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ORIGINAL PAPER

A quantum-like model of homeopathy clinical trials: importance of *in situ* randomization and unblinding

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Background: **The randomized controlled trial (RCT) is the 'gold standard' of modern clinical pharmacology. However, for many practitioners of homeopathy, blind RCTs are an inadequate research tool for testing complex therapies such as homeopathy.**
Methods: **Classical probabilities used in biological sciences and in medicine are only a special case of the generalized theory of probability used in quantum physics. I describe homeopathy trials using a quantum-like statistical model, a model inspired by quantum physics and taking into consideration superposition of states, non-commuting observables, probability interferences, contextuality, etc.**
Results: **The negative effect of blinding on success of homeopathy trials and the 'smearing effect' ('specific' effects of homeopathy medicine occurring in the placebo group) are described by quantum-like probabilities without supplementary *ad hoc* hypotheses. The difference of positive outcome rates between placebo and homeopathy groups frequently vanish in centralized blind trials. The model proposed here suggests a way to circumvent such problems in masked homeopathy trials by incorporating *in situ* randomization/unblinding.**
Conclusion: **In this quantum-like model of homeopathy clinical trials, success in open-label setting and failure with centralized blind RCTs emerge logically from the formalism. This model suggests that significant differences between placebo and homeopathy in blind RCTs would be found more frequently if *in situ* randomization/unblinding was used.** *Homeopathy* (2013) **102**, 106–113.

Keywords: Quantum probabilities; Entanglement; Contextuality; Non-local interactions

"*Inexplicable observations are not always signs of the supernatural*"

John Maddox[1]

Introduction

Homeopathic remedies are considered by many scientists and physicians as implausible and ineffective. At best they consider that homeopathy works, but only because of the consultation.[2,3] For many detractors of homeopathy, the final word has been spoken with the study of Shang *et al*.[4–6] The authors of this study reported a comparison of randomized placebo-controlled trials of homeopathy and allopathy; they concluded that – despite comparable quality of homeopathy and allopathy trials – the clinical effects of homeopathic medicines were not different from placebo effects. In contrast with allopathy, blinding of trials of homeopathic drugs strongly decreased the probability of success compared to open-label setting.

Although this study was heavily criticized,[7–9] its conclusions were not completely unexpected since the main reason for rejection of homeopathy is the difficulty for homeopathic remedies to pass successfully the test of blind randomized controlled trials (RCTs), which is the 'gold standard' of modern clinical pharmacology. Some supporters of homeopathy argue that blind RCTs are an inadequate research tool for testing complex therapies

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such as homeopathy.[10,11] In the present article, I propose a possible way to increase the chance of demonstrating a difference between homeopathy and control in blind RCTs.

Homeopathy and non-local theories

Homeopaths are convinced that homeopathy is effective, but there is a debate among them about the way in which it works.[12] For many homeopaths, there is 'something' in the homeopathic medicine, which explains the patient's response. In other words, there is a specific factor or cause located in the water or in the granules that acts locally as does a pharmacological compound. The 'local' explanation – frequently referred as 'Memory of Water' since Benveniste's experiments – is supported by some laboratory investigations.[13–17] In these experiments, the states of biological systems were significantly different in the presence of highly diluted pharmacological compounds or corresponding controls. Shaking between each dilution appeared to be necessary for 'memory' while some physico-chemical treatments such as heating were reported to erase it. However modification of water structure or local information storage in high dilutions remains to be convincingly demonstrated by physical methods.[17]

Besides the 'classical' hypothesis of local causality, other authors have more recently proposed that the cause of homeopathy effectiveness is not specifically located in water samples or remedy. Instead they used concepts derived from quantum physics, such as non-locality and entanglement.[18–21] Entanglement is a central concept of quantum theory: two quantum systems isolated from environment become entangled after interaction and as a consequence they share a single quantum state. This means that when a measurement occurs, the respective outcomes of the two quantum systems are correlated. Entanglement is also expected in systems that need both local and global descriptions; if these descriptions are complementary, then theoretical models predict non-local correlations between the elements of the system.[22,23]

The authors who apply quantum concepts to homeopathy differ in what is entangled among practitioner, patient and medicine.[12] Moreover, quantum physics describes particles and atoms and quantum phenomena are supposed to vanish in macroscopic world due to the decoherence mechanism, which is related to the numerous interactions of any macroscopic object with its environment. To overcome this obstacle, Walach proposed applying a 'generalized' version of quantum theory to homeopathy, which makes the theory applicable in more general contexts than the original quantum physics.[22,24]

In the present article, I present a simple model for global description of homeopathy trials. This model describes the cognitive states of practitioner and patient using notions from quantum physics such as superposition and non-commuting observables. Operations are non-commutative if changing the order of operations does not change the result. For instance washing and drying clothes are not commutative, the order in which the operations are carried out makes a big difference to the outcome. Putting on socks is commutative, the order in which they are put on makes no difference to the outcome.

This modeling is in the spirit of an emerging discipline named 'quantum cognition' at the frontiers of artificial intelligence, psychology and social sciences. Indeed, in some research areas, which have in common the description of cognition mechanisms and information processing in the brain, quantum probabilities have been proposed to address problems that were unresolved in a classical frame.[25] A quantum-like formalism has thus been applied to human memory, information retrieval, decision making, opinion forming, personality psychology, etc.[26–30] This new approach does not rest on the hypothesis that there is something quantum mechanical about the physical brain. The quantum formalism is simply used as a source of alternative new tools such as contextuality or entanglement. In these studies, the mental states of agents were characterized by state vectors in Hilbert space and, in several experimental models, quantum probabilities had better predictive power than classical probabilities. Some 'paradoxical' statistical data, particularly in psychology and cognitive sciences, can be modeled by this method.[26,27,31–33]

In order to make the notions of quantum physics more easily understandable, I will draw a formal comparison between homeopathy trials and single-particle interference in quantum physics. In both cases, contextuality has been shown to play a chief role.

From single-particle interference to trials of homeopathy

Single-particle quantum interference illustrates the superposition principle and some characteristics of quantum probabilities. The classical two-slit interferometer of Young is usually used for such a description, but the Mach–Zehnder device has the advantage of including only two detectors (D1 and D2) as depicted in Figure 1.[34] Light is emitted from a monochromatic light source: 50% of light is transmitted by beam splitter (BS1) in path T and 50% is reflected in path R. In BS2, the two beams are combined and 50% of light is transmitted by beam splitter in detector D1 and 50% in detector D2. If light is considered as a wave, it can be calculated that waves from the two paths are constructive when they arrive in D1 and destructive in D2. Therefore, clicks after light detection are heard only in D1. This is indeed what experiment shows and it is an argument for the wave-like nature of light.

On the contrary, if we consider light as a collection of small balls (photons), they should randomly go into path T or R (with a probability of 0.5 for each path) and then in BS2 they go into D1 or D2 randomly (again with a probability of 0.5 for D1 or D2). As a consequence D1 should click in 50% of cases and D2 in 50% of cases. However, even if photons are emitted one by one (by decreasing light intensity), the interference pattern persists (100% of clicks in D1). This is a quite counterintuitive result. Even more