

A DETAILED METHODOLOGY: HOMOEOPATHIC MEDICINES FOR IMPROVING SLEEP QUALITY IN ELDER ABUSED AND NON-ABUSED GERIATRIC PATIENTS- RANDOMIZED COMPARATIVE TRIAL

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ABSTRACT

Elder abuse is one of the causes of reduced health and especially reduced quality of sleep in elderly patient. A study conducted for improving sleep quality by homoeopathic medicines in Geriatric patients who were elder abused or non abused. It was a single blind Randomized comparative trial. A double arm prospective study was done in the year 2020-21 in Bikaner, Rajasthan. This article focuses only on the methodology followed by the research; the blinding technique, the randomization procedure, the statistical technique used and the tools used in the research which were used to analyze the data.

KEYWORDS: Homoeopathy, Elder abuse, Geriatric, Sleep quality.

INTRODUCTION

Sleep becomes more fragmented as we age, such that there are more frequent sleep stage shifts, arousals, and awakenings. This results in decreased sleep efficiency (i.e. the proportion of actual sleep time compared to time spent in bed), which indeed, continues to decrease with increasing age, despite slow-wave sleep proportion stabilization^[1] A second study found that among men, sleep time decreased an average of 27 min per decade from midlife until the eight decade.^[2] Accumulating evidence points towards changes in sleep architecture, increased risk for sleep disorders, circadian rhythm shifts, medical and/or psychiatric conditions, and medication use (and likely a combination of these factors) as possible factors contributing to older adult sleep disturbance. Considering the impact that sleep disturbance

can have on health, it is important to pay special attention to sleep quality among older adults.^[3]

The international classification of sleep disorders-2 (2005) (ICSD-2) classifies the sleep disorders in six major categories.^[4]

I. Insomnia

II. Sleep related breathing disorders

III. Hypersomnias

IV. Circadian rhythm sleep disorder

V. Parasomnia

VI. Sleep related movement disorders

Elder abuse is an act in which an individual above 60 years of age is being troubled physically, mentally, emotionally or sexually by another individual. The major reasons for such abusive behavior include: lack of adjustment, economic dependence of the abused and increasing longevity of the old. Elderly suggested sensitizing children and strengthening intergenerational bonding, increasing economic independence of the abused and sensitizing young adults, as the measures to deal with Elder Abuse.^[5] Globally, the number of cases of elder abuse is projected to increase as many countries have rapidly ageing populations whose needs may not be fully met due to resource constraints. It is predicted that by the year 2050, the global population of people aged 60 years and older will more than double, from 900 million in 2015 to about 2 billion, with the vast majority of older people living in low- and middle-income countries. If the proportion of elder abuse victims remains constant, the number of victims will increase rapidly due to population ageing, growing to 320 million victims by 2050.^[6]

Literature searches done on different disorders of Sleeplessness show good results with Homoeopathic interventions. Researches have shown that old age with Elder abuse have great impact on the sleep quality. Hence, this study was done to assess the role of Homoeopathic medicines for improving the sleep quality in elder abused and non abused geriatric patients.

MATERIALS AND METHODOLOGY

Detailed methodology used in the research is being described here.

Study setting: Study was conducted in M.N. Homoeopathic Medical College & Research Institute, Bikaner.

Study design: Randomized, double arm, comparative, prospective, single blind trial. Patients were randomly selected in two groups. Group A consisted of Elder abused Geriatric age group patients with reduced sleep quality. Group B consisted of Non-abused geriatric age group patients with reduced sleep quality. Both the groups were given homoeopathic treatment according to the totality of symptoms.

Study duration: The study was conducted for a period for 12 months. Each case was followed up for a period of 4 months. The cases were assessed on PSQI scale every 2nd month.

Selection of samples: Following tests were used to calculate sample size.

t tests - Means: Wilcoxon-Mann-Whitney test (two groups)

Options: A.R.E. method

Analysis: A priori: Compute required sample size

Input:	Tail(s)	= Two
	Parent distribution	= Normal
	Effect size d	= 0.6600000
	α err prob =	0.05
	Power (1- β err prob)	= 0.84
	Allocation ratio N2/N1	= 1
Output:	Noncentrality parameter δ	= 2.9905348
	Critical t =	1.9900162
	Df =	80.1239506
	Sample size group 1	= 43
	Sample size group 2	= 43
	Total sample size	= 86
	Actual power	= 0.8400211
	Total Sample size = 86 + 10% Drop outs	= 94 samples
	Sample size group 1 = 47; Sample size group 2	= 47

Inclusion criteria

- Age more than 60 years.

