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·方法学研究·

大语言和专病GPT赋能咨询和管理肺结节意义的对比研究方案

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［摘要］ 本研究旨在对比通用大语言模型（DeepSeek GPT）与专病优化模型（BAIMGPT）在肺结节咨询与管理中的临床价值。通过多中心真实世界研究，招募12家医院的1000例肺结节患者，采用随机自身对照设计，评估两种模型在便捷性、亲切感、安全感、问题理解准确性、回答专业性、语音交互、视觉赋能及需求程度8个维度的表现。核心方法包括：用户双重评价，三方盲审，终点指标。研究预期验证专病BAIMGPT在提升筛查知晓率、个性化管理及医患信任度的优势，并为AI赋能肺癌早筛提供循证依据。方案通过伦理审查，数据匿名化处理，兼顾创新性与安全性。

［关键词］ 肺结节；BAIMGPT；DeepSeek GPT

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A comparative study of the significance of GPT-enabled counseling and management of pulmonary nodules

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［**Abstract**］ This study aims to compare the clinical value of a general large language model (DeepSeek GPT) and a disease-specific optimized model (BAIMGPT) in pulmonary nodule consultation and management. Through a multicenter real-world study, 1,000 patients with pulmonary nodules from 12 hospitals will be recruited for a randomized self-controlled trial evaluating the performance of the two models across eight dimensions: convenience, friendliness, sense of security, accuracy in question comprehension, response professionalism, voice interaction, visual empowerment, and demand level. The core methodologies include dual user evaluation, third-party blinded review, and endpoint assessment. The study was expected to validate BAIMGPT's advantages in improving screening awareness, personalized management, and physician-patient trust, providing evidence-based support for AI-powered early lung cancer screening. The protocol has passed ethical review, with anonymized data processing ensuring both innovation and safety.

［**Key Words**］ plmonary nodule; BAIMGPT; DeepSeek GPT

1　The importance of pulmonary nodule consultation and management in promoting early diagnosis and treatment of lung cancer

Pulmonary nodule consultation and management play a crucial role in improving the early diagnosis and treatment of lung cancer[1]. Through professional medical consultation, patients can receive accurate information about the nature of pulmonary nodules, potential cancer risks, and necessary medical

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measures, which is essential for the timely detection and treatment of lung cancer. Management focuses on encouraging patients to take responsibility for their health under medical guidance, including adhering to medical advice for regular check-ups, making lifestyle adjustments, and continuous health monitoring. In terms of demand, the promotion of low-dose computed tomography (LDCT) screening programs [2] has led to the early detection of an increasing number of pulmonary nodules. Consequently, there is a growing need for medical professionals who can accurately interpret these screening results and provide appropriate advice. At the same time, patients need to understand how to monitor their health in daily life and when to seek medical assistance.

Clinically, pulmonary nodule consultation and management help raise public awareness about the early diagnosis and treatment of lung cancer. This not only improves treatment outcomes and extends patient survival but also reduces the high medical costs associated with late-stage disease detection. Moreover, effective management can alleviate the burden on healthcare systems and optimize the allocation of medical resources. In short, pulmonary nodule consultation and management are integral to raising public health awareness and promoting early detection and treatment of lung cancer, making them an indispensable part of modern healthcare services.

2 Current Challenges and Pain Points in Pulmonary Nodule Consultation and Management

Currently, pulmonary nodule consultation and management face several challenges and pain points. (1) Lack of widely adopted consensus guidelines: Differences between regions and medical institutions, as well as insufficient familiarity and experience with consensus guidelines among physicians, often lead to suboptimal consultation quality, delaying timely diagnosis and treatment of early-stage lung cancer. (2) Lack of professional knowledge: Many patients and their families have limited understanding of pulmonary nodules, making it difficult to make informed decisions. Some non-specialist doctors may also provide misguided advice due to unfamiliarity with consensus guidelines, potentially leading to inappropriate patient behaviors. (3) Uneven distribution of medical resources: In some areas, quality medical resources are scarce, limiting access to professional and timely consultations. In other regions where resources are abundant, patients may face high medical costs. (4) Challenges in follow-up management: Long-term follow-up is essential for managing pulmonary nodules, requiring strong patient adherence and management capabilities. In practice, many patients fail to attend follow-up appointments for various reasons, affecting disease management and outcomes. (5) Inadequate psychological and social support: Patients with pulmonary nodules often experience anxiety or depression, and existing support systems may not meet their needs. Furthermore, families and society often lack sufficient awareness and understanding of pulmonary nodules, leading to insufficient support for patients[3]。

To address these issues, it is necessary to leverage new forms of productivity to strengthen public education on pulmonary nodules, enhance awareness, promote the widespread adoption of diagnostic standards and consensus guidelines, optimize the allocation of medical resources, improve the service capacity of primary care institutions, enhance patient follow-up management, and provide more comprehensive psychological and social support services.

