

ORIGINAL PAPER

Chronic primary insomnia: Efficacy of homeopathic simillimum

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Introduction: Chronic primary insomnia is defined as difficulty in initiating or maintaining sleep or of non-restorative sleep that lasts for at least 1 month and causes significant distress or impairment in social, occupational or other important areas of functioning. The homeopathic simillimum is that remedy which most closely corresponds to the totality of symptoms; remedy selection is based on a full evaluation of the patient's physical, emotional and mental characteristics.

Aim/Purpose: The purpose of this randomised, double-blind, placebo-controlled study was to evaluate the efficacy of homeopathic simillimum in the treatment of chronic primary insomnia.

Method: 30 participants were selected in accordance with DSM-IV TR (2000)¹ criterion 307.42 Primary Insomnia and then randomly divided between treatment and placebo groups. The measurement tools used were a Sleep Diary (SD) and the Sleep Impairment Index (SII).²

After an initial consultation, 2 follow-up consultations at 2-week intervals took place. Homeopathic medication was prescribed at the first and second consultations. The SII was completed at each consultation and participants were instructed at the first consultation to start the SD.

Results: SD data revealed that verum treatment resulted in a significant increase in duration of sleep throughout the study, compared to the placebo treatment which resulted in no significant increase in duration of sleep. A significant improvement in SII summary scores and number of improved individual questions were found in the verum group, responses to all 11 questions having improved significantly upon completion of the study. An initial improvement occurred in the placebo group, but was not sustained. Comparison of results between the groups revealed a statistically significant difference.

Conclusion: The homeopathic simillimum treatment of primary insomnia was effective, compared to placebo. Homeopathy is a viable treatment modality for this condition and further research is justified. *Homeopathy* (2010) 99, 63–68.

Keywords: Insomnia; Simillimum; Homeopathy

Introduction

Chronic primary insomnia is defined as difficulty in initiating or maintaining sleep or of non-restorative sleep

that lasts for at least 1 month and causes significant distress or impairment in social, occupational or other important areas of functioning.¹ It is a prevalent and distressing problem reportedly affecting 9%–10% of the population in the United States.³ Chronic insomnia, if untreated, can have social, economic and occupational impacts on the individual.²

Insomnia is the most commonly reported sleep problem in industrialized nations, leading to emotional distress, daytime fatigue and loss of productivity. The enormity of this problem indicates that routine clinical assessment and

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treatment of insomniacs may have important health benefits for the individual.⁴

Commonly prescribed pharmacological agents such as anxiolytics and hypnotics even when used intermittently (to prevent tolerance) can result in a cycle of drug-dependent insomnia.⁵ The use of non-prescription drugs such as antihistamines is not recommended for more than 7–10 days due to the risk of adverse effects.⁶ Besides the risk of adverse effects, chronic use of sleep medication may undermine the development of self-management skills to cope with insomnia.⁵

These factors contribute to the need to conduct clinical studies investigating other treatment modalities.⁵

There is much literature regarding the use of homeopathic remedies in the treatment of insomnia. Unfortunately, there is a paucity of controlled clinical trials evaluating the efficacy of homeopathic treatment of chronic primary insomnia. A literature search revealed only two related studies. The first study assessed the effectiveness of homeopathic simillimum in the form of 50 Millesimal (LM) potencies in the treatment of secondary insomnia in peri- and post-menopausal women.⁶ The second study tested the efficacy of a commercially available homeopathic complex in secondary insomnia.⁷ Although both studies produced statistically significant results in favour of the homeopathic interventions, both suffered from number of methodological weaknesses. No studies assessing the effectiveness of homeopathic simillimum in chronic primary insomnia were found.

The purpose of this double-blind, placebo-controlled study was to evaluate the efficacy of homeopathic simillimum in the treatment of chronic primary insomnia in terms of the patient's perception of the treatment, using a Sleep Diary (SD) and the Sleep Impairment Index (SII).²

Material and methods

Ethical approval for the conduct of this study was granted by the Faculty of Health Sciences Research Committee at Durban University of Technology (DUT) in Durban, South Africa. The study was conducted at the DUT Homeopathic Day Clinic.

Recruitment and sampling

Following a series of advertisements placed in the local press, the first thirty consenting participants were recruited *via* convenience sampling (a form of non-probability sampling utilising the most conveniently available participants to the researcher).⁸ Participants were considered suitable if they met diagnostic criterion 307.42 Primary Insomnia according to Diagnostic and Statistical Manual of Mental Disorders (DSM), 4th edition and were not using additional sleep aids, interventions or medication.¹ Informed consent was obtained from all participants who were free to withdraw from the study at any stage.