- PSQI score > 6.^[7]
- Both the genders.
- Patients residing in communities.
- Patients were kept under a wash-out period of 2 weeks who were initially taking sleeping pills.^[8]
- Screened with H-S/EAST for Elder abuse.^[9]

Exclusion criteria

- Patients taking sleeping pills from other modes of treatment and who were not willing to discontinue the treatment.
- Patients requiring emergency treatment.
- Patients with any other Psychiatric conditions- Anxiety, depression, etc.
- Patients with clinical symptoms of Prostatitis, uncontrolled Diabetes Mellitus, which hamper the sleep quality due to waking during night hours due to frequency in micturition.

Previous medication, if any: Patients on other modes of treatment for sleeplessness were required to leave their treatment with consultation of their physician. Medication for other diseases was continued with their physicians consultation.

Withdrawal - Patients, who did not show any improvement or whose sleep quality was deteriorate more than 40% from the baseline in PSQI scale, were withdrawn from the study.

In case of acute disease- If during the treatment a patient suffered from any acute disease, he/she was treated for that acute disease by an acute totality in that phase and PSQI scoring was not be done during that period. Thereafter the treatment for sleep quality was started.

Discontinuation of treatment: If the patient discontinued treatment in the last 2 months or later, the PSQI scores of 2 months was analyzed.

Change of Therapy: If there was no change in sign and symptoms of the patient after adequate repetition of assigned medicines, in various potencies judiciously, those patients were treated in the general O.P.D. of the respective institution and their records were kept separately.

Blinding: This was a single blind trial, hence, the patient was unaware of the medicine administered so that the patients don't presume any treatment strategy if they discuss between themselves. Both the groups got medicine of same globule number.

Technique of randomization: Flip coin method of sampling was used for selection of samples from the community. All patients were selected from the OPDs itself.