3 How GPT can address current challenges in pulmonary nodule consultation and management

In recent years, the development of artificial intelligence has attracted widespread attention, with natural language processing (NLP) emerging as a key area of application. As a leading model in NLP, GPT (Generative Pre-training Transformer) has achieved significant success in text generation, classification, and is gradually being applied in medicine and healthcare[4], GPT demonstrates significant potential in pulmonary nodule consultation and management, contributing to medical innovation and improving the efficiency and accuracy of healthcare services, thereby better meeting patient needs.

From a socio-economic perspective, such

technologies are expected to accelerate the digital transformation of the healthcare industry[5], increase the level of intelligent healthcare services, reduce costs, and improve accessibility.

However, whether large language models like GPT can accurately empower diagnosis and management remains uncertain. Small-scale studies suggest that general-purpose GPT models struggle to provide accurate consultation and management for pulmonary nodules. In contrast, specialized GPT models, i.e., disease-specific pretrained transformer models, show promise in addressing the pain points in pulmonary nodule consultation and management.

This study aims to compare the performance of BAIMGPT and DeepSeek GPT in the consultation and management of pulmonary nodules to evaluate their clinical relevance and potential to benefit users or patients through the following applications. (1) Patient Consultation: Using natural language processing, GPT can communicate directly with patients, understand their questions and concerns, and provide preliminary diagnostic suggestions. This reduces the burden on physicians and improves the efficiency and quality of patient consultations. (2) Disease Prediction and Diagnosis: By analyzing electronic medical records, GPT can help predict potential health issues, including the nature and progression of pulmonary nodules[6]. This assists doctors in making faster diagnoses and offering personalized management plans. (3) Medical Knowledge Graph Construction: GPT can aid in constructing comprehensive medical knowledge graphs, helping physicians understand the relationships between different diseases and enhance the overall knowledge base for diagnosis and treatment[7]. (4) Medical Text Summarization: GPT is capable of processing large volumes of medical literature and extracting key information, enabling healthcare professionals to quickly grasp the latest medical advancements.

In summary, the application of specialized GPT models is expected to improve various aspects of pulmonary nodule management and diagnosis — from enhancing diagnostic accuracy to optimizing the patient consultation experience — thus holding significant practical value.

4 Research methodology

4.1 Research objectives

This study aims to investigate the clinical significance of large language models (LLMs) and disease-specific GPTs in pulmonary nodule consultation and management. To achieve this objective, we designed a real-world, randomized self-controlled comparative study evaluating BAIMGPT, DeepSeek GPT, and related technologies across multiple dimensions: convenience, approachability, perceived safety, question comprehension, answer accuracy, voice interaction, visual assistance, and demand level. The study seeks to elucidate the clinical value of both general-purpose LLMs and specialized GPTs in pulmonary nodule care. Anticipated benefits for users/patients include the following aspects. (1) Enhanced educational outcomes, awareness, screening rates, and consultation efficacy: Through digital human GPT technology, users/patients can acquire comprehensive knowledge about pulmonary nodules, thereby improving educational benefits[8]. The GPT systems facilitate increased awareness and screening participation, ensuring timely detection and management of pulmonary nodules. Additionally, the GPT-powered consultation services effectively address various patient inquiries, significantly improving consultation outcomes. (2) Improved training effectiveness: The digital human GPT optimizes training benefits for user/patient education. By delivering personalized and efficient medical services, the technology enhances both the quality and effectiveness of educational interventions. (3) Reduced delayed diagnosis rates: Access to accurate medical information and consultation services through digital human GPT minimizes diagnostic delays caused by information gaps. This improvement enhances healthcare service efficiency and accuracy, ensuring timely and appropriate diagnosis and treatment. (4) Enhanced prevention and management outcomes: The digital human GPT strengthens health awareness and self-management capabilities, significantly improving prevention and treatment efficacy[9]. By providing AI-generated medical knowledge and health recommendations, users/patients gain better

understanding of pulmonary nodule prevention and management strategies. (5) Supporting China's Healthy China initiative for grassroots healthcare coverage: The application of digital human GPT extends medical services to broader primary care settings, realizing the Healthy China vision of comprehensive grassroots coverage[10]. Through remote medical education and science popularization functions, the technology expands healthcare accessibility to patients' homes and communities, improving both the availability and quality of medical services.

