scopus, and IEEE Xplore. The SLRs by Laranjo et al. [25] and Milne-Ives et al. [24] covered the literature up to November 29, 2019. In these two SLRs altogether eight RCTs on healthcare chatbots were identified all of which fulfilled our eligibility criteria (detailed below), hence these were included in our current review. We conducted a

complementary literature search for the period between Mar 01, 2018, and August 11, 2022.

Another branch of the literature search involved identifying SLRs and examining their citations. If an SLR met our eligibility criteria (NLP-based chatbot, English full text, within the specified time frame), the cited articles were further assessed according to our criteria.

Using the Cochrane Library's suggested search terms [26], which are widely recognized as a gold standard for evidence-based healthcare information, the search failed to identify an extensive list of synonyms for the term "chatbot". Therefore, an alternative strategy was built to ensure a thorough and comprehensive examination of relevant literature for our research question [27] (<https://osf.io/4x57r>). These terms were: "Avatar"; "Chat Bot"; "Chatbot"; "Conversational Agent"; "Conversational Interface"; "Dialog System"; "Digital Assistant"; "Digital Characters"; "Digital interlocutors"; "Embodied Agent"; "Embodied Conversational Agent"; "Intelligent Agent"; "Interactive Agent"; "Natural Language System"; "Relational Agent"; "Virtual Agent"; "Virtual Assistant"; "Virtual Coach" and "Virtual Human".

To identify RCTs, we applied the highly sensitive Cochrane search strategy for RCTs (2008 revision) in the PubMed format [26]. The exact search terms are provided in electronic supplementary material (<https://osf.io/4x57r>).

2.2 Selection of Studies: Selection Process, Inclusion and Exclusion Criteria

Study selection was performed in two phases. First, two reviewers (JTC, ÁH) independently screened the records for inclusion by title and abstract. Second, the selected publications were reviewed by the same two reviewers independently for inclusion by full text. In both phases disagreements between the two reviewers were discussed, remaining disagreements were solved by involving a third reviewer (MP). An Excel database was developed to record the decision process and final decisions.

All RCTs investigating the effectiveness of AI-based chatbots in healthcare were included regardless of the condition. Studies involving any human participants were included (e.g., patients, citizens attending healthcare, informal caregivers etc.) without any age limit. Studies involving AI-based chatbot that applies natural language processing as a communication method to be used for any health-related intervention (e.g., screening, treatment, patient management etc.) were included. Chatbots that were based on predefined response options (rule-based chatbots) were excluded. Any comparator or control was accepted, including the "to do nothing" option. No limits were set regarding the outcomes of the studies. Only RCTs were included in the analysis, observational studies and other forms of

experimental studies, such as non-randomized and quasi-experimental studies, were excluded. Only original studies published in English and available in full text were considered. Conference abstracts, proceedings, editorials, letters to the editor, and opinion papers were excluded. Systematic reviews were examined to identify relevant original studies. Any study context was accepted (e.g., hospital, outpatient).

2.3 Data Extraction and the CONSORT-AI Checklist

The CONSORT-AI is an extension of the widely used CONSORT statement, which provides guidelines for reporting RCTs [23]. It allows researchers to ensure that AI-based interventions in clinical trials are properly reported, enabling other researchers to replicate or build upon the results. The guideline emphasizes the need for clear and detailed descriptions of the AI intervention, its integration into the trial setting, and its performance during the study. The extension part of the CONSORT-AI checklist includes 14 items specifically designed to address the unique aspects of RCTs involving AI interventions. The 14 items are related to the Title abstract (2 items), Introduction (1 item), Methods (9 items), Results (1 item) and Funding (1 item) part of the study report [23]. (The items are detailed in the Results section below.)

First, an Excel spreadsheet database was developed, where the columns contained general article information, study data from the publication in terms of healthcare area, patient information, interventions, chatbot names, additional details, and the CONSORT-AI statements along with their explanatory fields. Each row represented one included publication. One researcher (JTC) performed the data extraction, one third of the studies was randomly checked by an independent reviewer (MP). Disagreements between individual judgements were resolved by discussions and, if necessary, a third researcher (ÁH) was involved.

