

## The influence of Aconitum Napellus versus placebo, on anxiety and salivary cortisol, in stress induced by intense and short term physical effort

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**Background:** Intense and short term physical effort is a stress factor for sedentary persons. The correctly chosen homeopathic remedy, in other words the simillimum, modulates physical, emotional and mental level of the person to whom it was given, therefore also the psycho-emotional state stress-induced. Aconitum Napellus (AN) is characterized by a state of anxiety, anguish of mind and body, fear, physical and mental restlessness.

**Aims.** The objective of the study is to highlight the AN influence on the dynamic of two parameters, anxiety and salivary cortisol, in peri - stress changes induced by intense and short term physical effort, on sedentary subjects.

**Methods:** All chosen subjects (n = 30) had AN recommendation and had voluntarily participated, according to the requirements of the study. Stress was represented by an intense and short term physical effort, made with a Monark Ergomedic 839E cycle ergometer. Three groups of subjects were selected, the first, the control group (C), who was not given anything; the second, who received placebo (P); and the third who received AN. Test was made the days after taking P and AN. Analyzed indicators were anxiety and salivary cortisol. Statistical evaluation was made on the basis of Student test.

**Results:** Although the values for anxiety and salivary cortisol were slightly higher on C compared with P, differences between them were not significant. At all peri-stress times, anxiety and salivary cortisol values in C and P were higher than in AN, significant differences being: immediately pre-stress for anxiety; immediately pre-stress and immediately post-stress for salivary cortisol.

**Conclusions:** 1) Influence on anxiety and salivary cortisol was significantly more intense in AN compared to P. 2) Under AN influence, anxiety and salivary cortisol were significantly reduced immediately pre- and post effort. 3) AN significantly influenced more anxiety than salivary cortisol, immediately pre- and post-stress times. 4) AN may be an effective, safe and accessible modulation path for stress caused by intense and short term physical effort, on AN constitutional sedentary persons.

**Keywords:** Stress, Homeopathy, Aconitum Napellus remedy, Anxiety, Salivary cortisol, Physical effort

## Towards an evidence-based homeopathic treatment for PMS

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**Objective:** Homeopathy could offer safe and effective treatment for women with premenstrual syndrome/symptoms (PMS/S). A research program on effectiveness and efficacy was initiated to evaluate a semi-standardised individualised homeopathic treatment of women with PMS/S.

**Methods/Results:** The first step of our research program was to standardise individualised homeopathic treatment, to facilitate clinical research. Therefore, a semi-standardised computerised algorithm was developed and validated for homeopathic treatment of women with PMS/S with 11 medicines. A questionnaire was used to collect the women's keynote symptoms and characteristics for the 11 medicines. The first homeopathic prescription had to be according to the algorithm outcome. At follow-up, the prescription could be changed according to the analysis of the doctor. This semi-standardisation of the treatment minimised variability in prescription between the participating doctors, enabled optimum reproducibility of the treatment, yet respected the individualised approach.

Secondly, the use of this algorithm was evaluated in Dutch homeopathic practice in 38 women with 3 months follow-up. In an extension of this feasibility study, with 9 months follow-up and in a sample of 77 women suffering from PMS/S, we further evaluated the utility of the semi-standardised algorithm, measured changes in premenstrual symptom scores and detected possible predictive characteristics. This research was conducted in practices of 20 homeopathic doctors in the Netherlands between 2007-2011. Recruitment in this study proved difficult and the dropout rate was considerable. The algorithm proved useful and effective in daily homeopathic practice. We detected a significant decline in mean PMS-symptom scores over time, especially in women with moderate to severe PMS.

Next, in October 2012 we started an international pragmatic trial to evaluate the feasibility of a larger trial to establish the added value of this homeopathic treatment compared with usual care only. This project is a collaboration between research groups at the Louis Bolk Institute, Driebergen, the Netherlands, the Mid-Sweden University, Sundsvall, Sweden and the Women's Hospital, University of Heidelberg, Germany.

