



**Effectiveness of Proactive Health Care Interventions on Chemotherapy Related Side Effects and Self Care Behaviour among Patients with Breast Cancer: Study Protocol of a Randomized Controlled Trial**

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**Abstract**

**Background**

Globally, female breast cancer (FBC) is the most prevalent cancer. Chemotherapy is the main treatment of breast cancer, but it results in numerous physical and psychosocial concerns. In Kerala, Patients undergoing chemotherapy for breast cancers have varying severity of symptoms and chemotherapy may not be completed at the scheduled time. Breast cancer survivors did not routinely engage in healthy lifestyle behaviours to manage the side effects. At present there is no separate nurse run clinic to provide supportive care to patients receiving chemotherapy. So, the current study aim is to assess an effectiveness of proactive health care interventions on chemotherapy related side effects and self-care behaviour among patients with BC.

**Methods/design**

A research is a Randomized Controlled Trial comparing health care intervention with standard medical care. Sample size calculated for the research is 340 with confidence level of

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95% and power 80% with equal size of 170 each in experimental and control group. Patients undergoing chemotherapy for breast cancers in Govt. Medical College Thiruvananthapuram, who meet the inclusion criteria will be recruited as participants for the study. The outcome variable of the study are chemotherapy related side effects and self-care behaviours in managing chemotherapy related side effects. The sociodemographic and clinical data will be assessed on a day of their first cycle of chemotherapy. The outcome will be assessed at two points, during second and third cycle of chemotherapy using Common Terminology Criteria for Adverse Events Version 3.0 and Self Care Diary (SCD).

### **Discussion**

A result of the study will show the effectiveness of proactive health care intervention (Jacobson's Progressive Muscle Relaxation (JPMR) and health education) on chemotherapy related side effects and self-care behaviour of patients with BC.

### **Trial Registration**

Clinical Trials Registry in India, CTRI/2020/09/028178. Registered on 30 September 2020

### **Keywords**

Breast cancer, chemotherapy, side effects, self-care behaviour, Jacobson's Progressive Muscle Relaxation (JPMR), Randomized Controlled Trial, self-care education, proactive health care intervention

### **Background**

Cancer is a group of diseases described by uncontrolled and unregulated cells growth. There were an estimated 18.1 million new cases of cancer and 9.6 million deaths from cancer worldwide in 2018 (1). One of the most prevalent cancers is female breast cancer (FBC). In 2019, there were 1.98 million new cases of FBC recorded globally, with an age-standardized incidence rate (ASR) of 45.86 per 100,000 people, and there were 688,562 fatalities (2). According to data from the Indian Council of Medical Research's National Cancer Registry Program, there were 1,59,924 estimated cases of breast cancer in India in 2018 (3). Regional Cancer Centre's Hospital Based Cancer Registry (HBCR), (2018-2019) reported breast cancer as the most common cancers in females (28.5%) and Population Based Cancer Registry (PBCR), Thiruvananthapuram District in 2017 reported a crude incidence rate of 57.6 breast cancer in females (4).

Cancer requires intense treatment with surgery, radiation therapy, chemotherapy, hormone therapy, biotherapy, gene therapy and bone marrow transplantation which may be combined or used separately. Chemotherapy is the most often used form of treatment. Chemotherapy

medications can now greatly extend patients' lives and reduce cancer mortality due to advances in medical science and pharmacy. But because of its systemic nature of treatment, chemotherapy results in numerous physical and psychosocial concerns. Most of the of chemotherapy regimens can cause complications such as nausea, vomiting, alopecia, fatigue, oral mucositis, bowel disorders, anaemia, thrombocytopenia, infection, water and electrolyte imbalances, weakness etc in patients. Chemotherapy side effects might range in severity from person to person. Some patients' side effects could be so bad that the medication would need to be stopped.

The most frequent side effects of chemotherapy for BC were reported as fatigue (82%), followed by constipation (76%), diarrhoea, pain, rashes (74%), mucositis (72%) and vomiting (67%) (5). Another study reported the Mean (SD) of uncertainty 76.70 (13.55), self-efficacy 27.15 (5.67), and Self-care practices 53.96 (6.08) in breast cancer chemotherapy patients (6). A research on the side effects of chemotherapy found that 43% of patients reported headaches, 90% of them said they felt fatigued or weak, 95% said they felt weak, 76% said they lost hair, 77% said they felt sick, and 40% said they had abdominal cramps, mouth sores, or dry mouth. 14% reported memory loss, and 49% reported feeling numb (7). The majority of patients claimed that chemotherapy side effects had decreased their quality of life (8).

