CHAPTER III

METHODOLOGY

The study was designed to determine the effectiveness of sleep hygiene practices on quality of sleep, psoriasis severity and activities of daily living among patients with psoriasis. This chapter deals with the research design, setting of the study, population, sample, sample size, sampling technique, sample selection criteria, development, description, administration and scoring procedure of the tool and statistical analysis used for this study.

3.1 Research design

The research approach selected was evaluative and the design is true experimental design.

Randomized pretest-posttest control group design was adopted for this study. This study instituted two groups, one as study group which has undergone tailored training on sleep hygiene practices and the other control group which has not undergone training on sleep hygiene practices but has received the routine care and information. The experimental design is randomized controlled trial.
Table 4. Illustration of research design

Randomized controlled trial

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest</th>
<th>Intervention</th>
<th>Posttest</th>
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<td></td>
<td></td>
<td>I</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>30th day</td>
</tr>
<tr>
<td>R Study</td>
<td>*O₁</td>
<td><em>X</em>Ω†</td>
<td>*O₂</td>
</tr>
<tr>
<td>R Control</td>
<td>*O₁</td>
<td>*†</td>
<td>*O₂</td>
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(after Posttest III) - XΩ

KEY

R     - Randomization
*     - Routine care.
X     - Intervention
†     - Issue of sleep diary
Ω     - Issue of pamphlet
O₁, O₂, O₃, O₄, O₅ - Assessment of quality of sleep, psoriasis severity and activities of daily living

Manipulation

The independent variable is sleep hygiene practices and the dependent variables are sleep quality, psoriasis severity and activities of daily living. The independent variable sleep hygiene practices are given as a intervention to improve the sleep quality, reduce the psoriasis severity and improve the activities of daily living. The patients with moderate psoriasis vulgaris were given education as a small group the structured teaching on sleep hygiene practices. A group of 3-4 patients were included at a time in dermatology OPD
for 20 minutes. This was followed by structured teaching demonstration was done on relaxation position and techniques which would promote the sleep. The patients were asked to do the return demonstration and their doubts were clarified. After the demonstration session pamphlet on the sleep hygiene practices were issued along with the sleep diary. The patients were taught how to maintain the sleep diary. The entire session was planned for 30 minutes and the patients continued the sleep hygiene practices at their home set up. During the 30th day the patients were given reinforcement on sleep hygiene practices, relaxation position and techniques. On the 120th day the patients were motivated to continue the practices and maintain the sleep diary. Sleep hygiene practices intervention package has been explained below.

**Structured teaching on Sleep hygiene Practices**

The package of structured teaching on sleep hygiene practices, pamphlet on the same, sleep diary and relaxation position and technique were developed by the investigator. This package of teaching imparted the knowledge, and necessary practices required to promote the sleep quality, reduce the psoriasis severity and promote the activities of daily living. This package of teaching helped them to reduce their sleep disturbances and promoted full day time alertness.

The sleep hygiene practices structured teaching was on topics such as importance of sleep, food selection, outfit selection, environment, napping tips, physical hygiene, regular exercise, habit formation, bedtime rituals, follow-up of drugs and seeking help
**Demonstration**

At the end of the teaching the relaxation position and technique were demonstrated. The relaxation position is to lie on a convenient position and relax the muscles of the body and take a deep breath and be conscious of the inspiration and expiration. The relaxation technique includes counting the numbers 1-100 and counting in reverse 100-1 for 3 minutes.

**Pamphlet**

After the demonstration the pamphlet in Tamil and English which contained the same information of the teaching was issued.

**Sleep Diary**

The participants were issued the sleep diary and were educated on how to maintain it. The sleep diary is the calendar sheet and the patients were asked to write the sleeping hours, wake up time, whether the practices were followed or not.

