

“IMPACT OF KNOWLEDGE ENHANCEMENT PROGRAM (KEP) ON STRESS AND QUALITY OF LIFE AMONG BREAST CANCER SURVIVORS: A RANDOMIZED CONTROLLED TRIAL”

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ABSTRACT:

Introduction: Breast cancer is the most common cause of cancer death among women worldwide. Patients diagnosed with breast cancer experience considerable stress, anxiety, fear, and depression.^{1,2} The emotional response to breast cancer adversely affect quality of life (QOL), and this may persist beyond treatment.^{3,4} Proper knowledge regarding a disease clear patients doubt, relaxes a patient and helps a person to undergo the treatment modalities planned for him. Thus making the client compliant to the treatment plan and yielding effective outcome both in terms of cure and prevention of reoccurrence and help him to relieve stress and enhance resilience.^{5,6}

Objective: To evaluate the impact of a knowledge Enhancement program (KEP) on the knowledge, stress and QOL of breast cancer survivors.

Methods and analysis: This is a randomized controlled Trial which will be performed using single blind parallel groups of 165 newly diagnosed breast cancer survivors admitted in medical and surgical oncology departments of a tertiary hospital in Goa to assess the impact of a knowledge enhancement program (KEP) on the stress and quality of life (QOL) of breast cancer survivors. Initially participants will be selected using purposive sampling method. Baseline data will be collected from the participants using knowledge, Stress & QOL assessment tools and then the participants will be allotted to intervention and control group using Simple block randomization sampling technique. The intervention group will receive knowledge enhancement program while the control group will receive regular hospital care. The study participants will be assessed before intervention, at 4 weeks and 12 weeks interval from the day of baseline data collection. Participants will be single blinded during data collection. Intention-to-treat will be used for the statistical analysis and descriptive and inferential statistics will be used to analyse the data

Ethics and dissemination: Ethics approval has been obtained from the Institutional ethics committee of the Tertiary hospital and Ph.D. Scholars University. Information sheet prepared based on Declaration of Helsinki to take informed consent from participants. The Protocol, Pilot Study and the Manuscript of main study findings of the trial will be disseminated through Scopus indexed peer-reviewed journals, national and international conference presentations.

Trial registration number: Trial acknowledgement number is REF/2025/05/106646 and the registration number for this trial is CTRI/2025/06/088201.

Key words: Knowledge Enhancement Program (KEP), Stress, Quality of life, Breast Cancer Survivors, Randomized Controlled trial.

Introduction:

According to World Health Organization, around 2.26 million new cases of breast cancer were identified in 2020, making it the frequently occurring cancer worldwide⁷. Around 1.05 million new cases of breast cancer are reported every year, which represent around 20% of all malignancies among females. Incidence of Breast cancer is increasing in most countries.^{8,9} Cancer of breast constitutes 14.3 to 30.0% of all cancers in women. The report on ‘Development of an Atlas of Cancer in India’ showed that Chandigarh (39.5), North Goa (36.8), Aizawl (36.2) and Panchkula (34.6) had the higher incidence rates of breast cancer compared to that seen in Delhi.^{10,11} Of the estimated 14.5 million cancer survivors in the USA in 2014, more than three million are breast cancer survivors, a number that continues to increase. Breast cancer outcomes highly depend on the post-diagnosis lifestyle habits of survivors. A growing body of evidence suggests that a healthy diet, regular physical activity, and a normal body weight are associated with better breast cancer outcomes. According to the 2006 Institute of Medicine (IOM) report entitled, “From Cancer Patient to Cancer Survivor: Lost in Transition”, all patients completing primary treatment for cancer should receive a survivorship care plan, and the Commission on Cancer now requires survivorship care plan implementation.¹²