2.4 Data Analysis

We analyzed the studies based on publication year, journal, clinical area of disease, characteristics of the patient samples, interventions and controls and the use of chatbot.

The evaluation focused on the quality and compliance of the articles with the AI part of the CONSORT-AI guideline. The 14 AI-extension items of the CONSORT-AI checklist [17] [23] were applied and compliance with each item was assessed in a binary ('yes' or 'no') format. Additionally, an explanatory field was included to facilitate understanding of how each statement was applied within the articles.

3 Results

3.1 Search Results

The searches in ACM DL, Embase, PubMed, Scopus, Web of Science, and IEEE databases yielded a total of 1166 records after automated (Endnote function) deduplication (N=107). Number of excluded publications and the reasons for exclusion are summarized in a PRISMA flowchart (Figure 1) [28].

During the citation screening process, we identified 2205 records from the SLR citations. We excluded duplicate records, those outside the search period, studies that were not RCTs, and those not involving chatbots. As a result, a total of 2204 records were excluded. The last record was excluded under the full text review, because there was no evidence for RCT.

3.2 Main Characteristics of the Randomized Controlled Trials

Main characteristics of the publications and RCTs are summarized in Table 1. The earliest study dates back to 2010 while a continuous growing in the number of studies was observed by time, achieving seven published RCTs both in 2021 and 2022. The most RCTs (N=14) were published in Journal of Medical Internet Research (JMIR) journals (JMIR, JMIR mHealth and uHealth, JMIR Mental Health, JMIR Formative Research), the other papers were published in the Internet Interventions journal (N=2) and single papers in further different journals. Regarding the clinical area in which the chatbot was used, mental health was dominant (N=7), followed by public health (N=4) and cancer (N=3), but other patient groups were also involved in other studies. The characteristics of the patient (sample) groups were highly heterogeneous [29-56].

In most cases, adult patients constituted the target population; however, two studies focused on children, one involving child aged 3-6 years [56] and the other comprising children diagnosed with social anxiety disorder [31]. Three studies targeted university or college students who self-reported anxiety and depression [35, 37, 43]. The target populations of the remaining studies varied, with each study focusing on a distinct group. For example, one study included individuals engaged in hazardous drinking behaviors [34], while another concentrated on patients with breast cancer [33].

The studies investigated the use of chatbots for various interventions across different health contexts (Table 1). The research also explored the role of chatbots in enhancing data collection, facilitating behavior change (e.g., smoking cessation or physical activity), and improving mental health outcomes, with a focus on assessing their effectiveness relative to established practices. Chatbots were often

compared to traditional methods such as usual care, human counseling, providing information only, putting patients on waitlists, predefined expert responses, or no intervention at all. In most cases, the chatbot used during the intervention was applied specifically for that particular study. Only two chatbots, Tess [37] [42] and Woebot [35] [51] (along with one of its derivatives), were utilized in two studies each. However, in nine articles, the virtual assistant was not explicitly named.

3.3 Compliance with AI-specific Items of the CONSORT-AI Checklist

We provide an item-by-item analysis of the 28 RCTs using the AI extension part of the CONSORT-AI guideline in Supplementary file (<https://osf.io/y2t8r>) and summarize the main findings in text. We present the analysis of the 10 best performing RCTs in Table 2.

None of the RCTs complied fully with the AI extension part of the CONSORT-AI checklist, highlighting that adherence to the reporting standards proposed by the checklist remains sub-optimal in the current literature. Among the 28 RCTs, the number of "Yes" responses, indicating compliance, ranged from 4 to 11, and compliance percentages ranged from 28.6% to 78.6%. Studies such as those utilizing Pegasys-VR [31] and Dejal@bot [49] showed higher adherence to reporting standards, with compliance rates of 71.4% and 78.6%, respectively. Conversely, several studies demonstrated limited adherence, achieving compliance rates below 30% [29, 34-36, 42, 47]. Key areas of weakness include inadequate descriptions of inclusion and exclusion criteria at the data level, insufficient reporting of AI versioning, and limited analyses of performance errors.

