

**PATIENT-CENTRIC CLINICAL TRIAL- THE ROLE OF CHATBOAT IN
ENGAGEMENT- A REVIEW**

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ABSTRACT

This review examines the integration of chatbots in clinical trials to enhance patient engagement. Leveraging advancements in artificial intelligence (AI) and natural language processing (NLP), chatbots present a promising solution for addressing key challenges in participant recruitment, retention, and compliance. The review synthesizes current literature and case studies on the application of chatbots in clinical trials, highlighting their benefits, including real-time communication, personalized support, and 24/7 availability. By providing easier access to trial-related information, reminders, and support, chatbots can improve patient adherence to study protocols and enhance data accuracy. Despite these advantages, the review also discusses potential limitations and challenges, such as data privacy concerns, the need for continuous monitoring and updates to chatbot algorithms, and the importance of ensuring accessibility for diverse patient populations.

KEYWORDS: Patient Engagement, Clinical Trials, Chatbots, Artificial Intelligence, Patient-Centric, Digital Health, AI in Healthcare, Natural Language Processing, Patient Recruitment, Informed Consent, Data Collection, Patient Retention, Personalized Communication, Data Privacy, Patient Experience, Healthcare Innovation.

INTRODUCTION

The success of clinical trials is increasingly recognized as being deeply intertwined with participant engagement and satisfaction. Traditionally, clinical research has faced significant challenges related to patient recruitment, retention, and adherence to study protocols, which have often hindered the efficiency and effectiveness of trials. As the landscape of clinical research continues to evolve, there is a growing emphasis on adopting innovative strategies to enhance patient experiences and streamline trial processes. One such innovation is the use of chatbots, powered by advancements in artificial intelligence (AI) and natural language processing (NLP). These digital assistants have demonstrated significant potential across various sectors, and their application in clinical trials offers promising solutions to many persistent issues associated with patient engagement. Chatbots enable real-time, interactive communication with participants, transforming the way patients interact with clinical trial protocols and researchers. They offer functionalities that address common trial challenges, such as delivering personalized reminders, answering questions about the trial, providing logistical support, and facilitating continuous interaction without the constraints of traditional communication methods.^[1] By

improving accessibility and providing timely information, chatbots have the potential to enhance participant compliance, reduce dropout rates, and contribute to the overall success of clinical trials. However, the integration of chatbots into clinical trials is not without its challenges. Issues such as data security, algorithmic biases, and the need for patient training and support must be carefully managed to ensure that chatbots effectively complement the clinical trial experience. Additionally, understanding and accommodating the diverse needs of patient populations is crucial for the successful implementation of this technology. This review aims to explore the role of chatbots in fostering patient engagement within clinical trials by examining current applications, evaluating their impact on participant experience and trial outcomes, and discussing associated challenges and limitations. Through a synthesis of existing literature and case studies, this review seeks to provide a comprehensive overview of how chatbots can be leveraged to develop more patient-centric clinical trial models and offer recommendations for future research and implementation strategies.^[2,3]

1. Background

1.1. Patient Engagement in Clinical Trials

Patient engagement in clinical trials is a multifaceted concept that refers to the active involvement of participants throughout the research process, including the design, conduct, and evaluation of clinical studies. This engagement encompasses various dimensions such as informed consent, adherence to study protocols, communication with researchers, and overall satisfaction with the trial experience. The importance of effective patient engagement cannot be overstated, as it plays a crucial role in the success of clinical trials for several compelling reasons. First and foremost, improved recruitment and retention are directly linked to patient engagement. When patients are actively engaged, they are more likely to understand the value of the trial, feel a sense of ownership and commitment, and thus be more inclined to enroll and remain in the study. This enhanced commitment results in higher retention rates, which is essential for achieving reliable and statistically significant results. Engaged participants are less likely to drop out, ensuring that the study maintains its sample size and statistical power, which in turn contributes to the robustness and validity of the research findings.