Self-management, according to Ruth McCorkle, is the process by which people deal with the emotional and medical aspects of managing their health issues. When patients actively participate in their own care and develop into competent and self-assured managers of their health and illness, productive exchanges take place. Patients need to have the necessary knowledge and abilities to set priorities and manage their illness in order to be effective and confident managers (9). According to the assumptions of the Dorothea Orem's theory, individuals should be independent and responsible for their own care and their family members should help them if they need help (10). Another study reported a positive significant correlation in self-efficacy and quality of life (QOL) (11).

In a qualitative study, four main categories of tasks required for chemotherapy symptom management were identified which included communication of chemotherapy-related concerns, management of chemotherapy-related symptoms, management of emotional and interpersonal disturbances, and acquiring relevant resources (12).

Patients with breast cancer who receive face-to-face psychoeducational intervention (PEI) have improved knowledge, resiliency, and QOL during and after chemotherapy. (13) In an intervention group that received ginger extract treatment as opposed to the control group, nausea severity and the frequency of vomiting episodes were considerably reduced ( $p > 0.05$ )

(14). Progressive Muscle Relaxation (PMR) and Guided Imagery (GI) are found to be effective in reducing fatigue and pain and to enhance health related QOL-HRQoL experienced by patients undergoing chemotherapy (15). Another study's findings demonstrated the value of self-care instruction in decreasing a physical adverse effects of chemotherapy (16).

14 self-care strategies, including acupressure, biofeedback, exercise, diet, hypnosis, cognitive distraction, music therapy, systematic desensitization, psycho-education, vitamin E cream, relaxation, oral hygiene programs, comprising mouthwashes, oral cryotherapy and scalp cooling, were recognized in a systematic review of articles reporting randomized trials to assess an effectiveness of various self-care strategies to control the side effects of chemotherapy. Progressive muscle relaxation and guided visualisation were relaxation techniques (17). A Systematic review showed that Health Literacy is associated with important self-management behaviours in cancer (18).

A self-care diary (SCD) was developed by Nail LM et al. to record the presence of side effects of chemotherapy, a severity of each side effect, and self-care practices and their effectiveness in reducing adverse effects (19). Knowledge has linked to self-care behaviors among cancer patients who had chemotherapy, according to a cross-sectional study (20).

After exposure to supportive care interventions (counselling and mind-altering activities), experimental group members showed moderate to high self-care behaviors and pleasure, according to a pilot study (21).

Findings of another study showed that self-care education improved the self-care behaviours and significantly reduced the frequency and severity of gastro intestinal side effects of chemotherapy in patients with cancer (22). Breast cancer survivors did not routinely engage in healthy lifestyle behaviours to manage the side effects (23).

When undergoing chemotherapy, the psychoeducational intervention group distinguished itself from the control group by significantly reducing the intensity of symptom clusters, exhaustion, sleep disturbance, depression, and anxiety (24).

### **Need of the Study**

The health care provider should inform patients receiving chemotherapy on the typical side effects and self-care techniques for managing them, coping with the situation, and maximizing well-being from the very beginning of chemotherapy. A growing corpus of research shows that numerous non-pharmacological therapies can successfully reduce the symptoms. In Govt. Medical College Thiruvananthapuram, Radiotherapy Department is a well-structured department with expert Oncologist and other health team members provide

free medical service for cancer patients. More than 2500 new cancer cases are being registered every year, and more than 1400 patients are receiving chemotherapy per month. The most common cancer in this centre is breast cancer and they receive adjuvant and neo adjuvant chemotherapy divided into 4-6 cycles with an interval of 21 days depending on the stage of the cancer. On an average 20-25 new cases of breast cancer patients are receiving chemo therapy per month. our setting, patients undergoing chemotherapy for breast cancers have varying severity of symptoms and chemotherapy may not be completed at the scheduled time. At present there is no separate nurse run clinic to provide supportive care to patients receiving chemotherapy. So, the current study aim is to assess an effectiveness of proactive health care interventions on chemotherapy associated side effects and self-care behaviour among patients with breast cancer.

