



RANDOMIZED CONTROL TRIAL TO EVALUATE THE EFFECTIVENESS OF HAND AND FOOT MASSAGE THERAPY ON THE LEVEL OF PAIN AND QUALITY OF SLEEP AMONG BREAST CANCER PATIENTS IN SELECTED HOSPITALS, SANGRUR, PUNJAB.

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ABTRACT:

OBJECTIVES: The aim of the study is to assess the effect of hand and foot massage therapy on the pain and quality of sleep among breast cancer patients. **BACKGROUND OF THE STUDY:** Cancer is a global problem and it is a leading cause of death worldwide. Pain and quality of sleep are affected among the cancer patients. Foot massage is a complimentary therapy that has great potential for use by nurse in multidisciplinary pain management programme. Foot massage acts like an analgesic and inhibits those pain signals from being transmitted to the brain. It is the manipulation of superficial and deeper layers of muscle and connective tissue to enhance function and in the healing process and promote relaxation and well being. **DESIGN:** Control and experimental groups were taken and manipulation was given to the experimental group. Two groups pretest – posttest (experimental and control) design were used in this study. **RESEARCH METHODOLOGY:** The quantitative evaluative approach, randomized control trail design was used. The samples of 200 cancer patients were selected probability simple random technique sampling technique and the samples were divided into experimental and control group based on matching criteria. The data was collected by using two tools a) demographic variables tools, b) pain scale, c) european organization for the research and pittsburg quality of sleep index. The hand and foot massage was administered for the patients. The data was analyzed by using descriptive and inferential statistics. **FINDINGS OF THE STUDY:** The findings were in experimental group, pretest mean score was 8.31, post test mean score was 4.16, in pretest maximum 83% of subjects had very severe level of pain, in posttest 63% of subjects had mild pain. Whereas in control group, pretest mean score was 8.22, post test mean score was 6.55, in pretest 86% of subjects had very severe level of pain, and in post test 56% of subjects had moderate pain. The “t” value in between pretest and post pain scores of experimental group is 29.43, that shows hand and foot massage therapy is effective in reducing pain among breast cancer patients.

In experimental group, pretest mean score was 19.56, after administration of hand and foot massage therapy it was changed to 12.45, and t test value in between is 24.89, that clearly indicates the hand and foot massage therapy is effective in improving the quality of sleep among breast cancer patients. **CONCLUSION:** The hand and foot massage was effective in reducing pain, enhancing the quality of sleep. **RECOMMENDATIONS:** the study recommends using other techniques to reduce pain and improve quality of sleep. The study recommends exploring the factors affecting the quality of life and expectations from the cancer patients. **KEY WORDS:** breast cancer, pain, quality of sleep, hand and foot massage, **INTRODUCTION:**

Cancer is derived from the Latin word "carcinoma," which meaning "crab." cancer is a frightening word and it is most common lifestyle diseases. The uncontrolled growth of abnormal cells in the body is known as cancer.

Although sleep disorders are associated with medical conditions such as cardiovascular disease, and respiratory and musculoskeletal problems, some of these disorders are recognized in cancer patients. It seems that the mental and physical discomforts from cancer can be associated with sleep disorders; difficulty in sleeping is one of the most prominent concerns of cancer patients. This disorder is the most prevalent symptom among women with cancer. a lot of women with breast cancer have trouble sleeping because of the cancer itself, stress, a recent surgery, or an emotional problem like worry about starting chemotherapy. Also, flushing can be caused by chemotherapy, hormone therapy, and the length of time since a cancer diagnosis, a recurrence of cancer, the stage of cancer, the type of treatment, a person's mental state during a cancer diagnosis and treatment, fatigue, and the surroundings. Age, education, marital status, and menstruation can cause sleep disorders. More than 60% of patients with metastatic breast cancer have been reported to have more than one type of sleep disorder. Increased depression and adverse changes in sleeping patterns, compared to other predictions (pain and stress), have been associated with this disease. Fatigue, pain, psychological disorders, and sleep problems are predicted in heterogeneous samples of patients with advanced cancer. Sleep disorders not only cause discomfort to patients and interfere with their daily activities, but also affect their desire and willingness to receive treatment, and the treatment outcomes

