

EDITORIAL

## Reinventing the Wheel Will Not Make It Rounder: Controlled Trials of Homeopathy Reconsidered

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### HOMEOPATHY— A PUZZLING PHENOMENON

I love homeopathy—for the clinical effects I have noticed in myself, in my children, and in other people. These are sometimes so quick and strong that only the blind and intransigent could attribute them to chance, placebo, wishful thinking, or deceit. Sometimes these effects fail. At other times they are similar to miracle cures. Thus, I am also puzzled by homeopathy, by the many apparent contradictions, and paradoxes. I suggest that the following propositions are compatible with the known facts about homeopathy and with both formal and informal experience:

1. Homeopathy has some clinical effectiveness. If it did not, it would have died out. Indeed it is more sought after now by patients at a time when modern medicine prides itself in being more powerful than ever.
2. There is no such thing as “true homeopathy.” Instead there are many different forms, which appear contradictory in theory and practice, all of which claim to be effective and probably are.
3. There is a long record of research into homeopathy but this has produced conflicting results, offering little clarity about principles and basic mechanisms, let alone clinical efficacy.

The favorable results produced by the widely quoted meta-analysis conducted by Linde and coauthors (Linde et al., 1997) must be updated in the light of more recent data (e.g., Friese et al., 1997a; Lewith et al., 2002; Linde and Melchart, 1998; Linde et al., 1999; Vickers et al., 1998) and a second analysis including some of that data (Linde and Melchart, 1998; Linde et al., Melchart, 1999).

Thus, at present it is not possible to claim clinical superiority for homeopathy—individualized or otherwise—over placebo. Basic research has neither isolated a possible information carrier, nor has it generated a theory or mechanism that is plausible and/or universally accepted, nor has it given rise to enough stable, replicable results to attract the interest of mainstream research (Vickers, 1999), with the exception of the histamine model (Belon et al., 1999), which awaits further support. Space prohibits lengthy discussion of this in this paper but some arguments and conflicting evidence have been presented in more detail elsewhere (Walach and Jonas, 2002).

### LOCALISM IN HOMEOPATHY

It is the lack of consistency that appears to go unnoticed by Oberbaum et al. (Oberbaum et al., 2003) and that leads them to presuppose what I would like to call a localist hypothesis

of homeopathy. This is the position from which I myself departed when embarking on research into homeopathy more than 15 years ago, so I understand it well. However, my own experience (Walach, 1993; Walach et al., 1997a, 1997b, 2000, 2001), as well as the work of others have convinced me that a localist hypothesis is the most unlikely candidate for a plausible theory of homeopathy. The arguments supporting this have been advanced elsewhere (Walach, 2000), but a brief outline follows.

The localist hypothesis of homeopathy is intuitively appealing, simple, and the most straightforward. It presupposes that:

1. Homeopathy works; we know this from clinical practice. This is conceded as a heuristic starting point.
2. If homeopathy works, it cannot be molecules that are the active principle, because at high homeopathic potencies they are statistically too few to be biologically active. This is a logical extrapolation from the known body of biomolecular knowledge.
3. If molecules are not the active principle, it must be something else that is fixed to or in the remedy, and hidden from ordinary analysis for lack of sufficiently sensitive instruments, or theory, or both.

It is a localist hypothesis because it presumes the active principle has to be a local resident to the remedy. It is construed as residing in the material substance. It could be a clathrate or zwitterion pattern, a ratio of isotopes, a “vibrational” pattern (this is the esoteric form of the same localist hypothesis), an ordered structure of dipole lasers, to name but the most prominent propositions. If any of these hypotheses were empirically confirmed, it would remain unclear how this would explain the clinical effects.