## **Methods**

### **Objectives**

1. Evaluate the effectiveness of proactive health care interventions on severity of chemotherapy related side effects among patients with breast cancer.
2. Evaluate the effectiveness of proactive health care interventions on self-care behaviours among patients undergoing chemotherapy for breast cancers.

### **Hypothesis**

H1: There will be difference in the mean score of chemotherapy related side effects among patients with breast cancer between experimental and control group after the intervention

H2: There will be difference in the mean score of self-care behaviours among patients undergoing chemotherapy for breast cancer between experimental and control group after the intervention.

### **Study Design**

The study is a Randomized Controlled Trial- Parallel Group Design comparing proactive health care interventions with standard medical care. The protocol is designed as per the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement (table 3) (25) and Consolidated Standards of Reporting Trials (CONSORT) 2010 statement (26).

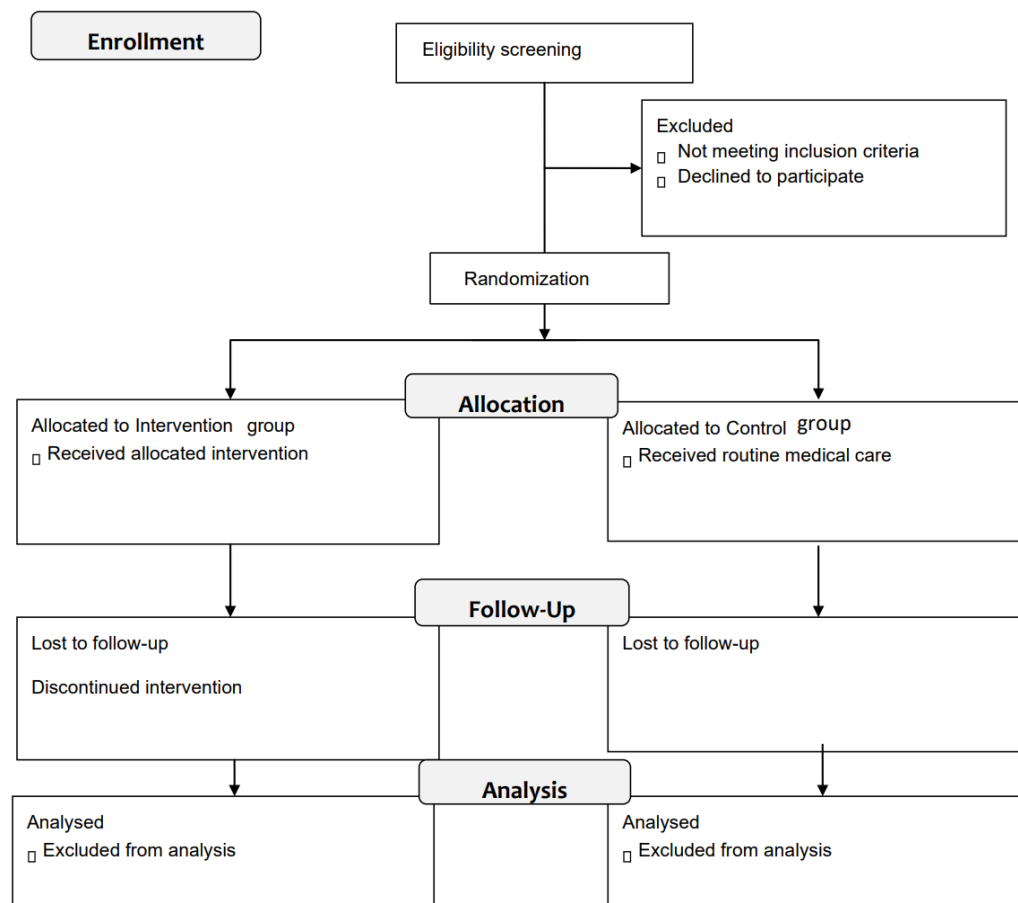


Figure no.1: CONSORT flow diagram

### Study Setting

The study will be conducted at Day care chemotherapy unit of Radiation Oncology Department, Govt. Medical College Hospital Thiruvananthapuram.

### Randomization

Computer generated random allocation sequence using Random allocation Software is used to generate Block Randomization with block size four (27). The researcher created sealed, opaque envelopes and arranged them in ascending randomization order using this list as a basis. An independent person not involved in the research will randomly draw a sealed envelopes and assign participants to either experimental or control group. Patients with breast cancer attending Radiation Oncology OPD, Medical College Hospital Trivandrum who satisfied the eligibility criteria will be enrolled in the research after getting written informed consent.