Kuo quotes that some of the sleep problems that can happen to people who are getting chemotherapy are short sleep, trouble falling asleep, waking up often during the night, and sleeplessness. **Koopman et al.** reported that in 63% of samples with metastatic breast cancer, one or more types of sleep disorders were observed. Furthermore, in the study by **Fortner et al.**, in 61% of a sample of 72 people with breast cancer, sleep disorder was significantly observed. Sleep disorder itself is a significant problem associated with breast cancer. Therefore, with knowledge of the nature and prevalence of sleep disorders among cancer patients and based on new approaches, supportive care can slow down this process because many sleep disorders can be handled well. Since there are many things that can cause sleep disorders, it can be helpful to use both drugs (like benzodiazepines or melatonin receptor agonists) and non-drug treatments together.

Barry v Fortner(2002), the sleep and quality of life in breast cancer patients, 61% of breast cancer patients had significant sleep problems. Sleep was characterized by reduced total sleep time with sleep frequently being disturbed by pain, nocturia, feeling too hot, and coughing or snoring loudly. Despite the frequency of significant sleep disturbance, pharmacological and cognitive-behavioral treatments of sleep problems were observed to be inadequate.

Otte jl,(2016)sleep disturbances are common symptoms in individuals with breast cancer. The incidence varies across studies depending on the study design and assessment methods, but most studies have reported that 60%–90% of patients with breast cancer have sleep disturbances—much higher than that in the healthy population.

Lack of medication is another problem associated with economic issues. According to the statistics of the world health organization, 80% of the populations of third-world countries do not have access to even their basic medicines for common ailments, or due to the high price of drugs, they cannot buy and use them.

NEED OF THE STUDY:

QUALITY OF SLEEP: sleep disturbance is one of the most common complaints in cancer patients. Insomnia is defined as difficulty in initiating or maintaining sleep for a duration of at least 1 month and hence resulting in clinically significant distress and/or social and occupational impairment. Cancer can cause insomnia and other sleep problems before and after the diagnosis, and they can last during and/or after treatment. Cancer patients' insomnia is often made worse by their medicines and their side effects, so it's important to find it as soon as possible and deal with it. Insomnia has many different causes and effects on different parts of a person's life.

Patients with insomnia are prone to emotional disturbances, chronic fatigue, poor professional performance, and dependence on sedatives. There is a lot of data that shows a strong link between bad sleep and a lot of bad things, like decreased physical and mental functioning and a lower quality of life. Furthermore, sleep disturbances can result in unplanned interruptions, poorer compliance and tolerance for treatment, or many a time a change in the treatment plan and

may even be linked to more adverse events and a worse prognosis. Based on the **pittsburgh sleep quality index (psqi) measures**, it has been found that insomnia in cancer patients at the initiation of treatment is higher than that in the general population and ranged between 26% and 57%. Sleep problems hurt the quality of life, raise health worries and the risk of cancer coming back, cause serious pain and vasomotor symptoms, and drain energy. Breast cancer patients who have trouble sleeping often have clusters of symptoms like depression, worry, and fatigue caused by the cancer. When women with breast cancer and sleep problems are in the hospital, they have more problems and stay longer. Several studies have also shown that getting less sleep is linked to higher risks of breast cancer coming back, dying from breast cancer, and dying from any cause. Randomized controlled studies have reported that patients with breast cancer who underwent cognitive behavioral therapy for insomnia demonstrated decreased depression and anxiety levels, alleviated general and clinical fatigue, and improved global quality of life.

Previous studies have shown that massage therapy can help people with pain, anxiety, fatigue, the quality of their sleep, and their overall quality of life. Therefore, this study was performed based on previous investigations and keeping in mind the high prevalence of sleep disorders and their problems, lack of adequate medical care for the patients' sleep disorders, cultural differences of Indians compared to people of other countries, and lack of sufficient and specific studies in this field. This study was conducted with an aim to examine and provide solutions for decreasing sleep disorder and improving physical and mental health by investigating the effects of hand and foot massage therapy on the quality of sleep, quality of life and pain of patients with breast cancer.

