

CHAPTER-III
METHODS

The present study was designed to examine the Cognitive and Psychological Alterations due to Chronic Insomnia and its assessment and management. Those suffering from insomnia also show from some degree of impairment in social, occupational, or other important areas of daytime functioning. That is, all these problems are associated with a lack of sleep that seems to be originated by any of a number of factors such as physical illness, a stress-filled lifestyle, excessive caffeine consumption, or chronic pain.

Extensive review of literature reflects that insomnia is perceived as the major problem of everyday living of our society. Most of the theoretical and empirical evidence reveal that insomnia and its related problems are common which leads to major negative outcomes, such as disturbances in interpersonal relationships, social failure, anxiety, fear etc. Sleep is considered as an inevitable requirement for healthy survival, the present study has been undertaken to find out the alterations caused by chronic insomnia and its assessment and management.

Sample

A total of 100 subjects suffering from chronic insomnia (clinically diagnosed and those who have been suffering from sleep disturbances at least for the last 3 months or above and must have atleast social, occupational or other important areas of daytime dysfunctioning without any apparent cause) were selected from various clinics in Gurgaon with the desired age group i.e. adults between 25-40 yrs of age. Both working as well as non-working population was selected. Inclusion criteria shall also be based on being under medication and also not continuing with medicine regimen.

Exclusion criteria - persons suffering from any other medical or psychiatric disorders were excluded.

For phase 1, a purposive sample of 100 subjects was selected from a general sample with equal number of matched controls (age, socio economic status etc.)

Design

The study was conducted in 2 phases

Phase 1: The aim of this phase was to segregate the insomniacs and the matched controls. The groups were formulated as follows:

Table- 1: Segregation of insomniacs and matched controls

| | |
|-----------------------|-----------------------------|
| Insomniacs (N=100) | Matched controls (N=100) |
|-----------------------|-----------------------------|

They were administered all the measures of cognitive tasks and GHQ-12 at time 1.

Phase 2: The main aim of this phase was to categorize those insomniacs who were taking regular prescriptions (actual medication or drug given for promoting sleep) and those who were not taking regular prescription (taking placebo- a substance containing no medication and prescribed or given to reinforce a patient's expectation to get well) into the groups on the basis of given management or not.

A multigroup design with 4 groups was used. The groups were formulated as follows:

Table- 2: Categorization of insomniacs into groups

| Insomniacs (N=100) | | | |
|----------------------------------------|--------------------------------------|-------------------------------------------|--------------------------------------|
| Taking regular prescriptions (n=50) | | Not taking regular prescription (n=50) | |
| Management (Group-1) (n=25) | No management (Group-2) (n=25) | Management (Group-3) (n=25) | No management (Group-4) (n=25) |

Then the post-management changes in performances were assessed. The structure of design was as follows (it was a mixed design of between and within comparisons).

Table- 3: Between and within comparisons before and after management

| Group | Phase-I testing done on cognition and sleepiness | Management strategy intervention (10 days) | Post-intervention testing with a gap. (days) | | |
|-------|--------------------------------------------------|--------------------------------------------|----------------------------------------------|----|----|
| | | | 20 | 40 | 60 |
| 1 | 25 | Given | | | |
| 2 | 25 | Not given | | | |
| 3 | 25 | Given | | | |
| 4 | 25 | Not given | | | |

The dependent measures were: sleepiness, general health, simple reaction time, learning and memory.

Tools

The following tools were used in the study: (see appendix)

1. General Health Questionnaire-12 (GHQ-12): (Appendix-I)

GHQ was developed by Goldberg in 1972. It was designed to be a self administered psychiatric disorder among respondent in community settings and non-psychiatric clinic settings such as primary care or among general medical out patients. The questionnaire was designed to be easy to administer, acceptable to respondents, mainly short and objective in the sense that it didn't require the person administering it to make subjective assessments about the respondent.

