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

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Abstract

Background: Breast cancer is the most widespread cancer worldwide, with around 2.3 million fresh cases reported in 2020. Breast cancer survivors frequently experience psychological distress, stress, and impaired quality of life (QOL) during and after treatment. Educational and supportive interventions such as Knowledge Enhancement Programs (KEP) may assist survivors in coping with disease-related challenges; however, evidence from randomized controlled pilot studies remains limited.
Objective: To assess the feasibility and preliminary effectiveness of a Knowledge Enhancement Program (KEP) on knowledge, stress, and quality of life among breast cancer survivors in preparation for a full-scale randomized controlled trial.
Methods: A randomized controlled pilot study was conducted among 22 newly diagnosed breast cancer survivors attending a tertiary care hospital in Goa, India. Participants were selected using purposive sampling and randomly allocated into intervention (n = 11) and control (n = 11) groups using block randomization. The intervention group received the Knowledge Enhancement Program in addition to routine care, while the control group received routine care alone. Outcomes including knowledge, stress, and quality of life were assessed at baseline (T0), immediate post-test at 4 weeks (T1), and follow-up at 12 weeks (T2) using validated tools under single-blinded conditions. Descriptive analysis was performed using per-protocol analysis, while inferential statistics were analyzed using intention-to-treat principles. The Shapiro–Wilk test was used to assess the normality of the study variables as the sample size was small. Since several key variables were not normally distributed ,Non-parametric tests including Mann–Whitney U test, Wilcoxon Signed-Rank test, Friedman test, and Spearman's correlation were used for analysis.
Results: In descriptive analysis the intervention group demonstrated marked improvement in mean knowledge scores from baseline to 12 weeks (5.5 to 11.7), compared with minimal improvement in the control group (5.0 to 6.7). Stress scores reduced in both groups, with greater reduction observed in the intervention group (38.8 to 26.2). In inferential statistics the intervention group demonstrated statistically significant improvement in knowledge scores from baseline to post-test ($Z = -2.504$, $p = 0.012$) and follow-up ($Z = -2.560$, $p = 0.010$), indicating sustained knowledge retention. Stress scores significantly decreased at post-test ($Z = -2.549$, $p = 0.011$) and follow-up ($Z = -2.395$, $p = 0.017$). Quality-of-life scores showed statistically significant improvement at follow-up compared to baseline ($Z = -2.803$, $p = 0.005$). Friedman test findings also revealed significant differences across time points for knowledge ($\chi^2 = 10.947$, $p = 0.004$), stress ($\chi^2 = 6.684$, $p = 0.035$), and quality of life ($\chi^2 = 8.600$, $p = 0.014$) among intervention participants. In contrast, the control group demonstrated no statistically significant improvements in knowledge and quality of life across repeated assessments. Correlation analysis among all participants revealed a statistically significant moderate positive association between knowledge and stress at follow-up assessment ($r = 0.480$, $p = 0.024$).
Conclusion: The Knowledge Enhancement Program demonstrated promising effects in improving knowledge and reducing stress among breast cancer survivors and was found to be feasible and acceptable for implementation in the main randomized controlled trial. Although improvements in quality of life were observed, statistically significant changes may require longer follow-up duration. The pilot findings support proceeding with the main study with minor methodological modifications. The findings support the implementation of a larger randomized controlled study to further evaluate the long-term impact of structured educational interventions on psychosocial outcomes among breast cancer survivors.

Keywords: Breast cancer survivors, Knowledge Enhancement Program, stress, quality of life, pilot study, randomized controlled trial.