OBJECTIVES OF THE STUDY

The objectives of the study are;

1. To assess the pre and post-test level of pain among breast cancer patient in experimental and control group.
2. To assess the pre and post test level of quality of sleep among breast cancer patient in experimental and control group.
3. To develop and implement the hand and foot massage and its effectiveness on levels of pain and quality of sleep among breast cancer patients in experimental group.
4. To compare the pre test and post test levels of pain, quality of life and quality of sleep among breast cancer patients in experimental and control group.
5. To find the association between the level of pain and quality of sleep with selected socio-demographic variables of breast cancer patients in experimental and control group.

METHODOLOGY:

RESEARCH PPROACH:

Quantitative research approach was used in the present study.

RESEARCH DESIGN:

Control and experimental groups were taken and manipulation was given to the experimental group. Two groups pretest – posttest (experimental and control) design were used in this study.

RESEARCH SETTING:

The study was conducted in selected hospitals, sangrur, punjab.

TARGET POPULATION:

The populations of the study were all breast cancer patients in selected hospitals of district sangrur.

SAMPLE SIZE:

Total sample selected 200 i.e. experimental group 100, control group 100=200

SAMPLING TECHNIQUE:

Probability random sampling technique was used to select the samples.

CRITERIA FOR SELECTION OF SAMPLE:

Inclusion criteria: breast cancer patients-

- 1] admitted at selected hospitals.
- 2] who are willing to participate in the study.
- 3] who available at the time of data collection.
- 4] who able to understand and respond in punjabi/hindi/english.

Exclusion criteria: breast cancer patient-

- 1] who are not present during the time of data collection.
- 2] who are not able to understand punjabi /hindi/ english.

3] who are not meeting the inclusion criteria.

DEVELOPMENT OF STRUCTURED DATA COLLECTION TOOLS:

PART I – SOCIO-DEMOGRAPHIC PROFILE.

It consists of 09 items related to selected socio-demographic data which includes age, marital status, educational status, and presence of concurrent illness, duration of breast cancer, treatment received, mastectomy, monthly income, and family support.

PART II – PAIN SCALE

This section consists of numerical and visual pain scale. The scale ranges from the 0-10 scores and visual pain scale had various pictures showing about the levels of pain.

Scoring of pain scale:

No pain	0
Mild pain	1-3
Moderate pain	4-6
Very severe	7-9
Worst pain possible	10

PART III: PITTSBURGH QUALITY OF SLEEP SCALE

The pittsburgh sleep quality index (psqi) is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. It consist of 15 items with rating ranging from very good to very bad, not during the last month to two to three times in a week, no problem at all to very big problem. First four items are related to general items, item 5th to 10 have ratings. The item 5 and 10 has sub items.

The scoring is done based on total score.

1.	No sleep difficulty(0)
2.	Mild sleep difficulty (1-7)
3.	Moderate sleep difficulty (8-14)
4.	Severe sleep difficulty (15-21)

Hand and foot massage therapy

The procedure for hand and foot massage procedure and the duration is mentioned in the annexure part along with the tool.

CONTENT VALIDITY: the word content validity refers to the substance of the chose apparatus is the means by which fitting and how it measures the factors. To portray as it were whether items, perspectives or other inquiries measure variable unequivocally and precisely what should quantify. The substance legitimacy is notably vital when anybody is making accomplishment exams in instructive sector.

The tools covering socio-demographic variables. Pain scale, quality of life scale and quality of sleep scale were content validated by giving to seven experts from nursing field and obstetrician and gynecologist, oncologist. There was some changes were suggested by the experts agreement by all experts on all the items. However there were few ideas to change some of the components and they were put in final tool.

