

Authors' reply: We would like to emphasise that our study included nationwide data on the use of all antidepressants in Denmark wherever prescribed (including from primary care), however nationwide data on the diagnosis of depression were only available from in-patient and out-patient psychiatric hospital settings (and not from primary care). Thus, as argued in our paper, we believe our findings can be generalised to all women taking antidepressants during pregnancy regardless of the indication for treatment (depression, anxiety disorder, etc.) or the severity of illness.

Although, the study included more than 34 000 women who used an antidepressant before or during pregnancy, this number was too small for separate analyses of the individual antidepressants divided into the eight risk groups defined in the study. Register-based medication studies at present do not have access to data on the dose of drug treatment or on patient adherence to the drug. We did try to adjust our analyses for physical disorder in the mother as all analyses were adjusted for all other types of medication (in addition to antidepressants) that the mother may have used during pregnancy, in this way taking account of treated physical and mental disorders as well as depressive and anxiety disorders. We further adjusted analyses for maternal age, employment status, smoking status, calendar year, parity, gender of the newborn, \pm birth weight and \pm gestational age, however we did not include data on nutrition of the mother and on obstetric complications as suggested. Obstetric complications may rather be intermediary factors than confounders.

Regarding the gestational age of all mothers, this was correctly indicated in Table 1 as a median of 39 (interquartiles 39–39), as infants with a gestational age less than 22 weeks were excluded from analyses and the vast majority of children were born within week 39.

Like Nebhinani & Soni, we hope the study will provide impetus for future research in this increasingly important area, especially as the use of antidepressants during pregnancy is believed to increase even further in the future.

Declaration of interest

L.V.K. has been a consultant for Bristol-Myers Squibb, Eli Lilly, Lundbeck, AstraZeneca, Pfizer, Wyeth, Servier, and Janssen-Cilag.

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Are the conclusions supported by the evidence?

Many people might be confused about the term 'placebo' that is used in Baxendale *et al's* study.¹ The paper clearly refers to the low-intensity-light arm as receiving placebo treatment, and the clinical trial registration (<http://clinicaltrials.gov/show/NCT01028456>) also indicates that the low-intensity group is receiving a placebo. However, this has some implications for the interpretation of the results.

If the low-intensity arm is indeed a placebo, the active treatment group did not differentiate from placebo and this is, therefore, a negative study. If, however, the low-intensity arm is receiving an active treatment then there is no placebo group and we cannot determine whether any changes in symptoms were due to the treatment or would have occurred by chance.

The conclusions that light therapy may 'be an effective treatment for symptoms of low mood in epilepsy at lower

intensities than those typically used to treat seasonal affective disorder' cannot be supported by the findings of this study, since there was not an adequate control group. Further, the authors acknowledge that a number of non-specific factors may account for any improvements in depression and anxiety and all participants received relaxation. I strongly suspect that the fact that the participants had their eyes open during relaxation does not negate the effects on anxiety that relaxation training might have. In addition, most of the improvement in both groups (particularly on the depression subscale) had occurred before they were exposed to the intervention, i.e. at T_2 .

The clinical trial registration indicates that the control arm should have been receiving 100 lux for 30 min a day and the active arm 10 000 lux for 30 min a day. The study suggests that both arms received 20 min of light per day, with the control arm receiving an intensity of 2000 lux. It is not clear why the intensity was increased.

The attrition rate was high in both groups: 18/45 (40%) in the control arm and 15/46 (32.6%) in the active arm. Five patients in the active arm had an increase in seizures or required their medication to be increased (compared with two patients in the control arm). In the other paper emerging from this study,² the authors caution about using bright light in this population because 'it may result in an increase in seizures for some'. None of this caution is evident in the paper published in the *British Journal of Psychiatry*. Indeed, there is not a single mention of adverse effects, despite them being reported elsewhere.

The analysis does not appear to have been intention-to-treat, and the results are only reported for those patients that completed the trial. This is a significant weakness when the authors have reported the possibility of adverse effects in other journals and when the attrition rates are relatively high. It is not clear why this intervention in an epilepsy population is treated with some reservations, yet it is reported much more favourably when there are some improvements in a secondary outcome measure reflecting some aspects of mental health (anxiety and depressive symptoms) which occurred before the intervention.

- 1 Baxendale S, O'Sullivan J, Heaney D. Bright light therapy for symptoms of anxiety and depression in focal epilepsy: randomised controlled trial. *Br J Psychiatry* 2013; **202**: 352–6.
- 2 Baxendale S, O'Sullivan J, Heaney D. Bright light therapy as an add on treatment for medically intractable epilepsy. *Epilepsy Behav* 2012; **24**: 359–64.

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Author's reply: Dr Christmas is quite correct in reiterating the uncertainty we expressed in our discussion about the placebo condition in our study. This does indeed have very significant implications for the interpretation of our results. It is for this reason that we suggested a number of different interpretations for our findings in the Discussion, including the possibility that light therapy 'may, therefore, be an effective treatment for symptoms of low mood in epilepsy at lower intensities than those typically used to treat seasonal affective disorder'. We also discussed the possibility that this could indeed be a negative finding or that the results we found could be due to other factors unrelated to light therapy, such as the establishment of fixed morning routines.

Dr Christmas is correct in that in the original protocol for the study the control arm should have been receiving 100 lux. The modifications to the original protocol were submitted with the paper as an online appendix, to conform to the CONSORT