### Blinding

Outcome assessor and participants will be blinded. Outcome measures at two time points (T1 and T2) will be assessed by an independent assessor who is blinded to group allocation.

## **Participants**

Patients undergoing chemotherapy for breast cancers in Govt. Medical College Thiruvananthapuram, who meet the inclusion criteria will be recruited as participants for the study.

### **Inclusion criteria**

Female patients undergoing chemotherapy for breast cancer who is

- >20 years of age
- Clinical staging of breast cancer, stage I, II or III
- undergoing their first cycle of chemotherapy with a curative purpose (Adjuvant and Neo adjuvant)
- receiving combination chemotherapy with a minimum of 2 drugs which consists of Cyclophosphamide, 5Fluro uracil, adriamycin and paclitaxel
- having ECOG performance less than or equal to 2
- able to speak, read and understand Malayalam
- Willing to participate and able to give an informed consent.

### **Exclusion criteria**

Patients undergoing chemotherapy for breast cancer who

- Have previous exposure to chemotherapy
- Have concurrent radiotherapy
- Have visual, hearing or cognitive impairment
- Have known psychiatric illness

### **Interventions**

The proactive health care interventions will be given for the patients in the intervention group on the day of first cycle of chemotherapy. Proactive health care interventions include health education session and demonstration of progressive muscle relaxation technique for a total duration of 40 minutes. Education session for a duration of 20 minutes is given as individual teaching by lecture cum discussion method using power point presentation regarding side effects of chemotherapy for breast cancer and self-care behaviours to be practiced by the patient for the management of each side effect. A pamphlet in Malayalam with all this information will also be given. Demonstration includes Jacobson's progressive muscle relaxation (JPMR) technique for 20 minutes (28). Instructions for JPMR technique will be given as an audio clipping in mobile phone for practicing at home in the morning and evening daily. Reinforcement of the intervention will be given weekly over phone and the participants and care givers will be asked to maintain a daily diary.

Table No. 1: Description of Intervention

<b>Intervention Group</b>		<b>Comparison Group / control Group</b>
Description of intervention	Duration	
Individual teaching with power point on side effects of chemotherapy for breast cancer and self-care behaviors to manage the side effects	20 minutes	<b>Standard treatment only.</b> Routine care such as Doctor's prescription of medications, advice by nurses on chemotherapy drugs, side effects and care to be followed at home and importance of follow up.
Demonstration of Jacobson's Progressive Muscle Relaxation using instructions from an audiotape (shown in Table 2)	20 minutes	

### **Data Collection**

Patients prescribed with chemotherapy who meet the selection criteria of this research, will be evaluated for baseline data and randomized either into intervention or control group after obtaining an informed written consent. Patients in the intervention group will receive Proactive Health Care Interventions (Health education on self-care strategies to control the side effects and JPMR). The only treatment given to patients in the control group is standard medical care. Reinforcement of intervention will be given through telephone every alternate day. Participants will be asked to do JPMR in the morning and evening and whenever they feel fatigued or nauseated. Both the patient and the caregiver in experimental group will be asked to maintain a diary daily to document the self-care behaviours for managing the side effects of chemotherapy. Another diary will be given to participants and care givers of both experimental and control group to document the occurrence and severity of side effects daily at home after the chemotherapy. Outcomes will be assessed at two times, when the participants come for second (T1) and third chemotherapy(T2) administration.

### **Outcomes**

The outcome variable of the study are chemotherapy related side effects and self-care behaviours in managing chemotherapy related side effects.

#### *Self-care behaviours*



An ability of the individual to engage in behaviors or actions during and after chemotherapy to maintain a healthy lifestyle and a higher quality of life is referred to as self-care behavior. In this study, self-care behaviours are the activities performed by the patients for the management of side effects of chemotherapy. In the post test, self-care behaviours will be measured by Self Care Diary (SCD) used for patients undergoing chemotherapy.