There have been 6 validity studies of GHQ-12: in 4 of these, the relevant questions were disembedded from a larger set of items. Sensitivity ranges from 71% (Radavanonic and Eric, 1983) with a median value of 86%. Value of the specificity ranges from 71% obtained by Shamasunder, Murthi et al (1986) using Indian Psychiatric Survey Schedule as the criteria.

The GHQ distinguishes specifically between psychological sickness and psychological health. The theory behind GHQ is, therefore, consistent with any of the many hierarchical models that

have been proposed by workers as diverse as eclectic psychiatrist's Clinical psychology (Fould and Bedford, 1975) and even psychological analyst (Menninger, Mayman and Pruyser, 1963).

A comparison between GHQ 12 and SRQ 20 in Brazil showed them to be approximately equally effective as case detector (Mari and Williams, 1985).

The method of test construction guarantees that GHQ does not possess content validity and predictive validity, since it was intended as a state measure rather than a trait measure. However, its concurrent validity has been of most concern to investigator. Scores on GHQ can be interpreted in 3 ways: severity of psychological disorder, estimate the prevalence of psychiatric illness and indicator of morbidity.

2. Wechsler memory scale-III (WMS-III): (Appendix-II)

In clinical practice, measures of intellectual functioning and memory are often administered concurrently so that a broad spectrum of cognitive abilities can be examined. In the view of this purpose, the *Wechsler Adult Intelligence Scale—Third Edition* (WAIS-III; Wechsler, 1994) and the *Wechsler Memory Scale—Third Edition* (WMS-III; Wechsler, 1994) were co developed that share similar research methodologies, normative samples and similar clinic a validation procedures. As a result, these two instruments provide a mean of assessing a broad range of cognitive abilities and now allow for more meaningful comparisons between intellectual ability and memory functioning.

The WMS—III is the most recent revision of the original *Wechsler Memory Scale*, and the *Wechsler Memory Scale—Revised* (WMS-R; Wechsler, 1987). Like its predecessors, the WMS—III is an individually administered, clinical instrument designed to assess important domains of memory and learning in older adolescent and adult populations. Although the WMS-III has maintained many aspects of its predecessors, significant improvements have been made to the test in response to both current research and theory and the needs of clinicians.

In 1987, WMS was revised for the first time. The WMS-R provided improved norms, extensive scoring rules, additional subtests for measuring delayed recall of information, and other new subtests with visually presented stimuli. These additional subtests were developed by Wechsler,

although, the final revision was not published until after his death. The WMS-R has been the subject of numerous research studies since its publication. Although the WMS-R provided clear advantages over its predecessor, several comprehensive reviews have identified areas in which the scale could be improved.

Reliability coefficients for the WMS-III Primary subtests and Primary Indexes are generally higher than those of the WMS-R. Average subtests internal consistency reliability coefficients range from the .70s to the .90s. With one exception, average composite reliability coefficients of the Primary Indexes range in the .80s and .90s. The Auditory Recognition Delayed Indexes has a reliability coefficient of .74.

Subtest raw scores for the WMS-III are transformed to age corrected subtest scaled scores with a mean of 10 and a standard deviation of 3 (the WMS-III also includes some instances in which raw scores are transformed to percentile ranks). A subtest scaled score of 10 reflects the average performance of a given age group (or the reference age group). Scores of 7 and 13 correspond to 1 *SD* below and above the mean, respectively, and scaled scores of 4 and 16 deviate 2 *SDs* from the mean.

3. Epworth Sleepiness Scale (ESS): (Appendix-III)

M.W.Johns has developed this questionnaire. This is a self-administered questionnaire; the item scores provide a new method for measuring sleep propensity (SP) in eight different real-life situations.

The Epworth sleepiness scale (ESS) uses a simple questionnaire to measure excessive sleepiness during eight situations such as while Sitting and reading, watching TV, sitting inactive in a public place (e.g., a theater or a meeting), as a passenger in a car for an hour without a break, lying down to rest in the afternoon when circumstances permit, sitting and talking to someone.