4.2 Study design

This real-world randomized self-controlled cross-comparison study evaluates BAIMGPT, DeepSeek GPT, and other technologies in terms of convenience, approachability, perceived safety, question comprehension, answer accuracy, voice interaction, visual assistance, and demand level for pulmonary nodule consultation and management. The study aims to explore the clinical significance of general LLMs versus specialized disease-focused GPTs in pulmonary nodule care.

4.3 Literature review

A comprehensive review of existing research on GPT-based LLMs and specialized disease GPTs for pulmonary nodule consultation and management will be conducted to understand current advancements and challenges in this field.

4.4 Study protocol design

The study protocol includes the following aspects. (1) Project Initiation & Literature Review: Define research objectives and tasks, assemble the research team, conduct preliminary literature reviews and model development preparations[11]. Based on large-scale medical text data, clinical data, and a specialized pulmonary nodule knowledge base, construct and optimize BAIMGPT, a disease-specific GPT for pulmonary nodule consultation and management. (2) Model Development & Optimization: Build and refine the Medical Digital Human BAIMGPT model based on research findings and medical data[12]. The model optimization requirements shall focus on: convenience, approachability, sense of security, question comprehension, answer accuracy, voice interaction, visual empowerment, and demand level for pulmonary nodule consultation and management[13].

4.5 Cross-user comparative evaluation of three gpts in pulmonary nodule consultation and management

A horizontal comparison study was conducted between the specialized BAIMGPT and the general large language model DeepSeek, focusing on eight key dimensions in pulmonary nodule consultation and management: convenience, approachability, sense of security, question comprehension, answer accuracy, voice interaction, visual empowerment, and demand level. The specific methodology involved: Introducing trial participants to the three GPT systems and their usage methods; Presenting standardized questions (including "What are pulmonary nodules? " and "How are pulmonary nodules diagnosed? "); Allowing users to pose 3-6 self-selected questions, with each GPT autonomously responding to all questions. Later, users independently selected one of three evaluation grades: (A: Very Satisfied; B: Satisfied; C: Dissatisfied). The evaluation covered the following eight aspects:

Convenience: Ability to provide time/location-independent and efficient service (All GPTs can achieve this).

Approachability: Ability to establish a personalized, reassuring interaction (Only Digital Human GPT can achieve A).

Perceived Safety: Ability to build trust and confidence (Only Digital Human GPT can achieve A).

Question Comprehension: How well each GPT understands user queries.

Answer Accuracy: Alignment of responses with medical accuracy.

Voice Interaction: Usability of voice-based Q&A (Models without voice capability cannot score A).

Visual Assistance: Effectiveness of visual aids in enhancing understanding (Models without visual interfaces cannot score A).

Demand Level: User-rated need for GPT in healthcare: Urgent Need; Need; No Need.

4.6 Third-party evaluation of question comprehension and answer accuracy

In this study, question comprehension and

answer accuracy constitute the two most critical factors directly influencing the clinical applicability of various GPT models. Therefore, a dual-evaluation approach was adopted involving: User self-assessment; Independent third-party evaluation (conducted by non-researchers without conflicts of interest). The third-party evaluation methodology included: Direct analysis of real-world interaction logs from BAIMGPT, DeepSeek GPT, and other GPT models[14], comparative assessment against consensus guidelines, authoritative medical literature and expert knowledge from Grade-A specialists of the China Lung Cancer Prevention Alliance was conducted. Accuracy is evaluated by third-party experts (A: Inaccurate; B: Partially accurate; C: Fully accurate).

4.7 Study design selection

An open-label, multicenter real-world study was conducted to horizontally compare BAIMGPT and DeepSeek GPT across eight dimensions: convenience, approachability, security perception, question comprehension, answer accuracy, voice interaction, visual empowerment, and demand level. This design evaluated the efficiency of GPT-enabled pulmonary nodule consultation and management[15]。

4.8 Research tool selection The study utilized BAIMGPT and DeepSeek GPT systems (see Supplementary for technical specifications).