INTRODUCTION:

Globally, cancer incidence is rising, with approximately 19.3 million new cases reported in 2020, of which breast cancer accounts for the highest burden (2.3 million cases). India ranks third worldwide, with an estimated 1.46 million new cancer cases in 2022 and a lifetime risk of one in nine individuals developing cancer. Breast cancer is the leading cancer among females in India, contributing to 13.5% of all cases, and this trend is also reflected regionally in Goa, where it accounts for 26.85% of cancers with a crude incidence rate of 39.14 per 100,000 populations. The continuously increasing burden of breast cancer underscores the urgent need for effective interventions such as knowledge enhancement programs to promote early detection, risk reduction, and improved management.[1,2.]

The treatment of breast cancer currently involves a multidisciplinary approach that may include surgery, chemotherapy, radiotherapy, endocrine therapy, targeted therapies, and immunotherapy. Advances in diagnostic and therapeutic modalities have substantially increased survival rates among breast cancer patients. Nevertheless, survivorship is often accompanied by a range of treatment-related physical and psychological consequences that can hinder the transition back to normal life. As the number of long-term survivors continues to grow, greater emphasis has been placed on minimizing therapy-associated adverse effects and promoting quality of life. Effective management of both physical symptoms and psychological well-being is essential not only for enhancing survivors' quality of life but also for supporting better treatment outcomes and long-term prognosis.[3]

Breast cancer survivors frequently face a range of physical, emotional, and psychosocial challenges after treatment. Persistent symptoms such as fatigue, chronic pain, lymphedema, osteoporosis, treatment-related menopausal symptoms, sexual health concerns, and adverse effects associated with hormonal therapy can significantly affect daily functioning. In addition, psychological issues including fear of cancer recurrence, uncertainty about the future, anxiety, and persistent worry often contribute to heightened levels of emotional distress among survivors.[2]

Psycho educational and peer-support interventions have been widely recognized as effective strategies for addressing the informational and emotional needs of individuals living with cancer. Evidence suggests that these interventions can alleviate symptoms of anxiety, depression, fatigue, and pain while enhancing self-efficacy, disease-related knowledge, perceived control over health, and overall quality of life. However, most of these programs are delivered through multiple sessions, requiring considerable time, financial resources, and sustained participation, which may limit their accessibility and feasibility for many patients.2,4

As the leading cancer affecting women globally, breast cancer imposes significant and lasting burdens on those diagnosed with the disease. Beyond the immediate effects of the illness, treatment-related complications can negatively influence quality of life and psychological well-being. Consequently, there is a growing need for patient-centered educational interventions that equip individuals with the knowledge and skills required to effectively cope with the disease and its long-term consequences.[5]

The unpleasant side effects of breast cancer treatment are one of the most motivating factors to find some alternative methods. The use of herbs for treating the patients having breast cancer is considered a natural alternative, because some plants may contain properties that naturally have the ability to treat breast cancer.[6]

Although the internet has become a common source of health information, many individuals face difficulties in evaluating the accuracy and relevance of online content related to cancer. Concerns regarding misinformation, exaggerated claims, and inadequate health literacy often limit the effective use of web-based resources.[7]

Knowledge plays a pivotal role in empowering breast cancer survivors to understand their disease, cope with treatment-related challenges, and actively participate in their care. Adequate and accurate information can reduce uncertainty, alleviate psychological distress, improve treatment adherence, and enhance overall quality of life. Although many patients increasingly rely on the internet, social media, friends, and informal support groups to obtain health-related information, the reliability and accuracy of such sources are often variable. Studies have shown that breast cancer patients frequently encounter misleading, incomplete, or difficult-to-interpret online information, leading to confusion, anxiety, and misconceptions regarding their condition and treatment. Furthermore, many survivors report difficulties in evaluating the credibility of health information and require professional guidance to make informed decisions regarding their care.[8]

NEED FOR THE STUDY/ AIMS & OBJECTIVES:

In 2019, a national cancer statistics report showed that breast cancer, continuing to threaten the health and quality of life of women across the world, remains the leading cause of death in women. It is estimated that by 2030, the number of cases and deaths from breast cancer worldwide will reach 26.4 million and 1.7 million, respectively.[9]