#### *Chemotherapy related side effects*

Side effects refers to problems occur in patients receiving chemotherapy in addition to the desired therapeutic effects. The selected side effects taken in the study are haematological adverse events (anaemia, neutropenia, thrombocytopenia), constitutional adverse events (fatigue, insomnia, hair loss), gastrointestinal adverse events (anorexia, constipation, diarrhoea, mucositis, nausea, vomiting, taste alteration), fever and myalgia. The severity of each side event is assessed in this study using the Common Terminology Criteria for Adverse Events Version 3.0.

#### **Sample size calculation**

When comparing POST-randomization mean outcomes between two groups in a two-group study with a normally distributed outcome, the number of subjects per group (n), assuming equal sample sizes and standard deviations (SDs) per group for a two-sided significance level  $\alpha$  and power  $1-\beta$ , is (29,30).

$$N = \frac{2\sigma^2 (Z\alpha + Z(1-\beta))^2}{(\mu_1 - \mu_2)^2}$$

Where n = Sample size in each of the group,  $\mu_1$  = Population mean in treatment Group 1,  $\mu_2$  = Population mean in treatment Group 2,  $\mu_1 - \mu_2$  = The difference the investigator wishes to detect  $\sigma$  = Population variance (SD),  $Z\alpha$  = Conventional multiplier for alpha = 0.05,  $Z(1-\beta)$  = Conventional multiplier for power = 0.80. For pooled standard deviation,  $\sigma^2 = (S_1^2 + S_2^2) / 2$

In this study, Sample size calculated separately for chemotherapy related side effects and self-care behaviours using the above formula.

Based on self-care behaviour,

In a previous study (31), there was statistically significant difference in mean score of self-care behaviour at the fourth cycle of chemotherapy.  $\mu_1=85$   $\mu_2=80.42$ ,  $S_1=5.46$ ,  $S_2=8.28$ ,  $N = (5.46^2 + 8.28^2) (1.96 + 1.64)^2 / 4.58^2$

$$N = 61$$

Based on side effects of chemotherapy, from the previous study (32)

$$\mu_1=22.9 \quad \mu_2=28.6, \quad S_1=16.9 \quad S_2=18.9, \quad N = (16.9^2 + 18.9^2) (1.96 + 0.84)^2 / 5.7^2$$

$$N = 155$$

The higher value, 155 is taken. Considering 10 % attrition the sample size is taken as 170 in each arm. The sample size for the study is 340.

### **Statistical Analysis**

The software IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA), will be utilized to analyze the data. Based on the structure and distribution of the data, descriptive statistics, like mean, SD, frequencies, and proportions, will be utilized to present the patient characteristics separately for each group. Homogeneity of both groups will be ensured by chi square test of socio demographic and clinical variables. The effectiveness of intervention will be analysed by independent t test or Mann Whitney U test at an alpha level of 0.5%. A comparison of effectiveness of intervention at two points within group will be analysed by Wilcoxon Signed- rank test or ANOVA at an alpha level of 0.5%.

### **Ethics Approval**

The institutional human ethics committees of the Govt. College of Nursing and Medical College in Thiruvananthapuram (CNT/IEC/37/03/19) and Sri Ramachandra Institute of Higher Education and Research in Chennai (IEC-NI/19/NOV/71/88) have both given their approval to the trial protocol. The trial is listed with the Clinical Trials Registry-India (CTRI/2020/09/028178). A study will be performed as per ethical principles for clinical trials and Covid- 19 protocols. Participant information sheet will be given for each patient and an informed consent will be obtained.

### **Discussion**

It is the responsibility of health professionals to promote and encourage self-care among chemotherapy patients. According to the American Cancer Society, patient education should cover the drugs prescribed, the dosing schedule, any side effects, and any measures taken to lessen those negative effects. Adult cancer services should ensure that patients and their families are informed, looked for, and supported, according to National Institute of Clinical Excellence [NICE] advice.

Non pharmacological management with proactive health care interventions (Health education on self-care strategies to manage the side effects and Jacobson's Progressive Muscle Relaxation, JPMR) will enhance the self-care behaviour of patients undergoing chemotherapy for cancer and it will enable them to alleviate the side effects resulting from chemotherapy. For 20 minutes each morning and evening, cancer patients can practice the JPMR technique, a sort of therapy that focuses on tightening and releasing specific muscles.

It is a simple relaxation technique without any undue strain on patients during the post chemotherapy period. Many studies reported its positive outcomes.