Furthermore, patient engagement significantly enhances data quality. Active involvement often leads to more accurate and consistent data collection, as engaged patients are more likely to adhere to study protocols and provide complete and honest information. This adherence is crucial for minimizing data discrepancies and ensuring that the collected data accurately reflects the participants' experiences and responses to the treatment or intervention being tested. Accurate data collection is vital for drawing valid conclusions and making informed decisions about the efficacy and safety of new treatments. Inadequate or inconsistent data can lead to erroneous conclusions, which could compromise the reliability of the study results and potentially affect future treatment recommendations. Additionally, greater patient engagement can contribute to the overall success of clinical trials. When participants are more engaged, they tend to have better adherence to treatment regimens and follow-up procedures. This adherence is critical for assessing the true effects of the treatment and determining its potential benefits and risks. For instance, patients who are actively involved in the trial are more likely to follow prescribed protocols, attend scheduled visits, and complete required assessments, all of which are essential for evaluating the treatment's efficacy and safety comprehensively. As a result, trials with high levels of patient engagement are more likely to achieve their objectives and produce meaningful, actionable outcomes that can advance medical knowledge and improve patient care.

The impact of patient engagement extends beyond individual trials to influence the broader clinical research landscape. Engaged participants contribute to the generation of high-quality evidence that can lead to the

development of effective and safe treatments, ultimately benefiting public health. Therefore, fostering patient engagement is not just a matter of improving trial efficiency but also a critical component of advancing clinical research and enhancing the overall quality of care. Strategies to boost engagement, such as personalized communication, patient education, and feedback mechanisms, are essential for maximizing the potential of clinical trials and ensuring that research efforts translate into tangible benefits for patients and the healthcare system as a whole.^[4]

1.2. Common Challenges

Achieving and maintaining patient engagement in clinical trials poses several significant challenges that can impact the overall success of the research. One of the primary issues is recruitment difficulties, where identifying and attracting suitable participants becomes a complex and resource-intensive endeavor. Many potential participants may be unaware of available trials or may be deterred by perceived burdens associated with participation, such as time commitment, travel requirements, or potential side effects. This challenge is compounded by the need to meet specific eligibility criteria, which can further narrow the pool of eligible candidates and complicate the recruitment process. Retention problems also pose a major obstacle, particularly in long-term studies where maintaining participant interest and compliance over extended periods is crucial. Factors such as inconvenience, lack of motivation, and the presence of adverse effects can lead to participant dropouts, jeopardizing the integrity of the study and potentially skewing the results. Ensuring adherence to study protocols is another critical challenge, as participants may struggle to follow prescribed medication regimens, attend scheduled visits, or adhere to other study requirements. Non-adherence not only compromises the validity of the trial results but can also introduce biases and variability that undermine the reliability of the data collected. These challenges highlight the need for effective strategies to engage and retain participants, such as improving communication, offering incentives, and providing support to address barriers to participation. Addressing these issues is essential for enhancing the overall efficiency and effectiveness of clinical trials and ensuring that they generate meaningful and reliable results that advance medical knowledge and improve patient care.

2. Introduction to Chatbots

Chatbots, or conversational agents, are sophisticated software applications designed to simulate human conversation through text or voice interactions. These systems leverage advancements in artificial intelligence (AI), natural language processing (NLP), and machine learning (ML) to deliver interactive and responsive user experiences. At the core of chatbot functionality is AI, which refers to the capability of machines to perform tasks that typically require human intelligence. By utilizing AI, chatbots can comprehend and process

natural language, allowing them to engage with users in a manner that mimics human conversation. NLP, a specialized branch of AI, focuses on the interaction between computers and humans through natural language. It equips chatbots with the ability to understand, interpret, and generate human language in ways that are both meaningful and contextually appropriate. NLP techniques enable chatbots to parse user inputs, extract intent, and generate relevant responses, thereby facilitating smooth and intuitive interactions. Additionally, ML algorithms play a crucial role in enhancing chatbot performance over time. By analyzing data from interactions and feedback, chatbots equipped with ML can continuously refine their responses, improve accuracy, and better understand user queries. This adaptive learning process allows chatbots to become increasingly effective at addressing user needs and providing valuable assistance. Through the integration of AI, NLP, and ML, chatbots offer a powerful tool for improving user engagement, streamlining communication processes, and delivering personalized experiences across various applications.^[3,7]