This hypothesis is a “localist” one because it silently adheres to the accepted notions of causation. This modern notion of causation is only one element of the old Aristotelian notion of cause. Four kinds of cause were known to Aristotle, one of which he called “efficient cause,” that cause which is the dynamic reason for an observed change. Modern science has adopted efficient causation as the only “real” one. Thus,

all modern theories are either modelled on efficient causation, or interim models are constructed in order to bridge gaps (Hulswit, 2000). A prominent example is the theory of gravitation. This posits a lawful force active at a distance that keeps material bodies in a delicate balance of attraction and repulsion and accounts, for example, for the motion of celestial bodies. However, Newton already saw that his theory contained an element of nonlocality, calling it “shameful” in a letter to Bentley (Stapp, 1990). Modern theory attempts to bridge the gap and account for the seemingly ghostlike action at a distance, by introducing virtual particles, so called gravitons. They fulfil the function of conveying the force of gravitation by local exchange of energy. The same is true of photons which are exchange particles of electromagnetic force. But contrary to photons, gravitons have not yet been physically detected. At present they are theoretical constructs. However, such localist thinking is so deeply entrenched in our minds that we cannot conceive of anything other than local causes and their interactions to offer proper scientific explanation for observed phenomena. It is this unspoken presupposition which appears to go unnoticed by Oberbaum et al. (pp. 105–111), and indeed by many other researchers in the CAM community. By trying to be scientifically acceptable and to play by the rules—both of which are necessary, of course—they adopt the implicit ontology and theoretical framework without questioning whether it is truly adequate for the phenomenon under study, in this case homeopathy.

#### **TRIALS AS DETECTORS OF LOCAL CAUSES**

The quest for randomized, double-blinded, placebo-controlled clinical trials of homeopathy is not a new one. It has been expressed, pursued, and has failed many times. The presupposition of clinical trials is that there is a stable, locally active cause that is only active in the treatment group, irrespective of blinding and the circumstances of the trial or any changed clinical context as a result of the trial. This presupposition is already questionable for con-

ventional drugs, which are either locally-causally active or useless. Let us take a recent example here: the case of serotonin reuptake inhibitors (SSRIs) for the treatment of depression, the most widely known of which is Prozac (Eli Lilly and Company, Indianapolis, IN). The application of SSRIs is based on the serotonin theory of depression, which states that part of the reason for depression is an imbalance of central serotonin metabolisms causing reduced bioavailability (Anderson, 2000). Thus it is logical, plausible, and possibly effective to bring more serotonin into the system, where it is needed (i.e. centrally in the brain). This is achieved by SSRIs, the theory goes, and the public believes. It is theoretically convincing, practically feasible, and apparently clinically effective. However, looking closely at the data from all 47 studies submitted to the Food and Drug Administration (FDA) for approval and licensing of these drugs, Kirsch and colleagues (Kirsch et al., 2002) discovered a different picture. In four studies placebo was statistically insignificantly superior to the experimental drug, only a fraction of the studies were independently statistically significant, and taken together the difference between treatment and placebo was only 1.8 points on the Hamilton Depression Scale (effect sizes could not be calculated because data often lacked standard deviations; thus proportions had to be used), and 80% of the treatment effect was duplicated by placebo. One can conclude that despite a strong, plausible, and experimentally verified background theory (i.e., the serotonin hypothesis of depression), despite a potent potentially causally active therapeutic agent (i.e., SSRIs), clinical trials do not resoundingly corroborate the combination. Among critics, therefore, it is still debatable as to whether SSRIs really are efficacious.

Against this background is it not simplistic to presume that a purported locally active, causative agent residing in homeopathic remedies could be vindicated by blinded clinical trials in the long term, when not even a plausible testable theory exists for such testing? If, for argument's sake, one accepts the localist hypothesis for homeopathy, supposing a causative agent in homeopathic remedies to exist, one does not even know what it might be or con-

sist of, and hence one could not take precautions unwittingly not to destroy it. What if, for argument's sake it were electromagnetically sensitive: how could one ensure that substances are not made inactive, cross-fertilized, cross-talked, or criss-crossed somehow during the process of preparing and conducting a trial? What if the active component were sensitive to heat, radiation, or maybe even to the perfume used by the study nurse? Surely, if such a minute mass of material as three globules of sugar, thousands of which have been impregnated with a few drops of the original solution can affect the human organism so profoundly as to cure severe diseases, surely they might also be sensitive to the attentions, intentions, or maybe even thoughts of anyone who handles them? Furthermore, most localist theories of homeopathy seem to forget that the vast majority of homeopathic treatments are not given in liquids, but using globules containing only a fraction of the original liquid. Without a sound theory, how can one make sure that the decisive factors are not overlooked?

