

## Substantial recovery rate with placebo effect in headache treatment

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Headache is a very common complaint, with over 90% of all persons experiencing a headache at some time in their lives. Headaches commonly are tension-type (TTH) or migraine. They have high socioeconomic impact and can disturb most daily activities. Treatments range from pharmacologic to behavioral interventions. In a study published online today in the *Journal of Manipulative and Physiological Therapeutics*, a group of Dutch researchers analyzed 119 randomized controlled clinical trials (RCTs) and determined the magnitude of placebo effect and no treatment effect on headache recovery rate.

"Although the intention of control and placebo interventions in research studies is to be relatively ineffective, the question rises as to what factors might cause improvement seen in these groups," commented corresponding investigator Arianne P. Verhagen, PhD, Assistant Professor, Department of General Practice, Erasmus Medical Center, Rotterdam, The Netherlands. "The aim of this study was to analyze the observed effects in the 'no treatment' and placebo control groups in <a href="clinical trials">clinical trials</a> with TTH and migraine patients."

In the headache clinical trials studied, the "no treatment" and placebo groups had a high overall recovery rate of 36%. Control groups in pharmacological trials showed a higher response rate than the behavioral (non-pharmacological) trials (38.5% vs. 15.0%). Patients had higher recovery rates in the acute treatments compared with the prophylactic treatments (39.6% vs. 32.8%). Knowing that a substantial portion of patients improve without treatment is important when considering the



benefits and risks of daily headache treatment.

Pharmacological treatment typically starts when non-pharmacological treatments like <u>lifestyle changes</u>, relaxation therapy, cognitive therapy, and reassurance do not work. Many of the prescribed or over-the-counter medications, such as <u>non-steroidal anti-inflammatory drugs</u> (NSAIDs), may lead to adverse events and medication overuse headache. Considering the risks of adverse events, the authors recommend that "the prescription of medication needs to be carefully considered and evaluated with each individual patient. Because of the recovery results in 'no treatment' control groups in pharmacological trials, the question rises whether or not this way of prescription is always preferable over no treatment (wait and see) especially in the TTH population."

**More information:** The article is "Headache: The Placebo Effects in the Control Groups in Randomized Clinical Trials; An Analysis of Systematic Reviews" by Femke M. de Groot, BSc, Annieke Voogt-Bode, BSc, Jan Passchier, PhD, Marjolein Y. Berger, MD, Bart W. Koes, PhD, and Arianne P. Verhagen, PhD. It will appear in the *Journal of Manipulative and Physiological Therapeutics*, Volume 34, Issue 5 (June 2011), DOI 10.1016/j.jmpt.2011.04.007

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