



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

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ABSTRACT:

OBJECTIVES: The aim of the study is to assess the effect of hand and foot massage therapy on the pain, quality of life among breast cancer patients. **Background of the study:** Cancer is a global problem and it is a leading cause of death worldwide. Pain, Quality of life is 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 Treatment of Cancer Quality of Life Questionnaire. 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, 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.

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. **Conclusion:** The hand and foot massage was effective in reducing pain, enhancing the quality of life. **Recommendations:** The study recommends using other techniques to reduce pain and improve quality of life. The study recommends exploring the factors affecting the quality of life and expectations from the cancer patients. **Key words:** breast cancer, Pain, quality of life, 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.

Cancer comes in a variety of forms. There isn't just one sickness here. Cancer can begin in the lungs, breasts, colons, or even the bloodstream. Lung, prostate, colorectal, stomach, and liver cancer are the cancers men get most often, whereas breast, colorectal, cervical, lung, and thyroid cancer are the most common cancers in women.

The news that you have cancer can have a big effect on your mental health and wellbeing, anxiety, depression, reduced quality as well survival of life. Depression and anxiety are going to affect the gratification of everything that makes and individuals happy. It is like someone has kidnapped thought process and makes individuals think negative thoughts all the time. Cancer has serious impact on patient life aspects in both psychological and social. Patient with cancer may have

frequently feelings of depression and anxiety because of treatment that gives impact on physical and emotional level in daily life of the patients.

Complementary and alternative medicine is a topic of discussion between patients and medical professionals as non-pharmacological treatments which are rapidly developing. Some of these methods are in the range of a nurse's job and can be a part of the care program. Guided imagery, hypnosis, training coping skills, cognitive-behavioral treatment, relaxation, music therapy medication, and mind and body interventions are among the interventions that improve pain, fatigue, and sleep disorders in patients with cancer. Massage therapy is one of the most popular extra treatments used by people with cancer. Unlike the other complementary treatments listed above, the patient does not have to do anything during the technique. When the patient finds someone in the stressful hospital setting who listens to their problems and talks to them in the right way, they can adjust better to both the surroundings and their illness.

Touch-based methods of comfort are offered in many cancer treatment centers, hospice programs, and other palliative care settings. However, there are significant problems to wide use and consistent delivery to patients over time, often resulting in such therapy being a novel or special event outside routine care. For many, the cost of such services and lack of insurance coverage makes regular use unaffordable. For those with the means, treatment settings often lack sufficient availability of personnel who are trained or have time to deliver this form of care. For home-based patients, to visit a provider requires travel from home and the scheduling of appointment times into the future—both of which can be problematic for patients carrying high burdens of distress.

The integration of touch as routine supportive care may be achievable through tapping an underutilized resource in the patient's natural social environment: family members and friends who have the need and desire to contribute to relief of suffering in their loved one. Many studies have shown that care partners can feel as much or even more distress than cancer patients. This is often because they feel powerless or like they can't make a difference in the patient's health. There is also evidence that care partners benefit from doing active, hands-on caregiving. One study found that family caregivers receiving instruction in reflexology can reduce pain and anxiety in cancer patients. Caregiver education for partners is needed to help build their sense of self-efficacy and empower them with the ability to have an impact on patient well-being. Such programs hold the potential to benefit the patient, the partner, and the quality of their relationship.

Touch, like talking, is a way of communication in care and can have treatment effects. In fact, this method can make the patient independent and can be performed by the patient and their families with simple tools. Moreover, the patients easily accept and collaborate well in this method. It also does not have the side effects and negative consequences of the pharmacological interventions. The benefits of complementary therapies can be considered in two parts. Firstly, it is used as the cause of psychological healing in order to create a degree of

comfort and peace in stressful situations. The second part is that these treatments can be used to facilitate the therapeutic relationship between the nurse and patient by improving trust and communication.

The quality of life (QoL) is one of the most concerning health issues for oncology patients. It is a type of patient-reported outcomes (PROs) that is unique and has many different parts. Patients see it as something that includes their social, financial, psychosocial, and physical actions. Due to the improvement in medical science and continuing advancement in early detection and treatment, the expected survival time of cancer patients has become longer. This has resulted in an increased interest in exploring the health-related quality of life (HRQoL) of cancer survivors. So, there is a consequent need to satisfy cancer patients' requirements which would enable them to live a healthy life. After being identified and treated for cancer, many people have trouble sleeping, feel sad, and have a low quality of life. So, it is important to measure QoL in cancer patients in order to come up with ways to help them feel better and live longer. In the same way, QoL assessment helps people understand how treatment, health, and sickness affect quality of life. Also, it helps to know what might be good and bad about a treatment. This makes it easier to weigh the pros and cons of a choice.

The cancer patients experience a variety of symptoms. Inadequate management of symptoms might hamper the performance of the daily activities of an individual. The treatment of symptoms will help relieve the suffering and improve the quality of life (QOL). The symptoms have a major impact on QOL among the patients with breast cancers. Greater symptom load has been associated with the higher levels of emotional suffering and poor physical and societal functioning and global QOL. Thus, effective management of symptoms can improve the QOL in breast cancer patients.