4. Comprehensive sleep management strategies: (Appendix-IV)

Were developed and standardized on 5 insomniacs. Management strategies of chronic insomnia begin with identification of its underlying causes. Various management approaches used on 5 insomniacs were stimulus control (instructions for elimination or reduction of bedroom activities that are not compatible with sleep and to associate the bed and bedroom only with sleep), sleep

restriction (curtailing the amount of time the patients spends in bed to increase the efficiency of sleep), meditation training (focusing attention on a repetitive stimulus), and counseling. The preliminary tryout revealed that out of all of these, meditation along with counseling was found to be most beneficial. Thus, all the subjects were given this cognitive behavioral therapy (CBT).

5. Cognitive tasks

(i) *Electric Stylus Maze*: this task was used for obtaining an objective measure of learning. The instrument was used to take the responses of subjects. The human subject is presented with many equidistant pathways to the goal on the wooden board. The pathway consists of metallic bearings, some with electric current and some without current. [The subject was asked to reach the goal without touching the bearings with current. Touch on the ones with current indicated errors. This score was noted down till two consecutive errorless trials.]

(ii) *Chronoscope*: Simple Visual Stimulus was used for obtaining the simple reaction time of the subjects. The simple reaction time is the time between the end of stimulus presentation and the onset of the response. [In this task, the subject stood on one side of the instrument and the presenter on the other side with a screen in between. The presenter presents a stimulus (green light) to the subject and the subject was asked to respond to the given stimulus in as little time as possible. 20 such trials were taken and the time in milliseconds was noted down.]

6. Personal Profile

Personal profile includes information in respect to age, gender, education, family structure, number of siblings in family, etc.

Procedure

For selecting 100 subjects suffering from chronic insomnia (atleast for the last 3 months), the help of doctors from various clinics and hospitals was taken. They were urged to prepare a list of all the patients coming to them for treatment and were asked to give the details whether the patient was under placebo or not. The patients were thus contacted and all their details were furnished which were of use in the study, e.g.; still undergoing medication or not, duration of medication, etc. to determine about whether the patient was appropriate for the study. For matched controls, 100 subjects were selected from general population (based on age, socio economic status etc.) on random bases but only those who had no complaint of sleep, sleepiness, insomnia and any other chronic ailment and were under no medication. For this phase, approximately 400 people were contacted and only the relevant ones were taken.

After selecting the required sample, a structured interview was conducted along with a structured questionnaire (paper-pencil version). The Epworth Sleepiness Scale to identify sleepiness was administered in real-life situations along with other relevant information. If patients met the criteria for inclusion in the study, they were invited to the clinic to participate. Patients who were eligible and interested in the study completed informed consent proforma and the pretreatment test was given before leaving the clinic. They were given a one-week sleep diary to complete at home.

The interviews continued until the desired sample size was reached. The insomnias were categorized into groups of 50 each on the basis of details furnished by them and the doctors that is those taking regular prescription and those not taking regular prescription. They were further segregated into four groups on the basis of given management or not given (25 each). Thus, four groups were formed that is both management and prescription, only prescription, only management and neither management nor prescription.

GHQ-12 was administered to these respondents to obtain information about psychological health. Both the scales were also administered to match controls

Then, cognitive tasks (maze learning to two errorless trials was performed and the number of trials was recorded. The number to achieve this criterion was the dependent measure. Simple

reaction time was obtained from all the participants 20 times. Mean and SD of SRT with 20 presentations was the scores. Wechsler memory scale was also used to obtain an objective measure of memory. This is how the first phase was completed.

In the end, appropriate management strategies as was developed and standardized on 5 insomniacs (described earlier) were used to those taking regular prescription and those not taking regular prescription. The strategy continued for 10 days. Post management changes were assessed and thus the management strategy was finalized.