In 2019, a national cancer statistics report showed that breast cancer, is the leading cause of death in women. The age-standardized incidence rate (ASIR) of breast cancer was expected to be the highest among women between 45–49 years of age by 2030 worldwide.⁷ GLOBOCAN estimated that breast cancer cases detected were 1 in 4 cases while the cancer deaths occurred were 1 in 6 cases among women, in majority of countries in 2020.¹³ Kim, J., *et al.* reported 2.3 million new cases and 670,000 deaths occurred among breast cancer survivors in 2022. Breast cancer will disproportionately impact low- Human Development Index (L-HDI) countries and will increase the incidence of , new cases and deaths of breast cancer by 38% and 68%, respectively by 2050.¹⁴ Data from Goa Medical College, Bambolim, revealed that 2,343 cancer patients were admitted to the hospital in 2023, and 1,821 received treatment until July 2024. Among this breast cancer cases detected were 574 in 2023 and 467 cases were identified till July 2024.

Cancer patients experience, serious psychological symptoms as a result of impact of cancer, its treatment and social issues surrounding it. Research has suggested that approximately 7%–46% of breast cancer patients are distressed in the early stage of the disease and suffer psychological problems such as stress, anxiety, fear and grief, which affects their quality of life.¹⁵

Studies conducted in developed countries like the United States, the United Kingdom, and Sweden, highlighted the significant role of specialist nurses in addressing informational and educational needs, providing supportive care, and improving care coordination for breast cancer patients. Despite demonstrating enhanced patient outcomes and treatment adherence, the review underscored a notable lack of research from developing countries, particularly Asia, calling for further studies in these regions to establish the global applicability of specialist nurse interventions in breast cancer care.¹⁶

Participants valued the nurse-led care program for its provision of information, psychological support, and enhanced communication, which helped them alleviate discomfort and build confidence in the chemotherapy day center of an acute care hospital in Hong Kong.¹⁷

A Qualitative study in Boston and New York identified logistical barriers such as childcare and transportation, as well as patient preferences, as the primary reasons for incomplete therapy, which included missed, delayed, or prematurely stopped treatments, underscoring the need for research to assess how breast cancer knowledge can impact adherence to treatment and overall cancer care.¹⁸

An integrative review conducted by Groen WG *et al.* (2015) on *Empowerment of Cancer Survivors Through Information Technology* concluded that educational services positively impact empowerment by improving knowledge, decision-making, satisfaction, and quality of life.¹⁹

Support from healthcare professionals is crucial for newly diagnosed patients, as they provide guidance on treatment expectations, coping strategies, encouragement, and methods to overcome recovery barriers.

Research focusing on enhancing knowledge of breast cancer survivors can be immensely beneficial for improving their quality of life. As the knowledge enhancement will empower the breast cancer survivors to have a good control over their health journey. Additionally, it can equip them with coping mechanisms to navigate the emotional and psychological challenges that often accompany a cancer diagnosis and treatment.

Implementing a randomized clinical trial allows researchers to rigorously evaluate the effectiveness of such interventions. By comparing outcomes, researchers can assess the true impact of the program.

Objectives of the study:

Primary objectives:

1. To evaluate the impact of a knowledge Enhancement program (KEP) on the stress and QOL of breast cancer survivors.

Secondary Objectives:

1. To find an association between knowledge regarding breast cancer, stress levels and QOL among breast cancer survivors.

2. To find an association between the knowledge, stress and QOL among breast cancer survivors and the selected socio-demographic variable.

HYPOTHESIS:

- H1: The knowledge enhancement program (KEP) has a significant impact on the knowledge, stress, and quality of life (QOL) of breast cancer survivors.
- H2: There is a significant correlation between knowledge, stress, and the quality of life (QOL) among breast cancer survivors.
- H3: There is a significant association between the knowledge, stress, and quality of life (QOL) among breast cancer survivors and the selected socio-demographic variables.