On an average over 4 cases of cancer were reported everyday in 2025 at the Medical oncology unit of Goa Medical College ,Bambolim, Goa. The Department saw nearly 1550 casesof cancer in 2025. Almost 58% cases reported were that of women and 42% were that of men as informed by Dr. Annupama Borkar, Professor and Head of Oncology Department to the news agencies in Goa. [10]

Throughout the course of the disease, serious psychological symptoms may result from the patients' experiences of stress related to the cancer itself, treatment and social issues. 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.[11]

There is a compelling link between post-diagnosis lifestyle habits and breast cancer outcomes. 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]
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.[13]
Consequently, there is a need for structured educational interventions delivered by healthcare professionals who can provide accurate, evidence-based, and individualized information. Knowledge Enhancement Programs serve as a reliable platform to improve understanding, address misconceptions, strengthen self-management skills, and support informed decision-making among breast cancer survivors, thereby promoting better psychosocial outcomes and quality of life.[7]
In accordance with methodological recommendations for pilot studies, approximately 10% of the projected sample size of the main study was recruited for the pilot phase. The pilot study aimed to evaluate the feasibility of recruitment, randomization, intervention implementation, data collection procedures, and outcome measurements, while identifying potential challenges that could affect the conduct of the definitive randomized controlled trial.[14,15]

AIM OF THE PILOT STUDY

To assess the feasibility, acceptability, and practicality of implementing a Knowledge Enhancement Program (KEP) among breast cancer survivors and to evaluate the suitability of the study procedures, instruments, recruitment strategies, and outcome assessment methods for conducting a full-scale randomized controlled trial on stress and quality of life.

OBJECTIVES OF THE PILOT STUDY:

PRIMARY OBJECTIVES:

❖ To assess the feasibility and preliminary effectiveness of a Knowledge Enhancement Program (KEP) on knowledge, stress, and quality of life among breast cancer survivors in preparation for a full-scale randomized controlled trial.

SECONDARY OBJECTIVES:

1. Assessing study feasibility and practicability of research study.
2. Establishing validity and reliability of the research tools.
3. Ensuring the appropriateness of methods and procedures of data collection.
4. Understanding the study variables and other confounding variables.
5. Planning for the data analysis and interpretation of the final larger research.

OBJECTIVES OF THE MAIN STUDY:

PRIMARY OBJECTIVES:

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

SECONDARY OBJECTIVES:

❖ To findthe correlation between knowledge, stress and QOL among breast cancer survivors.
❖ To find the determinants of levels of knowledge, stress and quality of life variables among breast cancer survivors.

1.HYPOTHESIS:

H1: The knowledge enhancement program (KEP) has a significant impact on the knowledge, stress, and quality of life (QOL) among 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 with their selected socio-demographic variables.

VARIABLES[22]:

- **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.

• **Extraneous Variables:** Stage of breast cancer, Duration of breast cancer diagnosis, Type of Breast Cancer Diagnosed, family history of cancer, associated chronic conditions, Treatment modalities received, treatment status, experienced side effects from cancer treatment, Reproductive health factors & Previous knowledge about 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 and resources 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.[16,22]

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.[17,18,22]

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.[19,22]

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 [25] as measured using the WHOQOL Based Structured Quality of Life Assessment scale.[20,21,22]

RESEARCH METHODOLOGY:

- **Research approach:** Quantitative evaluative Approach
- **Research Design:** A Randomized controlled trial(RCT)
- **Setting**: Goa medical college and Hospital, a tertiary care hospital in Goa.
- **Samples:** 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 to above 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. Male breast cancer survivors.
2. Female Breast cancer survivors not willing to participate in study or having chances of moving out of location.
3. Participants with significant cognitive impairment or severe mental health conditions.

