

A closer look at the placebo effect

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Placebos are "dummy pills" often used in research trials to test new drug therapies and the "placebo effect" is the benefit patients receive from a treatment that has no active ingredients. Many claim that the placebo effect is a critical component of clinical practice.

But whether or not placebos can actually influence objective measures of disease has been unclear. Now a study of asthma patients examining the impact of two different placebo treatments versus standard medical [treatment](#) with an albuterol bronchodilator has reached two important conclusions: while placebos had no effect on lung function (one of the key objective measures that physicians depend on in treating [asthma patients](#)) when it came to patient-reported outcomes, placebos were equally as effective as albuterol in helping to relieve patients' discomfort and their self-described [asthma symptoms](#).

The study was led by Harvard Medical School investigators at Brigham and Women's Hospital (BWH) and Beth Israel Deaconess Medical Center (BIDMC) and appears in the July 14 issue of *The [New England Journal of Medicine](#)* (*NEJM*).

"We were trying to understand whether a placebo effect exists and, if so, whether it was similar with regard to both objectively and subjectively reported measures, and whether similar effects could be observed using different types of placebo," explains lead author Michael Wechsler, MD, Associate Director of the Asthma Research Center at BWH and Assistant Professor of Medicine at Harvard Medical School (HMS).

The study examined 39 patients with [chronic asthma](#) who were randomly assigned to undergo treatment with an active albuterol inhaler, with a placebo albuterol inhaler, with sham acupuncture, or with no intervention at all. The researchers administered one of each of the three treatment interventions to each of the study participants, plus a no intervention session, in random order during sequential medical visits (three to seven days apart from each other). The procedures were repeated in two more blocks of visits, such that each patient had a total of 12 medical visits.

At the study's conclusion, findings showed that treatment with the albuterol inhaler resulted in a 20 percent increase in FEV1 (maximum forced expiratory volume in one second), a measure of lung capacity. This compared with an increase of approximately seven percent in each of the two placebo treatments as well as the "no treatment" control.

"Since there was no difference between either of the placebo treatments and the placebo 'control' [no treatment], we can report that there was no objective placebo effect with regard to change in lung function," says Wechsler.

However, patients' descriptions of their symptoms suggested that a subjective placebo effect does exist: patients reported statistically significant symptomatic improvement with albuterol, as well as with the placebo inhaler and with sham acupuncture. This compared to little improvement, if any, when patients received no treatment at all.

"We chose to study patients with asthma because earlier evidence had suggested that placebos would change the underlying medical problem," explains senior author Ted Kaptchuk, Director of the Program in Placebo Studies at BIDMC and Associate Professor of Medicine at HMS. "While I was initially surprised that there was no [placebo effect](#) in this experiment [after looking at the objective air flow measures] once I

saw patients' subjective descriptions of how they felt following both the active treatment and the placebo treatments, it was apparent that the placebos were as effective as the active drug in helping people feel better."

These findings, says Wechsler, suggest that physicians and investigators reconsider the implications of subjective, patient-reported outcomes in clinical trials, and consider having a "placebo for the placebo" to monitor a patient's natural history.

"Despite beneficial effects on objective physiological outcome, pharmacologic therapy may not provide incremental benefit on subjective symptoms provided by placebos," Wechsler adds. "But while placebos remain an essential component of clinical trials to validate objective findings, assessment of natural history is essential in the final assessment of patient-reported outcomes."

At the same time, adds Kaptchuk, the study results imply that [placebo](#) treatment is just as effective as active medication in improving patient-centered outcomes.

"It's clear that for the patient, the ritual of treatment can be very powerful," notes Kaptchuk. "This study suggests that in addition to active therapies for fixing diseases, the idea of receiving care is a critical component of what patients value in health care. In a climate of patient dissatisfaction, this may be an important lesson."

Provided by Beth Israel Deaconess Medical Center

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