

## ***Open-Label Placebos Are Deceptive and Should Not Be Used in Clinical Practice***

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Open-label placebo (OLP) research has proliferated rapidly in the past two decades, with studies claiming benefit for irritable bowel syndrome, chronic pain, ADHD, allergic rhinitis, and other conditions.<sup>1</sup> Some scholars even suggest using OLPs in clinical practice.<sup>2</sup> A central tenet of such research is that OLPs carry the benefits of placebos but without the deception.<sup>3</sup>

The premise is simple. Patients are told they are receiving an inert pill, something “like sugar pills,” often paired with an explanation that placebos have been shown to produce mind–body healing “in rigorous clinical testing.” This message, or close variants, appears across much of the literature.<sup>4</sup> What follows is often framed as a surprising result: the pill, despite being openly disclosed as inert, still appears to help.

This apparent breakthrough, however, rests on a sleight of hand. The improvement observed in OLP trials does not follow from the pill itself (such as if it were to be shorn of its context and administered surreptitiously). OLP researchers are well aware of this, attributing the effect to the total encounter: the framing, the ritual, the patient–clinician relationship, uncertainty, subtle cues of hope and legitimacy, and even mechanisms such as prediction, error

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<sup>1</sup> Fendel JC, Tiersch C, Sölder P, Gaab J, Schmidt S. Effects of open-label placebos across populations and outcomes: an updated systematic review and meta-analysis of randomized controlled trials. *Sci Rep.* 2025;15(1):29940. <https://doi.org/10.1038/s41598-025-14895-z>

<sup>2</sup> Hardman D, Miller F. A worthwhile wager: the ethics of open-label placebo treatment in clinical practice. *J Med Ethics.* 2025;51:689-692. <https://doi.org/10.1136/jme-2024-110270>

<sup>3</sup> Kaptchuk TJ, Friedlander E, Kelley JM, et al. Placebos without deception: a randomized controlled trial in irritable bowel syndrome. *PLoS One.* 2010;5(12):e15591. <https://doi.org/10.1371/journal.pone.0015591>

<sup>4</sup> Heiss U, Rosenfield M, Bernstein MH. Can the open label placebo rationale be optimized? *Front Pain Res (Lausanne).* 2021;2:734882. <https://doi.org/10.3389/fpain.2021.734882>

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processing, and embodied cognition.<sup>5</sup> Indeed, what OLP research has indicated is that, unlike traditional placebos, the mechanisms underlying OLPs' putative positive effects don't appear to strongly involve positive expectations.<sup>6</sup>

However, in OLP trials, researchers treat the taking of the pill as if it were the active element and do not clearly or accurately explain to study participants how OLPs might exert their putative benefits. This problem would seem to reach a boiling point in clinical practice: even if it were theoretically possible to explain to patients how OLPs work, or at least their risks and benefits, in a way that adequately informs them according to principles of informed consent, clinicians should explain that context is the likely source of the potential benefit; it could arise from ritual, hope or optimism, or even the attention from the doctor. Clinicians should be careful not to overstate effectiveness or extrapolate potential outcomes based on clinical trials with a blinded placebo arm. Patients should be told that placebos administered openly are qualitatively different from traditional placebos in terms of mechanisms and potential or expected effects.

OLPs thus engage in a different kind of dishonesty than that of traditional deceptive placebos—one that centers not on what the patient is physically given, but on what they are led to believe. Patients are told the name of what they're receiving ("a placebo"), but not the ambiguity of that term. They're told it's inert, but also that it can help. But if a placebo is inert, then by definition it does not have a therapeutic effect. The claim that it has been shown to produce improvement contradicts the very definition OLP researchers offer. In this sense, the deception has not been removed but has been subtly reframed. What this reveals is not merely a problem of communication, but of conceptual coherence. There is no consensus—philosophical, clinical, or regulatory—on what a placebo even is. Yet OLP scripts speak as if there were. The result is a contradiction embedded in the heart of the treatment. Patients are not just misled about the pill's therapeutic features. They are misled about its significance and about the very nature of the placebo concept. Some patient testimony already points to the idea that if OLPs were offered in clinical practice, this could make them feel frustrated and disheartened, as if they were being told their ailments were all in their mind.<sup>7</sup>

Other concerns have also been raised, including confusion between placebo effects and responses, the lack of patient involvement in OLP research, and ethical risks such as stigmatization, erosion of trust, and delayed access to effective care.<sup>8</sup> None of this denies that meaning and ritual can heal. Indeed, what OLPs inadvertently highlight is that the context of medicine—the words, the theatre, the rituals—matters deeply. While our focus here is on OLP use in clinical practice, research on OLPs may be beneficial. For example, it could further elucidate the role of hope and other mechanisms in medical treatments in general. But the ethical response in clinical practice is not to rebrand these forces as a new, honestly delivered, scientifically grounded treatment. That is where they would represent a step backward. In trying to mitigate the deceptive aspects of placebos, OLPs obscure both their epistemic fragility and their philosophical complexity. They replace one kind of ambiguity with another while claiming to do neither.

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<sup>5</sup> Kaptchuk TJ. Open-label placebo: reflections on a research agenda. *Perspect Biol Med*. 2018;61(3):311-334. <https://doi.org/10.1353/pbm.2018.0045>

<sup>6</sup> Ibid.

<sup>7</sup> Jones CMP, Lin CC, Blease C, Lawson J, Abdel Shaheed C, Maher CG. Time to reflect on open-label placebos and their value for clinical practice. *Pain*. 2023;164(10):2139-2142. <https://doi.org/10.1097/j.pain.0000000000003017>

<sup>8</sup> Blease CR, Bernstein MH, Locher C. Open-label placebo clinical trials: is it the rationale, the interaction or the pill? *BMJ Evid Based Med*. 2020;25(5):159-165. <https://doi.org/10.1136/bmjebm-2019-111209>

Nonetheless, as some have argued,<sup>9</sup> given their potential safety, low cost, and ease of administration, OLPs may appear to offer a useful option in clinical practice for certain patients. However, given the ambiguity of the term “placebo,” respecting informed consent would require that such interventions not be presented as open-label *placebos*, but rather as what they are—for example, sugar pills—explained in a way that makes that simple fact clear to patients. Moreover, if claims of effectiveness are to be made, then, as with other treatments, these interventions should first be evaluated in appropriately controlled trials. This raises the question of what would count as a valid control for a sugar pill. Yet a sugar pill in clinical practice is never just a sugar pill; it is administered within a therapeutic encounter shaped by explanation, ritual, and clinician interaction. What such trials would therefore need to isolate is not the pill itself, but the contribution of that broader context. Extensive research on the placebo effect has shown these contextual elements to indeed have therapeutic value.<sup>10</sup> But if so, the challenge is to deliver them honestly and effectively, not to repackage them under the label of a placebo. What clinical practice may need more than OLPs, then, is not sugar pills embedded in contextual healing, but stronger and more transparent forms of contextual care alongside treatments with independently established clinical effects.

Open-label placebos were meant to resolve a long-standing tension: how to harness the placebo effect without deception. But in trying to remove deception, a subtler and more conceptually troubling form has taken its place.

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<sup>9</sup> Hardman D, Miller F. A worthwhile wager: the ethics of open-label placebo treatment in clinical practice. *J Med Ethics*. 2025;51:689-692. <https://doi.org/10.1136/jme-2024-110270>

<sup>10</sup> Louhiala P. *Placebo Effects: The Meaning of Care in Medicine*. New York: Springer 2020.