The point being made here is that unless the causative agent is known, it is impossible to ensure the integrity of the real treatment against the sham. Without a plausible theory, a placebo-controlled clinical trial is at worst a shot in the dark and at best a pragmatic test that will not convince anyone. Of course a full-blown theory is not a prerequisite for a trial but it helps. There are many examples, aspirin being the most prominent one, of pharmaceutical substances that proved active and efficacious when tested in trials without a good theory as to their mechanism of action. But in those cases the presupposition was and still is for homeopathy that a localist hypothesis is valid in a very generic sense. One can however argue that there are many indications and facts that make a localist hypothesis for homeopathy implausible (Walach, 2000).

For the sake of argument let us assume that the theoretically more challenging idea of a nonlocal hypothesis for the actions of homeopathy reflect the facts better. What then would happen if blinded trials were conducted? Suppose that the "active" principle of homeopathy resides in a complex mix of the homeopathic situation between patient, practitioner, rem-

edy, history of medicinal substances and their use as codified in the homeopathic materia medica, with some mental interaction between the doctor and patient—such as a flash of security, a spark of trust and hope. In other words, suppose homeopathy is a kind of field effect with no single element that can be isolated and attributed to the remedy alone. If that were the true picture, then testing the remedy alone would be like taking one transistor out of a radio set and testing it for its capacity to play music.

If the effect of homeopathy is the result of a generalized version of entanglement (Atmanspacher et al., 2002), the theoretical model that appeals most to me, then the prediction would be that every action disturbing this entanglement would result in destroying it partially or wholly. Blinding, for instance, is such an action, apart from the fact that it distorts the therapeutic situation and introduces unknown psychologic factors into the interaction between practitioner and patient (Walach, 1996). If that were true, blinded trials of homeopathy would simply be invalid.

Therefore, my contention is that as long as there is no clarity about the general nature of homeopathy, clinical trials, being the type of research that is most complicated, most expensive, and most difficult to control, are a bad investment of time, money and effort. Other ways could be adopted to make the clinical effects of homeopathy plausible. Conventional medicine is in a process of reconsidering its methodological dogmas (Horton, 2001), and if I am not mistaken, no longer necessarily puts blinded trials at the top of the pyramid, although they may be necessary at some stage. We have argued in other places that evidence does not come from one type of research alone but from the mosaic (David Reilly's phrase) of evidence offered by different approaches and methods (Lewith et al., 2002). Outcome studies with large numbers of subjects over long-term observation periods (Thompson and Reilly, 2002; Walach et al., 2002), pragmatic trials that randomize patients to open treatment (Harrison et al., 1999), nonrandomized quasi-experimental studies that study patient cohorts in their self-chosen treatment modalities (Friese et al., 1997b; Schneeweis et al., 2002), have hardly

been tried in homeopathy, although promising results have been found or are being gleaned at present.

### AGAINST REINVENTING THE WHEEL

To argue for a seemingly clear-cut hierarchy of blinded trial methodology, as Oberbaum et al. (2003) is not only not helpful, but outdated and counterproductive.

It is not helpful, because it makes unwarranted presuppositions and lures potential researchers into entering land that has already been shown to be barren as I have elaborated above.

It is outdated because it does not acknowledge the already long history of discussion and debate, which must be known to at least some of the authors. Studies such as the one proposed by Oberbaum et al. (Oberbaum et al., 2003), with unrestricted homeopathic prescribing, and following the homeopathic principle of fully individualized remedy and potency selection, have in fact been carried out (De Lange de Klerk et al., 1994; Kainz et al., 1996; Siebenwirth and Rakoski, 1997; Walach et al., 1997a). Such studies contribute the smallest effect sizes to the homeopathic database. It is not likely that a further test will change the picture in the long run. Furthermore, a new study model might show strong effects initially but may fail when replicated or probed thoroughly for its causal stability. This has been the case with virtually every promising clinical model investigated thus far: initial successes were not replicable and did not bear out their early promise.