In the Title and Abstract section, nearly all articles (96.4%) successfully indicated that the intervention involved AI or machine learning and specified the type of model in the title or abstract. Only one article failed to meet this requirement [29]. Additionally, 92.9% of the articles stated the intended use of the AI intervention within the trial in a clear manner, with two studies lacking this essential information [29] [35]. Likewise, the Introduction section demonstrated strong compliance, with 96.4% of articles effectively explaining the intended use of the AI intervention, in the context of the clinical pathway, detailing the purpose and specifying the target audience. Only one article didn't satisfy the requirement [29].

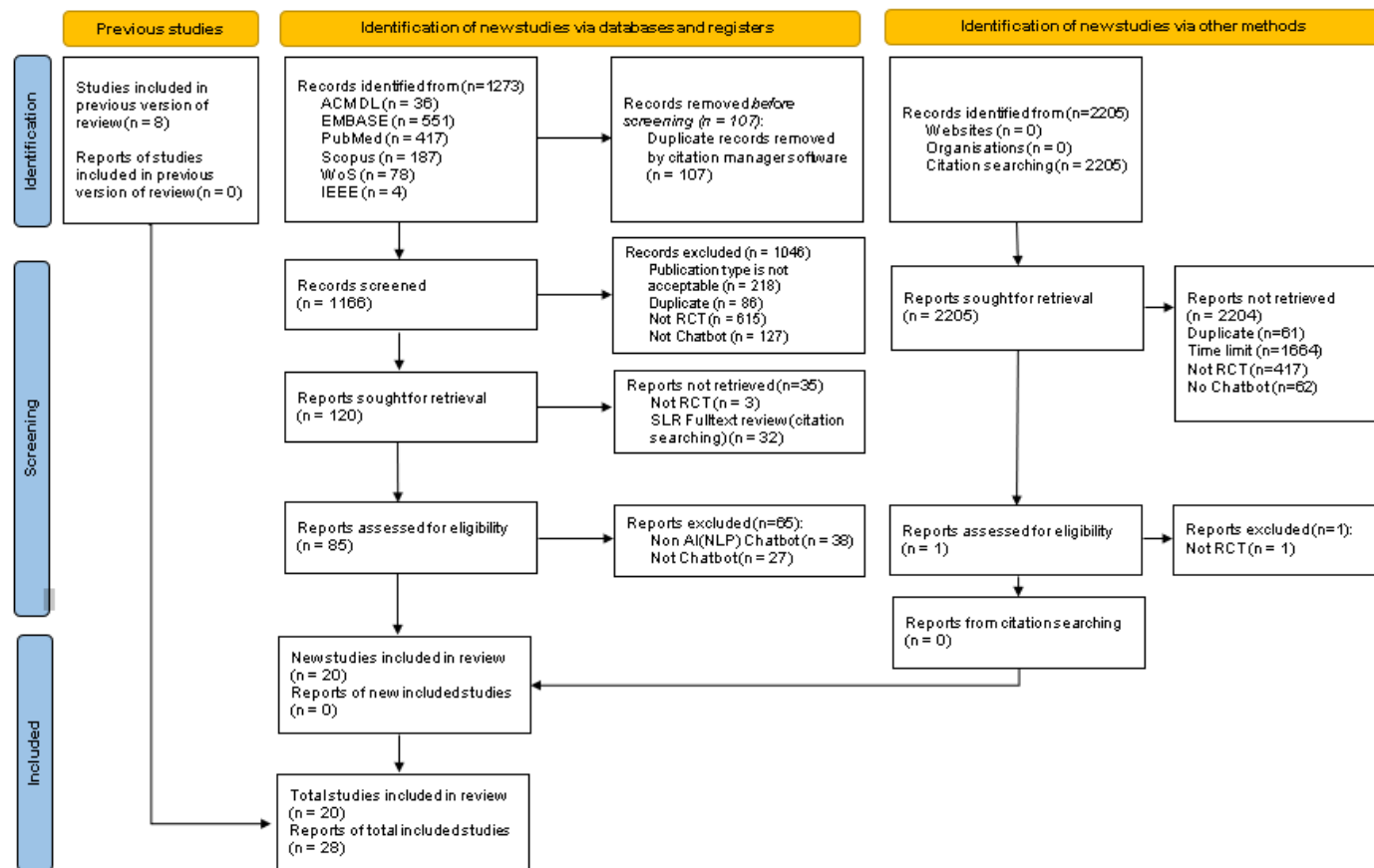


Figure 1
PRISMA Flowchart

In the Methods section, there was a notable discrepancy in reporting standards. The inclusion and exclusion criteria at the participant level were well articulated in 96.4% of the articles, with only one study failing to provide this information [53]. However, reporting on the inclusion and exclusion criteria for input data was significantly lacking, with only 3.6% of the articles addressing this aspect [40]. This substantial gap suggests a critical area for improvement, as input data criteria are essential for understanding the applicability and reliability of AI interventions. Furthermore, 71.4% of the studies described how the AI intervention was integrated into the trial setting, but eight articles did not provide sufficient detail on integration, highlighting a need for more comprehensive explanations.

The Interventions section revealed several areas requiring improvement. Only 21.4% of the studies specified the version of the AI algorithm used [43, 46, 49, 50, 53, 54], and fewer than one-third (28.6%) described how input data were acquired and selected [31, 38, 40, 46, 48, 49, 54, 56]. The handling of poor quality or unavailable data was inadequately reported, with just 17.7% of articles addressing this concern [31, 44, 48, 49, 55]. Moreover, only 10.7% of studies explained human-AI interactions and the level of expertise required from users, indicating a significant gap in detailing the operational aspects of the intervention [31, 49, 55].

Despite these shortcomings, 60.7% of the studies did specify the output of the AI intervention, yet only 28.6% articulated how these outputs contributed to decision-making in clinical practice [29, 31, 38, 46, 48, 51, 54, 55]. This highlights a need for clearer reporting on the practical implications and usability of AI outputs.