- **Sampling technique**: Simple block randomization sampling.
- **Main Study Sample size**: Experimental + Control group+ 20% non-response=69+ 69+ 27= 165
- **Pilot study Sample size** = 10% of sample size (165) + 20% non-response = 16.5+ 3.3= 20

Sample size taken for current pilot study was 22.

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 was 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 were selected using purposive sampling method and a pre-test was given to this participants using knowledge, Stress & QOL assessment Scales. After this every single data collection day participants were numbered and allotted to experimental and control group using lottery method. Experimental group participants were taught about various aspects of breast cancer, its treatment and prevention of recurrence through

a Knowledge Enhancement Program in a single sitting of 30 to 40 minutes duration. Post-test was given to both intervention and control group at 4 weeks and 8 weeks. [22]

CONTROL:
Control / comparator participants in this study received standard care of the hospital. Standard care of hospital included 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. Counseling of patients wasdone of breast cancer survivors only if required.[22]

RECRUITMENT OF PARTICIPANTS:
After obtaining ethical and clinical permission from the concern ethics committee and departmental heads researcher introduced 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 then explained 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 were 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 was maintained by giving codes to the research participants and by using the data exclusively for the purpose of research outcome.[22]

ATTRITION RATE OF PILOT STUDY:
Attrition Rate= Number of participants lost X 100 = 4/22 X 100= 18.2
Total number of Participants enrolled

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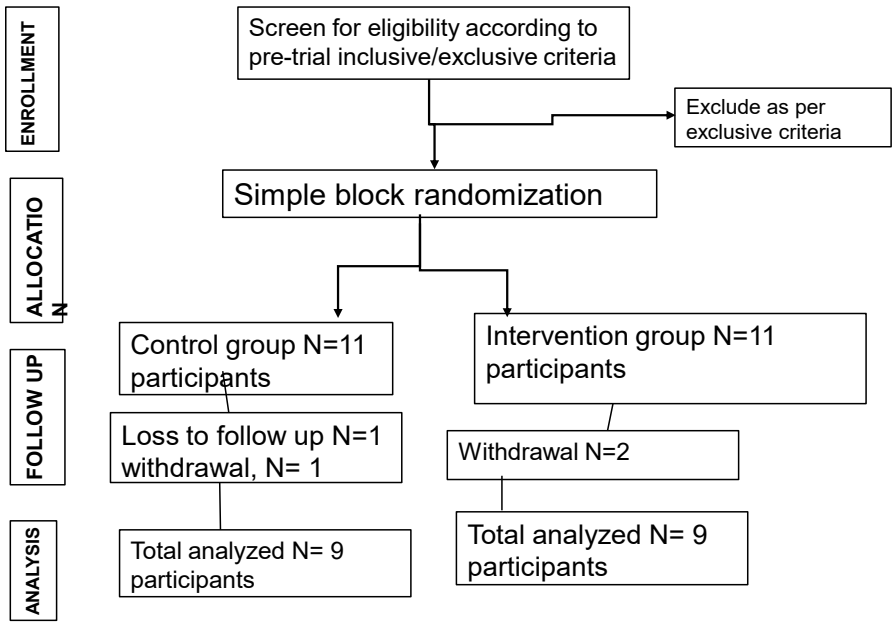

Figure 1 Perceived Participant Movement During Pilot Study Flowchart

IMPLEMENTATION OF SEQUENCE GENERATION AND ALLOCATION CONCEALMENT:
Participants recruited to the study on a single day were given code numbers. These code numbers were written on a separate slip of paper. These slips were folded, put in a container or box and mixed well. Slips were drawn randomly from the container and the participants were allotted to the interventional and control group.[22]

BLINDING:
Single blinding was used in this study. The investigator casually spoke to both the intervention and control group whenever she came in contact with the participants. In this process she imparted knowledge enhancement program to the intervention group while the control group receive only casual talk. Single blinding helps keep the participants expectations neutral. Participants do not exaggerate improvement in single blinding. Single blinding helps to reduce participant-related biases, especially placebo effect and response bias. This help to get more reliable study results.[22]

