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SHAM TREATMENT? SHOULD IT BE REDEFINED FOR ITS USE IN MANUAL THERAPY CLINICAL STUDIES?

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You and your friend were at a restaurant about to enjoy your hamburgers. You had ordered a 'pure beef' hamburger, while your friend had chosen a veggie burger. However, a mix-up occurred when the waiter mistakenly placed the 'beef' flag on the veggie burger and enthusiastically presented it to you as a fantastic beef burger. As a result, you ended up eating your friend's veggie burger while your friend had the real beef burger. The persuasive waiter made both burgers seem identical, 'You are in for a real treat with this fantastic all-beef burger,' he said to you, and 'You are in for a real treat with this healthy veggie burger,' he said to your friend. And it wasn't until the end of the meal that you realized the mistake. You felt deceived as if you had eaten a 'sham burger.'

That is the sensation people often feel when comparing a 'genuine' and a 'fake' manual therapy treatment: two seemingly distinct treatments that may yield similar results.

What is a placebo?

The definition of 'a placebo' is: 'an inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied' [1]. The 'placebo effect,' which results from contextual and nonspecific effects [2–4], can be defined as changes within the patient(s) treated in all healthcare contexts (with or without a placebo). Indeed, placebo mechanisms are integral to any pain treatment [5]. The so-called placebo contextual effects include neurobiological and psychological mechanisms of expectation, which could be mediated by verbal/non-verbal instructions or situational signs

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that affect treatment expectations. They are often described as modulators in the form of e.g. environment, verbal communication, professional reputation, patient expectation, and therapeutic touch [6–8]. Nonspecific effects include the natural course of the disease and regression to the mean [2].

Doubts about the placebo effect of sham in manual therapy studies

The placebo effects observed in manual therapy may be attributed to the neurophysiological and physical impacts of touch, as well as to the treatment environment or context [6]: 'Placebo effects result from the psychosocial context surrounding the clinical encounter and are reliably produced in the laboratory through manipulating expectations and conditioning and learning' [5,9]. In musculoskeletal research, sham interventions are commonly used to evaluate the effectiveness of placebos in clinical trials [10–12]. These interventions are designed to be non-active and harmless [13]. For instance, in many manual therapy studies, a sham treatment involves applying the studied technique with minimal force, with the intention of not producing any therapeutic effect on the subjects [13]. Nevertheless, the use of a sham therapy to test the specific effect of a 'real' manual technique may be incorrect [14]. The use of sham treatment, through physical intervention on the body (e.g. manual), is probably not an 'inactive or inert technique' since simple light touch can result in many physiological processes [15–17]. Therefore, the results of studies using a sham should be interpreted with caution since even non-inert techniques can distort the comparison [18]. The assumption that a sham treatment is inert (and therefore considered a placebo) when, in fact, it is not, introduces a bias against the physiotherapeutic procedure for which the sham procedure is used as a control. In contrast to pharmacological placebo studies, for which it is easy to point out the specific effects of the drugs, studying manual techniques is more complex as they include the effects of physical touch, which is present in any manual technique and may thereby have a greater effect on patient- reported outcomes such as pain [19–22].

Even when described as a sham, the mechanical action of touch during massage, mobilization, or manipulation on a patient induces neurophysiological mechanisms [23,24], even with light pressure [25] and even when applied remotely [26]. Touch encompasses emotional and affective responses, physical properties, and analgesic modulations [19]. Would performing a grade 1 mobilization on an irritable patient be considered a placebo? [27,28] Another example would be comparing a high-velocity thrust to a sham high- velocity thrust, allowing us to assess the added value of a high-velocity thrust compared to a simple touch. But if there is no difference, that does not equate to the high-velocity thrust having no effect because therapeutic touch can have beneficial effects.

Finally, since manual treatment and manual sham can be considered as two separate interventions with their own specific characteristics, it appears valuable to reconsider our understanding of the sham. This is not to question the fact that some aspects of manual therapy mechanisms may be related to placebos [5], but rather to enhance our comprehension and interpretation of this so-called placebo.

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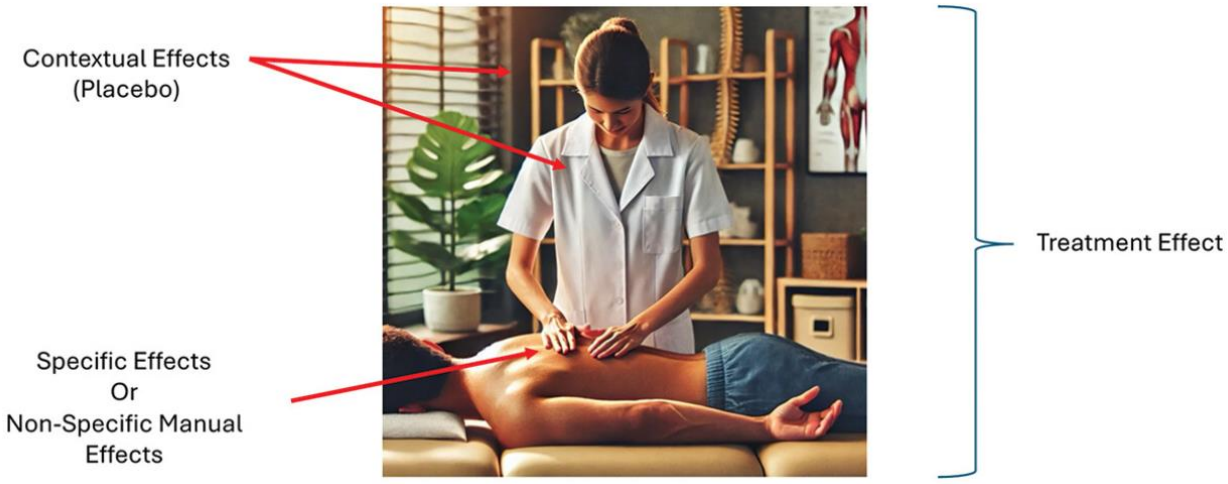
Figure 1. Representation of the elements making up a treatment that should be considered in future studies [9]. The context (a comfortable and welcoming environment with a physiotherapist who seems serious/professional) represents the placebo effect. Specific effects are, for example, the desired effects of a particular technique; here, the hand placement could be aimed at truly manipulating joint structures. Non-specific effects could be just touching and/or moving the patient's skin. Are the effects linked to a treatment that is a sham but nevertheless has an effect that we cannot consider a real placebo?



So what?

If we take up the metaphor from the beginning of this Editorial, the veggie burger has been mistaken for a beef patty, which, once the error has been disclosed, has caused confusion among the customers. This confusion arises from the different expectations and contexts surrounding the two products. It's important to note that the vegetarian burger is not at all like a placebo. This situation is similar to the misleading nature of sham manual treatments (Figure 1).

So, for manual techniques, the term 'sham technique' can be used, whereas 'sham effect' is not appropriate. As we have pointed out, a sham manual 'technique' is an active, i.e. non-inert intervention, as a 'real technique.'

We propose simplifying the terminology by referring to the *'*nonspecific *manual* effects' experienced by patients who receive sham manual interventions. This could reduce confusion when interpreting results. Therefore, in randomized placebo-controlled clinical trials involving manual therapy techniques, any changes in the placebo group should be attributed to contextual effects rather than the actual effects of the sham intervention.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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