know why the authors did not try to compare the efficacy of citalopram with existing antidepressants.

Cochrane, A. L. (1989) *Effectiveness and Efficiency: Random Reflections on Health Services*. London: British Medical Journal.

Klysner, R., Bent-Hansen, J., Hansen H. L., *et al* (2002) Efficacy of citalopram in the prevention of recurrent depression in elderly patients: placebo-controlled study of maintenance therapy. *British Journal of Psychiatry*, **181**, 29–35.

National Health and Medical Research Council (1999) *National Statement on Ethical Conduct in Research Involving Humans*. Canberra: NHMRC.

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Authors' reply: Drs Jainer and Soni have addressed an important issue in clinical trials in depression when commenting on our article. Our study was the first specifically designed and conducted to evaluate the therapeutic value of prevention of recurrence of a depressive episode in an elderly population. The study was designed using the concept of the three phases of antidepressant treatment: acute, continuation and maintenance treatment (Montgomery *et al*, 1988). The study is unique in that the majority of the population had suffered only one documented depressive episode upon admission into the study.

At the time the study was initiated, there was sparse evidence for the value of prophylactic treatment after a first episode of depression in elderly patients. Thus, the requirement that there be no 'other available treatment [that] has already been clearly shown to be effective' was fulfilled.

Prior to initiating the study, the local ethics committee approved the protocol as well as the patient information and the informed consent form. The patient information explicitly mentioned the use of placebo in the double-blind period. All patients gave written informed consent before being included in the study.

Existing guidelines clearly stipulate that treatment of at least 6 months' duration is necessary to reduce the risk of relapse. The study complied with this by providing active treatment with citalopram for 24 weeks. Only patients in remission, after a total of 24 weeks of treatment with citalopram, were randomised to double-blind treatment with citalopram or placebo. The patients were closely monitored during the double-blind period until discontinuation or completion. Patients with recurrence of depression in the double-blind treatment period were withdrawn and treated at the investigators' discretion.

In addition, an active-comparator trial can only provide information regarding relative effect, but not whether prophylactic treatment is clinically warranted. The absolute value of prophylactic treatment can only be concluded from a placebo-controlled trial. Thus, the study had a placebo-controlled design for the double-blind period, in accordance with the National Health and Medical Research Council guidelines as cited by Drs Jainer and Soni ('If there is a genuine uncertainty about the net clinical benefit of a treatment, a placebo controlled trial or a trial with a no-treatment arm may be considered').

The study established that long-term treatment with citalopram is effective in preventing recurrence of depression in the elderly and is well tolerated. With this knowledge, along with other currently available information, we certainly agree with the authors that the appropriateness of conducting similar studies in the future should be considered. However, our opinion notwithstanding, there is no consensus regarding the need for prophylactic treatment in the elderly. Until clinical practice and guidelines are changed, studies of a similar nature will have to be undertaken to convince the scientific community of the value of long-term treatment.

Declaration of interest

The study in question was funded by H. Lundbeck A/S. M.A. is an employee of H. Lundbeck A/S.

Montgomery, S. A., Dufour, H., Brion, S., *et al* (1988) The prophylactic efficacy of fluoxetine in unipolar depression. *British Journal of Psychiatry*, **153** (suppl. 3), 69–76.

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Costs of dementia

In their recent paper, Wolstenholme *et al* (2002) demonstrated that changes in cognitive and functional status have independent and significant effects on the costs of care in dementia. We agree with the authors that models of costs based solely on measures of cognitive changes are inappropriate to describe variables influencing the costs of dementia. From 1994 to 1999 we conducted in Italy a longitudinal study on costs of Alzheimer's disease (the CoDem Study), based on information obtained every 6 months from a sample of 148 patients with Alzheimer's disease living at home (73.6% female, mean (s.d.) age 78 (7.8) years, mean (s.d.) Mini-Mental State Examination (MMSE) score at baseline 8.9 (8.3)), estimating direct and indirect costs of dementia (Trabucchi *et al*, 1996). In a preliminary analysis after the first year of observation, using a logistic regression analysis, we found that greater annual costs for Alzheimer's disease are significantly associated more with disability than with cognitive decline (Bianchetti *et al*, 1998). Following this line of investigation, we evaluated the modification of costs with the progression of the disease at the end of the 6-year longitudinal study with a Markov state transition model based on the comparison of costs for different states of cognitive and functional decline (measured using the MMSE and the Basic Activities of Daily Living (BADL) scale) (Jönsson *et al*, 1999). In our study total costs (per year) for dementia care varied from €15 450 (£9972) for independent patients (BADL lost=0), to €21 463 (£13 853) for partially independent subjects (1–3 BADL lost) and €23 762 (£15 336) for totally dependent patients (4–6 BADL lost). Using the MMSE, the costs varied from €18 024 (£11 633) for patients with mild Alzheimer's disease (MMSE >20), to €19 665 (£12 692) for patients with moderate decline (MMSE 15–20) and €25 351 (£17 077) for patients with severe cognitive decline (MMSE 8–14) (Trabucchi, 1999).

Our data, obtained in a sample of subjects with Alzheimer's disease living in a different social and cultural context, strengthen those obtained by Wolstenholme and colleagues, emphasising in particular the need to demonstrate an effect on functional status in the cost-effectiveness analysis of interventions in dementia.

Declaration of interest

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