DATA COLLECTION TOOLS:
Given below are the content areas and scoring method used to score each data collection Tool:

I. Structured Knowledge questionnaire:

Sr. no	Content area	Number of questions	Percentage
I	Introduction	2	13%
II	Understanding Breast Cancer	2	13%
III	Treatment options for breast cancer	6	40%
IV	Prevention of Recurrence of Breast cancer and health maintenance	5	34%
	TOTAL	15	100

Scoring of Knowledge Questionnaire:
Each correct item was given a score of "1" and wrong item will be given a score of "0"

II. Structured Stress Assessment Scale:

Sr. No.	Stress Area	No. of Items	Percentage
1	Cancer Diagnosis	3	15 %
2	Treatment Options	2	10 %
3	Family Life	2	10 %
4	Sexual Life	2	10%
5	Social Life	2	10%
6	Personal Stress	2	10 %
7	Financial Stress	2	10 %
8	Body Image & Self-Perception Stress	3	15 %
9	Emotional & Psychological Stress	2	10 %
	Total	20	100 %

- This scale is self-administered, or the investigator collected the response in an interview where experiencesof respondents were rated based on a 5-point scale:
- All odd numbered statements are negative items and are scored as follows:
  - 0 = Never
  - 1 = Almost Never
  - 2 = Sometimes
  - 3 = Fairly Often
  - 4 = Very Often
  - All even numbered statements are positively stated items and are scored inversely i.e. "Very Often" 0 to "Never" 4
- There are 10 positive statements and 10 negative statements in the stress assessment scale.

III. **WHOQOL Based Structured Quality OfLife Assessment scale**: Includes

Sr. No.	Domain	No of questions	Weightage
I	Physical	3	13 %
II	Psychological	5	21%
III	Level Of Independence	4	16%
IV	Social	3	12%
V	Environment	8	33%
VI	Spirituality	1	5%
	TOTAL	24	100%

Scoring:

Scoring key	score
Extremely	1
Very much	2
moderate	3
Slightly	4

Not at all	5

Negative Items will be scored inversely i.e." Extremely" 1 to "Not at all" 5

IV. DETAILS OF INTERVENTION USED IN THE STUDY ARE:

Title: "Knowledge Enhancement program (KEP) on breast cancer for Breast Cancer Survivors"
Duration: 30 to 40 minutes

- Content outline:

a. Introduction to Cancer
b. Understanding Breast Cancer
c. Treatment Options for Breast Cancer:
d. Prevention of Recurrence of Breast Cancer And Health Maintenance:
e. Cancer Surveillance &Follow-Up Care
f. Quality Of Life &Long-Term Well-Being

- Method of delivery: Lecture cum discussion method. Sessions were mostly conducted using individual sessions and sometimes through group sessions.

5. VALIDITY OF THE TOOL

Content validity of the tools and Intervention was done by sending the tools to 13 experts from the field of Medical surgical Nursing, Mental Health Nursing, ObstetricsandGynaecology Nursing, a Psychiatrist and an Oncologist. Received comments from 9 Validators while a demonstration certificate from a team of oncology specialty. The tools were translated in three vernacular languages viz. Konkani, Marathi and Hindi, by taking opinion from language experts. Calculated Item content validity Index (I-CVI), Dimension Content Validity index (DCVI) and Scale Content Validity Index (SCVI) for each tool.

RELIABILITY OF THE TOOL:

Reliability of the tools was calculated using Split-Half Method followed by Spearman Brown Prophecy formula.