2.2. Evolution of Chatbot Technology

Chatbot technology has undergone remarkable evolution since its inception, driven by significant advancements in computing and growing demands for automated communication solutions. The journey began with early chatbots like ELIZA, developed in the 1960s. ELIZA was a pioneering effort, utilizing simple rule-based systems to simulate conversation through predefined responses and pattern matching. Although groundbreaking for its time, ELIZA's conversational capabilities were limited, primarily serving experimental and academic purposes rather than practical applications. Following this, rule-based systems emerged as a more structured approach to chatbot design. These chatbots operated based on a fixed set of predefined rules and decision trees, handling scripted interactions with users. They were effective at managing specific, predictable queries but struggled with complex, unscripted conversations. Their rigidity made them less adaptable to the nuances of natural human dialogue, highlighting the need for more advanced solutions.^[1]

The introduction of AI-powered chatbots marked a significant leap forward. Leveraging advancements in artificial intelligence (AI) and natural language processing (NLP), these chatbots could process natural language inputs, understand contextual meanings, and deliver more relevant and personalized responses. Unlike their predecessors, AI-powered chatbots could handle a broader range of queries and engage in more dynamic interactions. They also began to incorporate learning capabilities, enabling them to improve their performance over time by learning from user interactions and feedback. The latest phase in chatbot technology is represented by conversational AI, which integrates multiple advanced AI components, including NLP, machine learning (ML), and deep learning.

Conversational AI represents a paradigm shift, enabling chatbots to engage in more natural, fluid conversations and handle complex queries with higher accuracy. These systems are designed to simulate human-like interactions more effectively, learning from vast amounts of data to continuously enhance their understanding and response capabilities. The incorporation of deep learning algorithms allows conversational AI chatbots to grasp subtleties and context in user inputs, providing a more refined and intuitive user experience. The evolution of chatbot technology reflects a trajectory from simple, rule-based interactions to sophisticated, AI-driven conversational agents capable of engaging in nuanced and intelligent dialogue. This progression underscores the significant strides made in enhancing chatbot functionality and adaptability, positioning them as valuable tools in a wide range of applications, from customer service to healthcare.^[5]

2.3. Types of Chatbots

Chatbots come in a variety of forms, each tailored to different applications and use cases, reflecting their versatility and adaptability in enhancing user interactions across various platforms. Rule-based chatbots represent the simplest form of chatbot technology, operating based on a set of predefined rules and scripts. These chatbots are best suited for handling straightforward, repetitive tasks and addressing frequently asked questions. Their functionality is limited to the scenarios they have been programmed to manage, making them highly efficient for routine inquiries but less capable of handling complex or unexpected interactions. Rule-based chatbots excel in environments where the scope of interactions is well-defined, providing quick and consistent responses to users' standardized queries. In contrast, AI-powered chatbots leverage machine learning and natural language processing (NLP) to handle more sophisticated interactions. These chatbots are designed to understand and respond to complex queries by analyzing the context and intent behind user inputs. They can provide personalized interactions by learning from past interactions and adapting their responses based on user behavior and preferences. AI-powered chatbots are capable of engaging in more dynamic and nuanced conversations, making them suitable for applications that require a deeper level of interaction, such as customer support, healthcare guidance, and personalized recommendations. Their ability to evolve and improve over time through machine learning algorithms enhances their effectiveness in delivering relevant and accurate responses. Voice-activated chatbots represent another significant advancement, designed to interact with users through voice commands. Integrated with voice recognition technology, these chatbots are commonly found in virtual assistants like Amazon Alexa and Google Assistant. Voice-activated chatbots enable hands-free interactions and provide users with the convenience of voice communication. They are particularly valuable in environments where users prefer or require vocal interactions, such as in smart home devices, automotive

systems, and accessibility applications. These chatbots leverage advanced speech recognition and natural language understanding to process spoken inputs and provide audible responses, facilitating seamless and intuitive user experiences.^[2]

