

Application of an AI-Based Health Management System in Long-Term Epilepsy Management in Rural Areas

Sponsor: The First Affiliated Hospital of Air Force Medical University

Study Duration: December 1, 2025 – November 30, 2027

Project number: XJLL-KY-20252555

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Study Objectives

- **Primary:**
- Evaluate the efficacy of an AI-assisted telemedicine system versus conventional management in reducing seizure frequency and improving self-management capabilities among rural epilepsy patients.
- **Secondary:**
- Assess impacts on medication adherence, health status, quality of life QoL, safety, and user acceptance.

Study Design

- **Type:** Prospective, multicenter, cluster-randomized controlled trial.
- **Sample Size:** 756 participants.
- **Randomization:**
Clusters health centers randomized by patient volume large/medium/small.
Central randomization via an independent data center.
- **Blinding:** Participants, intervention administrators, outcome assessors, and statisticians are blinded.

Intervention

- **Control Group:**
- Conventional management monthly follow-ups, paper seizure diaries, patient education.
- **Intervention Group:**

- Conventional management + AI-enabled WeChat mini-program "Epilepsy Smart Monitoring and Diagnosis System":

Patient Module: Real-time monitoring, medication reminders, AI consultations, seizure logging, educational resources.

Physician Module: AI-assisted diagnostics, online consultations, data analytics dashboard.

Participant Selection

- **Inclusion Criteria:**
 - Meets ILAE 2017 diagnostic criteria for epilepsy.
 - ≥ 1 bilateral tonic-clonic seizure in the past 12 months.
 - Aged 18–65 years.
 - Access to a smartphone patient/caregiver.
 - Written informed consent.
- **Exclusion Criteria:**
 - Pregnancy, lactation, or planned pregnancy.
 - Seizures with identifiable triggers e.g., alcohol withdrawal.
 - Allergy to phenobarbital/sodium valproate.
 - Severe comorbidities e.g., organ dysfunction, malignancy, psychiatric disorders.

Outcome Measures

Category	Tool/Method	Assessment Timepoints
Primary		
- Seizure reduction	$\geq 50\%$ reduction from baseline	Month 12
- Self-management	Epilepsy Self-Management Scale ESMS	Baseline, Month 12
Secondary		
- Seizure frequency	Monthly seizure rate	Months 3, 6, 9, 12
- Medication adherence	Morisky Scale + pill count	Baseline, Months 3, 6, 9, 12
- Depression	Patient Health Questionnaire-9 PHQ-9	Baseline, Months 3, 6, 9, 12
- QoL	Quality of Life in Epilepsy-10 QOLIE-10	Baseline, Months 3, 6, 9, 12

Category	Tool/Method	Assessment Timepoints
Safety	Adverse events AEs/Serious AEs SAEs	Monthly
Acceptance	Satisfaction survey patients/physicians	Month 12

Statistical Analysis

- **Software:** SPSS 25.0.
- **Methods:** T-test, U-test, χ^2 , Mann-Whitney U.
- **Significance:** $P < 0.05$ two-tailed.
- **Analysis Sets:**
Intention-to-treat ITT for efficacy.
Safety set all receiving ≥ 1 intervention.

Ethics & Compliance

- Approved by the Institutional Review Board IRB.
- Adheres to the Declaration of Helsinki.
- All participants provide informed consent.
- Data anonymization and confidentiality maintained.

Study Workflow

1. **Preparation** Dec2025–Feb2026:
Mini-program optimization.
Cluster randomization, participant screening, baseline data collection.
2. **Intervention** Mar2026–Feb2027:
12-month intervention with monthly follow-ups.
Real-time AE monitoring.
3. **Data Analysis** Mar–May2027:
Database lock and statistical analysis.
4. **Reporting** Jun–Nov2027:
Manuscript and final study report preparation.

AI Model Validation

- **Accuracy Metrics:**
BLEU/ROUGE scores textsimilarity.
Expert evaluation factual correctness, safety, completeness, absence of hallucinations.
- **Clinical Validation:**
IIa trial ($N = 120$): 6-month seizure-free rate.
IIb cRCT ($N = 300$): AI-assisted vs. conventional surgery.

Quality Assurance

- **Training:** All staff certified in protocol and GCP.
- **Data Integrity:**
Case Report Forms CRFs audited within 24 hours.
Double verification for primary endpoints.

- **Oversight:**

Quarterly on-site monitoring.

Independent Data Safety Monitoring Board DSMB for interim analysis.