Ethical Approval and Consent to Participate

Ethical approval was obtained from the KAHER Ethics Committee (Human) and the Institutional Ethics Committee of Goa Medical College and Hospital, Bambolim, Goa, before the initiation of the study. The registration of trial was done with the Clinical Trials Registry–India (CTRI). Written informed consent was obtained from all participants prior to enrolment. Participation was voluntary, and participants were free to withdraw from the study at any time without any impact on their ongoing treatment. Confidentiality and anonymity were maintained throughout the study, and all data were used exclusively for research purposes. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

POST-TRIAL PROVISION:

As declared in the protocol of the study the intervention of my study was administered to the control group participant's post-trial as it was identified as beneficial and reasonably safe in the pilot 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. The treatment fidelity of the knowledge Enhancement program was maintained by adhering to Good Clinical Practice (GCP) recommendations. Before initiating the teaching intervention, the Principal Investigator conducted a demonstration of the Knowledge Enhancement Program (KEP) for a multidisciplinary team of clinical experts, including the Head of the Department of Oncology, a Junior Resident, the Ward In-charge of the Oncology Ward, and Occupational Therapist from the Oncology Department of Goa Medical College and Hospital, Goa. This was undertaken to obtain expert feedback and ensure the appropriateness of the intervention. The trial was 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 was prepared following the guidelines given in the Declaration of Helsinki and was approved from the concern ethics committees. Before the trial was initiated, probable risks and inconveniences such as "anxiety" was weighed against the anticipated benefits that is "reduced stress" for the individual trial subjects and society. The trial was continued only if the anticipated benefits justified the risk. The rights, safety and wellbeing of the trial subjects was considered most important as compared to the interest of science and society. All the data collected during the clinical trial was recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.[22]

9. DATA ANALYSIS:

Descriptive analysis was performed using per-protocol analysis, while inferential statistics were analyzed using intention-to-treat principles. The Shapiro–Wilk test was used to assess the normality of the study variables as the

sample size was small. Since several key variables were not normally distributed,Non-parametric tests including Mann–Whitney U test, Wilcoxon Signed-Rank test, Friedman test, and Spearman's correlation were used for analysis.
Mann–Whitney U test was used to test theefficacy outcomes by comparing the outcome measures at T0,T1 &T2 between the intervention and control group. The Friedman test was applied to compare knowledge, stress, and quality of life scores across three time points (T0, T1, T2) to assess the prolonged effect of KEP.Participant feedback was obtained following the Knowledge Enhancement Program to evaluate the acceptability, clarity and feasibility of the intervention.

RESULTS OF THE PILOT STUDY:

SECTION A. Scale Content Validity Index (SCVI) and Reliability of Data collection instruments and Intervention of the study:

Table 1:

SR. NO.	Data Collection Instrument	Scale Content Validity Index (SCVI)	Reliability
1	Proforma	0.95	----------
2.	Structured Knowledge questionnaire:	0.93	0.98
3.	Structured Stress Assessment Scale:	0.96	0.99
4.	WHOQOL Based Structured Quality Of Life Assessment scale	0.96	0.99
5.	Knowledge Enhancement program (KEP)	**1**	----------

SECTION B: Descriptive Statistics using Per-Protocol Analysis

I) Descriptive Analysis of Demographic Data

Table 2: Frequency distribution of Breast cancer Survivors according to Socio-demographic Variables**.**

Sr.no.	Socio-demographic Variables	Experiment Group (N=10)		Control Group (N=11)	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
I	**Age Groups (in years)**				
1	☐ 20 – 29	0	0 %	0	0 %
2	☐ 30 – 39	1	10 %	0	0 %
3	☐ 40 – 49	3	30 %	3	27 %
4	☐ 50 – 59	3	30 %	4	36 %
5	☐ 60 – 69	2	20 %	3	27 %
6	☐ 70 and above	1	10 %	1	10 %
II	**Marital Status**				
1	Single	0	0 %	0	0 %
2	Married	10	100%	7	64 %
3	Widowed	0	0 %	3	27 %
4	☐ Separated	0	0 %	1	9 %
5	☐ Divorced	0	0 %	0	0 %
III	**Education**				
1	□ Professional or Honors degree	0	0 %	0	0 %
2	□ Graduate or Postgraduate	3	30%	0	0%
3	□ Intermediate or Post High School Diploma	1	10 %	2	20 %
4	□ High School Certificate	3	30 %	2	20 %
5	□ Middle School Certificate	3	30 %	2	20 %
6	□ Primary School Certificate	0	0%	2	20%
7	□ Illiterate	0	0%	2	20%
IV	**Occupation**				
1	□ Legislators, senior officials and managers	0	0 %	0	0 %
2	□ Professionals	0	0%	0	0%