Hybrid chatbots combine elements of both rule-based and AI-powered approaches, offering a versatile solution that balances structured and conversational interactions. These chatbots are capable of switching between predefined responses and more flexible, AI-driven interactions based on the context of the conversation. For example, a hybrid chatbot might use rule-based responses for straightforward queries and switch to AI-powered capabilities for more complex or personalized interactions. This hybrid approach allows for efficient handling of routine tasks while also accommodating the need for more sophisticated dialogue, providing a comprehensive solution that can adapt to varying user needs and scenarios. Each type of chatbot has its unique strengths and is suited to different contexts, reflecting the diverse ways in which chatbot technology can enhance user interactions and streamline communication. Whether handling simple queries, engaging in complex conversations, processing voice commands, or combining multiple interaction strategies, chatbots offer valuable tools for improving user experience and operational efficiency across a wide range of applications. Understanding the capabilities and limitations of each type of chatbot is essential for selecting the appropriate solution to meet specific needs and achieve desired outcomes in various domains.^[8]

3. Role of Chatbots in Clinical Trials

3.1. Enhancing Recruitment

Recruitment is one of the most critical and challenging phases of clinical trials. Chatbots can significantly streamline this process by

- **Pre-Screening and Qualification:** Chatbots can engage with potential participants through web forms or messaging platforms, asking qualifying questions to determine eligibility based on inclusion and exclusion criteria. This automated pre-screening helps filter candidates efficiently and reduces the burden on clinical staff.

- **Information Dissemination:** They can provide prospective participants with detailed information about the trial, including objectives, procedures, and potential risks. By delivering this information in an easily accessible format, chatbots help ensure that participants are well-informed and more likely to proceed with enrollment.

3.2. Improving Retention and Adherence

Once enrolled, maintaining participant engagement and adherence to study protocols is crucial. Chatbots can aid in this by

- **Automated Reminders:** Chatbots can send personalized reminders for upcoming appointments, medication

intake, or other study-related tasks. This helps ensure that participants adhere to the study schedule and complete necessary activities.

- **Real-Time Support:** Participants can interact with chatbots to address concerns, seek clarification, or receive guidance on protocol-related questions. Instant support reduces uncertainty and helps participants feel more connected and supported throughout the trial.

4. Benefits of Chatbots in Patient-Centric Clinical Trials

4.1. Personalization and Accessibility

Chatbots offer substantial benefits in enhancing patient engagement during clinical trials through personalization and accessibility. These digital assistants are designed to provide tailored interactions, around-the-clock availability, and support for diverse communication needs, which can significantly improve the overall trial experience for participants. One of the primary ways chatbots enhance patient engagement is through tailored interactions. Advanced chatbots, powered by artificial intelligence (AI) and machine learning, have the capability to offer responses that are specifically tailored to individual participants. Unlike traditional, static systems, these chatbots can remember past interactions, recognize user preferences, and identify specific needs. This personalized approach ensures that each participant receives information and support that is relevant to their unique circumstances. For instance, if a participant has previously asked about medication schedules or side effects, the chatbot can provide updated, context-specific information without requiring the participant to repeat their questions. This level of personalization not only makes interactions more meaningful but also helps participants feel valued and understood, which can contribute to higher levels of engagement and adherence to trial protocols.^[6]

Another significant advantage of chatbots is their 24/7 availability. Traditional support systems often operate within set hours, which can be restrictive for participants in different time zones or those needing assistance outside of regular business hours. Chatbots, however, provide around-the-clock assistance, enabling participants to access information and support whenever they need it. This constant availability is particularly valuable in clinical trials, where participants may have questions or require support at various times, including during nights or weekends. By offering uninterrupted access, chatbots ensure that participants are never left without the support they need, which can improve their overall experience and commitment to the trial. Moreover, modern chatbots are equipped with language and accessibility support features that broaden their utility and inclusivity. These chatbots can communicate in multiple languages, making trial information accessible to a diverse patient population. This capability is crucial for addressing language barriers and ensuring that participants from different linguistic backgrounds receive the same level of support and information.