The sample size was set at 30 participants, with an additional three participants being recruited to allow for potential patient exclusions or withdrawals. Each participant was assigned a number sequentially as they entered the study.

These numbers had previously been randomly allocated into two groups by the research supervisor (by means of drawing numbers from a hat) to form a randomisation list. Of the 33 participants recruited, 30 completed the study. Three participants were excluded either due to scheduling difficulties resulting in non-attendance of their follow-up consultations or poor compliance with medication instructions. Of the remaining 30 participants, 14 comprised the treatment group and 16 the placebo group. During the study, neither the participant nor the researcher was aware of which group the participant belonged to. Dispensing of medication was performed by an independent dispenser at the DUT Homeopathic Day Clinic, according to the randomisation list. Unblinding took place only once all participants had completed the study (see Figure 1).

Measurement tools

Two outcome measures were used: in this study: SD and SII.

A SD is a daily, written record of an individual's sleep-wake pattern containing such information as time of retiring and arising, time in bed, estimated total sleep period, number and duration of sleep interruptions, quality of sleep, and daytime naps.⁹ Sleep diaries can provide clinically useful information in the initial assessment of the complaint, particularly as it relates to the patient's perception of the problem.¹⁰ The SD format used in this study has been used by Bakea (2003) as a subjective measurement against polysomnograph readings and was designed by a patient of the sleep laboratory where she is based.¹¹

The SII is a 7-item measurement tool that yields a quantitative index of sleep impairment. It is a brief and global self-report instrument which provides valuable information on the patient's perception of his or her insomnia, its severity, level of distress and impairment of daytime functioning.² The SII has been found to be sensitive to changes in insomnia research. It is a reliable and valid measure for the assessment of insomnia severity in a clinical population. It is a cost-efficient method to quantify perceived insomnia severity and may be used either as a screening device or as a measure of treatment outcome.¹²

Case management

At the first consultation, a full homeopathic case history was taken and a physical examination was performed. Participants completed the SII which provided a baseline measurement for statistical purposes. Each participant was instructed to record data in a SD related to the hours slept for 1 week before taking the medication prescribed, so as to provide a baseline measurement for statistical purposes. Recordings in a SD were continued throughout the trial.

Medicines

Limitations were not set as to the potency of the simillimum prescribed but rather the most suitable potency(s) was determined for each case. The dosage form however was limited to the prescription of three single dose lactose powder sachets per consultation, one of which was dissolved sublingually each night consecutively before going to sleep.

