



Psychological Database For Brain Impairment Treatment Efficacy

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### Target Area: Seizure Control, Quality of life

Fisher, R., Salanova, V., Witt, T., Worth, R., Henry, T., Gross, R., et al. (2010). Electrical stimulation of the anterior nucleus of thalamus

for treatment of refractory epilepsy *Epilepsia 51*: 899-908

PEDro score - 7/10

# Method/Results

#### Design

- Study Design: double blind RCT
- **Population:** N = 110 adults (18-65, mean 36.1 +/- 11.1, 50% female) with medically refractory partial seizures (at least 6/month, no more than 10/day) who respond poorly to AEDs (at least 3 AEDs failed to produce adequate seizure control).
- Groups:
  - 1. Bilateral stimulation of anterior nuclei of thalamus (n = 54)
  - 2. sham stimulation (n = 55)
- > Setting: Clinical

#### Primary outcome measures:

- ➤ Monthly seizure frequency change from baseline in blinded phase
- Unblinded and long term follow up seizure frequency change

#### Secondary outcome measures:

- Liverpool seizure severity scale (LSSS)
- Quality of life in epilepsy (QoLIE-31)

**Results:** Significantly reduced monthly seizure frequency in those stimulated compared to controls during the blinded phase\* and continued through unblinded and long term follow up phases. Seizure severity decreased and quality of life increased over the 24 months compared to baseline as measured by LSSS and QoLIE-31 respectively.

\*Most effective in subjects with seizure origin in one or both temporal regions. This could be due to n=66 in these subjects compared to the second largest group, n=30 for frontal lobe seizure origins.

## Rehabilitation Program

Aim: Reduce seizure frequency in adults with poor responsiveness to AEDs

Materials: Seizure diaries, LSSS, QoLIE-31, DBS\*

#### Treatment Plan:

- > **Duration:** 2 years
- **Procedure:** Screening and consent. Three month baseline (seizure diary). DBS implanted. One month wait. Three month blind phase (5V 90 µs pulses, 145 pulses 1 min on 5 min off vs. 0V for control). Nine month unblinded phase (100% received stimulation, same parameters as blinded phase). Patients enter long term follow up.
- Content: Treatment occurred at home with continuing use of AEDs

\*Medtronic Model 3387 DBS leads (Medtronic, Minneapolis, MN, USA) connected to a dual-channel Model 7428 Kinetra Neurostimulator (Medtronic) via Model 7482 Low Profile Extensions (Medtronic) connectors tunnelled subcutaneously. Surgeons implanted DBS electrodes in AN bilaterally using a stereotactic technique. Patients were under general anaesthetic. Lead positions were verified with MRI and surgeons were allowed to implant with the use of a frame or a frameless system.