Additionally, chatbots can accommodate various communication needs, including those related to accessibility. For example, they can be designed to assist users with visual or auditory impairments by offering text-to-speech options or supporting voice commands. This inclusivity helps in providing equal support to all participants, ensuring that no one is disadvantaged due to language differences or specific accessibility requirements. By integrating these features, chatbots contribute to a more engaging and supportive clinical trial environment. Their ability to offer personalized, timely, and accessible interactions helps in addressing common challenges related to participant engagement, such as maintaining interest, ensuring adherence to protocols, and providing necessary support. Overall, the use of chatbots in clinical trials represents a significant advancement in improving participant experience, making the process more user-friendly, and enhancing the efficiency of trial management.

4.2. Efficiency and Cost-Effectiveness

The integration of chatbots into clinical trials can lead to increased efficiency and reduced costs

- **Reduction in Administrative Burden:** By automating routine tasks such as scheduling, reminders, and data collection, chatbots reduce the workload on clinical staff. This allows researchers to focus on more complex aspects of the trial, such as data analysis and patient care.
- **Streamlined Processes:** Chatbots can handle multiple interactions simultaneously, which accelerates processes like recruitment, consent, and follow-ups. This streamlined approach can lead to faster trial initiation and completion.
- **Cost Savings:** The use of chatbots can lead to cost savings by reducing the need for additional administrative staff and minimizing errors associated with manual processes. The efficiency gains can also help in reducing overall trial costs and improving resource allocation.

4.3. Data Collection and Analysis

Chatbots play a crucial role in data management and analysis during clinical trials

- **Real-Time Data Collection:** Chatbots can collect data from participants in real-time, including responses to surveys, adherence reports, and feedback on trial experiences. This real-time data collection ensures timely monitoring and prompt responses to any issues that arise.
- **Enhanced Data Accuracy:** By automating data entry and reporting, chatbots reduce the risk of human error and improve the accuracy and consistency of collected data. This leads to more reliable and valid research outcomes.

5. Limitations

Despite their promising benefits, the implementation of chatbots in clinical trials comes with several limitations that need to be carefully addressed to ensure their effectiveness and compliance. One major limitation is regulatory considerations. Compliance with regulatory

standards and guidelines is a significant challenge, particularly concerning data protection and privacy. Clinical trials are governed by strict regulations to safeguard patient information, and integrating chatbots into these systems necessitates adherence to these regulations. Ensuring that chatbots meet regulatory requirements involves navigating complex legal frameworks and maintaining rigorous standards for data handling and security. This can be a resource-intensive process, requiring ongoing monitoring and adjustments to ensure compliance with evolving regulations. Data privacy remains a critical concern in the use of chatbots for clinical trials. Protecting the security and confidentiality of patient data is paramount, as breaches or misuse of this information can have severe consequences. Chatbots, which handle sensitive patient information, must implement robust security measures to prevent unauthorized access and data leaks. This includes employing encryption, secure data storage, and strict access controls. Additionally, chatbots must be designed with features that allow for the anonymization of data and provide transparency about how patient information is used. Ensuring data privacy is not only a regulatory requirement but also a fundamental aspect of maintaining trust and safeguarding the interests of trial participants.

Another limitation is related to chatbot design and functionality. The effectiveness of chatbots largely depends on their design and how well they meet the needs of users. Poorly designed chatbots can lead to a range of issues, from misunderstanding user queries to providing inaccurate or irrelevant responses. This can result in user frustration, reduced engagement, and diminished trust in the technology. To be effective, chatbots need to be carefully designed with a user-centric approach, incorporating intuitive interfaces, clear navigation, and contextually relevant responses. Regular updates and continuous improvement based on user feedback are also essential to ensure that chatbots remain effective and responsive to the evolving needs of participants.

