DISCUSSION

AI-Mind: Revolutionizing Personalized Neurology Through Automated Diagnostics and Advanced Data Management

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INTRODUCTION

Dementia affects nearly 10 million new individuals every year, with Alzheimer disease (AD) accounting for about 60–80% of cases.1 AD and other dementias represent a growing global crisis, especially in regions with rising life expectancy.2 AD is characterized by macroscopic brain atrophy, amyloid plaques, neurofibrillary tangles, and synaptic loss, leading to significant memory deficits. Advances in diagnostics and care have increased patient survival times but also imposed a substantial socioeconomic burden on health systems, families, and caregivers.3,4 Timely and accurate diagnostics, along with innovative therapies, are urgently needed.5,6

The AI-Mind Project

AI-Mind, funded by the European Union’s (EU) Horizon 2020 Research and Innovation Program (grant agreement no. 964220),7 aims to transform diagnostics for mild cognitive impairment (MCI) and dementia through fully automated digital diagnostics and advanced data management. The prodromal phase of dementia is most frequently characterized by MCI, corresponding to “mild neurocognitive disorder,” classified as 6D71 in ICD-11,8 and as 331.83 in DSM-5-TR.9,10 The project runs from 2021 to 2026, integrating two artificial intelligence (AI) tools: the AI-Mind Connector, which identifies dysfunctional brain networks from MEG and EEG recordings, and the AI-Mind Predictor, which uses these data, along with cognitive tests, biomarkers, and clinical variables, to assess dementia risk.

Fully Automated Digital Diagnostics

The AI-Mind Connector and Predictor utilize machine learning (ML) algorithms to analyze complex EEG patterns and biomarkers,
predicting dementia risk with high accuracy. Approximately 50% of individuals with MCI progress to dementia within a few years. Automated diagnostics offer speed, scalability, and consistency, significantly reducing time between screening and diagnosis, handling large data volumes efficiently, and providing consistent results.\(^1,^3\)

**ADVANCED DATA MANAGEMENT AND GOVERNANCE**

AI-Mind excels in data management, operating within a federated infrastructure that ensures robust data protection and compliance with stringent European data privacy standards. The key components include the following:

a) Data integration: merging data from diverse sources, facilitated by advanced data governance frameworks.

b) Standardization: ensuring reliable comparison and analysis through standardized hardware calibrations and data collection procedures.

c) Data curation: using sophisticated algorithms to curate data, ensuring high-quality information for research and diagnostics.

**REVOLUTIONIZING PERSONALIZED NEUROLOGY**

AI-Mind enhances diagnostic accuracy and transforms neurological care:

a) Personalization: identifies individual risk factors and predicts disease progression, allowing for tailored interventions.

b) Predictive modeling: anticipates disease progression, crucial for conditions like dementia where early intervention can significantly alter outcomes.

c) Innovation in research: facilitates novel research methodologies, such as simulation-based studies and virtual labs, enabling hypothesis testing and intervention strategies before clinical trials.

**METHODOLOGY**

AI-Mind’s clinical study involves 1000 MCI participants aged 60–80 years from four European countries (Finland, Italy, Norway, and Spain). Participants undergo clinical assessments, EEG/MEG recordings, computerized cognitive testing, and genetic and protein analyses. Data are stored centrally in Norway, and an AI framework is developed to analyze the data.

**Clinical Study Design**

The study includes a clinical assessment, a baseline visit, and three follow-up visits, each separated by 8 months. Five clinical centers across Europe are involved in recruitment and data collection. Participants are recruited through hospitals, neurological clinics, and community centers, with inclusion and exclusion criteria based on cognitive impairment, functional independence, and the absence of dementia.\(^11,^12\)

**Global Cognitive Screening and Neuropsychological Assessment**

Global cognitive performance is assessed using the Mini Mental State Examination and the Montreal Cognitive Assessment. Neuropsychological assessments evaluate memory, language, attention/executive function, and visual constructive ability. These tests help differentiate between healthy aging, MCI, and dementia.\(^13–^15\)

**Neurophysiological Recordings**

EEG and MEG recordings are collected at clinical sites, with standardized protocols for data acquisition. EEG data are preprocessed using automated pipelines, while MEG recordings enable comparative analysis. Individual magnetic resonance imaging (MRI) templates are used to facilitate data analysis.\(^15\)

**Computerized Cognitive Testing**

The Cambridge Neuropsychological Test Automated Battery tests are administered to assess cognitive functions affected in neurodegenerative conditions. These tests are validated for use on an iPad, ensuring accurate and consistent administration across sites.\(^17,^18\)

**Genetic and Protein Analyses**

Blood samples for DNA isolation and plasma protein assessment are collected. Genetic biomarkers, such as APOE ε4, and plasma tau levels (181, 217) are measured to predict disease progression. These biomarkers are integrated into the AI-Mind Predictor model.\(^19–^22\)

**Data Governance**

All data are stored centrally at the University of Oslo, with metadata collected using secure web forms. Data are verified, curated, and prepared for AI model development at the AI-Mind platform’s file staging area. Ethical approvals and informed consent are obtained from all participants.\(^23,^24\)

**AI Framework**

The AI-Mind Connector identifies brain dysfunction from MEG/EEG data using classical ML and deep learning (DL) models.\(^25\) The AI-Mind Predictor integrates additional data to estimate dementia risk. The AI framework is designed to improve over time, incorporating bias mitigation techniques and uncertainty assessments.