VARIABLES:

- **Independent variable:** knowledge Enhancement program(KEP) on breast cancer
- **Dependent variable:** Knowledge regarding breast cancer, Quality of life and Stress among Breast Cancer Survivors

Demographic Variables- In this study, the Demographic variables are , age, marital status, educational qualification, occupation, religion, monthly income, area of residence, Type of family, Lifestyle Factors like Physical Activity, Dietary Habits , Tobacco Use, Alcohol Consumption, Clinical Information like Duration of breast cancer diagnosis, stage & type of breast cancer, family history of breast cancer, history of chronic illness, history of receiving hormonal tablets, treatment received & side effects experienced, & Previous knowledge on Breast Cancer.

Operational definitions:

1) **knowledge Enhancement program (KEP) on breast cancer:** In this study it refers to an educational package designed to provide breast cancer survivors with relevant information aimed at improving their understanding of disease management, stress reduction, and lifestyle modifications. This package will be delivered to the participants through group sessions or individual sessions over a period of 30 to 40 minutes.

2) Breast Cancer Survivor's:

Breast cancer survivor: In this study it refers to all individuals who are diagnosed with stage I to stage IV of breast cancer from the time of their diagnosis till the remaining days of their life.^{20, 21}

3) Stress among Breast Cancer Survivor's:

In this study it refers to the state of worry or mental tension caused by cancer among breast cancer survivor's and which is measured by administering, a Structured Stress assessment Scale.²²

4) Quality of Life:

In this study it refers to the outcome of quality of life of breast cancer survivor's perception of their position in life in the context of the culture and value systems in which they live as measured using the Structured Quality of Life Assessment, Scale: Based on WHOQOL.^{23, 24}

Methods and analysis:

Research approach: Quantitative evaluative Approach

Research Design: A Randomized controlled trial (RCT)

Setting: Goa medical college and Hospital, a tertiary care hospital in Bambolim, Goa.

Samples: Newly diagnosed Breast cancer survivors; Stage I to IV, undergoing treatment at the oncology department of a tertiary hospital in Goa.

Sampling criteria:

❖Inclusion Criteria:

Female breast cancer survivors who are:

1. Newly diagnosed and belonging to the age group of 20 years and 70 years;

2. Suffering from Stage I to stage IV breast cancer,
3. Undergoing treatment (e.g., surgery, chemotherapy, radiation therapy) at the oncology department of Goa medical college and Hospital Bambolim Goa
4. Receiving treatment between June 2025 to July 2026.

❖ **Exclusion Criteria:**

1. Old Female Breast cancer survivors who have completed their primary treatment and are coming for follow up to GMC hospital.
2. Male breast cancer survivors.
3. Female Breast cancer survivors not willing to participate in study or having chances of moving out of location.
4. Participants with significant cognitive impairment or severe mental health conditions.

- **Sampling technique:** Simple block randomization sampling.
- **Sample size**= experimental + control group+ 20% non-response=69+ 69+ 27= 165

Sample size calculation:

- Data obtained from previous study²⁵, $p_1 = 23$, $p_2 = 23$, $d = 20$, $Z\alpha = 1.96$, $Z\beta = 0.84$

Formula:

$$n = \frac{2pq(Z\alpha + Z\beta)^2}{d^2}$$

$$P = \frac{p_1 + p_2}{2} = \frac{23 + 23}{2} = \frac{46}{2} = 23$$

$$q = 100 - 23 = 77$$

$$n = \frac{2 \times 23 \times 77 (1.96 + 0.84)^2}{20^2} = \frac{3542 \times 7.84}{400} = 69$$

Add 20% non-response mean (20% X 165= 27) Sample size= experimental + control group+ 20% non-response=69+ 69+ 27= 165

Intervention:

Intervention of this study is a Knowledge Enhancement program (KEP).

