

CONTEXT EFFECTS IN WESTERN HERBAL MEDICINE: FUNDAMENTAL TO EFFECTIVENESS?

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Western herbal medicine (WHM) is a complex healthcare system that uses traditional plant-based medicines in patient care. Typical preparations are individualized polyherbal formulae that, unlike herbal pills, retain the odor and taste of whole herbs. Qualitative studies in WHM show patient–practitioner relationships to be collaborative. Health narratives are co-constructed, leading to assessments, and treatments with personal significance for participants. It is hypothesized that the distinct characteristics of traditional herbal preparations and patient–herbalist interactions, in conjunction with the WHM physical healthcare environment, evoke context (placebo) effects that are fundamental

to the overall effectiveness of herbal treatment. These context effects may need to be minimized to demonstrate pharmacological efficacy of herbal formulae in randomized, placebo-controlled trials, optimized to demonstrate effectiveness of WHM in pragmatic trials, and consciously harnessed to enhance outcomes in clinical practice.

Key words: Placebo effect, Context, Western herbal medicine, Patient–practitioner relationship, Herbal preparations

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INTRODUCTION

Changes in health status during treatment with herbs can be attributed to three sets of factors: those related to the specific pharmacological effects of the herbs; those variously labeled “placebo effect,”^{1,2} “meaning response,”³ or “context effects”⁴; and those having no direct association with the herbal treatment (e.g., natural history of the disease). Most research on herbal medicines investigates the first of these factors. This article explores placebo, or context effects, within the framework of Western herbal medicine (WHM).

WHM must first be distinguished from herbal medicines. Herbal medicines are crude or refined preparations of plants used as therapeutic agents. WHM is a varied but distinct healthcare system that uses herbal medicines in patient care. The theory and practice of WHM is rooted in traditional explanatory models of health but is increasingly informed by biomedicine.^{5,6} Clinical assessment is characterized by a holistic, biopsychosocial approach with treatment aimed at supporting or augmenting *vis medicatrix naturae* (the healing power of nature).^{7,8} WHM is primarily practiced in Europe, North America, Australia, and New Zealand.^{9,10} Prevalence surveys show it to be a small but noteworthy part of healthcare.^{11,12}

WHM practitioners report initial patient consults of at least 60 min with 30–60 min for subsequent visits.^{13,14} The lengthy consult time allows for holistic assessment and development

of a multifaceted treatment plan. It also reflects a philosophy and practice of engaging with patient narratives, patient–herbalist collaboration, and facilitation of patient empowerment.^{8,14,15} Treatment is individualized and incorporates dietary and lifestyle changes along with compounded herbal formulae. WHM practitioners typically dispense traditional preparations, in sharp contrast to the dominance of herbal tablets and capsules in the retail market.^{9,16} An Australian survey reported that 90% of WHM practitioners most commonly prescribed liquid extracts. Only 3.8% of respondents indicated a preference for tablets or capsules.¹⁶

The objective of this article is to support the position that herbal preparations, patient–herbalist interactions, and the physical healthcare environment in WHM evoke context effects fundamental to the overall effectiveness of herbal treatment. The importance of this position to research and clinical practice is discussed.

PLACEBO EFFECTS TO CONTEXT EFFECTS: AN OVERVIEW

The “placebo effect” is commonly conceptualized as the response to “dummy” pills or “sham” treatments. More recently, researchers have recognized that placebo effects are responses to the psychosocial context within which any treatment, “active” or “inert,” is embedded. The patient experiences treatment within the context of the patient–practitioner relationship, the physical treatment environment, and the broader socio-cultural environment.^{2,17} The physical form of the treatment (e.g., an injection, pill, or cup of tea) provides additional context.² This network of factors triggers psychological, cognitive, and physiological responses that can

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in turn affect clinical outcomes.^{4,18} Given its origins, “placebo effect” is a confusing term to describe these responses and some researchers have chosen to reconceptualize the placebo effect as “meaning response”³ or “context effects.”⁴

Placebo effects have been studied in a wide variety of disciplines. Psychological and cognitive models emphasize enhanced expectations and classical conditioning as key underlying processes.^{19–23} Other psycho-cognitive processes relevant to placebo effects include belief, learning, construction of “meaning,” and anxiety reduction.^{24–27} Medical anthropology proposes “direct embodied experience,” ritualism, and symbolism as central to placebo effects.^{17,26,27} Neurobiological studies have elucidated the role of dopaminergic, opioid, and endocannabinoid systems as mediators of placebo effects within the central nervous system (CNS).^{28,29} Further mechanistic research has demonstrated involvement of the autonomic, endocrine, and immune systems in mediating placebo effects outside the CNS.^{30–32}

Despite the wide range of explanatory models, the clinical relevance of placebo effects remains unclear. A commonly referenced early review of “the powerful placebo” proposed a large effect size based primarily on changes within placebo groups.¹ Subsequent analysis demonstrated that the author did not consider a host of confounding factors.³³ It is now recognized that comparing differences between a placebo group and “no treatment” group provides a more conservative and accurate estimate of the placebo effect.