While chatbots offer significant advantages in enhancing patient engagement and support in clinical trials, addressing their limitations is crucial for maximizing their potential benefits. Navigating regulatory considerations, safeguarding data privacy, and ensuring high-quality design are key factors that need to be managed to successfully integrate chatbots into clinical trial processes. By addressing these challenges, stakeholders can better leverage chatbot technology to improve the trial experience for participants and enhance the overall effectiveness of clinical research.^[9]

6. Future Research Directions: Recommendations

Based on the findings of this review, several areas for future research are recommended to further explore and refine the use of chatbots in clinical trials. One crucial area is investigating the long-term effects of chatbot use on patient engagement and trial outcomes. While

chatbots have demonstrated immediate benefits in improving patient interactions and adherence, understanding their impact over extended periods is essential. Future studies should assess how sustained chatbot engagement influences patient retention rates, adherence to study protocols, and overall trial success. This research could provide insights into whether the initial advantages of chatbot integration are maintained over the entire duration of a clinical trial.

Another important research direction involves identifying and addressing gaps in the current knowledge of chatbot technology in clinical trials. For instance, there is limited understanding of how different patient demographics interact with chatbots and how these interactions might vary based on age, technological proficiency, or cultural factors. Research should explore how chatbots can be optimized to cater to diverse patient populations, ensuring inclusivity and effectiveness across various user groups.

Future studies should examine the integration of chatbots with other emerging technologies, such as artificial intelligence (AI), machine learning (ML), and the Internet of Things (IoT). Investigating how these technologies can enhance chatbot capabilities and improve patient outcomes could lead to more sophisticated and adaptive systems. For example, research could explore how combining chatbots with AI-driven analytics might provide deeper insights into patient behavior and preferences, leading to more personalized and effective interactions. Another significant area for exploration is the development of robust frameworks for ensuring data security and privacy in chatbot systems. Given the sensitivity of patient information, it is vital to study advanced security measures and privacy protocols that can be integrated into chatbot platforms. Future research could focus on creating standards and best practices for safeguarding data, ensuring compliance with regulatory requirements, and building patient trust in chatbot technologies. Evaluating the cost-effectiveness of implementing chatbots in clinical trials is a valuable area for future research. Understanding the economic impact of chatbot integration, including the costs associated with development, implementation, and maintenance versus the benefits of improved patient engagement and trial outcomes, can help stakeholders make informed decisions about adopting these technologies. Studies could analyze the return on investment (ROI) for chatbot systems and assess their financial viability in various clinical trial settings.^[10]

Future research should focus on assessing the long-term effects of chatbots on patient engagement and trial outcomes, addressing gaps in understanding diverse patient interactions, exploring synergies with emerging technologies, developing robust data security frameworks, and evaluating cost-effectiveness. By pursuing these research directions, stakeholders can

advance the use of chatbots in clinical trials, optimizing their potential benefits and addressing current limitations to enhance the overall effectiveness of clinical research.

CONCLUSION

The integration of chatbots into clinical trials represents a transformative advancement in enhancing patient-centric approaches within clinical research. As the focus of clinical trials increasingly shifts towards improving patient engagement, chatbots emerge as powerful tools that align with this evolution, offering solutions to several key challenges and enhancing various facets of trial management and participant experience. By leveraging advanced artificial intelligence (AI) and natural language processing (NLP), chatbots provide a range of benefits that address fundamental issues in clinical trials, including recruitment, retention, and data collection. Chatbots have the potential to significantly improve patient engagement through their ability to offer personalized, scalable, and efficient support. They facilitate tailored interactions by remembering past conversations, understanding individual preferences, and addressing specific needs, thereby making participants feel more valued and supported. This personalization enhances patient adherence to trial protocols and improves overall engagement, as participants receive relevant and timely information that is crucial for their ongoing involvement.

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