Knowledge Enhancement program (KEP) on breast cancer is an educational package designed to provide breast cancer survivors with relevant information aimed at improving their understanding of disease management, stress reduction, and lifestyle modifications. This package will be delivered to the intervention group participants through individual/group sessions over a period of 30 to 40 minutes along with hospital standard care. Initially participants will be selected using purposive sampling method and a pre-test will be given to this participants using knowledge, Stress & QOL assessment Scales. After this every single data collection day participants will be numbered and allotted to experimental and control group using lottery method. Experimental group will be taught about various aspects of breast cancer treatment and prevention of recurrence through a Knowledge Enhancement Program in a single sitting of 30 to 40 minutes duration. Post-test will be given to both intervention and control group at 4 weeks and 8 weeks.

Control: Control / comparator participants in this study will get standard care of the hospital. Standard care of hospital includes breaking the news of cancer diagnosis after the confirmatory test and informing them about the type of treatment modality which they will receive in the hospital and

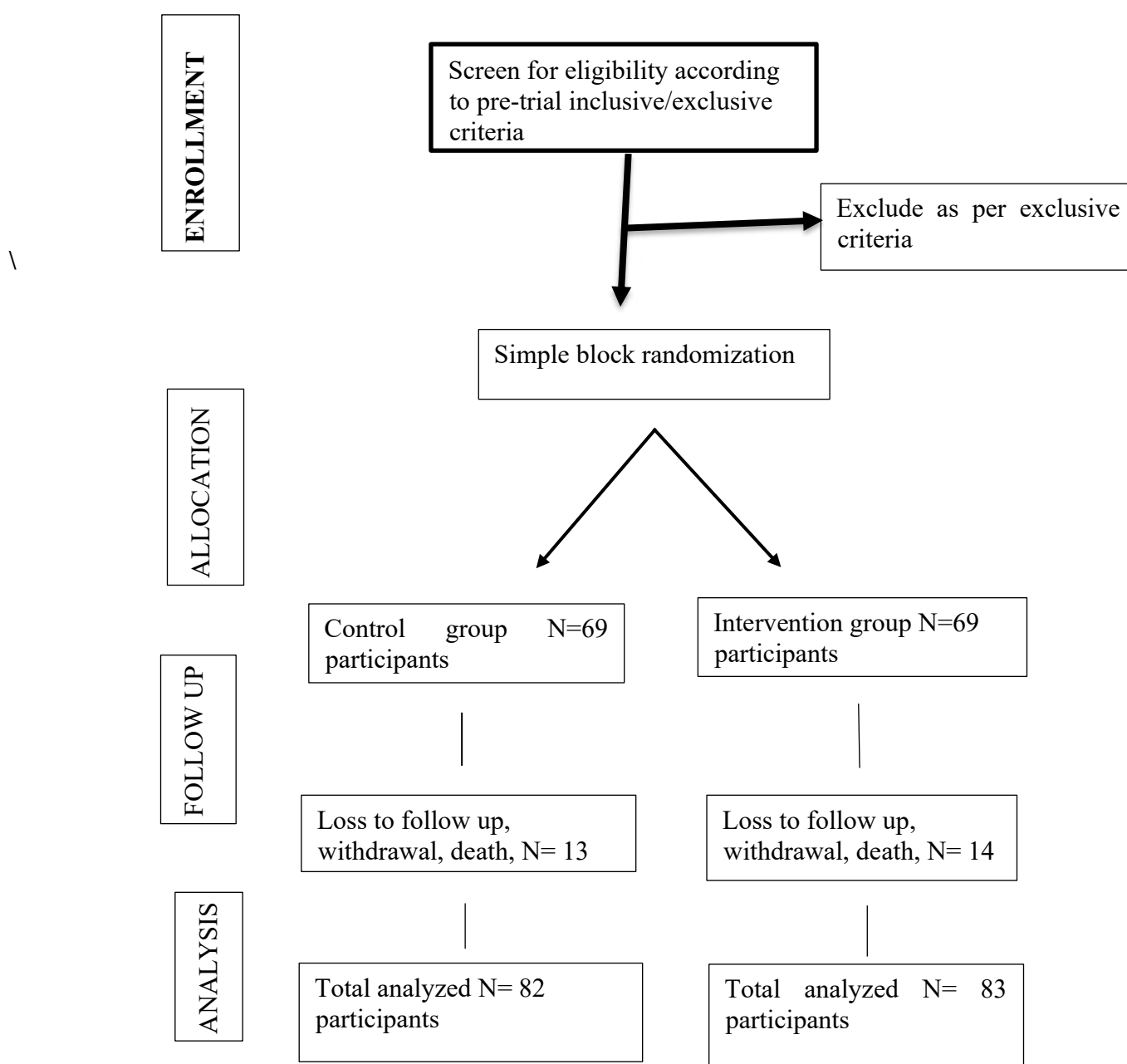
routine care during the administration of treatment modalities. Counselling of patients is done only if required.