### **Funding Self**

### **Acknowledgements**

The author thank Dr. A. Seethalakshmy, Ph.D ,Professor, Faculty of Nursing, SRIHER, Chennai and Dr. Aravindh S. Anand, Prof. &Head, Dept. of Radiation Oncology, Govt. Medical College, Thiruvananthapuram for their assistance in preparing the study protocol.

### **Conflicts of Interest**

The author has no potential conflicts of interest.

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Table No.2: Details of Jacobson's Progressive Muscle Relaxation Technique

SI No.	Procedure of Jacobson's Progressive Muscle Relaxation Technique	Tensing Time	Relaxation Time
1	<b>Hands</b>		
a.	Right and left fists should be independently clenched. Count to five sec while feeling the tightness in each hand and forearm. For 10 seconds, let go of the fist, relax, and experience peace.	5 sec	10 sec
2	<b>Arms</b>		
a.	Right and left arms should be bent up at the elbows independently. Five seconds of biceps tension should be felt while keeping the hands at a relaxed position.	5 sec	10 sec
b.	Straighten each arm separately (right and left) and triceps for five seconds, maintaining the hands relaxed and the lower arms supported by the chair.. For 10 seconds, relax and experience relaxation.	5 sec	10 sec
3.	<b>Facial Muscles</b>		
a.	Feel the strain for five seconds by making your forehead wrinkled and attempting to make your eyebrows meet your hairline. For 10 seconds, relax your eyebrows and experience relaxation.	5 sec	10 sec
b	Put your eyes closed and tighten the eyelid muscles for five seconds. For 10 seconds, release tension and enjoy relief.	5 sec	10 sec

c.	Feel the strain in the jaw muscles for 5 seconds while clenching your teeth. For 10 seconds, let go, unwind, and feel at ease.	5 sec	10 sec
d.	With lips closed, press the tongue firmly and flat on the roof of the mouth to feel the tightness in the throat for five seconds. For 10 seconds, let go, relax and experience relaxation.	5 sec	10 sec
4.	<b>Neck &amp; Shoulder</b>		
a.	Against a chair, push the head back as far as it will go and hold the tension for five seconds. Bring your head back into place, then take ten seconds to relax.	5 sec	10 sec
b.	For five seconds, lower the head and press the chin toward the chest.	5 sec	10 sec
c.	Feel the tightness in your shoulders by shrugging them up to your ears and holding them there for five seconds. For 10 seconds, relax and feel at relaxed.	5 sec	10 sec
5.	<b>Chest</b>		
a.	Completely fill your lungs with air as you inhale, hold your breath for a moment, and then slowly let it out. For 10 seconds, relax.	5 sec	10 sec
6.	<b>Stomach</b>		
a.	For five seconds, draw your stomach in and clench your stomach muscles.	5 sec	10 sec
7	<b>Back</b>		
a.	Tension, for five seconds, arch your back away from the chair.	5 sec	10 sec
8	<b>Thigh &amp; Buttocks</b>		
a.	Tends the muscles in the buttocks and thighs by squeezing them together and feeling the tension for five seconds. For 10 seconds, release your muscles, relax and experience the relief.	5 sec	10 sec
9.	<b>Lower Legs</b>		
a.	Point your toes in the direction of your head to tense your calves for five seconds. Ten seconds of relaxation are appropriate.	5 sec	10 sec
b.	Spend five seconds focusing on the tension as you point your toes away from your head. 10 seconds to relax and experience relaxation	5 sec	10 sec
10	<b>Toes</b>		

a	For ten seconds, relax and experience relaxation.	5 sec	10 sec
11.	<b>After Exercise</b>		
a.	Completely relax your body.		2 minutes
b.	Close your eyes and continue to sit in a relaxed manner.		
c.	When you open your eyes, you'll feel rested and rejuvenated and with more energy.		
d.	Sit up, stretch, and slowly stand up.		

Table No. 3: SPIRIT Chart

		STUDY PERIOD				
		Enrollment	Allocation	Intervention	Post intervention	
	TIME POINT	T0			T1	T2
ENROLLMENT	Eligibility Screening	X				
	Enrollment Visit	X				
	Written informed consent	X				
	Randomized allocation		X			
INTERVENTIONS	Health education & JPMR			X		
	Standard medical care			X		
ASSESSMENT	Socio demographic data					
	Medical record					
	Outcome – side effects of chemotherapy				X	X
	Outcome- Self-care Behavior				X	X