A recent meta-analysis of “placebo interventions for all clinical conditions” reported statistically significant but small effect sizes in pooled data for both binary [relative risk: .93 (95% CI: .88–.99)] and continuous outcomes [standardized mean difference: $-.23$ (95% CI: $-.28$ to $-.17$)].³⁴ Given the small effect size, the authors concluded, “We did not find that placebo interventions have important clinical effects in general.” There are, however, significant methodological concerns with estimating a single effect size and generalizing clinical relevance for “placebo interventions”: placebo effect size varies by the nature of the intervention and clinical condition, the effect is increasingly understood as the result of the context in which the intervention is given, and randomized controlled trials (RCTs) represent a very different context than usual care.^{35–37}

The methodology used in the meta-analysis also raises the challenge of defining placebo and placebo research. For the purpose of the meta-analysis, the researchers defined placebo as “dummy” or “sham” interventions in RCTs. In the majority of cases, the data was extracted from studies where placebo effects were not explicitly investigated. Subgroup analyses of studies with continuous outcomes showed significantly larger effect sizes in trials explicitly investigating placebo as well as in trials that did not inform patients of the possibility of placebo treatment.³⁴ This suggests that more direct and purposeful research on placebo, defined in the broader sense of all the contextual factors that affect clinical outcomes, is necessary to get a true sense of the clinical relevance of placebo effects.

A key factor in these broader placebo effects is the patient–practitioner relationship.³⁸ A recent meta-analysis of 13 RCTs studying manipulation of patient–practitioner relationship found a small ($d = .11$) but statistically significant ($P = .02$)

difference between intervention and control groups in both objective and validated, subjective health outcomes.³⁹ Placebo effects related to patient–practitioner interactions have been demonstrated to combine with placebo effects related to the treatment itself.⁴⁰ It is a reasonable assumption that effects associated with other components of therapeutic context (e.g., the physical healthcare environment) would also contribute in a cumulative fashion leading to an overall placebo effect of clearer clinical relevance.

The next section reviews treatment context factors within the framework of WHM. In order to distinguish these factors from the narrower concept of placebo this article will from here on use the term “context effects” instead of “placebo effect.” The term “placebo” will be limited to “dummy” preparations used as controls in research settings.

CONTEXT EFFECTS IN WESTERN HERBAL MEDICINE

Context Effects in WHM: Herbal Preparations

Herbal medicines embody not just pharmacological efficacy but also symbolic efficacy.^{41,42} Symbols and associated rituals encode meaning for patients and elicit physiological and psychological “meaning responses” (i.e., context effects).^{3,25,43} Qualitative research demonstrates that herbal medicines symbolize time-tested, natural healing to users and in turn engage beliefs, and elicit expectations of safety and efficacy.^{44–46}

The dominant use of liquid extracts and teas in WHM¹⁶ likely enhances these beliefs and expectations. Unlike tablets and capsules, herbal liquids, and teas retain the distinctive sensory characteristics (e.g., odor and taste) of whole herbs with significant implications for context effects. Moerman⁴² argues that these sensory qualities of medicinal plants, “offer endless possibilities for the construction of powerfully meaningful images ... likely to offer substantial opportunities for the enhancement of biological changes in human beings” (p. 456).

Preliminary research supports this perspective. Interpretation of the organoleptic properties of traditional herbal medicines plays a primary role in establishing expectations of plants’ healing properties.^{47,48} Such expectancies are not fixed. A study conducted in the UK demonstrated that links between chemosensory characteristics of five common medicinal plants and expectancy of their healing properties depended on personal experience and culture.⁴⁹ Expectancy of positive health outcomes, based on the intersection of chemosensory perception and personal experience, was also seen in qualitative analysis of 18 patients using herbal medicine in Germany.⁴⁵ A patient expressed the expectation as follows: “Well what is pleasant is that it does have an immediate effect as you have a taste of eucalyptus [sic] in your whole mouth, well in your nose, in your mouth. So you instantly feel that it’s working” (p. 4).⁴⁵

Chemosensory properties of herbs and traditional preparations may not only enhance context effects through expectancy but also through classical conditioning. While expectancy is considered central to modulating conscious functions and outcomes, conditioned responses are particularly relevant to enhancing unconscious physiological

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