Recruitment of participants:

After obtaining ethical and clinical permission from the concern ethics committee and departmental heads researcher will introduce herself to the breast cancer survivors visiting the OPD and those admitted in the medical and surgical wards of oncology department of the selected tertiary care hospital.

The researcher will then explain the purpose, plan and outcome of the study to the participant and her representative in the language she understands before requesting the consent for the study. Participants will be also explained that their participation in the study is purely voluntary and not mandatory. They can refuse to participate and withdraw from the study at any point of time. Confidentiality of the data obtained will also be maintained by giving codes to the research participants and by using the data exclusively for the purpose of research outcome.

Figure 1 Predicted participant movement through the study.



Implementation of sequence generation and allocation concealment:

Participants recruited to the study on a single day will be given code numbers. These code numbers will be written on a separate slip of paper. These slips will be folded, put in a container or box and mixed well. Slips will be drawn randomly from the container and the participants will be allotted to the interventional and control group.

Blinding

Single blinding will be used in this study. The investigator will casually talk to both the intervention and control group whenever she comes in contact with the participants. In this process she will impart knowledge enhancement program to the intervention group while the control group will receive only casual talk. Single blinding will help keep the participants expectations neutral. Participants do not exaggerate improvement in single blinding. Single blinding will help to reduce participant-related biases, especially placebo effect and response bias. This will help to get more reliable study results.

Tools for Data collection: Tools which will be used to obtain baseline and evaluation data from the participants are as follows:

1. Performance on demographic and clinical data of Breast Cancer survivors
2. Structured Knowledge Questionnaire to assess knowledge levels of Breast Cancer survivors regarding breast cancer.
3. Structured Stress assessment Scale to assess stress among Breast Cancer survivors
4. Structured Quality of Life Assessment Scale: Based On WHOQOL²⁷ to assess quality of life of breast cancer survivors.

Plan of Data Collection:

Ethical clearance will be obtained from KAHER Ethical committee (Human) for Ph.D. Research and Institutional Ethics Committee (IEC), Goa Medical College (GMC) Hospital, Bambolim, Goa, prior to data collection. Randomized controlled trial will be Registration with the Clinical Trials Registry-India. Developed structured knowledge Enhancement program (KEP), structured assessment tools for knowledge, stress and QOL will be finalised based on the comments given by 10-12 expert validators and pilot study outcomes.

Non-probability purposive sampling will be used to select participants. Informed consent will be taken from the selected newly diagnosed breast cancer survivors by assuring them to maintain confidentiality and anonymity throughout the data collection process and thereafter. Pre-test will be given to collect baseline demographic and clinical data, knowledge, and stress and, quality of life scores using validated self-report tools. Participants will be then assigned to control and experimental Group by using Simple Block Randomization Technique. Knowledge Enhancement program will be delivered to the intervention group through individual/ group sessions over a 30 to 40minutes duration. Participants contact numbers will be taken during baseline data collection in order to telephonically contact them and confirm their appointment for data collection at 4 weeks and 12 weeks interval. The control group will get only the standard care provided in the hospital.

Post-Trial Provision: I declare that the intervention of my study if identified as beneficial and reasonably safe in the trial will be administered to the control group participant's post-trial.

