



Real-world Study Of Lecanemab In Alzheimer's Disease Using An Integrated Digital Health Platform

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Background

- Lecanemab, the first disease-modifying therapy for early Alzheimer's disease (AD) approved in China, has shown efficacy in the global Phase 3 Clarity AD trial, but real-world data in Chinese populations remain limited. The Yin Fa Tong platform—a WeChat-based digital health ecosystem co-developed by Eisai and JD Health—was implemented as a centralized research database to support a multi-center real-world study in Shandong Province.

Methods

- This is a multi-center, prospective, observational real-world study enrolling patients with early AD (MCI due to AD or mild AD dementia) receiving lecanemab (10 mg/kg biweekly) across multiple sites in Shandong Province. The Yin Fa Tong platform was implemented as a centralized research database for this study. Following each routine outpatient visit, study physicians entered patient data into the platform, including demographic characteristics, clinical assessments (CDR-SB, ADAS-cog14, ADCS MCI-ADL), safety reports (ARIA), caregiver burden (Zarit Burden Interview), and health economic questionnaires.
- Critically, the platform integrates an online medication purchasing function, allowing patients/caregivers to order lecanemab directly through the platform with home delivery. This feature automatically records dispensing dates and quantities, providing objective medication adherence data analogous to pharmacy dispensing records in international studies.

Key platform functionalities included:

- (1) structured electronic case report forms (eCRFs) for all study instruments;
 - (2) automated data validation checks;
 - (3) secure data storage with audit trails;
 - (4) integration with hospital electronic medical record systems for multi-source data fusion;
 - (5) real-time data monitoring and periodic statistical analytics capabilities, providing investigators with multi-site data dashboards tracking enrollment progress, follow-up adherence, and data completeness across all participating centers.
- This approach—analogueous to electronic data capture systems such as REDCap in international research settings—enables standardized data collection, centralized data visibility, and proactive quality management. Feasibility outcomes included patient engagement metrics, follow-up adherence rates, data completeness, user satisfaction assessed via the System Usability Scale, and medication purchasing patterns.

Results

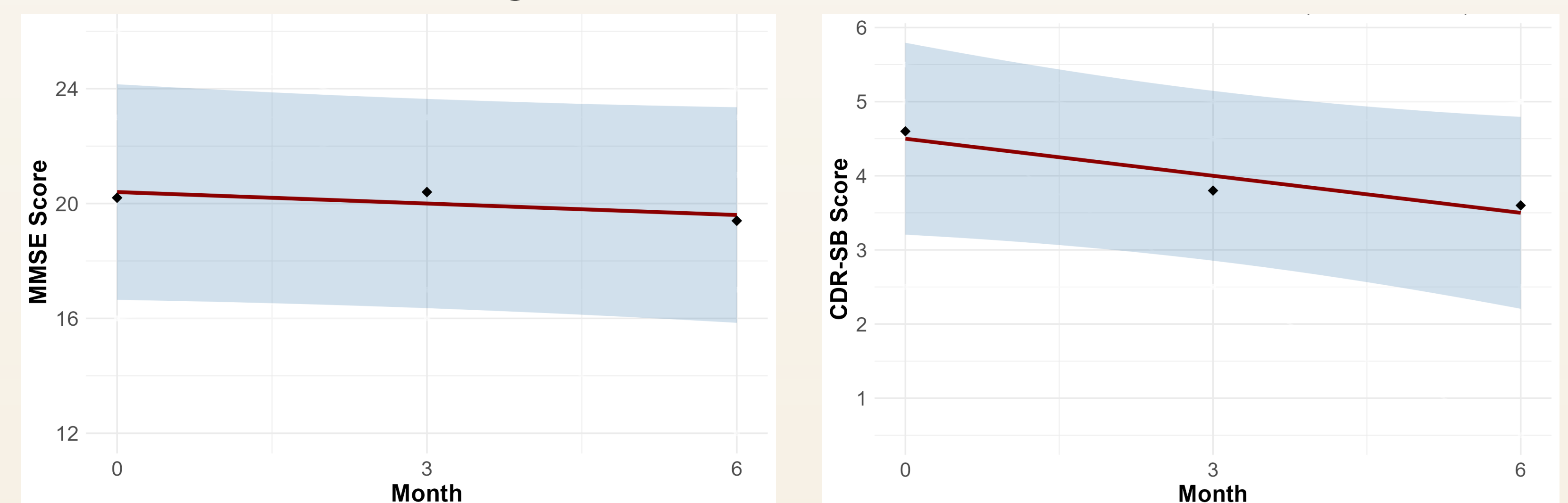
- As of February 2026, 32 patients were enrolled.

Preliminary feasibility data show:

- (1) patient/caregiver weekly active rate of 48%;
- (2) follow-up completion rates of 84.4% at 3 months and 75.6% at 6 months;
- (3) electronic scale data completeness of 98%;
- (4) mean System Usability Scale score of 68 (good acceptability);
- (5) 42% of patients used online ordering, with a mean refill interval of 14 days (high adherence).

- Platform analytics further demonstrate successful multi-site data aggregation, with real-time dashboards enabling study coordinators to monitor site-specific enrollment rates, follow-up completion by timepoint, and data completeness metrics. These analytics capabilities have supported timely study management decisions without awaiting manual data consolidation.
- To date, 16 patients have completed the 3-month follow-up, and 5 have completed the 6-month follow-up.
- The MMSE and CDR-SB results are shown in Figure 1.

Figure 1. MMSE and CDR-SB Results



Conclusion

- The Yin Fa Tong digital health platform, used as a centralized research database with integrated analytics and online medication purchasing, demonstrates feasibility and good user acceptability for real-world lecanemab studies in Chinese early AD patients. Its drug dispensing functionality enhances patient convenience and treatment adherence while providing objective adherence data. Structured data capture integrated into routine workflow improves data standardization, follow-up adherence, and data quality across multi-center settings, offering significant advantages for large-scale real-world studies in neurodegenerative diseases.