

## Study summary

### Effects of Neuravena® on cognitive function and smoking reduction: a pilot human study

#### Objective

The beneficial effects of the green oat herb extract Neuravena® on mental fitness, alertness and cognitive performance in stressful situations have been confirmed in clinical and preclinical studies. While smoking is not only harmful to health in general, it has detrimental effects on cognition, particularly on memory. Trying to reduce smoking causes severe stress to the human body, both physically and mentally. From previous research it was concluded that oat herb may have a beneficial effect on smoking cessation. Therefore, the underlying pilot study is a first attempt to confirm a positive influence of Neuravena® on stress levels and mental performance of healthy smokers who try to reduce their daily tobacco consumption.

#### Study design

Eight healthy Japanese men, aged  $32.5 \pm 3.9$  years, received 3 capsules of 300 mg Neuravena® daily for 28 consecutive days in an open application trial. Subjects were asked to report the number of smoked cigarettes as well as their feeling of mental stress each day. Furthermore, concentration and memory abilities of the subjects were tested using the Wechsler Memory Scale—Revised test at initiation of the trial and on day 28. The Wechsler test is a validated measure of different memory functions and reports a person's performance as five index scores: verbal memory, general memory, visual memory, attention / concentration, and delayed recall. In addition, levels of biochemical stress markers and exhaled carbon monoxide (CO) (an objective non-invasive method to assess smoking status) were measured at days 0, 14 and 28. Blood chemistry and vital signs were assessed for safety purposes.

#### Results

##### Memory function

The results of the Wechsler memory scale revised test showed that Neuravena® significantly improved verbal (+11.7 %), visual (+7.7 %) and general memory (+11.3 %), Fig. 1. Values of attention / concentration and delayed re-call remained unchanged.

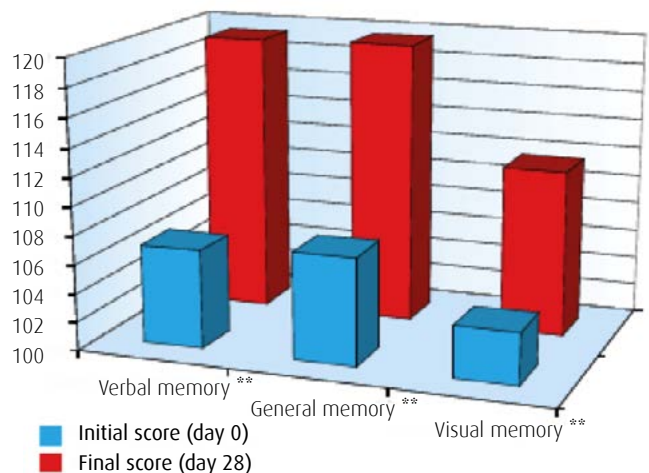


Figure 1: Effect of Neuravena® on memory performance (Wechsler Memory test) at study start (day 0) and after 28 days (n = 8) (\*\* p<0.05, \* p<0.1 vs initial).

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## Tobacco consumption

Neuravena® was found to significantly reduce the average number of cigarettes smoked per day by 55.4 % at the end of the trial, compared to initial numbers ( $p=0.002$ ), Fig. 2. These results are confirmed by decreased concentrations of exhaled CO compared with values at start of study, although this decrease was not statistically significant (not shown). Exhaled CO quantity reflects tobacco smoke inhalation and CO intoxication.

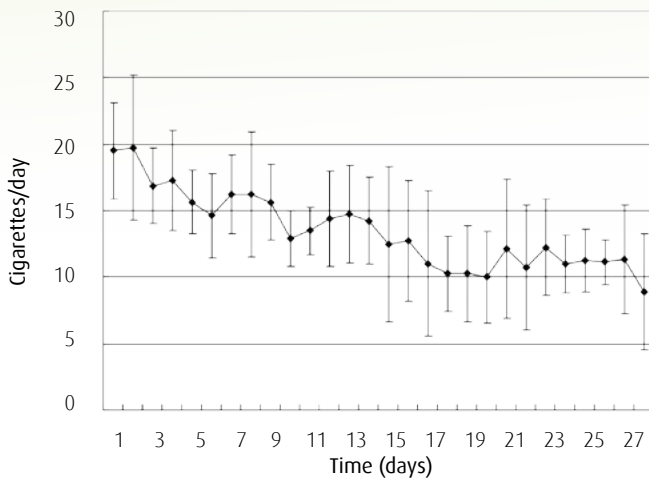


Figure 2: Effect of Neuravena® on tobacco consumption; amount of cigarettes smoked per day during the trial duration (28 days) (bars represent SD).

## Conclusion

From the findings of this clinical trial it can be concluded that Neuravena® mediates positive effects on memory function. Furthermore, Neuravena® helps to reduce the number of cigarettes smoked per day. Finally, the extract was able to stabilize stress levels in the pressured situation of reduced tobacco consumption. These results amend previous evidence for the beneficial effects of Neuravena® on mental fitness and cognitive performance in stressful situations.

## Reference

Fujii, F *et al* (2008). Pilot study of the standardized oats herb extract for smoking reduction. *Pharmacometrics* 75 (3/4): 47-53

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## Stress level

The self-reported mental stress levels as well as the biochemical stress markers urine biopyrin and serum cortisol showed no relevant changes (data not shown).

## Safety

Levels of blood biochemistry and clinical signs were normal during the whole study period. No adverse events related to the study medication were reported.

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