Training, outcome assessment and treatment fidelity:

The Knowledge enhancement program will be delivered by the principle investigator herself. The principle investigator is a clinical nurse and a nurse educator bearing master's degree. Delivering knowledge enhancement is the basic skill the nurses acquire during their training program. Hence the treatment fidelity of the knowledge Enhancement program will be maintained by adhering to Good Clinical Practice (GCP) recommendations. However as a preliminary requirement towards the teaching method the Principle investigator has demonstrated the administration of the Knowledge

enhancement program to a team of clinical experts comprising of the Head of Department, Department of oncology , Super Speciality Block, Goa Medical College & Hospital, Goa, Junior Resident, oncology ward, ward in charge oncology ward and a Social worker oncology department. The trial is planned based on Nurenbuerg code and is set up in such a way that the participants will not have any unnecessary physical and mental suffering or injury. The protocol is prepared following the guidelines given in the Declaration of Helsinki and is approved from the concern ethics committees. The trial is also registered in the clinical Trial Registry- India.

Before the trial is initiated, probable risks and inconveniences such as “anxiety” will be weighed against the anticipated benefits that is “reduced stress” for the individual trial subjects and society. The trial will be continued only if the anticipated benefits justify the risk. A psychiatrist will be consulted if any participant responds with anxiety to the knowledge imparted. The rights, safety and wellbeing of the trial subjects will be considered most important as compared to the interest of science and society. All the data collected during the clinical trial will be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

Outcome Measurement:

The primary outcome of the study is to evaluate the impact of Knowledge enhancement program regarding breast cancer in minimize the stress level of breast cancer survivors and help them to improve their quality of life.

The first secondary outcomes which will be measured involve assessing the association between the three main variables viz. knowledge, stress and quality of life. Here the investigator will find a correlation between knowledge and stress, stress and quality of life, and knowledge and quality of life.

Second secondary outcome which will be measured are the demographic and clinical factors which can affect the level of knowledge, stress and quality of life such as age, education, occupation, marital status, monthly income, religion, area of residence, type of family, lifestyle factors like physical activity, dietary habits, alcohol and tobacco use, medical and diagnostic history and treatment received.

Participant timeline and trial duration:

Participants will be enrolled in the study and followed up to 3months (12 weeks). The recruitment and data collection is expected to occur over 1 to 1.5 years. Participants will exit the trial when they: have been in the trial for 3 months post randomisation; withdraw consent; are lost to follow-up; die; or for another reason have to exit based on the clinical judgement of the attending physician. The study will be conducted over a period of 4 years and the study results will be analysed and published.

RESEARCH TIMELINE (GANTT CHART)																								
STUDY PLAN/ DURATION OF STUDY(M)																								
	0	2	4	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48
LITERATURE REVIEW																								
PROTOCOL																								

PREPARATION																						
DATA COLLECTION						✓	✓	✓	✓													
DATA ANALYSIS																						
PUBLICATION																						
THESIS WRITING																						

Withdrawal:

Reasons for withdrawal of participant who decides to withdraw from the trial after consent is given, will be noted. Existing data obtained during the trial will be retained and no further follow-up data collected. Patients who withdraw from randomised treatment prior to randomisation will be left in the study and reported in the flow chart as 'not received randomised intervention'. Patients who withdraw after they have received the intervention (ie, KEP)) will also be included and reported in the flow chart as 'received randomised treatment'.

