Methodology for a Symptomatic Impact study using a portable Essential Tremor (ET) monitor to direct therapeutic interventions

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Objective

➢ Describe methodology for a novel, symptomatic impact study to assess essential tremor (ET) using a portable ET monitor to direct therapeutic interventions.

Background

➢ Clinical rating scales are available to assess ET in office settings, but they do not capture objective tremor severity at home during activities of daily living.
➢ The ETSense system draws upon clinically validated, FDA cleared Kinesia Home View technology to allow home monitoring of tremor over several hours.
➢ This technology offers the potential to allow a daily time-severity log of tremor to help clinicians better target therapeutic adjustments.
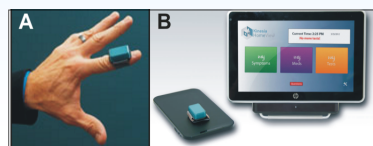

The Kinesia HomeView system includes a wireless finger-worn sensor unit (**A**) and a touch-screen tablet PC with a wireless inductive charging pad for the sensor unit (**B**).

Methods

➢ 40 ET subjects are being recruited at 2 centers.
➢ For the 20 subjects randomized to ETSense experimental group, these data are available to the treating physician and patient at each office visit when medication titration is permitted to improve tremor.
➢ For the 20 subjects randomized to the control group, the ETSense data are stored but not shared until the end of the study.
➢ At each visit, the treating physician and a blinded rater performs the Tremor Rating scale (wTRS), Clinical Global Impression (CGI) Severity (CGI-s) and Change (CGI-c) scales.
➢ The primary outcome measure is the difference in blinded rater's CGI-c score between the experimental and control groups. Secondary analyses will consider changes in the blinded rater's wTRS and CGI-s and patient-based quality of life measures.
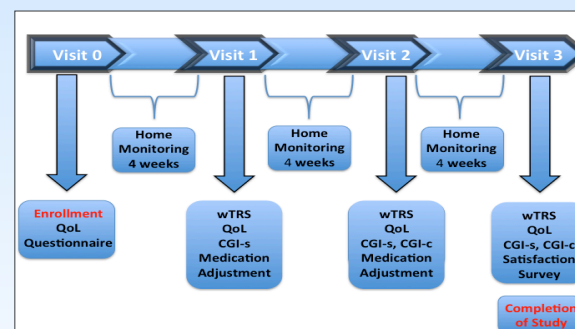
Sample Tremor Data
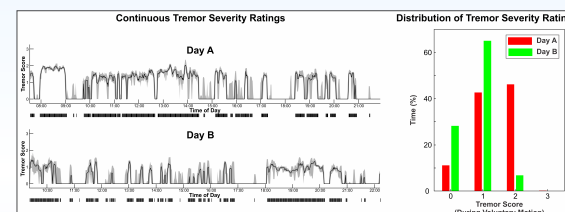
Results

➢ As of June 1 2014, the study has enrolled 32 subjects, and 20 have completed the study.
➢ Training has been straightforward, with successful data transmission for all subjects.

Conclusion

➢ Quantitative real-time assessment of movement disorders is challenging, and so far no studies clearly assess temporal distribution of ET to specifically target therapeutic interventions.
➢ The outcomes of the experimental and control groups will be analyzed to determine if tremor severities and quality of life can be better improved using ETSense continuous home monitoring in regular clinical care.

References

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