It is this background experience that has induced the German Carl-und-Veronica-Carstens Foundation and the Robert-Bosch-Foundation, both of which are funding agencies with the longest tradition and greatest experience in this field, not to fund any further blinded clinical trials of homeopathy but to support other types of research (Albrecht, 1999), a fact that might not be widely known outside Germany.

The puzzling fact is that the evidence seems to be that formula homeopathy is most robust in clinical trials (Oberbaum et al., 2001). Isopathy, the flagship of homeopathy research after the early work of Reilly et al., (1994) suffered a

severe blow from the failure to replicate Reilly's earlier results in a recent large-scale study (Lewith et al., 2002). In fact, a close inspection of the isopathy of Lewith et al. data shows that the effects were not as stable or robust as claimed. A fact which could indicate that non-local processes are at work (Lucadou, 2001a, 2001b).

The list of diseases that Oberbaum et al. (Oberbaum et al., 2003) suggest are most likely to respond to homeopathic therapy in trials is in fact a record of defeat. Earlier unpublished lists of diseases drawn up on the basis of discussions among experienced homeopaths and researchers, and that have sometimes been shown to yield positive results in clinical trials include some challenges to modern medicine such as asthma, atopic dermatitis, rheumatoid arthritis, migraine, chronic pain conditions such as fibromyalgia, and wound healing. But Oberbaum et al. (Oberbaum et al., 2003) now propose to apply homeopathy to diseases where no experience is on record, at least from systematic studies (liver diseases), with no conventional-medical impact (premenstrual syndrome), or with low *a priori*-probability of patient need (simple arthritis). Indeed a recent attempt at organizing a randomized study on rheumatoid arthritis in patients with early disease (duration less than 5 years) failed. We received support from an insurance company for a pilot study for a project had already been earmarked as a grant by the German Ministry of Research. The study was to be conducted in the Köln-Bonn-Düsseldorf area with a population of approximately 3 million. We spent approximately \$70,000 on a recruitment campaign organized in cooperation with the area's leading rheumatology clinics but had to break off the trial after 1½ years, because only eight patients were interested in participating in a trial offering an alternative to conventional treatment, which is still potent in early-stage rheumatism.

Oberbaum et al. try to reinvent the wheel, a strategy frequently seen in CAM. Rather than trying to make the rumbling cart of homeopathy research roll smoothly by inventing rounder wheels, perhaps it would be wise to stop and think about what produced the rumbling in the first place, and what alternative ways of traveling might be available. A multi-

plicity of methods is called for (Wittmann and Walach, 2002). Blinding may be one of the biggest mistakes in homeopathy trials, to which all the foregoing arguments are addressed. The second biggest mistake may be to put all one's eggs into one basket. As recent history shows us, this can have disastrous consequences. By emphasizing clinical trials as the high road to the medical grail, a strategy for centralization is being advocated. The third biggest mistake is relying on randomization only, without considering its problems, shortcomings, or taking alternatives into account (Abel and Koch, 1998; Black, 1998; Feinstein, 1998; MacLehose et al., 2000). These issues have been discussed at length elsewhere (Lewith et al., 2002; Walach et al., 2002).

The only way out of the impasse, it seems, may be through diversification of methods. Reinventing the wheel will not do. First and foremost a clear understanding of the nature of homeopathy is needed. It is imperative to know whether there is a local process or not. Let us be clear about the fact that Hahnemann himself always spoke of the spirit-like nature of homeopathy, hinting at the nonlocality behind it. Basic research and a simple research model—cells, animals, bacteria, plants, whatever is simple and can be repeated many times (Vickers, 1999)—could help to study this question. This could then inform theory. A solid theory will help to understand why blinded trials of single-remedy homeopathy have failed so often and what needs to be done to change the picture.

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