Focus on Alternative and Complementary Therapies
Contents

EDITORIAL

• The catwalk of CAM – fad and fashion in complementary medicine 167
  Peter Canter
• European herbal medicines regulations 169
  Desmond Corrigan

INTERVIEW

• Wayne B Jonas 171

FOCUS 173

• Complementary and alternative medicine for atopic dermatitis 173
  Katja Schmidt
• Placebo and placebo effects – a concise review 178
  Harald Walach

DEBATE 188

• Are herb–drug interactions clinically relevant? 188
  Angelo A Izzo
  Edzard Ernst

SUMMARIES AND COMMENTARIES 191

Herbal Medicine

• No benefit of *Echinacea* in the treatment of the common cold? 191
• Herbal combination useful in the treatment of acute upper respiratory tract infections 193
• Effective herbal prophylaxis for menstrual migraine? 194
• No convincing evidence for use of an Ayurvedic herbal formula in the treatment of alcoholic liver disease 196
• Kava and the potential for drug interaction 197
• Potential for herbal remedy in alleviating premenstrual syndrome symptoms 199
Vitamins, Minerals, Supplements and Dietary Approaches
- Soy may be of benefit for menopausal women with more severe symptoms 201
- Zinc nasal gel may shorten duration and reduce severity of the common cold 202

Homoeopathy
- A positive trial of homoeopathy for low back pain 205
- Effects of one dose of a 30 cH potency of Thyroidinum on weight reduction in fasting patients 206
- Homoeopathic Arnica for sequelae of hand surgery 207

Acupuncture
- Acupressure improves sleep quality in patients with end-stage renal disease compared with no treatment controls (but not compared with sham acupressure) 210
- Acupuncture effective and efficacious for low back pain 211
- Electro-acupuncture during the menopause altered mood but not vasomotor symptoms 212

Manipulative Therapies
- Does spinal manipulation afford benefit in the management of headache disorders? 215
- Promising results of manipulative therapy and exercise in the treatment of cervicogenic headache 216
- Doubts about the cost-effectiveness of chiropractic 218

Other Complementary Therapies
- Investigators claim that static magnets improve symptoms of pain and physical function in individuals with chronic knee pain 220
- Promising results of autologous blood therapy for atopic dermatitis 221
- Human pharmacological study on an anthroposophic cardiotonic 222
- Hypnotherapy – an effective treatment for functional dyspepsia? 224
- Psychological coping style is not associated with survival in cancer 225
- Is psychological therapy effective for chronic pain in children and adolescents? 226

SHORT REPORTS 229
NEWS 274
BOOK REVIEWS 276
NEW BOOKS 281
RECENT LITERATURE 282
Effects of one dose of a 30cH potency of Thyroidinum on weight reduction in fasting patients

Schmidt JM, Ostermayr B.


**Aim**
The aim of the investigators was to measure the effects of a homoeopathic ultramolecular dilution under standardised conditions in a clinical model.

**Design**
Randomised, placebo-controlled, double-blind, parallel group, monocentre study.

**Setting**
Hospital for naturopathy in Munich, Germany; a hospital with a tradition of homoeopathic treatments.

**Participants**
Fasting patients that experienced a stagnation of reduction of body-weight after a weight reduction of at least 100g/day in the preceding days. A total of 208 patients participated, 102 received Thyroidinum and 106 placebo.

**Intervention**
One dose of five pellets of either Thyroidinum C30 or placebo.

**Main outcome measures**
Primary outcome measure was weight reduction on the second day after medication. Secondary outcome measures were weight reduction on the first and third day after medication, complaints and laboratory findings.

**Main results**
Patients that received Thyroidinum had less weight reduction on the second day after medication than patients that received placebo, the mean difference was 92g [95% confidence interval (CI) 7–176]. Adjustment for baseline average weight reduction weakened the association.

**Authors’ conclusions**
‘Patients receiving Thyroidinum 30C had less weight reduction on the second day after treatment than patients receiving placebo. However, the results must be interpreted with caution because there were no significant differences in other outcome measures and adjustment for baseline differences rendered the difference for the main outcome measure non-significant.’

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Authors' reply

Because of the lack of space, we can only reply to the objections.

Information on primary diagnoses of the participating patients can be found on p. 198 of our paper, where it reads: 'Fasting therapy is applied to a broad spectrum of diagnoses including hypertension, diabetes, osteoarthritis, bronchial asthma, migraine, etc.' Furthermore, detailed information on diagnoses as well as on age, height, weight, peculiar symptoms, etc. of each single patient is given in the full publication.1

Yes, we treated 31 men with placebo and 26 men with Thyroidinum. Randomisation was stratified for males and females, in blocks of six. Again, an exact description had already been given in our German publication, on p. 27. To summarise: there were two sets of containers, one for male and one for female patients. We used M001-M057 and F001-F154. On p. 200 of our paper, we wrote: '211 patients were eligible and allocated a randomisation number. Three patients (two Thyroidinum, one placebo) withdrew consent before opening the container. Thus, 208 patients actually received study medication.' So, three containers were randomised but not used. Two of them were provided for females, one for a man (M045, containing Thyroidinum). In addition, just once during the trial, one of the physicians on duty, by mistake, gave the study medication out of a container from the set provided for female patients (F116, containing placebo) to a male patient. Of course, in the analysis this medication was counted for a male patient. Hence, to reconstruct the original randomisation numbers of males it is necessary to add one Thyroidinum male (M045) and to subtract one placebo male (F116), resulting in 27 Thyroidinum and 30 placebo males. A difference of three men is compatible with stratified randomisation in blocks of 6: M055-M057 were placebo.

Instead of performing an exploratory study before, we designed and conducted a two-step trial according to the sequential plan, with an interim analysis after 50 patients. A significant result (as well as a devastating one) would have led to termination of the study in an early stage. Unlike these extremes, the interim analysis showed a very promising, yet still not significant result (p. 30 in German publication). For that reason we felt encouraged to continue the trial under the same conditions, up to 208 patients. Compared with the interim analysis, however, the difference in weight reduction between groups on the second day after treatment dwindled from 181 g to 92 g, whereas the baseline differences increased. These unexpected findings weakened the otherwise significant result to a non-significant level (P = 0.09).

JM Schmidt, Munich, Germany

Reference