

## Clinical research in acupuncture and the placebo concept

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Placebo controls in clinical trials serve two purposes: 1) to separate specific and unspecific effects; 2) to reduce bias by blinding. The placebo should differ from the true treatment (*verum*) only by lacking the (postulated) active component. It should not have any direct physiological effect for the condition under investigation. The specific effect is the difference in the outcome between the *verum* and the placebo group. The difference between the outcome in the placebo group and an untreated control group is the unspecific or placebo effect. This concept – in spite of having some inherent logical inconsistencies – has greatly improved research on pharmacological agents. Due to the great success in pharmacology and the intuitive strength of this approach placebo-controlled trials are considered also highly desirable for complex interventions such as surgery, physiotherapy, chiropractic or acupuncture. However, in these areas important problems can occur. Specific problem related to acupuncture will be discussed.

A) The mechanism of action of acupuncture is unclear. While the adequate choice and localisation of points etc. is considered relevant, research suggests that correct point localisation is (if relevant at all) only one aspect. For example, some neurophysiologists believe that all repetitive mild painful stimuli at many locations and even repetitive touch can modulate pain perception. It is possible or even likely that many “placebo” or “sham” acupuncture procedures directly affect physiological processes relevant to pain and other conditions. Therefore, it might be inadequate to interpret “sham” acupuncture as placebo. If “sham” acupunctures should have direct activity it would be more difficult to prove an existing superiority of true acupuncture than, for example, in a trial with a placebo drug.

B) If placebo effects (effects “caused” by true placebos without direct physiological effects on the condition under investigation) should be real (i.e., an improvement is not only incorrectly reported but “truly existent”), there must be a mechanism. It seems very likely that these mechanisms have to do with cognition, emotion etc., and are “translated” by the brain into physiological changes. Currently, expectation and conditioning are considered as relevant potential mechanisms for “placebo” effects. It seems obvious that expectations, emotions etc. related to an intervention depend on its specific characteristics and its meaning for a patient. It seems likely that differences in expectations result in different expectation effects. If this is true the “placebo” or “unspecific” effects of different interventions probably differ, too. Acupuncture with its exotic framework, frequent and intense patient-provider contact, and its “needling ritual” might be a particular potent placebo.

In summary, most sham acupuncture interventions (including “placebo needles) might not be “true” inactive placebos, and acupuncture might be associated with particular strong, characteristic placebo effects. The author suggests that acupuncture researchers avoid the term placebo in relation to sham acupuncture interventions. Furthermore, as complex interventions might have “specific” or “characteristic” placebo effects different from the effects of placebo drugs it has to be discussed whether the placebo concept is misleading in case of complex interventions. This does not mean that specific aspects postulated to make a difference (for example, point location) should not be investigated rigorously. It means only that findings from such trials might say little on whether a treatment is beneficial.