Research on the Application of Mobile Health Management Mini-Programs in Long-Term Management of Epilepsy in Rural Areas

Sponsor:： The First Affiliated Hospital of Air Force Medical University

Study Duration: December 1, 2025 – November 30, 2028

Project number: XJLL-KY-20252555

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Study Objectives

- **Primary:**

- Evaluate the effectiveness of the remote medical management model using a mobile health management mini-program in improving the self-management ability of rural epilepsy patients.

- **Secondary:**

- Evaluate the impact of this model on patients' medication adherence, quality of life, health status, and frequency of epileptic seizures.

Study Design

- **Type:** Prospective, multicenter, cluster-randomized controlled trial.

- **Sample Size:** 1276 participants.

- **Randomization:** Clusters health centers randomized. Central randomization via an independent data center.

- **Blinding:** Statisticians are blinded.

Intervention

- **Control Group:**

- Conventional management monthly follow−ups, paper seizure diaries, patient education.

- **Intervention Group:**

- Conventional management + WeChat mini-program "Epilepsy Smart Monitoring System":

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

Physician Module: remote follow-up, data analytics dashboard.

Participant Selection

- **Inclusion Criteria**:

1. Meet the diagnostic criteria for epilepsy established by the International League Against Epilepsy (ILAE).

2. Participate in the national rural epilepsy prevention and management project.

3. Aged 18 to 64.

4. The patient or their primary caregiver possesses a smartphone and is capable of using WeChat.

5. Volunteer to participate in the study and sign a written informed consent form.

• **Exclusion Criteria**:

1. Women who plan to become pregnant, are in pregnancy, or are breastfeeding.

2. The seizures are caused by clear and reversible triggers.

3. Those who have achieved epilepsy remission criteria and currently do not require long-term antiepileptic drug management.

4. Severe infections, malignant tumors, severe dysfunction of heart, liver, and kidney functions, or severe physical diseases that the researcher believes will significantly affect epilepsy management, outcome evaluation, or follow-up completion.

5. Individuals with severe mental, cognitive, or communication impairments who are unable to cooperate with research and remote management.

6. It is expected that the participant will not be able to complete the required follow-up visits, or the investigator deems the participant unsuitable for participation in this study.

7. Have participated in any other clinical trials within the past 6 months.

Outcome Measures

Category	Tool/Method	Assessment Timepoints
Primary		
- Self-management	Epilepsy Self-Management Scale (ESMS)	Baseline, Month 6, 12
Secondary		
- Medication adherence	Morisky Scale + pill count Baseline,	Baseline, Months 6, 12
- QoL	Quality of Life in Epilepsy-10 (QOLIE−10)	Baseline, Months 6, 12
- Depression	Patient Health Questionnaire-9 (PHQ−9)	Baseline, Months 6, 12
- Seizure frequency	Monthly seizure rate	Baseline, Months 6, 12
Safety		

Category	Tool/Method	Assessment Timepoints
- Adverse events AEs	Spontaneous reporting + active inquiry, recorded in CRF	Monthly
- Serious AEs (SAEs)	Report Form	Report within 24 hours after occurrence

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–Nov2026: Mini-program optimization. Cluster randomization, participant screening, baseline data collection.

2. Intervention Dec2026–Nov2027: 12-month intervention with monthly follow-ups. Real-time AE monitoring.

3. Data Analysis Dec2027–Apr2028: Database lock and statistical analysis.

4. Reporting May–Nov2028: Manuscript and final study report preparation.

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.