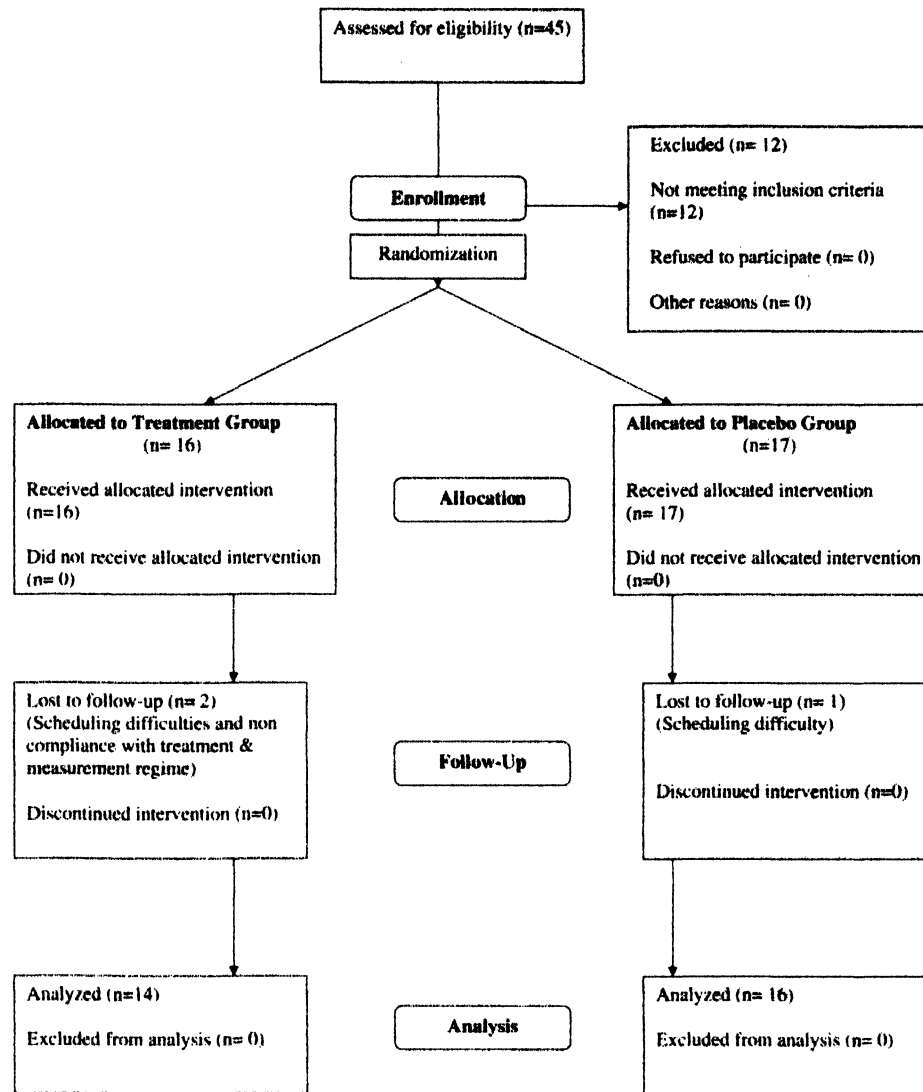


Figure 1 Consort flow chart.

Each active powder sachet comprised 10 medicated lactose granules which were placed into the sachets containing lactose powder. The medicated granules were produced in accordance with Method 10 of the German Homeopathic Pharmacopoeia.¹³ Lactose granules were triple impregnated (1% v/v) with centesimal potencies of the relevant remedy contained within 96% ethanol, prepared by Natura laboratories, Pretoria. Each placebo powder sachet comprised lactose powder and 10 lactose granules impregnated (1% v/v) with 96% ethanol alone and were indistinguishable from the active sachets in appearance and taste.

After discussion of each case between the researcher and the research supervisor the indicated homeopathic simillimum was determined for each participant based on repertorisation (RADAR¹⁴ version 9) of the totality of symptoms presented. The prescription was dispensed by an independent dispenser at the DUT Homeopathic Day Clinic, according to the randomisation list. Participants were instructed to start taking the prescription on the eighth night after the initial consultation.

The first follow-up consultation occurred after 2 weeks. Participants were re-assessed and the SII was completed.

At this stage the researcher, in keeping with classical homeopathic principals, could either repeat the first prescription, change the potency of the initial remedy, change the remedy, or leave the remedy to continue acting.

The second follow-up consultation occurred after 4 weeks (2 weeks after the first follow-up) at which the SD was collected and the final SII completed. No further medication was prescribed, although participants were referred to the DUT Homeopathic Day Clinic for further treatment if they so desired. Once the study was unblinded, participants who were on placebo were offered active prescriptions as per originally prescribed.

Data collection and analysis

Data obtained from the SD was analysed at the end of the study in terms of total hours slept per week.

Participants graded each question of the SII according to the severity of their symptoms using the scale 'none', 'mild', 'moderate', 'severe' or 'very much'. This included difficulty falling asleep, difficulty staying asleep and problems of waking up too early. The data obtained from the SII was analysed in the form of summary scores as well as per individual question.

Statistical analysis of the raw data was conducted using the Statistical Package for the Social Sciences (SPSS) (version 12.1) software suite. Inferential statistics were conducted. Non-parametric statistical tests (Wilcoxon's Signed Rank Test and Kruskal-Wallis Tests) were used due to the relatively small sample size ($n = 30$) and due to the data not being normally distributed. For all tests the type 1 error was set at 5% ($\alpha = 0.05$). If the p value as reported was less than 0.05 it was declared a significant result and the null hypothesis was rejected.

Results

Introduction

Inter-group statistical analyses of the symptom scores derived from the SD and SII on entering the trial revealed that the respective groups did not vary significantly in terms of their degree or severity of insomnia, thus the groups were statistically similar upon trial entry (see Table 1).

Demographic data

The study sample ($n = 30$) comprised 19 males (63%) and 11 females (37%), ranging from 20 to 58 years of age with a mean age of 37 years.

SD

Analysis within groups of total hours slept per week revealed significant differences within the Treatment Group between Baseline and Weeks 2 ($p = 0.001$), 3 ($p = 0.001$) and 4 ($p = 0.002$) as well as between Weeks 2 and 4 ($p = 0.028$). There were no significant differences between Baseline and any of the weeks within the placebo group ($p > 0.05$).