At the first treatment appointment, we reviewed the sleep diary and the tests with the patient and offered specific individualized behavioral recommendations and education to improve sleep (Morin, 1993). Patients were encouraged to take a scientific approach to examining their sleep problem using the sleep diary to monitor their sleep patterns. It was explained that patients would spend the next 3 to 4 weeks experimenting with modifying their sleep-related behaviors. They would then be in a better position to judge which behaviors they wanted to continue to minimize (e.g., keeping a napping, watching tv in bed, reducing caffeine) or increase (e.g., keeping a regular sleep/wake schedule). The behavioral component incorporated were sleep hygiene education, stimulus control, sleep restriction, relaxation.

Sleep hygiene education emphasized the modification of 5 behaviors found to affect sleep: (a) caffeine consumption, (b) smoking, (c) alcohol use, (d) exercise, and (e) napping. Patients were encouraged to moderate caffeine and alcohol use. Those who were smoking were encouraged to consider smoking cessation, and those who were not exercising were asked to consider beginning a minimal exercise routine such as walking. Napping was also discouraged during the treatment phase.

Stimulus control techniques were taught to patients to associate the bed with sleep rather than with the frustration or anxiety that is typically experienced in bed when people are unable to fall asleep. In this study, stimulus control was described to the patient as a powerful tool for breaking the cycle of wakefulness in bed and reestablishing the positive association of the bed as a place of peaceful rest. Recommendations to patients included (a) going to bed only when sleepy, (b)

using the bed only for sleep and sex (i.e., no TV or reading in bed), (c) getting out of bed when unable to fall asleep within 15-20 minutes and going to another room to read, (d) repeating this as often as necessary when either trying to fall asleep for the first time or when going back to sleep; and (e) setting a reasonable wake time and sticking to that time.

A brief relaxation technique including relaxed deep breathing and passive muscle relaxation was taught to some patients to counteract the frequent complaint of difficulty controlling thoughts at night. Patients were told to relax to could help distract them from worry or racing thoughts, thereby increasing the opportunity for sleep onset.

Participants averaged 5 treatment appointments following their initial assessment to assess progress and problem –solve difficulties that arose in the implementation of the recommended behavioral interventions. These treatment appointments were scheduled at the convenience of the patient in keeping with a typical primary care model and therefore some patients waited more than a traditional 1 to 2 weeks before follow up (due to vacation, other medical appointments, etc.). At each treatment appointment, sleep diaries were collected and examined with the patients. Modified recommendations regarding the strategies to address any adherence problems were made. During the final treatment appointments, participants completed the post treatment tests.

10 sittings over a period of one month were given to all the subjects in those groups whatsoever. All the settings were given under similar settings, time, place, etc. Post-testing on all parameters was done after a gap of 20, 40, 60 days on all the 4 groups (both prescription and management, with only management, with only prescription, neither prescription nor management,). The subjects were called to the same clinic for post-testings. During the gap of twenty days in between, the patients were constantly kept in touch and contacted regularly for any queries and providing with sleep enhancing instructions. They were encouraged and motivated to come for the next follow up. Thus, after 20 days they were called to the clinic and post testing was done. Similarly post testing was done after 40 and 60 days. All the subjects were under maintained level of communications and motivation until the study was over.

This continued for over 3 months. Obtained scores were recorded.

Statistical analysis

In order to verify the significance of difference between insomniacs and normal controls, t-test for independent groups was applied on all the 5 dependent measures- Sleepiness, Simple Reaction Time, trials to learning maze, Wechsler memory scores and GHQ based general health scores.

Data were analyzed by employing Analysis of Variance (ANOVA). Descriptive statistics, paired comparison t test, analysis of variance were carried out using the SPSS Package. Paired comparison was applied to find out the effect of duration i.e. 20, 40, 60 days on all the variables.

ANOVA was carried out in order to find the effect of time and conditions and there interactive effect on learning, health, sleepiness, memory, simple reaction time that is whether time, condition as well as altogether time and conditions had significant or non-significant effect on all the above mentioned variables. Level of significance to accept/verify the hypotheses shall be probability equal to or less than 0.05.

Since some of the subjects could not be tested under all the four time intervals thus finally the data in ANOVA could be used for 24 subjects only ($4 \times 4 \times 24 = 384$).