3	□ Technicians and associate professionals	2	20 %	1	9 %
4	□ Clerks	0	0 %	0	0 %
5	□ Skilled workers and shop and market sales workers	0	0 %	1	9 %
6	□ Skilled agricultural and fishery workers	0	0%	1	9%
7	□ Craft and related trade workers	0	0%	0	9%
8	□ Plant and machine operators and assemblers	0	0%	0	0%
9	□ Elementary occupation	1	10%	2	18%
10	□ Unemployed	7	70%	6	55%
V	**Monthly Family Income (INR) – 2025 Updated Kupaswamy scale**				
1	□ ₹78,063 and above	2	20 %	1	9 %
2	□ ₹39,032 – ₹78,062	3	30%	0	0%
3	□ ₹29,274 – ₹39,031	0	0 %	2	18 %
4	□ ₹19,516 – ₹29,273	1	10 %	1	9 %
5	□ ₹11,709 – ₹19,515	3	30 %	3	28 %
6	□ ₹3,903 – ₹11,708	0	0%	1	9%
7	□ ₹3,902 and below	1	10%	3	27%
VI	**Religion**				
1	☐ Hindu	8	80 %	9	82 %
2	☐ Muslim	0	0%	1	9%
3	☐ Christian	2	20 %	1	9%
4	☐ Other (Specify) _____	0	0 %	0	0 %
VII	**Area of Residence**				
1	☐ Rural	5	50 %	8	73 %
2	☐ Urban	5	50%	3	27%
VIII	**Type of Family**				
1	☐ Nuclear	7	70 %	5	46 %
2	☐ Joint	3	30%	3	27%
3	☐ Extended	0	0 %	3	27%

Table 2 indicates that Most of the breast cancer survivors in experimental group and control group participated were belonging to the age group of 40 to 59 years , married, had educational status from illiterate to Postgraduate level, Unemployed, had an monthly income of ₹39,032 – ₹78,062 or ₹11,709 – ₹19,515, were Hindu, were living in both Urban or Rural Areas, and were mostly living in nuclear families. Most of the control group participants were living in rural area.

Table 3: Frequency distribution of Breast cancer Survivors according to Lifestyle Factors

Sr. no.	Area of Residence:	Experiment Group (N=10) Frequency (f)	Percentage (%)	Control Group (N=11) Frequency (f)	Percentage (%)
I	Physical Activity				
1	Sedentary	1	10 %	2	18 %
2	Light	8	80 %	7	74 %
3	Moderate	1	10 %	2	18 %
4	Vigorous	0	0 %	0	0 %
II	Dietary Habits				
1	Vegetarian	2	20 %	3	27 %
2	Non-vegetarian	2	20 %	0	0 %
3	Mixed diet	6	60 %	8	73 %
4	High intake of fruits/vegetables	3	30 %	2	18 %

5	High intake of processed/junk food	0	0 %	0	0 %
6	High intake of processed/junk food	0	0 %	0	0 %
7	Skips meals regularly	0	0 %	0	0 %
8	Eats outside frequently	0	0 %	0	0 %
III	Tobacco Use				
1	Never used	9	90 %	10	91 %
2	Former user	0	0 %	1	9 %
3	Current smoker	0	0 %	0	0 %
4	Current smokeless tobacco user	1	10 %	0	0 %
5	Both smoking and smokeless use	0	0 %	0	0 %
IV	Alcohol Consumption				
1	Never used	10	100 %	10	91 %
2	Occasional (< once/week)	0	0 %	1	9 %
3	Regular (1–3 times/week)	0	0 %	0	0 %
4	Heavy(≥4 times/week or binge drinking)	0	0 %	0	0 %
5	Former user(quit >1 year ago)	0	0 %	0	0 %

