

Telemedicine with mobile internet devices for innovative care of patients with epilepsy (TELE-EPIC_RCT)

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Background: Telemedicine (TM) offers invaluable support to the follow-up of persons with epilepsy (PwE). However, robust data on TM application feasibility, safety, and costs are still lacking (1,2).

Methods: This multicenter, prospective, randomized two-arm controlled trial evaluates the effectiveness of tele visit (TV) *via* TM compared with usual in-office visit (IOV) for the monitoring of PwE. We included adult and pediatric patients with established diagnosis of epilepsy (randomly assigned in a 1:2 ratio to TV or IOV, respectively). Follow-up visits are scheduled at 6, 12, and 18 months. The primary outcome is the non-inferiority of TV compared with IOV on seizure control. Clinical worsening is defined as either: 1) upgrade of at least two frequency categories: daily; weekly; monthly; annually; 2) relapse after a seizure-free period of at least 12 months; 3) new-onset/relapse of convulsive seizures, seizure-related falls, status epilepticus. Secondary outcomes are adherence to treatment, anti-seizure medication-related adverse events, quality of life, mood disorders, patient/caregiver satisfaction, safety, and costs.

Results: We enrolled 505 PwE (mean age 31.4±19), 169 randomized to TV and 336 to IOV. Groups did not differ in gender (M = 52% TV, 47% IOV). Sixty-six TM patients had idiopathic generalized epilepsy, 95 focal epilepsy, three focal and generalized epilepsy, five epilepsy of unknown origin. Twenty-eight TM and 46 UC patients have drug-resistant epilepsy. Thirty-seven TV and 71 IOV patients completed follow-up at 12 months: among them, four TV and nine IOV patients worsened, according to the established criteria. Drop-outs were three (2 TV, 1 IOV).

Conclusions: This is the first randomized controlled trial on TV effectiveness in PwE. Our preliminary data show similar clinical outcomes in the TV and IOV groups, suggesting the non-inferiority of TV in PwE monitoring.

References:

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