**Model Bias and Uncertainty**

Model bias and uncertainty are addressed through bias mitigation techniques, representative sampling, and cross-validation. Uncertainty quantification improves the accuracy of AI-supported decision-making, increasing trustworthiness.\(^26\)

**AI Framework Front End**

The AI-Mind AI framework includes a front-end interface that generates model cards, providing information on model implementation and architecture. The interface guides users through parameter definition, dataset access, model training, and performance assessment.\(^27\)
Ethical Considerations

AI-Mind addresses the ethical implications of AI-based risk prediction, involving patients, relatives, and health professionals. The project follows European and national guidelines for AI development, the EU AI Act, ensuring transparency, fairness, and accountability.28,29

DISCUSSION

The AI-Mind project7 is a public health-oriented research and innovation initiative aiming to develop a screening tool for cognitive and brain health, specifically for determining dementia risk in MCI. As MCI is often a precursor to dementia, accurate identification and timely treatment of MCI patients at elevated risk have become increasingly urgent, particularly with the global aging population. Currently, subjective and objective cognitive impairments are frequently misattributed to normal aging rather than being further assessed.30 This misattribution is partly due to European clinical practices relying on individual practitioners’ judgments, with extensive neuropsychological evaluations historically bottlenecking healthcare systems and creating long waiting lists globally.31

To address these issues, AI-Mind conducts a comprehensive longitudinal clinical study on MCI subjects, forming the basis for developing two AI-based diagnostic support tools: the Connector and the Predictor. The cornerstone of this endeavor is constructing an extensive and standardized dataset, crucial for achieving the project’s objectives. The standardized and automated Connector and Predictor tools streamline applying these methodologies in future investigations, including potential cross-cultural validation with diverse MCI populations. By deploying these tools, AI-Mind aims to enhance diagnostic capabilities and improve management strategies for cognitive health concerns.

AI is increasingly viewed as key to enabling more efficient prediction of neurodegenerative disease risk in near-future healthcare. However, the technical, ethical, and societal challenges associated with this new technology have not been sufficiently investigated, including its safe use in routine clinical activities and public health programs.32,33 While AI can classify meaningful patterns from large datasets, its integration into traditional clinical work cannot hide the limitations posed by such algorithms’ inputs. Model input is susceptible to adverse influences, including unclassified comorbidities and unequal clinical resource access. Despite advancements combining AI with classic diagnostic tools for predictive medical purposes, its use presents significant ethical challenges. For instance, AI’s introduction in radiology and nuclear medicine is considered a success, yet MRI scanner accessibility varies significantly (e.g., 0.35 units per 100,000 in western countries vs <0.0004 units per 100,000 in Africa).34 The global distribution of positron emission tomography scanners is even more concerning. Additionally, a lumbar puncture for cerebrospinal fluid biomarker analysis is often perceived as invasive and poses greater risks than other dementia diagnostic procedures. Therefore, existing dementia diagnostics, even AI-supported ones, are not necessarily suitable for population-based screening.35 Most of the current AI healthcare research focuses on technical limitations and uncertainty while often ignoring ethical and social dimensions of prediction accuracy. It is crucial to consider the inevitable impact of algorithmic performance on global health responsibilities. Besides pharmaceutical-sponsored trials, few initiatives have been public health oriented and considered global transfer possibilities, with some exceptions.36

While technical challenges have received more attention than social and ethical aspects of AI in healthcare, AI technology remains in its infancy regarding medical applications. Classical ML models typically rely on vast databases of labeled data, but in medicine, most big data do not meet such requirements due to the lack of standardized data infrastructure and the inherent complexity of medical data. Another challenge is adapting AI architectures to various medical data modalities. In AI-Mind, the principal investigation modality is time-series data derived from EEG. While classical ML techniques have shown promising results in diagnostic classification based on features selected by human experts,37,38 relatively little research has applied unsupervised DL techniques to raw EEG data.39 AI-Mind employs both classic ML and DL strategies, acknowledging the challenges of transparency and explainability for their final use as supportive clinical decision-making tools.40–42