RELIABILITY OF THE TOOL:

Reliability of the tool was tested by test retest method by using karl pearson's co-efficient of correlation formula. Item analysis was done to test internal consistency. This is done by critically evaluating questions based on difficult index and discriminative index. The reliability of pain and quality sleep were $r = 0.72$ and 0.79 respectively. This indicates that tools were reliable to measure the variable. Even though the quality of life and quality of sleep tools were standardized tools and the permission was obtained by the authors.

QUALITY OF SLEEP:

In experimental group, pretest mean score of quality of sleep was 19.56, after administration of hand and foot massage therapy it was the mean post test score of quality of sleep was to 12.45, and t test value in between is 24.89, that clearly indicates the hand and foot massage therapy is effective in improving the quality of sleep among breast cancer patients.

In experimental group in pretest, maximum number of subjects 94% were had severe sleep difficulty in post-test administration of hand and foot massage therapy, level of quality of sleep has changed their maximum number 70% subjects had mild sleep difficulty.

Whereas in the control group in pretest, maximum number of subjects 90% were had severe sleep difficulty in pre test and in post-test, level of quality of sleep has changed their maximum number 92% subjects had severe sleep difficulty.

A study was supported by **ATENASAMAREHF EKRI** study on effect of foot reflexology on pain, fatigue, and quality of sleep after kidney transplantation surgery. Results are the mean pain score in the foot reflexology and control groups decreased from 9.44 ± 0.96 and 9.36 ± 0.91 on the day of surgery to 1.32 ± 0.94 and 4.32 ± 1.68 on the eleventh day after surgery, respectively. The mean sleep score in the foot reflexology and control groups increased from 33.38 ± 11.22 and 39.59 ± 12.8 on the day of surgery to 69.43 ± 12.8 and 56.27 ± 8.03 on the eleventh day after surgery, respectively. While pain, and sleep quality scores improved in both groups, those in the intervention group showed significantly greater improvement compared with the control group.

Another study was done on lower back pain and sleep disturbance are reduced following massage therapy. Treatment effects were evaluated for reducing pain, depression, anxiety and sleep disturbances, for improving trunk range of motion (rom) and for reducing job absenteeism and increasing job productivity. Thirty adults (m age=41 years) with low back pain with a duration of at least 6 months participated in the study. By the end of the study, the massage therapy group, as compared to the relaxation group, reported experiencing less pain, depression, anxiety and sleep disturbance. Also another study conducted on the effect of massage therapy on the quality of sleep in breast cancer patients. Results showed that mean and standard deviation of the overall score of the quality of sleep before the intervention that is massage therapy, out of 21, was 31.69 (5.34) in the experimental group and 13.15 (6.38) in the control group. After the intervention massage therapy, it was 8.24 (5.57) in the experimental group and 13.5 (6.5) in the control group. Paired t -test also showed significant difference between the scores of quality of sleep before and after intervention in the experimental group ($p < 0.001$). However, it did not show any significant difference between the mean scores of quality of sleep before and after the intervention in the control group ($p > 0.05$).

Association between pretest quality of sleep scores of breast cancer patients with their selected socio demographic variables in experimental group:

It shows that, the demographic variable presence of breast cancer shown association with quality of sleep scores of breast cancer patients, other socio-demographic variables like age in years, marital status, education, presence of concurrent illness, treatment received, mastectomy, monthly income in rupees/family and individual and family support does not show any associations with pretest quality of sleep scores of breast cancer patients statistically at 0.05 level.

CONCLUSION:

The main focus of this study was to determine the assess the randomized control trial to evaluate the effectiveness of hand and foot massage therapy on the level of pain, quality of life and quality of sleep among breast cancer patients in selected hospitals. A quantitative research approach and true experimental research design was used to get the answers for the research questions in the study. The study recruited two hundred samples divided equally into experimental and control groups and samples were recruited by using the probability random sampling technique. The tools of data collection were validated and reliability was checked. The data was collected from all two hundred samples by investigator and research assistants.

All the participants of the selected setting were cooperated and willingly take part in the study. They gave free and reliable responses for all the questions asked to them by the investigators.

