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# Focus on Alternative and Complementary Therapies

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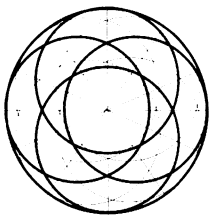

# Contents

## Effects of one dose of a 30 cH potency of Thyroidinum on weight reduction in fasting patients

*Schmidt JM, Ostermayr B.*
**Does a homeopathic ultramolecular dilution of Thyroidinum 30 cH affect the rate of body weight reduction in fasting patients? A randomised placebo-controlled double-blind clinical trial.**
*Homeopathy* 2002; **91**: 197–206.


### 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 100 g/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 92 g [95% confidence interval (CI) 7–176]. Adjustment for baseline average weight reduction weakened the association.

### Authors' conclusions
'Patients receiving Thyroidinum 30 C 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 trail, 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**

1 Schmidt JM. Die Thyreoidinum-Studie am Krankenhaus für Naturheilweisen, 2001, ISBN 3831122717, p. 366–436.