5 Clinical research plan

5.1 Research centers and study population

The study will be conducted across multiple centers, including: Zhongshan Hospital, Fudan University, Henan Provincial People's Hospital, The First Affiliated Hospital of Zhejiang University, The First Affiliated Hospital of Chongqing Medical University, Shanghai Geriatric Medical Center, Xinqiao Hospital, Army Medical University, The Second Hospital of Jilin University, ongshan Hospital Affiliated to Dalian University, Pudong Hospital, Fudan University, Xinhua Hospital, Shanghai Jiao Tong University, Shanghai Parkway Health, The First People's Hospital of Nanning. The study population consists of pulmonary nodule patients or users identified during outpatient visits or health check-ups at these centers.

5.2 Participant education and screening

Patients diagnosed with pulmonary nodules via thin-slice CT scans will first undergo education using the Digital Human's "16-Word Lung Cancer Prevention and Treatment" program. Eligible participants will be screened based on inclusion and exclusion criteria.

5.3 Informed consent process

Qualified participants (or their families) will receive a detailed explanation of the study's purpose, methods, potential risks, benefits, and their rights and responsibilities before signing the informed consent form (ICF). The ICF will clarify that: The study involves GPT-assisted consultation and management and does not replace real-world medical diagnosis. If participants require real-world expert consultation, study-affiliated specialists can provide clinical follow-up in outpatient settings. After consent is obtained, participants will receive GPT-based consultations.

5.4 Study procedures

Participants will be granted access to three GPT models (BAIMGPT and DeepSeek GPT variants) to: Answer standardized questions (e. g., "What are pulmonary nodules" and "How are they diagnosed"), and pose 3-6 self-selected questions.

Each GPT's responses will be evaluated on:

Convenience. Satisfaction with accessibility and efficiency (time/region-independent).

Approachability. Ability to foster a personalized, reassuring interaction.

Perceived safety. Degree of trust and confidence in the GPT's responses.

Question comprehension. Accuracy in understanding user queries.

Answer accuracy. Alignment with evidence-based medical knowledge.

Voice interaction. Usability of voice-based Q&A.

Visual assistance. Effectiveness of visual aids in enhancing understanding.

Perceived need. User-rated demand for GPT in healthcare (urgent need / need / no need).

5.5 Data collection

Clinical data will be recorded via paper-based and electronic Case Report Forms (CRFs), compliant

with GCP standards. Paper CRFs will be archived at Zhongshan Hospital, Fudan University; electronic data will be processed independently by the lead statistician.

6 Data analysis

6.1 User evaluation of GPT models

A cross-comparison of BAIMGPT (specialized disease model) and DeepSeek GPT (general LLM) will assess: convenience, approachability, safety, comprehension, accuracy, voice/visual features, and demand.

6.2 Third-party expert validation

An independent, conflict-free third party will evaluate: real-world response accuracy by comparing GPT outputs to consensus guidelines, authoritative texts, and A-tier expert opinions from the China Lung Cancer Prevention Alliance.

6.3 Endpoints

Primary endpoint: Accuracy of question comprehension and responses (measured against guidelines[16]. Secondary endpoints: Convenience, approachability, safety, and demand. Exploratory Analysis: Strengths, limitations, and future directions of GPT in lung cancer screening and nodule management.

7 Summary and discussion

The Sample Size is estimated to be around 1,000 cases. Appropriate statistical and analytical methods will be selected based on the study design.

A statistical analysis will be conducted on the comparative experimental results of GPT and three DeepSeek GPT models, focusing on the contrast between general large language models and specialized disease-empowered GPTs in pulmonary nodule consultation and management. The discussion will explore the advantages, limitations, and future directions of various GPT models in lung cancer screening and pulmonary nodule management, including the following aspects. (1) Analyzing the potential of Medical Digital Human-integrated GPT in lung cancer screening and pulmonary nodule consultation management [17], particularly its ability to enhance screening awareness, motivation, and compliance through approachability, perceived safety, and trustworthiness in aiding screening decision-making. (2) Investigating the application value of Medical Digital Human-integrated GPT in problem comprehension and response accuracy for management purposes, such as simulating physician expertise to provide personalized health recommendations and management plans. (3) Evaluating user experience with Medical Digital Human-integrated GPT[18], including voice interaction, visual empowerment, and demand assessment, to guide continuous product refinement and optimization[19]. (4) Assessing the role of Medical Digital Human-integrated GPT in education and training, particularly in improving healthcare professionals' knowledge and skills in lung cancer screening and management[20]。

Research findings will be compiled into reports and academic papers for dissemination at conferences and in peer-reviewed journals.