NEED FOR THE STUDY:

Quality of life:

WHO defines Quality of life is how a person sees where they are in life in relation to their goals, expectations, standards, and worries. It also depends on the society and value system in which they live. It is a broad idea that is complicatedly affected by a person's physical health. Psychological state, personal views, social relationships, and how they relate to important things in their surroundings.

From the patient's point of view, quality of life is a subjective, multidimensional concept that includes functional state, psychological well-being, health perceptions, and symptoms caused by the disease or treatment. Quality of life incorporates action, value systems and the many aspects of a person's life.

Physical QOL – It is a measure of the physical well-being of the survivor.

Overall QOL – It is a measure of the overall well-being of the survivor.

As the number of long-term cancer survivors grows, radiation oncologists should understand how their physical, mental, and financial needs combine.

1. **Biologic sequelae** results in disorganizing functions of different organs resulting in poor quality of life like sexual dysfunction, lymph edema, fatigue, infertility or even death.
2. **Psychological sequelae** can cause depression and distress which results in inability to function with full satisfaction in their personal or social life.
3. **Socioeconomic sequelae** due to financial constraints will lead to increasing difficulty in their daily life.

For cancer patients, QOL is a crucial concern, both when the cancer is diagnosed and when the disease is being or has been treated. Oncologic medical treatments may lead to QOL improvements but, sometimes, a wide variety of side effects can arise bringing about significant health-related complaints. Likewise, once the cancer is treated, patients may show different levels of QOL, depending on the physical and psychological sequels. Additionally, better QOL has been associated with longer survival of patients with cancer. Thus, identifying the determinants of QOL may provide insights into how to improve life conditions in breast cancer patients and, thus, their survival. Several studies have found that socio-demographic factors, such as age, education, marital status, and income, play an important role in determining QOL in breast cancer patients. While social and financial support have also been shown to significantly improve QOL, clinical parameters, such as disease stage and duration of disease, have not necessarily been associated with QOL.

Breast cancer survivors face many problems, such as worry, trouble sleeping, pain, tiredness, and fear about the future. Their quality of life is greatly affected by how they feel, how they look, and how they interact with other people.

Foot massage is a very effective means of communication. It provides physical contacting a very acceptable way within the Indian culture. It can be particularly valuable for those who receive little human touch. To be touched in a gentle and unembarrassed way can be very comforting. It is also a good way of getting to know someone well by developing a relationship based on honesty and trust.

Complementary and alternative medicine includes a set of therapies for preventing and managing health problems and improving health status which are used instead or in adjacent to conventional therapies. Studies show that the rate of using these therapies in European countries increased from 10%–39% in 1997 to 37%–73% in recent years. Health-care professionals, particularly nurses, can use complementary and alternative therapies to fulfill their clients' needs, promote their comfort, and improve their quality of life.

OBJECTIVES:

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 life 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, quality of life among breast cancer patients in experimental group.
4. To find the association between the level of pain, quality of life with selected socio-Demographic variables of breast cancer patients in experimental and control group.

METHODOLOGY:**RESEARCH APPROACH:**

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 – Quality of life scale

European Organization for Research and Treatment of Cancer (EORTCQLQ-C30version3) is a questionnaire is an instrument designed to assess (some of) the different aspects that define the QoL of (a specific group of) cancer patients. Version 3.0 of the QLQ-C30 differs from version 2.0 in that it has four-point scales for the first five items (QLQ-C30(V3), Appendix 1d). These are coded with the same response categories as items 6 to 28, namely “Not at all”, “A little”, “Quite a bit” and “Very much.” To allow for these categories, question 4 has been re-worded as “Do you have to stay in a bed or a chair during the day?” Version 3.0 has been tested in EORTC field studies. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. Each of the multi-item scales includes a different set of items - no item occurs in more than one scale.

This tool contains total 53 statements with each response of **Not at all, A Little, Quite aBit, very Much.**

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 were some changes 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 of life were $r = 0.72$ and 0.82 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 life scores:

With respect 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.

With respect of control group in **EORTC QLQ-C30 version 3.0**, in pretest mean scores are, Global health status 4.59, Functional scales 22.83, Symptoms scales 48.35, in **QLQ-BR 23** Symptoms scales 41.4, Functional scales 44.09.

Effectiveness of hand and foot massage therapy in quality of life in experimental group:

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.

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Sturgeon M(2009) conducted a study on Effects of therapeutic massage on the quality of life among patients with breast cancer during treatment. Pretest post test study design was conducted among 60 breast cancer patients at Wichita USA. The data on anxiety, pain, nausea, sleep quality, and quality of life was collected and intervention consisted of one 30-minute treatment per week for 3 consecutive weeks. Results showed that participants experienced a reduction in several quality of life symptom concerns after only 3 weeks of massage therapy. Respondents' cumulative pre- and post-massage mean for state anxiety, sleep quality, and quality of life/functioning showed significant improvement. Among study participants, there was variability in reported episodes of nausea, vomiting, and retching; although participants reported decreased pain and distress, changes were non-significant.

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

It reveals the associated between pretest quality of life scores of breast cancer patients with their selected socio demographic variables. It shows that, Socio-Demographic variables age in years, marital status, education, presence of concurrent illness, presence of breast cancer, treatment received, mastectomy, monthly income in rupees/family and individual and family supporter does not show any associations with pretest quality of life 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 shows hand and foot massage therapy is effective in reducing pain among breast cancer patients.

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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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