Aligning Research and Practice: Implications of Patient-Centered Care for Placebo Effects

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Throughout the history of medicine, placebo effects have played a critical role in the healing process. Moreover, research suggests that placebo effects remain a key contributor to patient well-being and, for some treatments (e.g. antidepressants), placebo effects appear to have increased in magnitude over the past several decades [1, 2]. Placebo effects can be defined as the component of a medical treatment effect that is directly attributable to patients' expectations of and prior learning experience with a therapeutic intervention [2, 3]. When defined in this way, placebo effects are not only a result of the administration of inert treatments but are a psychological component of all medical treatments.

A wealth of knowledge has now been gathered on the neurobiological and psychosocial factors responsible for placebo effects. These data are providing valuable insight into the contribution of the patient to medical treatment efficacy. However, a critical barrier currently impedes both theoretical development and the potential clinical application of placebo effects. Namely, in the research paradigms used to study placebos, participants are passive agents who are *assigned* to a treatment. This passivity is in stark contrast to many current health care practices in western medicine in which individuals are actively involved in treatment selection and decision making. This disconnect deserves attention and carries important implications for both researchers and practitioners.

Our knowledge of placebo effects primarily comes from two sources: experimental studies and randomized placebo-controlled clinical trials (RCTs). These designs have

different approaches and goals. Experimental studies examine placebo effects by directly comparing individuals given an inert treatment with individuals not given an inert treatment (no-placebo control group), with the goal of clarifying the psychological, physiological, and neurobiological underpinnings of placebo effects. RCTs are designed to evaluate the relative contribution of an active treatment beyond that of a placebo control group. Because RCTs are not specifically intended to evaluate placebo effects, they generally do not contain no-placebo control arms and thus provide limited information on placebo effects distinct from other non-specific factors. Nevertheless, RCTs supply valuable information about the magnitude of placebo effects and are more likely than experimental studies to use clinical samples and to be of longer duration, thus providing enhanced ecological validity.

Although the goals and approaches of experimental placebo studies and RCTs are distinct, a shared characteristic is that treatment randomization and distribution occurs *without* any participant/patient involvement. That is, rather than contributing to a treatment decision, individuals in both paradigms are relegated to a passive role. In experimental placebo research, participants are assigned a sham treatment or no treatment by the experimenter. In RCTs, individuals are assigned an active drug or a placebo. These designs have a long history in medicine and were established when doctors typically exercised full control over treatment decision making. However, as part of a larger movement toward patient-centered care and shared medical decision making, patients are taking greater control over their health care options. As active medical decision makers, patients frequently exercise choice in many phases of the health care process, including health care plans, physicians, forms of care, and treatments.

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Moreover, this shift toward patients having decisional control has been amplified by the advent of web-based medical tools, the development of patient-friendly medical decision aids, the rise in direct-to-consumer pharmaceutical advertising, and the increased availability of over-the-counter and self-treatment options (e.g. cough syrups, analgesics). As such, the absence of participant involvement in treatment decisions in placebo studies and RCTs now stands in contrast to many practices and trends in modern health care.

Critically, the lack of participant involvement in placebo paradigms may have consequences for inferences made from experimental placebo research and RCTs. For instance, one might question whether estimates of placebo effects in experimental studies and RCTs are an accurate representation of what occurs in contemporary health care. Indeed, research now indicates that the magnitude of placebo effects differs depending upon the amount of participant involvement via decisional control. In studies demonstrating this effect, participants are given choice or not given choice between different placebo treatments (e.g. analgesic ointments, emotive writing tasks) that can ostensibly impact their experiences (e.g. pain, sleep quality). Across numerous paradigms, greater patient involvement via choice making has corresponded to greater treatment efficacy, even when the treatment is completely inert [4–6]. Extrapolating from these findings with health volunteers, it can be hypothesized that traditional experimental placebo studies and RCTs can underestimate placebo effects in modern health care settings. In sum, most experimental placebo studies and RCTs do *not* include choice over placebo (or active) treatments, whereas recent research suggests that choice enhances placebo effects. Therefore, it can be surmised that some experimental placebo studies and RCTs fall short of capturing the true contribution of the placebo component of treatment effects in modern health care.

The disconnect between placebo research methodologies and health care practices has implications for researchers and practitioners. First, it is important for experimental studies on placebo effects to appreciate the role of patient involvement in their paradigms. At a minimum, when interpreting results from experimental placebo studies it is important to consider whether they correspond to clinical situations where patient involvement is high. Even better, adding experimental conditions in which participants or patients have choice over different placebo treatments could help in translating findings from placebo research into daily clinical practice. Furthermore, as experimental work on placebo effects has been uncovering the neurobiological circuitry underlying this phenomenon, it is important to clarify whether the same neurobiological pathways hold for placebo effects in high as well as low

patient involvement situations. In sum, consideration of patient decisional control is important for drawing accurate and ecologically-valid conclusions from placebo effect research.

Second, the potential for patient involvement to alter placebo effects in clinical practice has implications for RCTs. Specifically, as patient involvement is often a component of modern health care but not a component of placebo-controlled RCTs, there is a potential threat to the ecological validity of such trials. For example, because patient involvement can strengthen placebo effects, RCTs may be less accurate in accounting for treatment effects in high-involvement situations than low-involvement situations. To address this possibility, it would be valuable to include patient-involvement control groups to RCT designs. Such additional groups would not be needed to evaluate all treatments but would assist in evaluating treatments in which patients frequently hold considerable decisional control (e.g. weight management, chronic pain). Such control arms need to be added cautiously, however, as patient involvement could strengthen placebo effects to an extent that they interfere with the detection of active treatment effects.

Third, given that involvement may strengthen placebo effects, having patients participate in treatment decisions or planning should enhance treatment effectiveness. This provides a clear avenue for harnessing placebo effects in clinical practice. Further elevating patient control, of course, raises complex decisions in which the anticipated benefits, potential costs, and applicability of patient involvement need to be carefully weighed by health care providers. Moreover, there may be many situations where high patient involvement could actually be detrimental, such as when the decision requires significant expertise to evaluate or synthesize the available information, when the choice is about a serious illness (e.g. cancer), or when the patient (e.g. an elderly patient) does not want to be involved in treatment decision making.

In summary, placebo effects represent a key psychological component to treatment effects and they remain a fundamental contributor to health care outcomes. Based on recent research, it can be surmised that this effect may change when patients participate in their health care decision making. As patients' role in health care has increased, understanding the connections between patient involvement and placebo effects will be vital for clinical practice, clinical research, and the connection between these two interdependent enterprises. Clarifying these links is likely to become even more critical as patient involvement continues to increase and transform the health care landscape.

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