The Results section demonstrated a particularly concerning deficiency. Only 7.1% of articles discussed performance errors or how errors were identified, indicating a widespread lack of error analysis [53] [54]. This gap is crucial as understanding performance errors is essential for evaluating the reliability and safety of AI interventions. Lastly, the Other Information category, specifically concerning funding and accessibility, revealed that only 10.7% of articles mentioned whether and how the AI intervention or its code could be accessed [33, 39, 49]. This lack of transparency in reporting access and reuse restrictions, suggests a need for more consistent and detailed information to promote reproducibility and ethical sharing of AI resources.

Table 1
Summary of the randomized controlled trials on AI-based chatbots involved

First author (ref.), publication year	Journal	Country of the study	Clinical area / disease	Patients	Intervention (I), Comparator (C)	Chatbot
Simon et al [52], 2010	Arch Intern Med	USA	Colorectal Cancer	Members of Harvard Pilgrim Health Care	To participate in colorectal screening: I - Single telephone outreach with speech recognition; C - Usual care	Not defined
Adams et al [29], 2014	Pediatrics	USA	Pediatric primary care	Parents of children aged 4 months - 11 years	To prepare next visit: I - Phone call, tailored counseling IVR system; C - Phone call, 18-question Framingham Safety Survey Phone call, tailored counseling IVR system	Personal Health Partner (PHP)
Friederichs et al [36], 2014	J Med Internet Res	The Netherlands	Public health (physical activity)	Dutch adults	To motivate for physical activity: I - Motivational interview with an avatar; C1 - Intervention without an avatar; C2 - No intervention	AVATAR
Heyworth et al [40], 2014	Osteoporosis Int	USA	Osteoporosis (OP)	Women at OP risk	To encourage participation in OP screening: I - Usual care plus IVR; C1 - Usual care; C2 - Usual care plus mailed educational materials	Not defined
Fitzpatrick et al [35], 2017	JMIR Ment Health	USA	Mental health (Depression)	College students with self-reported anxiety and depression	To deliver CBT: I - CBT with a conversation agent; C - information only CBT with a conversation agent	WoeBot
Fulmer et al [37], 2017	JMIR Ment Health	USA	Mental health (Depression)	College students with self-reported anxiety and depression	To reduce symptoms: I - Chatbot 2 / 4 weeks;	Tess

