

## Is it the homeopathic case-taking that helps, or the homeopathic medicine?

### Introduction

A recently published study on the effectiveness of homeopathy in rheumatoid arthritis<sup>1</sup> was reported as demonstrating that the “Homeopathic consultations but not homeopathic remedies are associated with clinically relevant benefits for patients with active but relatively stable Rheumatoid Arthritis”. Rainer Lüdtké concludes that the results do not completely support this statement.

### Patients and Methods

This study was planned and conducted by the renowned research group led by George Lewith from the University of Southampton, Sarah Brien serving as the main investigator and first author. It was designed as a partially blinded randomized controlled multicenter trial aiming to assess the effects of homeopathic consultation and homeopathic medicines as an add-on treatment to conventional medicines.

83 adult patients suffering from long-standing, stable, and currently active rheumatoid arthritis were included. Disease duration was more than two years and the current disease activity exceeded a threshold of 2.6 in the internationally accepted DAS-28 questionnaire. Patients who were taking biological DMARDs (e.g. anti-TNF) were excluded, as were those who had changed their conventional medication during the previous three months or had a homeopathic treatment in this period.

All patients were randomly allocated to one of five treatment groups. Three treatment groups received a 90 minute consultation, including a complete state-of-the-art homeopathic case-taking. Subsequently the patients were treated with individually selected homeopathic medicines, matching placebos or a homeopathic complex remedy (Rheumaselect<sup>®</sup>, produced and distributed in Germany) which had been shown effective in a previous placebo-controlled trial.

Two further treatment groups received the complex remedy or placebo without any consultation.

Patients and homeopaths were blind as to who received a verum or placebo therapy, but not to who received homeopathic consultation.

A priori the study defined two primary outcome measures, based on the internationally accepted criteria of the American College of Rheumatology (ACR) and a global assessment of general health.

### Results

110 patients were required, however only 83 patients were recruited and immediately after randomization six patients withdrew from the study, leaving a total of 77 patients to be treated and analysed. Another 21 patients did not completely adhere to the study protocol, mainly because they needed steroid injections, suffered from adverse events, or withdrew from further treatment. Thus there were outcomes for just 56 patients for this five arm trial. No significant differences were observed for either primary outcome.

According to the ACR criteria, the percentages of successfully treated patients was essentially the same, whether they received verum or placebo (31.2% in each group) after homeopathic case taking, but patients in the complex remedy group performed worse (14.3%). These numbers were lower, if the patients did not receive a homeopathic consultation, with only 13.3% in the complex remedy group and 12.5% in the placebo group being successfully treated.

These figures change somewhat if the second primary outcome, the global assessments of health, is considered. Group differences were rather small and ranged from 26.7% (complex remedy without consultation) to 42.9% (complex remedy with consultation).

Statistical analyses could not demonstrate any effect of homeopathic verum medicines (individually prescribed or complex remedy) in any main outcome criterion. Moreover, even the effects of the homeopathic consultation could not be significantly proven with these measures ( $P=0.22$  and  $0.58$ , respectively). Only after considering secondary outcome criteria, including the current disease activity, the number of swollen joints and the actual perceived pain, were effects of the homeopathic consultation apparent.

### Comments

In the last years there were only a few publications on the effectiveness of homeopathy which report their methods and results so extensively and meet such high methodological standards as this publication does.

The results however are somewhat puzzling and inconclusive. The main reason for this is the lack of an adequate statistical power to detect any treatment effect. Two specifics are responsible for this: small patient numbers and relatively high withdrawal rates, e.g. only 32 patients (16 per group) contributed data to detect any differences between individualized homeopathic medicines and placebo, and 9 of them did not adhere to the protocol. Given the constraints of the study (all these patients were receiving conventional therapy in addition to a homeopathic consultation) one would expect only small add-on effects for the individually selected homeopathic medicines. Consequently there was a high probability to overlook such an effect in this study.

Moreover, the study was not able to detect a consultation effect in either of the primary outcome measures, although most researchers would agree that the consultation effects are relatively large compared to pure effect of the homeopathic medicine<sup>2</sup>. Consultation effects were only seen in some secondary outcomes and patterns of effectiveness were inconsistent across all outcome parameters: consultation appeared to be significantly better in disease activity ( $P=0.005$ ), somewhat better with the ACR criteria ( $P=0.219$ ), more or less equal in general health assessment ( $P=0.582$ ) and even somewhat worse in the case of the HAQ (Health assessment questionnaire,  $P=0.218$ ).

So the question arises: Did this study really “demonstrate” that “patients benefit from a long

and empathic encounter with a homeopath but not from the remedy” as the accompanying editorial said?<sup>3</sup> The answer has to be an unequivocal “no”. In my opinion the reported results do not support either of the claims.

This is especially true because of another puzzling aspect. As might be expected, patients receiving homeopathic consultations reported experiencing more empathy and enablement than those who did not. If “patients benefit from a long and empathic encounter” then we would expect a positive clinical outcome. However “Neither the empathy nor the enablement variable predicted changes in either primary outcome or DAS-28”.

### Conclusion

This was a well-designed and well-reported trial. It seems to have a clear unambiguous message, which fits into the current biomedical paradigm: it is not the highly diluted homeopathic medicine that helps patients, but the time-consuming process of homeopathic consultation and case-taking. However, these conclusions are not completely supported by the reported results.

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### References

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