Prognosis is intrinsically more complex than diagnosis, involving future projections and inherent uncertainty. For AI to evolve and improve healthcare, solutions must be trustworthy for patients, caregivers, health professionals, and other stakeholders.43 AI-Mind considers trustworthiness methodologically and ethically from three perspectives: explainability, fairness, and uncertainty quantification. Explainability, defined by the European Commission-appointed High-Level Expert Group on Artificial Intelligence, requires that AI system decisions be traceable and understandable by humans.44 Explainability involves interdisciplinary collaboration between medicine and AI experts. Fairness ensures that AI decisions do not introduce bias, discrimination, or stigmatization. In AI-Mind, holdout data is carefully allocated for internal model validation to ensure representativeness, and bias mitigation techniques are employed to address algorithmic bias. The AI development follows principles in the “White Paper on Artificial Intelligence: a European approach to excellence and trust.”28 For developing explainable and non-biased AI models, features and their classification, along with their contributions to decision-making, must be understood. Preliminary results indicate that EEG can be accurately classified by sex and age in a DL context, suggesting potential biases in AI-supported decision-making.45 Uncertainty quantification, often overlooked in AI systems, has been shown to improve human decision-making accuracy.46 Quantifying uncertainty can lead to more secure AI-supported decision-making and better prioritization.

In addition to describing the technical aspects of predictive AI tools in diagnostics, AI-Mind aims to highlight and facilitate discussion on the socioeconomic and ethical aspects of deploying such technology and its global impact. AI-Mind intends to stimulate the future clinical use of AI-supported decision-making tools in European and other hospitals reliably and trustworthy. Collaborating with global and EU-based scientific communities, including the European infrastructure for sensitive data and the eBRAIN-Health infrastructure, AI-Mind aims to deliver quality
AI model training data. These data will be accessible for future intervention studies in virtual lab scenarios, combining AI-Mind data and algorithms with simulation and synthesis technologies to overcome DL limitations and the scarcity of human expertise. Enhancing accuracy and efficiency through hybrid models may elevate medical diagnosis precision, enabling tailored treatment strategies based on individual needs. This paradigm shift improves outcomes for patients facing neurological diseases’ complexity. Moreover, this initiative offers hospitals and clinical research groups the opportunity to test tools, adapt algorithms, and conduct performance comparisons using a federated learning approach. Continuous integration of AI-Mind into the E BRAINS infrastructure, maintaining compatibility with its Knowledge Graph and openMINDS metadata schema, ensures secure data reuse and facilitates future needs like cross-cultural algorithm adaptation.

Developing and implementing AI tools in healthcare raises legal concerns, including liability, patient rights, data and subject protection, health technology assessment (HTA) requirements, medical device regulations, and sustainability requirements. AI-Mind is committed to the European AI strategy and adapts to the future liability and legislation framework of the EU, which is expected during the project period. Bringing AI-Mind innovations to clinics requires meeting these requirements at national and EU levels. Developing and implementing AI-Mind decision support tools necessitates extensive processing of personal data within a secure framework. AI-Mind data processing adheres to the General Data Protection Regulation of the EU and any applicable national legislation concerning data processing and privacy issues. This compliance is ensured by using the University of Oslo’s SSD server services and the E BRAINS infrastructure. All medical devices used in AI-Mind have been routinely employed clinically for several decades. All device deficiencies (malfunction, user errors, and inadequate labeling) are documented and reported by local investigators and appropriately addressed by the AI-Mind project’s management support team.

To meet the United Nations’ sustainable development goals for the 2030 healthcare agenda (United Nations, 2015), the EU aims to create an ecosystem of excellence with a strong value chain involving research, innovation, and eventual exploitation. The European Commission’s White Paper on Artificial Intelligence, the OECD’s High-Level Expert guidelines published in April 2019 (OECD Legal Instruments, 2019), and the World Health Organization’s ethical considerations for health policy and systems research emphasize the need for value-based research and innovation in AI-supported healthcare technologies. Adapting traditional clinical MCI diagnostic procedures to the digital AI age is essential for sustaining European healthcare systems amid aging societies and limited health budgets. The AI-Mind Connector and Predictor will identify MCI patients at risk of dementia, facilitating timely preventive strategies. Conversely, the tools will reduce unnecessary investigations for low-risk individuals. Timely selection of subjects for innovative disease-modifying drugs, which are expensive and have non-marginal side effect risks (e.g., brain edema and hemorrhage), will benefit from AI-Mind’s tools. Thus, AI-Mind may significantly impact healthcare systems and individuals affected by MCI and dementia. Timely identification of at-risk individuals will lead to broader and faster access to adequate care and treatments, improving patient care, resource allocation, and outcomes for those affected by MCI. Therefore, AI-Mind’s academic output will reflect scientific and technical insights in AI-supported medicine and socioeconomic and ethical considerations for global health.

CONCLUSION

AI-Mind aims to transform dementia diagnostics by developing AI tools for early risk prediction. This project addresses technical, ethical, and societal challenges, aiming to improve patient care and optimize resource allocation. The AI-Mind platform holds promise for a future of enhanced diagnostic capabilities and personalized intervention strategies.

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REFERENCES