2018				depression	C - Information only	
Bibault et al [33], 2019	J Med Internet Res	France	Breast Cancer	Breast cancer patients	To inform patients about breast cancer: I - Chatbot. C - Predefined experts' responses Chatbot	Vik
Greer et al [39], 2019	JMIR Mhealth Uhealth	USA	Cancer	Young adult patients after cancer treatment	To promote positive psychology and well-being: I - Chatbot; C - emotional ratings and chatbot only after	Vivibot
Ly et al [45], 2019	Internet Interv	Sweden	Mental health (mental well-being)	Adults	To promote mental well-being: I - Delivering positive psychology and CBT via an automated chatbot. C - Put on waitlist. Delivering positive psychology and CBT via an automated chatbot	Shim
Tanana et al [54], 2019	J Med Internet Res	USA	Therapists' training (psychotherapists)	Non-therapists	To train basic counseling skills: I - Real-life feedback via a chatbot. C - No feedback	Client-Bot
Bennion et al [32], 2020	J Med Internet Res	United Kingdom	Elderly health	Members (aged 50+) of the University of the Third Age	To facilitate problem solving: I - Chatbot type 1. C - Chatbot type 2	MYLO and ELIZA
Gong et al [38], 2020	J Med Internet Res	Australia	Diabetes (Type 2)	Adults with Type 2 diabetes	To support self-management: I - Chatbot; C - Usual care	My Diabetes Coach (MDC)
Maeda et al [46], 2020	Reprod Biomed Online	Japan	Fertility	Women 20-34 years old	To promote fertility awareness and preconception: I - Fertility education chatbot. C2 - A book about fertility and preconception health. C3 - A document about an irrelevant topic	Not defined
Piao et al [50], 2020	JMIR Mhealth Uhealth	South Korea	Public health (physical activity)	Office workers	Stair-climbing habit formation: I - Chatbot; C - Intervention started only on the fifth week	Not defined
Beidel et al [31],	Behavioral Therapy	USA	Childhood social anxiety	Children with social anxiety disorder	Social effectiveness therapy: I - Web-based Artificial Intelligence VR treatment.	Pegasys-VR

2021			disorder		C - Usual social effectiveness therapy	
Jang et al [41], 2021	Int J Med Inform	South Korea	Attention deficit	Adults with attention deficit	To alleviate attention deficit symptoms: I - Chatbot; C - Information only (book)	Todaki
Klos et al [42], 2021	JMIR Res Form	Argentina	Mental health (Depression, anxiety)	University students	To support mental health: I - Chatbot; C - Information only (book)	Tess
Loveys et al [44], 2021	JMIR Health	New Zealand	Mental health (menatl well-being)	Adults at greater risk for COVID-19	Remote loneliness and stress intervention: I - Cognitive behavioral and positive psychology exercises with chatbot; C – Waitlist	Bella
Prochaska et al [51], 2021	Drug Alcohol Depend	USA	Substance use	Adults with substance use disorder	To reduce substance misuse: I - Chatbot; C – Waitlist	Woebot-SUDs
Söderström et al [53], 2021	Behav Res Methods	Australia	Online surveying	Adults	To improve quality of data online data collection: I - Chatbot-guided survey; C - Self-guided survey	Not defined
Tsai et al [55], 2021	Psychol Mark	USA	Vaccination	College students with self-reported anxiety and depression	Health marketing communication about HPV: I - Interact with a chatbot; C - Interact with a human representative	Not defined
Beaman et al [30], 2022	Journal of Medical Systems	USA	Mental health	Patients newly admitted to behavioral medicine clinic	Completing the Patient Health Module-9 (PHM-9) questionnaire: I - Paper-based then Interactive Voice respond system-based format. C - Interactive Voice respond system-based then Paper-based format	Amazon Alexa
Dulin et al [34], 2022	JMIR Res Form	USA	Public health (drinking)	Hazardous drinking persons	To reduce alcohol consumption: I - Step Away chatbot. C1 - Step Away app; C2 - Assessment-only	Step Away