Further, the important conclusion drawn on from the present study includes the, most of samples had severe pain in experimental and control group, the quality of life based on eortic scale was quality life score was more in experimental and control group and quality of sleep was also affected. The hand and foot massage was showed significant improvement in the pain levels, the quality of life and quality of sleep. There was no significant change in the control group.

SUMMARY:

This section has managed a concise synopsis of the investigation. The main area of this part condensed the philosophy with brief exchange on notable discoveries of the examination. The following area talked about the suggestions for nursing work on, nursing instruction, nursing organization, nursing research, the impediments and the proposals. In all these segment it is clarified that how these discoveries can be used in future by the nursing overseers, nursing understudies, nursing research researchers others who are have their enthusiasm for the natural contamination related issues emerge because of unhygienic states of condition

In the prior segment of this section quickly portrayed about the idea of the issue, its criticalness, what is requirement for the examination, system followed, theoretical structure and insights utilized for the investigation.

This section through the light overall procedure of the examination, scientist experience and other part of the investigation

FINDINGS OF THE STUDY: the findings were in experimental group, pretest mean score was 8.31, post test mean score was 4.16, in pretest maximum 83% of subjects had very severe level of pain, in posttest 63% of subjects had mild pain. Whereas in control group, pretest mean score was 8.22, post test mean score was 6.55, in pretest 86% of subjects had very severe level of pain, in post test 56% of subjects had moderate pain. The “t” value in between pretest and post pain scores of experimental group is 29.43, that show hand and foot massage therapy is effective in reducing pain among breast cancer patients.

The qol of experimental group in **EORTC QLQ-C30 version 3.0**, in pretest mean scores are, global health status 4.7, functional scales 21.89, symptoms scales 47.47, in **QLQ-BR 23** symptoms scales 40.25, functional scales 27.53. where as in control group in **EORTC QLQ-C30 version 3.0**, in pretest mean scores are, global health status 5.59, functional scales 22.83, symptoms scales 48.35, in **QLQ-BR 23** symptoms scales 41.4, functional scales 44.09. In eortc qlq-c30 version 3.0, in global health status pretest mean scores was 4.79 and after administration of hand and foot massage therapy it was changed to 11.99, and t value is 50.46, in functional scales pretest mean scores was 21.89 and after administration of hand and foot massage therapy it was changed to 18.29, and t value is 12.31, in symptoms scale pretest mean scores was 47.47 and after administration of hand and foot massage therapy it was changed to 25.11, and t value is 60.48. All these scores indicate that hand and foot massage therapy is effective in improving quality of life in experimental group. In **QLQ-BR 23**, in symptoms scale pretest mean scores was 40.25 and after administration of hand and foot massage therapy it was changed to 23.60, and t value is 55.07, in functional scale pretest mean scores was 27.53 and after administration of hand and foot massage therapy it was changed to 43.62, and t value is 39.92, all these scores indicate that hand and foot massage therapy is effective in improving quality of life in experimental group.

RECOMMENDATIONS:

Based on findings of the present study, the following recommendations have to be made:

1. A similar research study can be replicated or carried out by moving through a large number of study participants to generalize and summarize the findings.
2. The significance of the real-world parameters discovered in this study can be tested by doing further studies of a similar sort.
3. The same type of people in diverse situations can drive a relevant research study.
4. The current examination can be replicated among different age groups of the population
5. The same study can be replicated on different professional workers.
6. A comparative study on the same subject can be undertaken by taking participants of different types of cancers i.e. breast cancer and cervical cancer and other cancer patients.
7. A comparative study can be performed to evaluate the effectiveness of different complementary therapies like foot massage with guided imagery and / or music therapy.
8. A similar study can be conducted on massage intervention to modify the distressing symptoms of cancer patients hospitalized with cancer.
9. A similar study can be conducted with a case study approach on specific site of cancer.
10. A comparative study can be conducted to assess the effects of partners administering foot massage and nurse administering foot massage

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