Intervention

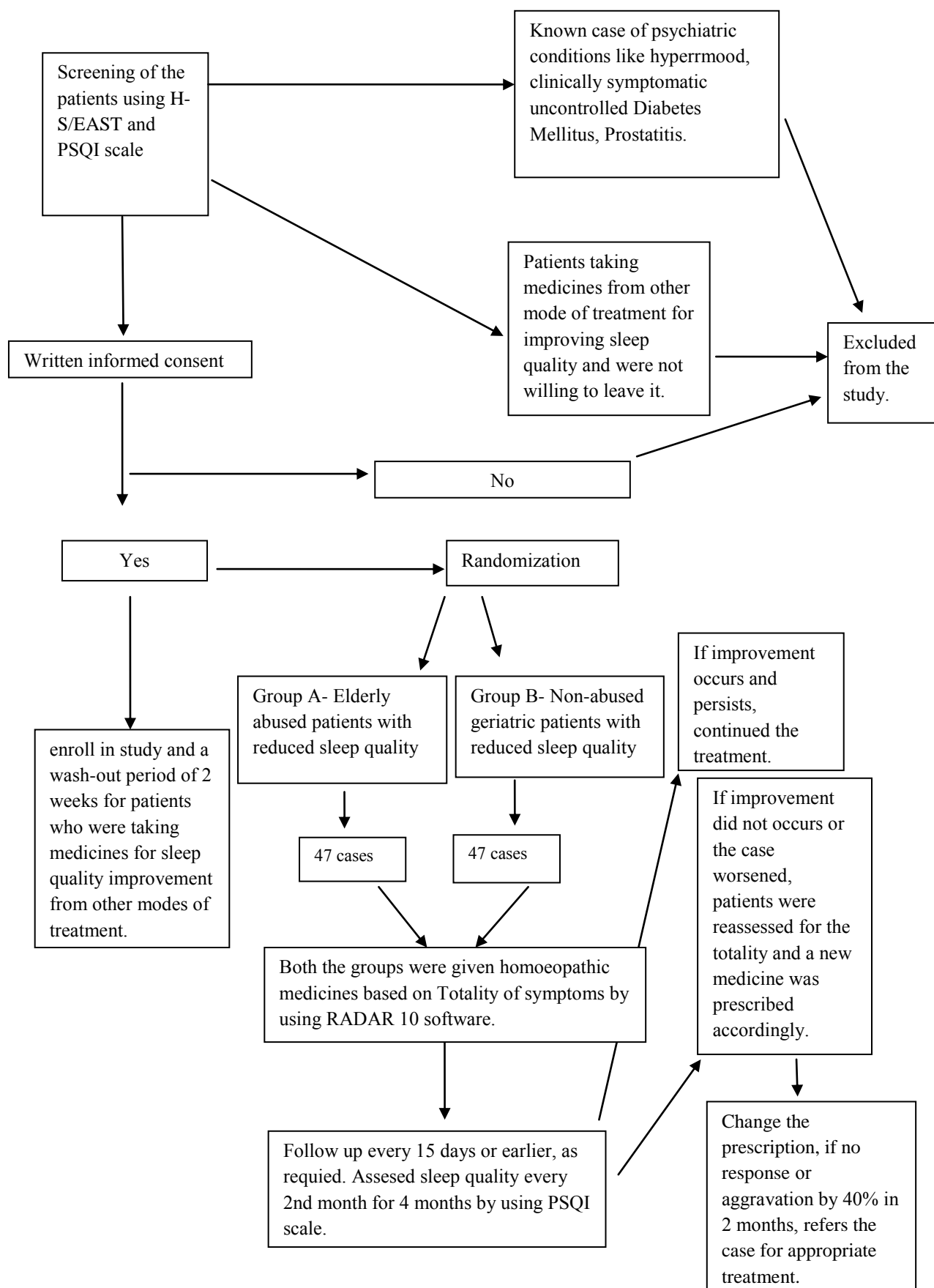
In both the groups

- Homoeopathic remedies selected on the basis of totality of symptoms.
- Potency-Selection of potencies was done according to patient's susceptibility and homoeopathic principles.
- Doses and repetition- According to patient's susceptibility and homoeopathic principles.
- Manufacturer- Medicines were obtained from a GMP certified company.
- Form- Globules No. 10.
- Route of administration- Oral.

Selection of tools

- **Screening** for Elders abuse- HWALEK-SENGSTOCK ELDER ABUSE SCREENING TEST (H-S/EAST)^[9]
- **Parameter scale- PSQI** (Pittsburgh Sleep Quality Index)- The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in the older adult. It differentiates "poor" from "good" sleep by measuring seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the last month.^[7]
- **The 5-item Geriatric Depression Scale (GDS)** is used as a screening tool for identifying depression in older adults. It can be used within a wide range of settings, and can be used with those that have a medical illness or those with mild to moderate cognitive impairment.^[10]
- **Generalized Anxiety Disorder** an anxiety questionnaire to screen patients suffering from anxiety.^[11]
- **RADAROPUS** was used to repertorize each case using Synthesis 9.1 repertory and remedy was prescribed accordingly.^[12]

Brief of Procedures



Outcome assessment: The data was analysed every 2nd month with PSQI[7]

Component 1	#9 Score.....	C1
Component 2	#2 Score (≤ 15 min=0; 16-30 min=1; 31-60 min=2, >60 min=3) + #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3).....	C2
Component 3	#4 Score (>7=0; 6-7=1; 5-6=2; <5=3).....	C3
Component 4	(total # of hours asleep)/(total # of hours in bed) x 100 >85%=0, 75%-84%=1, 65%-74%=2, <65%=3.....	C4
Component 5	Sum of Scores #5b to #5j (0=0; 1-9=1; 10-18=2; 19-27=3).....	C5
Component 6	#6 Score	C6
Component 7	#7 Score + #8 Score (0=0; 1-2=1; 3-4=2; 5-6=3).....	C7
Add the seven component scores together		Global PSQI Score

Fig.17: Components of PSQI and their calculation.^[7]

Data collection: Data was collected on especially designed Case Record Form for each patient. Informed consent form was taken for each patient. PSQI will be filled and analysed every month.

Confidentiality

- All the evaluation forms, reports and other records was kept in locked file cabinet. The patient was issued a unique identification number. Any information about the patient was not be leaked out until required.

Maintenance-

- There were forms that were completed by for each subject recruited, including two consent form for the patient's information and his/her written consent for the enrolment in the study. These were updated from time to time.

Statistical techniques

As data was normally distributed, **One way repeated ANOVA** test was used to assess improvement in between the 3 time frames within a group and **Independent t-test** was used to compare last (4th month) PSQI scores in between the groups.

Usefulness of the study

Scope of homoeopathy in geriatric cases with reduced sleep quality in elderly abused and non-abused patients was found out and hence helpful in clinical/OPD setups.

Ethical issues

Patients were continued with treatment if they were getting improvement or else they were referred to relevant treatment strategy.

Informed consent was taken by the researcher from patients for the study. Ethical clearance was taken from the Institutional Ethical Committee before the start of the study.

CONCLUSION

The study was aimed to analyze the role of homoeopathic medicines on sleep quality in elder abused and non abused geriatric patients and various results were obtained in context of epidemiology and intervention given which are stated in various other articles. A case report has been published from the same research which shows a good role of homoeopathic medicine in such a case.^[13]

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