Liu et al [43]. 2022	Internet Interv	China	Mental health (Depression)	University students	Self-help intervention: I - Chatbot; C – Bibliotherapy	XiaoNan
Nißen et al [47]. 2022	J Med Internet Res	Germany	Chatbot development in healthcare	Participants of an online panel	To test the social role of a chatbot: I - No choice on chatbot; C - Choice on chatbot persona	Not defined
Ogawa et al [48]. 2022	Parkinsonism Relat Disord	Japan	Parkinson's disease	Patients with Parkinson's disease	To improve smile and symptoms of PD: I - Chatbot and video conferencing sessions. C - Video conferencing sessions	Not defined
Olano-Espinosa et al [49]. 2022	JMIR Mhealth Uhealth	Spain	Public health (smoking)	Patients visiting primary care	To quit smoking: I - Chatbot; C - Usual clinical practice	Dejal@bot
Xu et al [56]. 2022	Child Dev	USA	Development of children's skills	Children aged 3-6 years	To improve children's story comprehension and engagement: I - Chatbot; C - Adult reading partner	Not defined

CBT=cognitive Behavior therapy, C= Comparator, I=Intervention group, IVR= Interactive Voice Response, OP= Osteoporosis

4 Discussion

We analyzed the available clinical evidence on AI-based chatbots in healthcare, focusing on RCTs and their compliance with the AI extension part of the CONSORT-AI guideline. Overall, reporting quality and adherence to the AI part of the CONSORT-AI was suboptimal. Common weaknesses included limited description of inclusion criteria, inadequate reporting of AI versioning, and sparse analyses of performance errors. Furthermore, only a few studies detailed human-AI interaction and algorithm outputs in decision-making. The Results section of the RCTs was particularly deficient, with minimal attention to error reporting, while information about funding and code accessibility was largely absent.

According to our best knowledge, to date, three SLRs have dealt with RCTs on AI-based chatbots. However, two of these (by Milne-Ives *et al.* [24] and Laranjo *et al.* [25]) did not analyze the quality of the AI part of the publications. In contrast, Martindale *et al.* analyzed the completeness of publications on RCTs for AI interventions (not restricted to any device or clinical area) that have been published since the publication of the CONSORT-AI guideline [57].

Table 2
Compliance of the 10 best performing AI-based chatbot RCTs with the AI-specific items of the CONSORT-AI checklist

Section	CONSORT-AI extension item	Olano-Espinosa <i>et al.</i> , 2022 [49]	Tanana <i>et al.</i> , 2019 [54]	Beidel <i>et al.</i> , 2021 [31]	Ogawa <i>et al.</i> , 2022 [48]	Maeda <i>et al.</i> , 2020 [46]	Gong <i>et al.</i> , 2020 [38]	Heyworth <i>et al.</i> , 2014 [40]	Xu <i>et al.</i> , 2022 [56]	Tsai <i>et al.</i> , 2021 [55]	Prochaska <i>et al.</i> , 2021 [51]
TITLE AND ABSTRACT											
Identification as an RCT	1a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Structured summary (design, methods, results, conclusions)	1b	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
INTRODUCTION											
Backgrounds and objectives	2a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
METHODS											
Participants: eligibility	4a (i)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

criteria											
	4a (ii)	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Participants: settings and locations of data collection	4b	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Interventions	5 (i)	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗
	5 (ii)	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
	5 (iii)	✓	✗	✓	✓	✗	✗	✗	✗	✓	✗
	5 (iv)	✓	✗	✓	✗	✗	✗	✗	✗	✓	✗
	5 (v)	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
	5 (vi)	✗	✓	✓	✓	✓	✓	✗	✗	✓	✓
RESULTS											
Harms	19	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗
OTHER INFORMATION											
Funding	25	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗
Compliance		0.8	0.7	0.7	0.6	0.6	0.6	0.6	0.5	0.5	0.5

Notes: 1a – “(i) Indicate that the intervention involves artificial intelligence/machine learning in the title and/or abstract and specify the type of model.”; 1b – “(ii) State the intended use of the AI intervention within the trial in the title and/or abstract.”; 2a (i) – “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).”; 4a (i) – “State the inclusion and exclusion criteria at the level of participants.”; 4a (ii) – “State the inclusion and exclusion criteria at the level of the input data.”; 4b – “Describe how the AI intervention was integrated into the trial setting, including any onsite or offsite requirements.”; 5 (i) – “State which version of the AI algorithm was used.”; 5 (ii) – “Describe how the input data were acquired and selected for the AI intervention.”; 5 (iii) – “Describe how poor quality or unavailable input data were assessed and handled.”; 5 (iv) – “Specify whether there was human-AI interaction in the handling of the input data, and what level of expertise was required of users.”; 5 (v) – “Specify the output of the AI intervention.”; 5 (vi) – “Explain how the AI intervention’s outputs contributed to decision-making or other elements of clinical practice.”; 19 – “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.”; 25 – “State whether and how the AI intervention and/or its code can be accessed, including any restrictions to access or re-use.” [23].