**Control**

The control group patients were patients with moderate psoriasis vulgaris who were allotted as a comparison to evaluate the effect of sleep hygiene practices. The investigator believed that the control group would serve as a mean to overcome the confounding variables and serve as a good comparison to highlight the effect of manipulation. The control group patients received the routine care during the study period and received the sleep hygiene practices teaching package after the study period.
**Randomization**

The investigator used randomization to have a control over the individual and extraneous variables and to secure good comparable groups. Block randomization was adopted using 8 blocks with 50 patients in each block. In each block the prepared lot numbered 1 to 50, blinding the group allotment (study and control group). Once the sample was selected the procedure was explained to them and written consent was taken from them. The patients were allotted to study and control groups based on the lots. Thus the allotment of subjects to groups was randomized.

**3.2 Variables**

**Independent Variable**

In this research the independent variable refers to sleep hygiene practices education package.

**Dependent Variable**

The dependent variable refers to sleep quality, psoriasis severity, and ADL.

**Extraneous Variables**

The extraneous variables in this study are age, sex, marital status, education, occupation, residence, family monthly income, duration of illness and the medication.
3.3 Setting of the study

The study was conducted at dermatology OPD of Sri Ramachandra Hospital G Block (SRH). SRH G block is a 1175 bedded multispecialty hospital. An average of 30 patients attend psoriasis clinic every Tuesday out of which 97% of the patients have psoriasis vulgaris. There is one dermatology unit functioning every day for different clinics. Tuesday is a psoriasis clinic day and nearly 5-6 new psoriasis patients attend the clinic. Both new and old patients were consulted, so it was easy for the investigator to select samples. The good infrastructure facilities available in the OPD enabled the investigator to meet the study and control groups separately.

3.4 Population

In this study the population refers to the patients with signs and symptoms of psoriasis vulgaris in the same setting. The target and accessible population for this study included the entire psoriasis vulgaris patients who attended the dermatology OPD of Sri Ramachandra Hospital vulgaris patients who attended dermatology OPD.

3.5 Sample

The plaque psoriasis (vulgaris) patients who had more than one year chronicity of illness and fulfilled the sampling criteria became the samples. The investigator adopted randomization in assigning the samples to study and control group respectively until the determined sample size was obtained.
3.6 Sample size/attrition

The sample comprised of 410 psoriasis vulgaris patients who were assigned randomly, two hundred and ten (210) to both study and control group. The sample size was determined by the following formula.

\[
\frac{Z\alpha^2 \times p \times q}{X^2}
\]

The estimated sample size was 400. The investigator increased to 410 and allotted the sample to 205 in the study and control groups. At the end of the study the attrition of samples in the study group was 6 members and 4 members in the control group. The patients lost to follow up without any reason. Hence these samples were not included in the study. The researcher was unable to control the attritions there were 199 samples in the study group and 201 samples in the control group. The total number of attrition of samples was 10.

3.7 Sampling criteria

Inclusion Criteria

Patients with moderate psoriasis vulgaris

- in the age group of 21-70 years.
- attended the dermatology OPD regularly.
- willing to participate in the study
- willing to continue treatment in the dermatology OPD.
- duration of illness more than a year.
**Exclusion Criteria**

**Patients with psoriasis’ vulgaris**

- with co-morbid illness like diabetes mellitus, hypertension and bronchial asthma
- on indigenous medicinal treatment
- on Psoralen Ultra Violet A (PUVA)
- on steroids and immunosuppressant therapy

**3.8 Sampling technique**

The investigator prepared eight blocks. Each block had chits numbered 1 to 50 blinding the group allotment (study and control group) kept aside before the data collection started. The investigator identified the samples with help of the nursing staff. The samples were asked to pick up the chit from the ballot box. The chit in the block was exposed to determine the group to which the sample belonged. Thus the allotment of subjects was categorized into study and control group with equal chance of entering in both the groups.

**3.9 Tools used for data collection**

The tools used for this study have been categorized into 5 sections

**Section 1: Background Variables**

This section questioned the participants on
1.1 **Demographic variables** of the patients with psoriasis. This includes age, sex, education, residence, occupation, marital status, family monthly income.

