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Kaptchuk T. Early use of blind assessment in a homeopathic scientific experiment

Commentary on: Storke EF, Martin R, Rosenkrans EM, Ford J, Schloemilch A, McDermott GC, Carlson OW (1880). Final report of the Milwaukee test of the thirtieth dilution. *Homoeopathic Times* 7:12/280-1.

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Blinding of participants in an experiment to prevent conscious or unconscious bias is considered a desirable component of contemporary medical research. The early history of the adoption of blind assessment is often found to be linked to the medical tug-of-war between mainstream and unconventional medicine in the nineteenth century (Kaptchuk 1998). In these debates blinding was perceived as a necessary safeguard to prevent enthusiastic bias, mental delusions and even calculated deceit. This type of radical skepticism at the time was usually reserved for the mutual recriminations that were exchanged across the medical divide. The need for blinding within mainstream medical research was a non-issue as these medical claims did not challenge normal "rationality." It should not be surprising, therefore, that a substantial proportion of the examples historians have been able to uncover concerning the early adoption of blind assessment relate to these medical wars. And nowhere was the conflict more acrimonious than around homeopathy (Ernst and Kaptchuk 1996; Jonas et al. 2003).

Historians have noted blind assessment and placebo controls as early as the mesmerism controversies of the late eighteenth century (Carlson and Simpson 1970; Kaptchuk 1998), but homeopathy seems to be the first domain in which substances were regularly given blindly, or given together with mimicking placebo controls. Homeopaths adopted placebo controls at least as early as the 1830's in their 'provings'. This is the homeopathic procedure of giving remedies to healthy volunteers to see which symptoms developed so that this symptom profile could be applied to treat sickness with the homeopathic principle of *Similia similibus curentur* — like cures like (Dean 2000). Many such examples have been documented (Dean 2000).

One of the most carefully crafted such homeopathic experiments was performed in 1879-1880. The trial was reported in March 1880 in the *Homoeopathic Times: a Monthly Journal of Medicine, Surgery and the Collateral Sciences*, published in New York City (Potter and Storke 1880). The study was designed to assess whether homeopathic medicines in the 30th dilution 'can produce any medicinal action on the human organism, in health or disease'. Sponsored by the Milwaukee Academy of Medicine, the experiment actually had two components: 'pathogenic' and 'therapeutic'.

The pathogenic component consisted of assembling a package of 10 vials, only one of which contained sugar pellets moistened with *Aconite* 30c, whereas 9 similar vials contained sugar pellets moistened only with pure alcohol. *Aconite* 30c means that the original *Aconite* tincture was diluted 30 times (in a series of 1:100 diluent-volume ratio), which leads to a concentration below the limit of molecular dilution [Avogadro's number], thus implying the likelihood that none of the material molecules of *Aconite* remained in the remedy.

Homeopathic 'provers', who were "physicians of acknowledged ability, who possess a good knowledge of the recorded symptomatology of *Aconite*, and who have faith in the efficacy of the 30th dilution", were asked to self-administer and prove the 10 vials and select the one containing the verum. The package of test vials was numbered, coded and dispensed by a minister and professor of mental and moral philosophy from Bowdoin College. Ensuring a "fair and honorable" test, the minister took "a solemn pledge that he will not, in any manner, reveal to any person which of the preparations coming from his hands have been medicated". The minister testified in the journal summary that:

"great pains have been taken to exclude entirely the possibility of guessing the medicated vials, instead of discovering them by scientific experiment. Nothing has been permitted to indicate a difference in the vials tested, or to make it possible for any experimenter to detect in any way the reasons for choosing one number rather than another, of all the vials numbered to contain the medicated pellets."

His words indicate a genuine concern for what we would now call 'double-blinding'.