Previously, a double blind randomised placebo controlled pilot study was conducted in Israel on individualised homeopathic treatment for PMS with 5 homeopathic medicines. The homeopathic treatment proved superior to placebo, with significant results. For the

homeopathic medicine selection, the 'symptom-cluster' approach was used: women first completed a questionnaire with symptoms representing keynotes of the homeopathic medicines. Women, whose symptom cluster matched the remedy picture of one of the homeopathic medicines were included in the trial. Other women were assigned to a parallel trial.

**Conclusions:** So far, positive clinical data have been obtained for the effectiveness and efficacy of homeopathic treatment in PMS. This line of research can act as an example on how to build up evidence for individualised homeopathic treatment in specific clinical conditions.

## Treatment of nervous complaints and exhaustion with the homeopathic medicinal product Manuia® - results of a cohort study

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**Background:** Exhaustion, nervousness and decreased physical and mental capability are recurrent challenges in GPs' daily routine. They are often resulting from overexertion, or disturbed sleep. Nowadays people feel exhausted and weak due to continuously increasing professional demands and rising challenges in daily life. The approved homeopathic medicinal product Manuia is used in the mentioned therapeutic area. It contains four single active substances: Damiana, Panax ginseng, Acidum phosphoricum and Ambra. So far, effectiveness and tolerability was confirmed by clinical experience, but systematically collected data were lacking.

**Patients and methods:** Between January and June 2011 the clinical effectiveness and tolerability of Manuia was systematically investigated in a prospective, multicentre, non-interventional cohort study. A total of 420 patients were observed by 76 German physicians in private practices. Median observation period was 24 days, median duration of symptoms since diagnosis 5 months.

As main outcome measure severity course of 20 symptoms (nervousness, irritability, sleep disturbances, hyperactivity, impaired concentration, listlessness, frustration, moroseness, exhaustion, dispiritedness, decreased capability, feeling of heteronomy, feeling lonely, feeling pressure to perform, feeling excessive demands, forgetfulness, gastrointestinal complaints, cardiovascular complaints, muscle tension, headache) was evaluated with a 5-item score (0 = not present; 4 = very severe). In addition physicians' Clinical Global Impression (CGI), patients' quality of life and ability to actively attend different domains of daily's life, and tolerability of Manuia were documented.

**Results:** The sum score as well as the severity of each single symptom decreased significantly during the observations' period ( $p < 0.01$ , paired t-test). Illness severity measured by CGI decreased significantly ( $p < 0.01$ , McNemar test; CGI 4-7: 71.7% to 35.2%). Ability to work and to attend social and family life improved significantly ( $p < 0.01$ , McNemar test). In 77.1% (n=324 out of 420) of the patients quality of life was good, very good or excellent during control visit, compared to 15.8% (n=66 out of 420) at baseline. 92.4% of the patients rated their condition as improved, 64.1% as much or very much improved. Median duration until onset of action was 7 days. Tolerability was good or very good in 98.1% of all cases.

**Conclusion:** The study data underlined the existing good clinical experience with Manuia and suggests Manuia as a therapeutic option in the treatment of nervous complaints and exhaustion. Further controlled studies are necessary to confirm these findings.

## Might evaporation-induced droplet patterns serve in agro-homeopathic research and support experimental trials?

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Agro-homeopathy provides numerous solutions for a sustainable agricultural production, like for instance cost-saving and residue-free treatments for yield improvement and management of diseases and pests. However, one of the main difficulties in this approach is the right treatment choice (i.e. the curative principle and its dilution level) that often requires numerous time & cost consuming experimental trials.

In the present experiment we applied the droplet evaporation method, previously developed by our research team for wheat quality analysis, to test the influence of highly diluted homeopathic treatments (HD) of *Arsenicum album* on both healthy and previously arsenic trioxide stressed wheat seeds (isopathic model). The pattern evaluation of the resulting polycrystalline structures consisted in (i) the calculation of their local connected fractal dimension, known to reflect the pattern complexity, and (ii) in the fluctuating asymmetry measurement, known to be inversely correlated with the symmetry exactness of the structures, and thus also the vitality of the sample. In polycrystalline structures formed under the same conditions these two measurements have been found to reflect the sample health. Additionally, in order to support the crystallographic data with traditional analysis methods for seed viability, we performed the seed germination test and measured the shoot