

ALZHEIMER'S DISEASE CLINICAL TRIALS IN 2001: A CHANGING RESEARCH ENVIRONMENT? V. O'Neill, H. Feldman, B. L. Beattie. *Clinical Trials Unit, Clinic for Alzheimer's Disease and Related Disorders, Vancouver Hospital & Health Sciences Centre – UBC Site, Vancouver, BC.*

Introduction: The future of placebo controlled clinical trials in Alzheimer's Disease (AD) has become uncertain, and we want to evaluate whether the recruitment of subjects at our AD clinical trials unit has changed following the approval of donepezil in Canada, in September of 1997.

Methods: A retrospective review of recruitment logs was compared for each placebo controlled clinical trial from 1992 to 1997

and then 1997 to 2000. Staff and recruitment strategies were constant throughout the study period. The average length of recruitment was 6-8 months.

Results: Between 1992 and 1997, there were 7 placebo controlled clinical trials conducted with a mean recruitment of 14.3 subjects per trial (SD=2.4). Following September 1997, there were 4 placebo controlled clinical trials conducted with a mean recruitment of 7.8 subjects per trial (SD=2.8).

Conclusion: These results indicate that it has become more difficult to recruit for AD placebo controlled clinical trials and that both innovative study designs and recruitment strategies will be needed for successful progress in future clinical trials.

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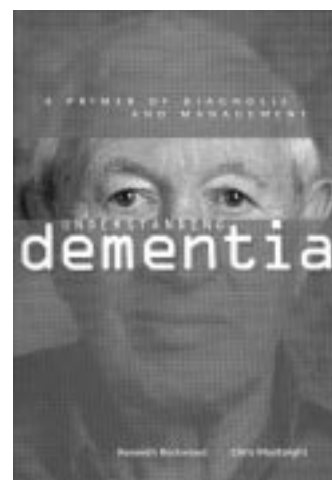
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