Analysis between groups of total hours slept per week revealed significant differences in favour of the Treatment Group i.e. at Week 2 ($p = 0.004$), Week 3 ($p = 0.042$) and Week 4 ($p = 0.036$). There was no difference between groups at Baseline ($p = 0.724$) (see Figure 2).

SII

Both groups reported significant improvements in 6/11 questions after 1 week of treatment, however, in the latter 2 weeks of the study the verum group reported significant improvements in 10/11 questions in comparison to the placebo group's 4/11. When comparisons were made between Baseline SII scores and those at Week 4 (trial entry and trial completion), significant improvements in all (11/11) questions within the verum group were observed. Within the

Table 1 Demographics and baseline scores per group

	Treatment group (n = 14)	Placebo group (n = 16)	P value
Males	9	10	–
Females	5	6	–
Mean age	32	40	0.134
SD score (baseline)	35	34	0.724
SII score (baseline)	3.344	3.528	0.226

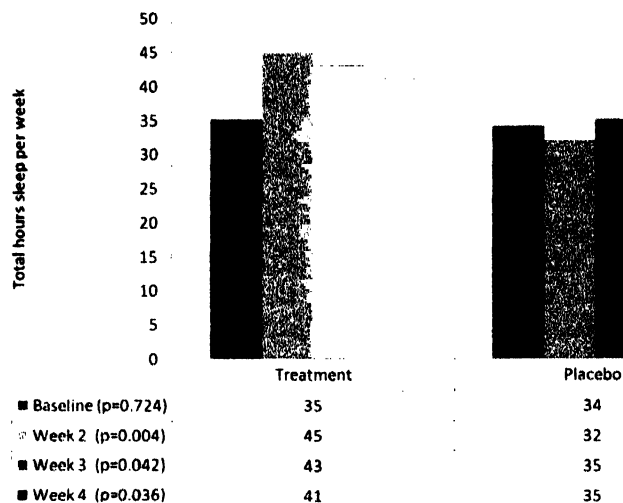


Figure 2 SD data (number of hours slept per week and p-value (Kruskal-Wallis)).

placebo group no significant improvements were noted for any of the questions (0/11) over the same period.

Within the treatment group significant improvements in SII summary scores occurred between baseline and each of the follow-up consultations. Within the placebo group an initial improvement occurred (between baseline and Week 2) but there was no difference between baseline and the final SII scores.

Comparisons between the groups for SII values revealed significant differences at the first follow-up consultation in 8/11 questions and 10/11 questions at the second follow-up consultation. When summary scores for the SII were compared between groups a significant difference in favour of the verum group was noted at Week 4 ($p = 0.000$) (see Figure 3).

Remedies and potency prescribed

See Tables 2 and 3

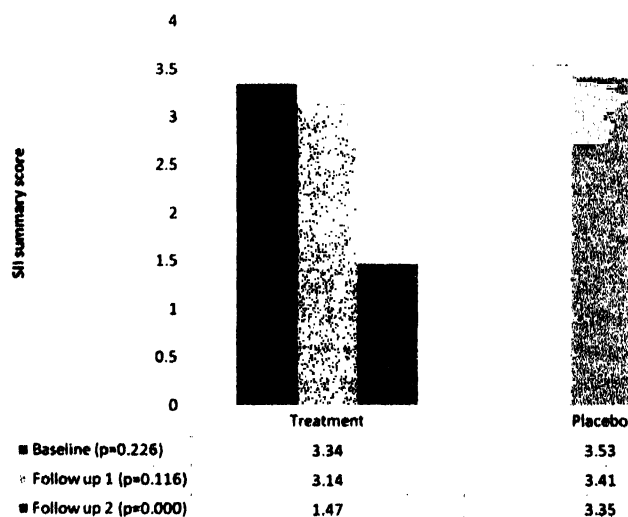


Figure 3 SII data (summary scores per consultation and p-values (Kruskal-Wallis)).

