Witt / Albrecht
New Directions in Homeopathy Research

Extrait du livre

New Directions in Homeopathy Research
de Witt / Albrecht
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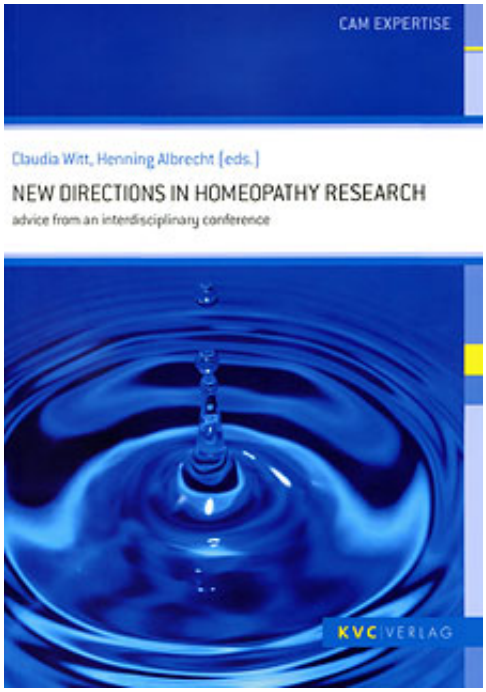

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The naive approach

The first double-blind study of Belladonna 30 C in healthy volunteers in a crossover design

In my PhD thesis I translated the rationale of an HPT into an experimental model[20]-[21]. Using a placebo-controlled, double-blind crossover design, I had 48 self-reportedly healthy volunteers take Belladonna 30 CH and placebo in a randomized sequence. After a placebo run-in week the participants took test substance for four weeks and placebo substance for another four weeks (always only at the beginning of the week), or the other way round. Data collection took place by a structured diary. I decided to reduce the complexity of data right at the beginning through offering a rich, yet restricted amount of categories in order to be able to quantitatively evaluate them.

The outcome of this study can be reported very briefly: there were a number of highly significant differences between the phases for single individuals. In fact, if summed across all individuals this is highly significant. However, the symptoms experienced did not correspond with the experimental conditions: there were individuals who had a huge number of symptoms under placebo but not under Belladonna and the other way round but without a systematic pattern.

When testing for global effects across all individuals, taking into account the experimental design, those strong effects averaged out pretty much. For example, there were significantly more symptoms in the category ,,negative feelings, pain", but under placebo, while there were more symptoms in the category ,,activation" under Belladonna. The results, thus, remained inconclusive.

Also, one could raise the point that taking medication, albeit only small doses, over a prolonged period of time, might either produce long-standing symptoms, inducing carry-over effects, or antidote effects as they arise, although none of these explanations did seem convincing enough to explain the data pattern.

Testing the individualized difference hypothesis: randomized single case studies

A solution to the problem seemed to be to conduct real single case studies. In order to do that we used randomization designs[22]. In such designs you randomize individual treatment periods. We had our participants take Belladonna 12/30 CH or placebo in a randomized order, double-blind. We randomized the sequence of Belladonna and placebo periods, four weeks each, where only the first day of each week was a day when a remedy was to be taken. We had participants note their symptoms in diaries that collected a predefined set of symptoms, half of which were Belladonna symptoms, the other half not typical for Belladonna. This enabled us to run straightforward randomization tests that allow the definition of statistical significance on an individual level in order to determine whether the number of Belladonna symptoms was different with Belladonna from placebo.

We again found quite paradoxical results[23, 24]. In all of the 25 experiments we carried out one individual had significantly ($p = 0.01$) more Belladonna symptoms with Belladonna, one had significantly more Belladonna symptoms with placebo, and in several cases there were interesting changes with Belladonna that were graphically obvious which, however, for internal reasons were not significant with this design. We concluded, again, that the situation was unclear, that such designs were not useful for HPTs and liable to produce spurious effects, and that different and more studies were needed.

Replicating the naive approach

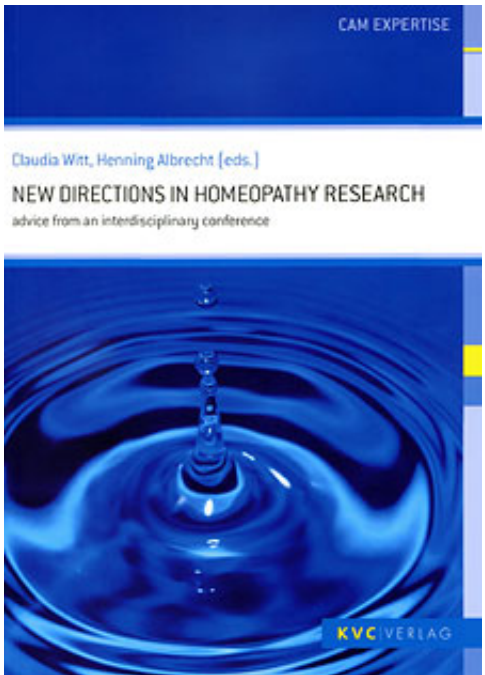
In the meantime we ran a larger replication study using a similar design as in the first Belladonna study, improved by several design features[25]: we included more participants ($n = 87$), we introduced a washout period of one week between the experimental phases of the cross-over-design and reduced the intake of medication or placebo to two weeks each, gave medication only during the first three days of the first

week and then had people observe for the rest of the two weeks. We used the same structured diary, though, and, based on our previous study, formulated some hypotheses that guided us towards combining symptom categories to clusters to be tested experimentally. Although there was a clear and significant difference between baseline and each of the experimental interventions in some of the variables, there was no significant difference between homeopathy and placebo in those predefined categories. Thus, the initial tentative results were not replicable, and there was no indication in this study that symptoms produced by placebo and those produced by Belladonna 30 CH were in any way different from each other[26].

Scrutinizing the data more carefully using grade-of-membership analysis

The standard interpretation of these attempts was once succinctly put by a departmental critic of my work. In a letter to me he icily remarked: ,,What the scientific sense of testing one placebo against the other should be, I do not quite understand". Of course, for a standard scientific reasoning placebo and homeopathic remedy had to be different. However, intrigued by the phenomenology of the results I thought that something different was actually going on in the background. I still saw a lot of variation, i. e. specific symptoms, but I saw them in both groups. Thus, to me the problem was that there were not only *any* symptoms that were indistinguishable under both conditions but that *Belladonna-specific* symptoms were seen to a large extent also with placebo. That was the scientific puzzle. Having ruled out methodological artefacts, such as carryover effects or response bias pretty much by design I was quite convinced that this was a genuine effect. To probe this further I employed a very sensitive multivariate method: grade-of-membership (GoM) analysis on the dataset of the 2001 study[27].

I am not going to bore you with technical details; they can be found in the original publication. In essence, GoM Analysis is a multivariate



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