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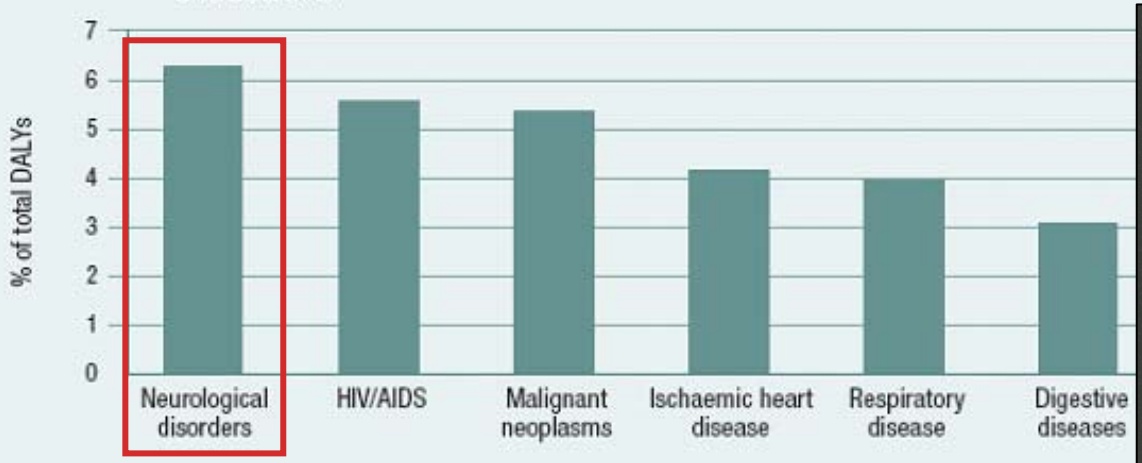
Patients are waiting – the unmet needs

World Health Organization

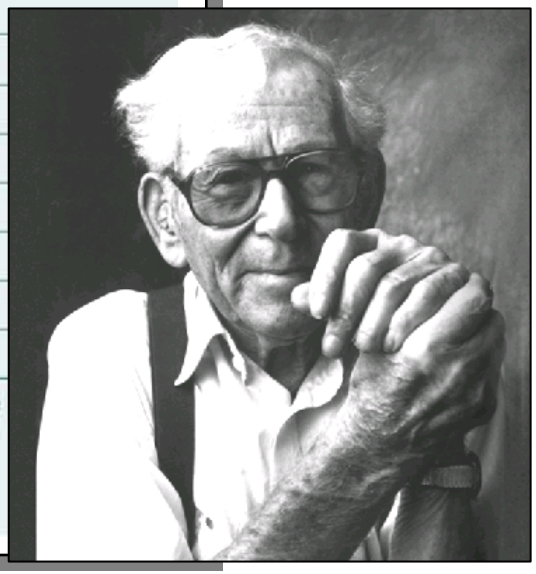
Neurological disorders affect millions globally: WHO report

27 FEBRUARY 2007 | BRUSSELS/GENEVA -- A new report from the World Health Organization (WHO)

Figure 2.1 Percentage of total DALYs for selected diseases[a] and neurological disorders[b]



[a] GBD cause categories
[b] Neuropsychiatric plus other categories



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Randomized Trials of Neurosurgical Interventions: A Systematic Appraisal

George Vranos, M.D.; Athina Tatsioni, M.D.; Konstantinos Polyzoidis, M.D.; John P.A. Ioannidis, M.D.

Neurosurgery 55: 18-26, 2004

- OBJECTIVE: Appraise study design and quality of reporting of randomized controlled trials (RCTs) on neurosurgical procedures; identify potential defects and biases.

- METHODS: Randomized controlled trials (n>/=5) comparing any neurosurgical procedure against another procedure, nonsurgical treatment, or no treatment were retrieved from MEDLINE, EMBASE, and the Cochrane Library. Study design, quality of reporting, and trial results analyzed .

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- RESULTS:
- 108 eligible reports
- median sample size: 68 patients.
- Ninety-nine trials (91.7%) reported inclusion and exclusion criteria,
- 55 (50.9%) mentioned the randomization mode
- 87 (80.6%) adequately described withdrawals
- Only 31 (28.7%) described allocation concealment
- Only 23 (21.3%) gave power calculations
- Only 20 (18.5%) were adequately powered.

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- RESULTS:
- Significant efficacy or trend for efficacy was claimed in 46 reports (42.6%), and no difference between the compared procedures was found in 60 trials (55.6%).
- Trials with a larger sample size were more likely to report withdrawals (P = 0.02) and power calculations (P = 0.006).
- Only 14 trials (13.6%) were double-blind, and this was less frequent in longer trials (P = 0.02).
- Among quality criteria, only the reporting of randomization mode improved significantly over time (P = 0.015).

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- CONCLUSION: Several aspects of the design and reporting of randomized controlled trials on neurosurgical procedures can be improved. Larger, adequately powered, and accurately reported trials are needed.

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Studying neurosurgical implants for Parkinson disease: A question of design

A. W. Prehn, PhD, D. E. Vawter, PhD, K. G. Gervais, PhD, R. G. DeVries, PhD, J. E. Garrett, JD, T. B. Freeman, MD and T. Q. McIndoo, MA

NEUROLOGY 2006;67:1503-1505

North American researchers' perspectives on designing neurosurgical implant studies for Parkinson disease (PD) challenged the custom of holding surgical trials to less stringent evidentiary standards than other clinical studies. Researchers supported placebo surgery–controlled trials. The framework they used to design and evaluate studies both of deep brain stimulation and cellular implants for PD may be applicable to a broad range of surgical implants for other disorders.

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Placebo-Controlled Procedural Trials for Neurological Conditions

Sam H. Horng and Franklin G. Miller ; Neurotherapeutics July 2007

Neurological disease has been a central focus in the ongoing ethical debate over the use of invasive placebo controls, especially sham surgery. The risk to research subjects and necessary use of deception involved in these procedures must be balanced against the methodological need to control for bias and the placebo effect. We review a framework formulated for the ethical assessment of sham surgery in the context of research evaluating novel procedures for neurological conditions. Special issues raised include the growing evidence of expectation and conditioning effects in a number of neurological diseases, the escalating scale of risk from different types of invasive placebo interventions, and the increasing use of cross-over designs, which allow a switch from placebo to active intervention without additional procedures.