Table 2 Frequency of simillimum prescribed

Indicated simillimum	No. times prescribed
<i>Lachesis muta</i>	8 (13.3%)
<i>Nux vomica</i>	7 (11.6%)
<i>Medorrhinum</i>	5 (8.3%)
<i>Sepia officinalis</i>	5 (8.3%)
<i>Lycopodium clavatum</i>	4 (6.6%)
<i>Carcinosin</i>	4 (6.6%)
<i>Sulphur</i>	3 (5%)
<i>Natrum muriaticum</i>	3 (5%)
<i>Calcarea carbonica</i>	2 (3.3%)
<i>Coffea cruda</i>	2 (3.3%)
<i>Ignatia amara</i>	2 (3.3%)
<i>Silicea terra</i>	2 (3.3%)
<i>Mercurius solubilis</i>	1 (1.6%)
<i>Arsenicum album</i>	1 (1.6%)
<i>Cannabis indica</i>	1 (1.6%)
<i>Calcarea arsenicosum</i>	1 (1.6%)
<i>Kalium carbonicum</i>	1 (1.6%)
<i>Tuberculinum</i>	1 (1.6%)
<i>Thuja occidentalis</i>	1 (1.6%)
Placebo*	5 (8.3%)

* Second prescription only; if first prescription was considered to be still acting.

Discussion

Analysis of data derived from the SD indicated that the treatment group experienced a statistically significant improvement in the number of hours slept when compared to baseline throughout the study, while the number of hours slept in the placebo group did not improve significantly.

Inter-group analysis of SD readings indicated that the degree of sleeplessness was comparable between the two groups at baseline ($p=0.724$). On comparing total hours of sleep per week between the groups there were significant differences between the groups at all weeks with the greatest difference being in Week 2 ($p=0.004$). By the end of the study the total hours gained within the treatment group was significantly higher than that of the placebo group ($p=0.036$). Data derived from the SD thus suggests that the quantity of sleep achieved by the treatment group improved and remained significantly higher throughout the study, in contrast to that of the Placebo Group which improved at first but was not sustained.

The SII revealed that within the verum group steady improvement in the responses to SII questions occurred during the study with 11/11 questions having improved significantly upon completion of the study. The placebo group experienced an initial improvement but this was not sustained and on completion of the study 0/11 questions had improved significantly.

A similar trend was revealed when calculating and comparing summary scores for the SII, the verum group experienced significant improvement throughout the trial

and the placebo group experienced a short lived initial improvement only.

Inter-group analysis of SII values at baseline revealed that the two groups were similar. Comparisons of data gathered at Week 2 revealed significant differences in favour of the treatment group in 8 of the 11 questions. Upon completion of the trial (comparisons of data obtained at Week 4) the significant differences had increased to 10 of the 11 questions.

In terms of the data obtained from the SD and the SII, the homeopathic simillimum proved to be effective, whereas the placebo did not. Furthermore, results revealed that a significant improvement occurred within a relatively short period (1 week). No adverse reactions to treatment were reported by any of the participants.

A descriptive analysis of weekly mean SD scores reveals the possibility of a slight decrease in response (although still significant) to treatment within the treatment group towards the end of the study; this trend is not seen within SII data which, in fact, shows the contrary. This may reflect spontaneous variation of symptoms of this chronic condition. Careful monitoring of patients is necessary in order to modify the prescription according to the patients needs and thus ensure a continued favourable response; in this study a third prescription could have addressed such a need. A trial of longer duration would be required to accurately describe the response to treatment over extended periods of time.

Although this insomnia study was the first to apply a randomised, double-blind, placebo-controlled methodological approach ensuring internal validity, the external validity of this study is challenged by the relatively small sample size and limited duration of the study particularly in the light of the chronic nature of the illness.

Given the encouraging findings of this study and the positive trends noted in previous studies a larger study of extended duration is warranted. Further homeopathic studies in this field are also necessary given the high incidence of the condition the limitations and risks associated with traditional pharmacological agents as well as the costs thereof. A safe, cost-effective method of treatment is thus desirable.

Based on a power calculation, future studies should comprise a sample size of 120 in addition, is recommended that the study be conducted over a 6 month period. Additional objective measurement methods should be considered such as polysomnography as well as a qualitative component of data collection and analysis. Future studies should consider additional homeopathic dosage forms such as LM potencies as well as multiple and/or group verification of the choice of simillimum for each case.

Conclusion

Homeopathic simillimum treatment was significantly superior to placebo in the treatment of chronic primary insomnia in a randomised, double-blind, placebo-controlled study as measured by a SD and SII. This method of treatment resulted in significant improvement of symptoms within a relatively short period without any reported

Table 3 Frequency of various potencies prescribed

Potency	Doses prescribed
30CH	23
200CH	63
1 M	38
10 M	5

adverse reactions. The homeopathic simillimum may be a viable treatment option for chronic primary insomnia. However, this must be verified by larger scale studies in the future.

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