1.2 **Clinical Variables** include duration of illness and medications prescribed.

**Section 2 : Sleep Quality**

Pittsburg sleep quality index (PSQI) was used to measure the sleep quality and is a self administered rating scale with 9 items to be filled by the investigator as reported by the subjects. The tool was developed by Daniel Bussy in the year 1984. The reliability of the tool is 0.78. Permission was obtained to use the tool. The components of the tool is sleep duration, sleep disturbances, sleep latency, day dysfunction due to too sleepiness, sleep efficacy, overall sleep quality, and need medication to sleep.

**Scoring**

The tool has got 7 components and the total score is 21. The minimum score is 5 and less, lesser the score higher the quality.

**Score Interpretation**

16-21 - Poor quality of sleep
11-15 - Mild quality of sleep
6-10 - Moderate quality of sleep
5&<5 - Good quality of sleep
Section 3: Psoriasis Severity

Simplified psoriasis area severity index (SPASI) was used to measure the psoriasis severity. This tool is a standardized tool was developed by Fredrickson & Patterson in the year 1978 and the reliability of the tool is 0.90. The tool is a rating scale with 4 components and each component has 5 items. For each component the score assigned is from 0-4. The total score is 16 with a score of 4 for each component. The components are erythema, plaque, scaling and pruritus. Permission was obtained from the author to use the tool.

Score Interpretation

15-16 Severe
12-14 Moderate
9-11 Mild
6-8 Very mild

To measure the intensity of pruritus, Numerical rating scale is used. Numerical rating scale is a standardized scale using a numerical scoring from 1 to 10 interpreting the intensity of itching in ascending order.

Section 4: Activities of Daily Living (ADL)

Katz and Lawton’s Activities of daily living scale was used to measure the ADL. It is a standardized tool developed in the year 1978 and the reliability is 0.78 and permission was obtained to use the tool. The tool has eight activities like feeding, bathing, grooming, toileting, locomotion, housekeeping, home
management and handling finance. Total score is 8, each activity is given 1, score ranges from 0-1.

**Score Interpretation**

- **7-8** Independent
- **5-6** Almost independent
- **3-4** Almost Dependent
- **1-2** Dependent

**Section 5: Sleep Diary**

Sleep diary was developed by the researcher to know the compliance. The sleep diary is a daily event calendar cum diary issued to the subjects to note their sleep timings, wake up hour's activities any sleep disturbance. This is evaluated for 7 days practice of sleep hygiene practices.

**Score Interpretation**

- 6 Days a week-Regular
- < 6 Days-Irregular

**3.10 Pilot study and Revision**

The pilot study was conducted with 40 samples allotted using randomization with 20 samples in study and 20 in control group from January 2009 to August 2009. The feasibility of the tool administration, research intervention and method of data collection were assessed.
Major modifications considered for the main study were as follows

- Regarding age, it was decided to add patients above 60 years also
- Under the clinical variables the current medications prescribed for the samples was also added.
- After the pilot study it was decided to give reinforcement after the first posttest ie, on the 30th day.
- Decided to give sleep diary to the control group also.
- After the pilot study investigator decided to include only psoriasis vulgaris patients so it was kept as an inclusion criteria.
- For the main study, the investigator decided to include moderately severe psoriasis vulgaris patients only.
- After the pilot study patients with co-morbid illness have been excluded in the study hence it was kept as an exclusion criterion.

3.11 Data collection procedure

The main study was conducted after obtaining approval from the Ethical Committee and Head of the Department of Dermatology. The data collection procedure was carried out in the dermatology OPD of G block SRH. The investigator prepared 410 chits (205 for study group and 205 for control group) which was kept in the ballot box. As the patients with moderate (severity) psoriasis vulgaris attended dermatology OPD, they were approached considering the inclusion and exclusion criteria and were explained clearly about the study and verbal consent was obtained from them. The study patients
were asked to pick up the chit and according to that they were allotted to
groups of study and control through simple random technique and thereby
randomization was done.