Data management:

All the items in the data collection tool will be coded before administering it to the participants. Participants will be given codes once they give consent to participate and complete answering the structured tools. Editing of the answered tools will be done twice; primarily in the field soon after the participants submit the completed tool to the investigator and later on in the office of the investigator to check for completeness, accuracy and uniformity. The investigator will then detect and correct complete abbreviated responses, rewrite illegible response and correct omissions. The data contained in questionnaires/ scales will be transferred to excel sheet of a computer for the purpose of tabulation. The tabulated data will be classified and analysed using, Statistical Package for the Social Sciences (SPSS),

Statistical analysis:

Descriptive Analysis and inferential statistical will be used to analyse the objectives of the study. Descriptive Analysis will be used to describe demographic and clinical factors such as age, education, occupation, marital status, monthly income, religion, area of residence, type of family, lifestyle factors like physical activity, dietary habits, alcohol and tobacco use, medical and diagnostic history and treatment received in terms of percentage, mean, standard deviation and range. Knowledge, stress and quality of life will be classified using mean and standard Deviation (Mean+ standard Deviation, between Mean \pm Standard Deviation and Mean - standard Deviation) Inferential statistical methods e.g. Chi-square test will be used to find association between knowledge, stress and quality of life. T-tests, ANOVA and regression analysis will be used to evaluate the impact of Knowledge Enhancement Program by comparing outcomes of intervention and control groups. Intention-to-Treat Analysis method will be used to evaluate the data of this study. This method will ensure that subjects allocated to a treatment group will be followed up, assessed, and analyzed as members of that group regardless of their compliance to that therapy or the protocol, irrespective of

whether they later crossed over to the other treatment group or not or whether they discontinued treatment.

Kaplan-Meier Estimate and Survival Curve used in this study will estimate the number of patients who were lost to follow up or any other reasons for incomplete results.

Ethics and dissemination: Ethics approval has been obtained from the Institutional ethics committee of the Tertiary hospital and Ph.D. Scholars Affiliated University. Information sheet prepared based on Declaration of Helsinki to take informed consent from participants. The Protocol, Pilot Study and the Manuscript of main study findings of the trial will be disseminated through Scopus indexed peer-reviewed journals, state and national conference presentations.

Risk ratios (RR), 95% confidence (CI) and Probability (p) values assuming a 5% significance level will be presented to control and minimize biases, confounding factors, and measuring random errors.

DISCUSSION:

Although survival rates for women with breast cancer have improved over time, several minority women, lower socioeconomic status (SES), young and old have a significantly higher risk of dying from their disease. Among the numerous factors contributing to these mortality differences, adherence to active treatments (including initiation and completion) plays a critical role. Freedman RA, et al. recommended that an improved understanding of one's breast cancer and the reasons that treatments are necessary to prevent its complications, might increase rates of treatment initiation and adherence.¹⁸ Past research provides evidence that knowledge about cancer can play a vital role in outcomes and receipt of cancer treatment for women.¹⁹

Shi et al. (2023), in their study found that although the reduction in lymphedema incidence was not statistically significant, the intervention group showed significantly less deterioration in handgrip strength, improved upper limb function, and better quality of life compared to the control group highlighting the value of integrating Knowledge, Attitude Practice -based education in enhancing postoperative rehabilitation.²⁶

Oswald et al. (2022), used smart phone interventions to improve cancer knowledge and coping among Latina breast cancer survivors and found that breast cancer survivors who made more use of My Guide app showed significant improvement in breast cancer knowledge and enhanced adaptive coping.²⁷

The study conducted by Hu RY et al. (2021) highlighted that Breast Cancer Survivors face multidimensional stress, including significant psychological and financial burdens, often overlooked by caregivers and social systems. Survivors coped through personal resilience and social support, and they expressed strong expectations for improved societal support and health services.²⁸

This reviewed literature holds great strength to support the breast cancer survivors as the KEP is a structured educational package, prepared considering the needs of breast cancer survivors, will enrich the knowledge of women suffering from breast cancer and enable them to take evidence based action of adherence to treatment and overall cancer care. Randomized Parallel Group Design used in the study will reduce selection bias while Single Blinding will minimize response bias in this study. The other strong points of this study are the structured valid tools used in the study will help to collect specific, objective data from participants and the psychosocial and educational gaps in care for breast cancer survivors, which is often under-addressed, will be explored by the study.