Their research interval spanned from September 2020 to September 2022 and among others, they identified only seven RCTs on AI-based chatbots. Our findings are in line with their results, showing that AI-specific items (e.g., algorithm version, accessibility of the AI intervention, and input data handling) were often poorly reported. Additionally, performance error analysis and data input criteria were identified as weak points in the reporting. Nonetheless, we found that eight out of the 10 best quality publications have been published since 2020 (Table 2).

To assess the trends of compliance with CONSORT-AI, we have grouped the articles by publication year (from 2010 to 2019 and 2020 to 2022) a slight improvement was observed, which aligns with our overall findings.

Among the strengths of our study, we would like to highlight that we have conducted a comprehensive search to identify all RCTs on AI-based chatbots in healthcare. Validated search terms are available to detect RCTs, however no such search term set is available for chatbots. While previous SLRs used a limited number of terms for chatbots, we developed and applied a broad set of terms that have contributed to the completeness of our SLR. (For instance, using this search term set provided 417 records in PubMed, while inserting the single search term 'chatbot' instead resulted only 130 hits.) However, we assume that SLRs on healthcare chatbots will gain increasing importance in the future. At the time of our study chatbot use was not widespread (e.g., ChatGPT was launched in November 2022) and we have witnessed its incredible evolution and impact on the chatbot market and functionality in the past three years. Therefore, it would be important to develop a validated (sensitivity, precision) search term set of chatbots for use in diverse literature databases considering the new chatbot synonyms and brand names as well. Another strength of our study is that we have provided a detailed analysis of the AI part of the RCTs based on the CONSORT-AI, so that researchers can make use of these experiences in their work.

Some limitations of our study need to be noted. Chatbot development is a rapidly evolving area, therefore, a significant number of articles may have been published in this field since the closure of our search (2022), potentially adhering more closely to the CONSORT-AI guidelines. The final version of the CONSORT-AI guideline was published in September 2020. Several studies included in our analysis were conducted before this date and may have been based on a preliminary version of the reporting guideline or without using any AI reporting guideline. Nevertheless, among the 10 most compliant publications with the AI part of the CONSORT-AI one was published in 2014 (Heyworth *et al.*, [40]) far before the establishment of CONSORT-AI.

The shortcomings that we have identified in the RCTs underscore the need for further research to advance the field of AI-based chatbot interventions. One potential research direction could focus on chatbots that leverage advanced AI models, such as generative transformers, multi-modal systems, or AI-augmented virtual reality tools. Another direction could emphasize a root cause analysis of the possible gaps, focusing on the timeframe from 2022 to the present. Above all, we would consider it important, that journals require the use of relevant reporting guidelines (checklists) prior to submission, but at the latest during the review process. Better quality RCT publications could make better, evidence-based use of AI-based chatbots to improve patient care. We aimed to support this goal with our work.

Conclusions

A notable increase in the number of RCTs on AI chatbots across various healthcare domains, can be observed. However, the usability of the studies for medical-decision making is hampered by the suboptimal reporting quality of the AI part. Key gaps include inconsistent reporting of input data inclusion and exclusion criteria, limited exploration of human-AI interaction in data handling, insufficient descriptions of performance errors, and a lack of transparency regarding code availability.

We recommend researchers use the CONSORT-AI guideline, during both the design and reporting phases of AI chatbot RCTs. Adopting this approach, both by researchers and journal editors, would enhance transparency, improve standardization, and facilitate the generation of more robust, evidence based RCTs on AI chatbots. This would increase the usability of AI chatbots in supporting medical decision-making and patient care.

Also, we encourage future research on the development and the validation of literature search strategy, for chatbots that include the terms, Large Language Model and ChatGPT. The usage of these terms has grown exponentially in recent years and they are increasingly regarded as synonymous with chatbots and virtual assistants, in contemporary literature.

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