

Most people don't sleep any worse when taking medicines with sleep disturbance warnings

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Medicines that carry warnings about sleep disturbances do not seem to contribute to the amount of sleep disturbances in the general population, according to new 'real world' research. The findings, which are published in the *British Journal of Clinical Pharmacology* suggest that investigators may need to provide more careful reporting of side effects in clinical trials, and emphasizes the value of research into the safety of medicines once they are being taken by the general population.

Sleep disturbances and their consequences can have considerable impacts on health. Drugs are labeled as sleep disturbing in patient information leaflets due to findings from <u>clinical trials</u>, but it's unclear whether these drugs actually lead to more sleep disorders—such as difficulties falling or staying asleep, or waking in the early morning—in the general population. To investigate Anna-Therese Lehnich, of the University of Duisburg-Essen in Germany, and her colleagues analyzed information on 4,221 individuals aged 45 to 75 years.

Interviews revealed no clear links between drugs labeled as sleep disturbing with actual experiences of problems related to sleep. "We found that drugs labeled as sleep disturbing do not contribute strongly to the high frequency of sleep disturbances in the general population. Moreover, the intake of several sleep disturbing drugs at the same time barely led to more sleep disturbances at night," said Lehnich. "Surprisingly, we could not show that the frequency



categories—'uncommon,' 'common,' and 'very common'—for the occurrence of sleep disturbances from patient information leaflets result in different frequencies of sleep disturbances."

More information: "Do patients with intake of drugs labelled as sleep disturbing really sleep worse? A population based assessment from the Heinz Nixdorf Recall Study." Anna-Therese Lehnich, Bernd Kowall, Oliver Kuß, Andrea Schmidt-Pokrzywniak, Gerhard Weinreich, Nico Dragano, Susanne Moebus, Raimund Erbel, Karl-Heinz Jöckel, and Andreas Stang. *British Journal of Clinical Pharmacology*. Published Online: June 9, 2016, DOI: 10.1111/bcp.13015

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