8 Research ethics

8.1 Ethics committee review

This study is the first research on GPT-empowered lung cancer screening needs and patient experience. Upon approval, it will help enhance the influence of Shenzhen-Zhongshan Hospital and serve as a critical reference for future transformations in medical practice. Therefore, we specially request an expedited ethics committee review. The researchers will submit annual progress reports (if applicable) to the ethics committee. Upon study termination and/or completion, the researchers will provide written notification to the ethics committee. Any changes in the research (e.g., protocol and/or informed consent revisions) will also be promptly reported.

8.2 Written informed consent

After obtaining ethical approval, before using participant data or samples, researchers will contact participants or their families via follow-up phone calls to explain the study's purpose, potential implications, and invite them to return to the hospital to sign the informed consent form (ICF). The ICF will be retained as a key document for the clinical trial. If a participant is unwilling to return to sign the ICF, verbal consent may be obtained via phone before using their data/

samples. If a participant cannot be contacted after three or more attempts，their data/samples may still be used in compliance with ethical regulations. This entire process will be fully documented. For individuals who cannot be reached，in accordance with Articles 38 and 39 of the National Health Commission's Ethical Review Measures for Biomedical Research Involving Human Subjects，if the study does not involve personal privacy or commercial interests，the requirement for signed consent may be waived when using identifiable human materials or data from untraceable participants.

8.3　Confidentiality measures

The research team will upload users′ or patients′ imaging data to the "Pulmonary Nodule Intelligent Auxiliary Analysis System" developed by Zhuhai Hengqin Shengao Yunzhi Technology Co.，Ltd. for AI analysis. Before uploading，we will anonymize the imaging information of users or patients. To maximize privacy protection，all uploaded imaging data will be promptly deleted from the server upon completion of the analysis.

The results obtained from this research may be published in medical journals，but the personal information of study participants will remain strictly confidential. Only the hospital ethics committee and authorized researchers may access the data when necessary. Participants will be identified only by their initials and assigned study numbers upon enrollment.

Participants will be informed about the anonymity of their data and their right to privacy protection. However，they must also acknowledge that the data may be submitted to the responsible research institution，government regulatory agencies（such as the Ministry of Health），for inspection and evaluation. The attending physicians will maintain a confidential list of participants′ personal information（study records and corresponding names）for verification purposes.

This initiative collaborates with the International Metaverse Medical Association and the China Lung Cancer Prevention and Treatment Alliance to develop a specialized disease and large language model-integrated knowledge base. On April 10，2024，at the inaugural meeting of the Metaverse Medical Professional Committee of the Shanghai Minhang Medical Association，the world-leading Metaverse Medical Digital Human GPT—BAIMGPT 1.0—was officially unveiled. Based on this knowledge base，experts have led the formulation of the first and continuously updated Asia-Pacific and Chinese consensus guidelines for pulmonary nodule evaluation and management，as well as expert consensus on OSA diagnosis and treatment management，along with 12 specialized publications. Supported by a team of over 100 internationally and domestically renowned experts，this project holds advantages in top-level design，academic leadership，technological innovation，and intelligent public benefit in the fields of metaverse medicine and medical digital human GPT.

Supplementary　BAIMGPT is developed by Shanghai Baichunxue Artificial Intelligence Technology Studio and holds independent intellectual property rights and a registered trademark（Figure 1）.

Figure 1　BAIMGPT Registered Trademark

These encompass virtual reality devices，computerized management of medical records and files，internet broadcasting services，education，training，medical training and teaching，provision of medical information services and clinical services via the Internet，and administrative services for medical referrals.

On April 10，2024，at the inaugural meeting of the Metaverse Medicine Committee of the Minhang District Medical Association in Shanghai，the world's

leading metaverse medical digital human GPT—BAIMGPT 1.0—was officially unveiled.

Based on this knowledge base and led by experts, the first and continuously updated Asia-Pacific and China consensus guidelines on pulmonary nodule assessment and management, as well as expert consensus on OSA diagnosis and treatment management, have been developed. Supported by 12 monographs and a team of over 100 internationally or nationally renowned experts, BAIMGPT demonstrates advantages in top-level design, academic leadership, technological innovation, and intelligent public service in the fields of metaverse medicine and medical digital human GPT.

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