After obtaining the written consent the investigator collected related
data and conducted pretest assessment of sleep quality, psoriasis severity and
ADL for both the groups and the data were kept confidential.

The study patients were clearly explained and instructed that they may
fall in to either study or the control group. Both the groups received the routine
care. The study group patients received the sleep hygiene practices package
after pretest as a small group structured teaching inclusive of 3-4 patients in a
group. At the end of the teaching the study group patients were demonstrated
relaxation position and technique and they were instructed to do return
demonstration. After the demonstration they received pamphlets insisting the
teaching and the sleep diary.

The entire session was planned for 30 minutes. At the end of the session
the doubts were clarified. The control group patients received sleep diary after
the pretest and both the groups were instructed on how to maintain the sleep
diary. Both study and the control group patients were instructed to come on the
30th day. Patients were given the investigators contact number to call if they
had any query.

On the 30th day first post assessment was done on sleep quality,
psoriasis severity and ADL for both the group. Patients from both the groups
received the routine care, but the study group patients were given
reinforcement on sleep hygiene practices, and relaxation technique. Both the
groups were instructed to come on the 120th day. During the first posttest six patients in the study group were lost for follow-up and in the control group the patients remained the same in number.

On the 120th day during second posttest both the groups were assessed for sleep quality psoriasis severity and ADL. The study group patients were motivated to continue the practice and both the groups received the routine care. In the control group four patients were lost for follow-up. Both the groups were instructed to come on 180th day for third posttest. On the 180th day third post assessment was done for both the groups on sleep quality, psoriasis severity and ADL.

The control group patients were given the same pamphlets given to the study group during the pretest and the relaxation technique was demonstrated. The information was collected and the data were kept confidential. The privacy was maintained for patients during data collection and their doubts were clarified. The ethical and scientific principles were adhered to by the investigator throughout the study.
Figure 4 Participants Flowchart

- Assessed for Eligibility (440)
  - Excluded Diabetes Mellitus (17)
  - Psoriasis severity – Severe (13)
- Randomization by block (410)
  - Assigned to study group (205)
    - Posttest I - Lost for follow-up (6)
      - (n = 199)
    - Posttest II - (n = 199)
    - Posttest III - (n = 199)
    - Analyzed (n=199)
  - Assigned to control group (205)
    - Posttest I
      - (n = 205)
    - Posttest II - Lost for follow-up (4)
      - (n = 201)
    - Posttest III - (n = 201)
    - Analyzed (n=201)
Figure 5. Data Collection Procedure
3.13 Data analysis and statistical methods used

The collected data was analyzed with **SPSS 17.0** version. The study used descriptive statistics includes frequency, percentage, mean and standard deviation to assess the study related variables (demographic and clinical variables, dependent and independent variable) and the effect of sleep hygiene practices on sleep quality, psoriasis severity.

To find out the existence of homogeneity between the study group and control group nonparametric test Goodman’s chi-square distribution was used to find out the distribution of variables in the study and control group.

To test the effect of sleep hygiene practices within the group Wilcoxon signed rank test was used and to find the effect of sleep hygiene practices between groups Mann Whitney U test was used.

Kruskal Walli’s test was used to differentiate the study related variable with outcome variables. Spearman’s correlation was applied to assess relationship between outcome variables.

Friedman’s test was applied to find out the effect on repeated measures in different period of the study.
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<th>Type of statistics</th>
<th>Purposes</th>
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<td>Frequency, Percentage, Mean, SD</td>
<td>Assess the study related variables</td>
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<tr>
<td>Inferential Statistics</td>
<td>Wilcoxon signed Rank test</td>
<td>Compare the data within the group</td>
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<td></td>
<td>Mann Witney U test</td>
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<td>Kruskal Wallis Test</td>
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<td>Spearman’s Correlation</td>
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