Reviewer’s report

Title: Quality of life and metabolic status in mildly depressed patients with type 2 diabetes treated with paroxetine: A double-blind randomised placebo controlled 6-month trial

Version: 3 Date: 1 October 2006
Reviewer: Ruth S Weinstock

Reviewer’s report:

General

The questions posed by the authors are interesting and important. I recommend that a biostatistician review this manuscript.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) My major concern relates to the small sample size. The power calculation should be reviewed by an independent statistician. The authors state that they needed 19 patients per group to show a significant difference in A1c, but they only had 14 subjects in the placebo group completing the study. The negative result could be due to inadequate numbers of subjects.
2) Only 56% (14/25) of the placebo subjects completed the study, whereas 96% (23/24) subjects randomized to drug completed the study. This is a big problem. Why? Again, a larger "n" would be helpful.
3) Was the study powered to detect a 20% improvement in the RAND-36 score (which the authors state is their primary global outcome)?
4) In the methods, the authors state that "Differences between groups in mean changes from baseline were analyzed..." but Table 2 and 3 only report median changes.
5) Because of the above concerns, I am concerned that the conclusions may not be valid.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

There are a number of spelling and grammatical errors. This manuscript needs editing by an individual fluent in English.

Discretionary Revisions (which the author can choose to ignore)

What next?: Reject because scientifically unsound

Level of interest: An article of insufficient interest to warrant publication in a scientific/medical journal

Quality of written English: Needs some language corrections before being published

Statistical review: Yes

Declaration of competing interests:

I declare that I have no competing interests