The second, therapeutic, component of the trial prepared the homeopathic remedies *Arsenicum album*, *Aurum metallicum*, *Carbo vegetabilis*, *Natrum muriaticum* and *Sulphur* in the 30th dilution. In consideration of "the inconvenience of experimenting on the sick arising from popular prejudices", the number of vials of "unmedicated pellets" were limited to one for each medicine, that is, each verum was matched with only one sham. The experimenter was supposed to give these 2 vials to "mostly chronic patients" and then decide on the basis of the patients' reactions which was verum. The ethical issues were discussed as follows: "The real gain to the healing art which will be accomplished by the establishment of the truth or falsity of the theory of 'potentization' will amply compensate for the risk of delaying a few cures." Provisions were also made that a prover could ask for any other common homeopathic medicine. The blinding in the 2-vial test was guaranteed by the same minister.

Money was made available for supplying an anticipated 100 provers with the *Aconite* 30c 10-vial sets. The paired therapeutic test required provers to pay for it themselves. All medicines were obtained from Boericke & Tafel (the leading supplier of homeopathic remedies in the United States) and the *Aconite* 30c was first pilot tested in an unblinded manner by several members of the Society, to ensure that they could produce the pathogenic effects of *Aconite* 30c. Advertisements were put in English and non-English homeopathic journals requesting participants.

25 physicians (far fewer than expected) from 10 different states volunteered for the pathogenic arm of the trial. For unknown or unstated reasons, only 9 physicians replied to the minister, indicating which vial they had identified as the verum. According to the minister's carefully recorded tabulations, none of the choices were correct. 47 physicians also requested the 2-vial therapeutic test; only one reported back to the minister. Here, the choice of verum (*Arsenicum*) was correct. These disappointing results were reported in the *Homoeopathic Times* in a matter-of-fact manner.

In the same year, the *British Medical Journal* also reported on the pathogenic arm of the trial, noting that the project had been "carried out with great care", and drawing attention to the act that the prover "was not to know which of the vials contained the *Aconite*" (Anon 1880), suggesting that the methodology of blind assessment to prevent bias was known in the general medical community (even if its necessity for preventing bias in evaluating mainstream practice was not yet a consideration). The *BMJ* report went on to observe that the study was "highly creditable to those who ventured on an experiment involving so much peril to a favourite theory," and that the 'negative results' had not come from "the opponents of homœopathy, but from its own adherents; and not from a local or partial source, but from a select body representing the more intelligent portion of the sect." The *British Medical Journal* report concluded by noting that:

"No notice of this report has appeared, it is stated, except in the journal named. It would appear that a general effort has been made to suppress it. In the meeting of the New York State Homœopathic Society lately held at Albany, the report was refused acceptance. The editor of the *Homœopathic Times* complains of this, saying that common courtesy required its reception, though its adoption might have been refused."

Although not clearly stated, it may well have been that this blind assessment was developed to counter orthodox medical criticism of homeopathic dilutions. The credit for the trial therefore may not be entirely an initiative from within the ranks of homeopaths. But, by 1900, well before orthodox medicine had incorporated this method into its evaluative process, homeopathic circles considered a blind procedure routine for participants in homeopathic drug proving. This is clearly seen in Kent's instructions on provings published in 1900 in *Lectures on Homeopathic Philosophy* (Kent 1900).

In retrospect, this early blind assessment experiment is probably best thought of as a significant example of what many medical historians have noted was the progressive attitude of many homeopaths towards therapeutic evaluation, which often showed homeopathy to be superior to the then current mainstream practices (Cassedy 1984). It is an important, early, well-designed example of blind assessment to prevent bias in medical research.

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Potter S, Storke EF (1880). Final report of the Milwaukee test of the thirtieth dilution. *Homoeopathic Times* 7:12/280-1. The paper summarizes the entire process of the trial in stages and is actually subdivided and written by three different groups of authors. The first part (dated 3 Dec 1878) is an announcement of the design of the trial-and an invitation for participants and is signed by EF Storke, R Martin, EM Rosenkrans et al.; the second part (dated 26 Jan 1880) is signed by GT Ladd and certifies the honesty of the trial; and the third part (dated 16 Feb 1880) summarizes the results and is signed by S Potter and EF Storke, President and Secretary respectively of the Milwaukee Academy

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