Participants being stressed of their disease often refuse to participate in the study. Hence to respect the participants right to reject, the study adopted Purposive Sampling technique to initially select the participants, may limit generalizability (external validity). Modern world is full of responsibilities. People don't find time to take care of themselves. Hence convincing participants to undergo long series of educational sessions is avoided in this study by planning a single 30–40 minute session which may not be sufficient to cause lasting behaviour or psychological changes; long-term impact may be limited but it will definitely clear participant's doubts about various facts on breast cancer.

The possibility of Potential Contamination Risk could not be prevented as the study participants had to be taken from the only tertiary hospital in Goa in order to get homogenous samples. Two different settings of the oncology also could not be selected for the intervention and control group as the participants will be transferred to different departments of oncology in the course of their treatment since the data collection period involves 3 months duration.

Offering a specialist nurse service such as a Knowledge Enhancement Program, helps the patients to meet their informational and educational needs supportive care and coordination of care. Specialist breast nurse services can be incorporated into hospital setting to improve patient care and treatment adherence.¹⁶

A systematic review study conducted by Hussain Rawther, et al. indicates that even though specialist nursing interventions can contribute to health outcomes of women with breast cancer, there is limited number of studies reported from developing countries. This warrants the need for specialist nurse interventions in breast cancer care from developing countries.¹⁶ this clearly justifies the need of present study.

Strengths and limitations of this study:

1. Internal validity of the study will be enhanced as the Randomized Parallel Group Design used in the study will help to reduce selection bias and allows for comparison between intervention and control groups.
2. Participants will be unaware of their group allocation, because of Single Blinding thereby minimizing response bias to some extent.
3. Evaluation of knowledge, stress, and quality of life through structured validated tools will add to reliability and objectivity of data.
4. The KEP is a structured educational package, prepared considering the needs of breast cancer survivors, ensures consistency in content delivery and reproducibility.
5. Multiple Follow-up Assessments through post-tests at 4 weeks and 8 weeks will allow for measurement of short-term and mid-term effects, increasing the depth of analysis.
6. Participants in both groups will continue to receive standard hospital care, maintaining ethical standards and reflecting real-world conditions.
7. Purposive Sampling followed by Random Allocation will ensure that participants meet strict inclusion criteria and then randomly assigned, maintaining homogeneity before allocation.
8. This study addresses psychosocial and educational gaps in care for breast cancer survivors, which is often under-addressed.

Limitations

1. Purposive Sampling used to recruit the participants in the study may limit generalizability (external validity), as the initial participant pool will not be randomly selected from the broader survivor population.
2. There is a possibility of observer bias as the researcher delivering the intervention is aware of the group allocation because of Single Blinding.
3. A single 30–40 minute session may not be sufficient to cause lasting behaviour or psychological changes; long-term impact may be limited.
4. There is a possibility of Potential Contamination Risk as the participants in control and experimental groups may interact within the hospital setting and share information,
5. Control group receives only standard care, which includes minimal or no counselling, potentially widening the intervention-control gap and leading to ethical concerns.
6. Single-Center Study status of this research will limit geographic and demographic representativeness.

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Author's contribution:

Primary investigator, Sulaksha Dessai¹, reviewed past literature, performed the primary statistical analysis and prepared the protocol manuscript as a requirement for her Ph. D. study. Dr. Preeti Bhupali² and Dr. Rajesh Patil³ edited the study protocol and approved the final manuscript of this article.

Funding Statement:

At present this research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. In rare cases investigator may apply and avail grant from funding agencies.

Conflict of interest:

This study is purely done as a requirement of Doctor of Philosophy degree and with a view to help cancer survivors to reduce their stress and improve their quality of life with a Knowledge enhancement program. No third party influence will be considered in the execution, analyses and interpretation of the data, neither in the decision to submit results of this study.

Trial status:

At the time of manuscript submission, ethics approvals have been taken from the concern authorities. The investigator has initiated the pilot study to finalize the planning phase in terms of its data collection tools, data collection method, reliability and feasibility of the study.

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