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Subjective ratings of sleep quality and anxiety after placebo, drug and a food drink

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Summary

Ten subjects (mean age 57 years) took part in a cross-over study between a food drink and nitrazepam 5 mg. They rated their anxiety and sleep quality. On half the sleep laboratory nights during baseline periods subjects were given an inert pill which they were told would improve sleep. A comparison was made between the six pill and six non-pill nights for each subject. Subjective ratings revealed no significant difference attributable to the inert pill. Sleep quality was rated to have been improved during both late drug and early food drink administration. On early drug withdrawal sleep quality was rated worse than baseline.

Introduction

There have been very few studies of the effect of placebo on sleep, and yet this is an important consideration when a treatment is administered whose nature cannot be disguised, and with which subjects may associate an effect. In a study comparing placebo, flurazepam and no treatment, Kales *et al.* (1971) demonstrated no effect of placebo on sleep induction, maintenance, stages or on subjective assessment of sleep quality. Davis and Hartmann (1973) recorded subjects electrophysiologically and found no significant difference in total sleep time and sleep onset latency between the means of three placebo and three treatment nights. In a later experiment, comparing the EEG recordings of subjects on placebo for 28 days with a preceding baseline period, Hartmann and Cravens (1973) believed they had found a rather tenuous connection between placebo administration and an increased amount of REM sleep which continued into early withdrawal from placebo. The present study differs from those mentioned above in that our subjects were told that the inert pill would have a beneficial effect on their sleep and hence more specifically investigated the power of suggestion.

Methods

Ten healthy subjects aged 41–62 years (mean 57 years) took part in a cross-over study between a food drink and nitrazepam 5 mg.

Subjects attended the sleep laboratory in pairs differing from each other for the experimental condition. Each subject slept in quiet and comfortable conditions on a total of 58 nights spread over 38 weeks according to the experimental design in Table 1.

TABLE 1. The experimental design used

Week No.	Treatment
1 and 2	2 Adaptation nights
	6 Baseline nights
5 and 6	1 Adaptation night
	6 Early treatment nights
7, 8, 9 and 10	Treatment continued at home
11 and 12	1 Adaptation night
	6 Late treatment nights
13 and 14	Treatment continued at home
15 and 16	1 Adaptation night
	6 Withdrawal nights

Six weeks later, subjects repeated the above schedule on the alternative treatment. Treatments were administered about 30 min before lights out (approximately 11.30 p.m. to 7.30 a.m.).

Subjects rated their own sleep quality in the morning and in the evening rated their daytime anxiety using visual analogue scales (0–100 mm) where sleep quality ranges from 'worst' to 'best' and anxiety from 'terrible agitation' to 'imperturbable tranquillity'.

On half the baseline nights and in balanced order each subject was given a pink placebo pill. They were told that these would 'help make your sleep more restful without causing any hangover'. The food

drink was made with 32 g of Horlicks powder mixed with 250 ml of hot milk. The drug and the food drink were each taken for 10 weeks by every subject.

Results

Ignoring the subjective ratings collected on the adaptation nights, each of the ten subjects had a total of twelve baseline nights (six pill and six non-pill) and six laboratory nights for each of the other experimental conditions.

Friedman's analysis of variance (Siegel, 1956) of the subjective ratings from both baseline periods demonstrated that when the inert pill had been taken the night before neither sleep quality improved ($\chi r^2 = 3{\cdot}45$, d.f. = 3, n.s.) (Table 2) nor anxiety altered ($\chi r^2 = 1{\cdot}32$, d.f. = 3, n.s.) (Table 4).

TABLE 2

Subjective sleep quality	mean ± s.e. (in mm)	
Mean baseline: pill	45·6±2·4	
non-pill	49·2±3·3	n.s.
	47·4±2·6	

TABLE 3

Subjective sleep quality	mean ± s.e. (in mm)
Mean baseline	47·4±2·6
Early drug	50·1±2·9
Late drug	53·0±3·0†
Drug early withdrawal	39·9±3·0*
Early food drink	50·7±2·7†
Late food drink	49·8±2·3
Food drink early withdrawal	50·7±2·6

* significantly lower than baseline at $P < 0{\cdot}05$ level (1-tailed test)
† significantly greater than baseline at $P < 0{\cdot}025$ level (1-tailed test)

Sleep quality was rated to have been improved during both the late drug ($t = 2{\cdot}28$, $P < 0{\cdot}025$, 1-tailed) and early food drink ($t = 2{\cdot}63$, $P < 0{\cdot}025$, 1-tailed) administration, when correlated t-tests were used to compare them with baseline (Table 2).

A difference between subjective ratings of sleep quality was seen when comparing the baseline mean with early withdrawal (laboratory nights 1, 2 and 3) from the drug, i.e. sleep being rated worse after drug withdrawal ($t = 1{\cdot}88$, $P < 0{\cdot}05$, 1-tailed).

TABLE 4. Subjective anxiety ratings for the day before and the day following a night spent at the sleep laboratory

	Mean ± s.e. (in mm)	
Before		
Mean baseline: pill	51·8±1·8	
non-pill	52·9±2·1	n.s.
After		
Mean baseline: pill	52·7±1·9	
non-pill	51·2±1·7	n.s.

No significant differences were found between the baseline anxiety rating and any subsequent treatment.

Discussion

Any experiment which sets out to investigate the value of a treatment whose identity cannot be concealed is faced with the problem of how big a part suggestion may play in the results. In this experiment subjects were specifically told that their sleep would be improved and yet this was not reflected in the subjective ratings. The results of the EEG sleep recordings made on the nights when subjects attended the laboratory appear also unaffected by placebo but will be reported at a later date.

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Notes