

## Sleeping pills owe half their benefits to placebo effect, study finds

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Half of the benefit of taking sleeping pills comes from the placebo effect, according to a major new study published in the British Medical Journal.

Researchers re-analysed results from more than a dozen clinical trials of the most common type of sleeping tablets, known as Z-drugs (nonbenzodiazepine hypnotics).

These drugs are frequently used in the UK and USA as a short-term treatment for insomnia with almost £25m worth of prescriptions handed out in Britain each year. However, some <u>health experts</u> have questioned whether the benefits of Z-drugs justify their side effects, which can include <u>memory loss</u>, fatigue and impaired balance.

Questions have also been raised about the validity of published research into the effects of these drugs based on trials sponsored by pharmaceutical companies themselves.

Academics from the University of Lincoln, Harvard Medical School and University of Connecticut conducted a meta-analysis of data from clinical trials of Z-drugs comparing drug effects with placebo effects. This type of comparison enables researchers to determine how much of the drug effect comes from the constituents of the drug itself, and how much is due to other factors (like the <u>placebo response</u> or regression to the mean).



They used data submitted by pharmaceutical companies to the <u>US Food</u> and <u>Drug Administration</u> (FDA) for approval of new products. This included 13 clinical trials containing 65 different comparisons and more than 4,300 participants.

The FDA collates results from both published and unpublished studies, enabling researchers to avoid common types of bias (such as reporting bias) which can undermine other research based on sponsored trials.

Their findings, published in this week's *British Medical Journal*, indicate that once the <u>placebo effect</u> is discounted, the drug effect is of 'questionable clinical importance'.

Lead author Professor Niroshan Siriwardena, from the School of Health and Social Care at the University of Lincoln, said: "Our analysis showed that Z-drugs did reduce the length of time it took for subjects to fall asleep, both subjectively and as measured in a sleep lab, but around half of the effect of the drug was a placebo response.

"There was not enough evidence from the trials to show other benefits that might be important to people with sleep problems, such as sleep quality or daytime functioning.

"We know from other studies that around a fifth of people experience side effects from sleeping tablets and one in one hundred older people will have a fall, fracture or road traffic accident after using them.

"Psychological treatments for insomnia can work as effectively as sleeping tablets in the short-term and better in the long-term, so we should pay more attention to increasing access to these treatments for patients who might benefit."

He said future studies of sleeping tablets should investigate a broader



range of outcomes, not just time taken to fall asleep, and that pharmaceutical companies should be more transparent in disclosing results from their studies so that researchers can independently analyse their results.

The paper 'Effectiveness of non-<u>benzodiazepine</u> hypnotics in the treatment of adult insomnia: meta-analysis of data submitted to the <u>Food and Drug Administration</u>' was published in the <u>British Medical Journal</u> on 17th December 2012.

**More information:** 'Effectiveness of non-benzodiazepine hypnotics in treatment of adult insomnia: meta-analysis of data submitted to the Food and Drug Administration'; Tania B Huedo-Medina, Irving Kirsch, Jo Middlemass, Markos Klonizakis, A Niroshan Siriwardena; BMJ 2012; 345 doi: dx.doi.org/10.1136/bmj.e8343 (Published 17 December 2012)

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