Table 3 indicates that most of the Breast cancer survivors participated in the study had light physical activity both in experimental (80%) and control (74%) group, most of them experimental (60%) and control (73%) used to consume mixed diet, most of them experimental (90%) and control (91%) had never used tobacco, also most of them experimental (100%) and control (91%) have never used alcohol.

II) Descriptive Analysis of Clinical Data

Table 4: Frequency distribution of Breast cancer Survivors according to Medical and Diagnostic History

Sr.no.	SECTION I: Medical and Diagnostic History	Experiment Group (N=10)		Control Group (N=11)	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
1	Duration of Breast Cancer Diagnosis:				
	Less than 1 year	5	50%	7	64%
	1 year to 2 year	4	40%	4	36%
	More than 2 year	1	10%	0	0%
2	Stage of Breast Cancer at Diagnosis:				
	☐ Stage I	3	30%	4	36%
	☐ Stage II	2	20%	4	36%
	☐ Stage III	3	30%	2	18%
	☐ Stage IV	2	20%	0	0%
	☐ Not aware	0	0%	1	10%
3	Type of Breast Cancer Diagnosed:				
	☐ Ductal Carcinoma In Situ (DCIS)	0	0%	0	0%
	☐ Invasive Ductal Carcinoma (IDC)	6	60%	5	45%
	☐ Invasive Lobular Carcinoma (ILC)	0	0%	0	0%
	☐ Triple-Negative Breast Cancer (TNBC)	2	20%	1	9%
	☐ER,PR-Positive Breast Cancer	0	0%	3	27%
	☐ HER2-Positive Breast Cancer	2	20%	3	27%
	☐ Triple-Positive Breast Cancer (TPBC)	2	20%	1	9 %

	□□□nfiltrating ductal Carcinoma	0	0%	2	18%
4	How was the breast cancer detected?				
	☐ Breast Self-Examination (BSE)	8	80%	9	81%
	☐ Clinical Breast Examination (CBE)	0	0%	1	9%
	☐ Mammography	0	0%	0	0%
	☐ Ultrasound	1	10%	1	10%
	☐ MRI	0	0%	0	0%
	□ Biopsy	1	10%	0	0%
5	Family history of cancer?				
	☐ Yes	2	20%	1	9%
	☐ No	8	80%	10	91%
	If Yes, specify relationship:				
	☐ Mother	0	0%	0	0%
	☐ Sister	2	20%	0	0%
	☐ Grandmother	0	0%	0	0%
	☐ Aunt	0	0%	0	0%
	Brother	0	0%	1	9%
6	History of Co-Morbid Conditions				
	Hypertension	3	30%	4	36%
	Diabetes	3	30%	2	18%
	Respiratory problems	0	0%	2	18%
	Heart Disease	0	0%	0	0%
	Stroke or transient disease ischemic attack (brain attack)	0	0%	0	0%
	Chronic kidney Disease	0	0%	0	0%
	Liver disease	0	0%	0	0%
	Cancer(past or current)	0	0%	0	0%
	Mental health disorders	0	0%	1	9%
	Autoimmune disease	0	0%	0	%
	Thyroid disorder	1	10%	0	0%
	None of the above	5	50%	5	45%

Table 4 indicates that Duration of Breast Cancer Diagnosis of most of the breast cancer survivors both in experimental (50%) and control (64%) group participated in the study was less than 1 year. Most of experimental group participants had stage I (30%)or stage III(30%), while most of control group participants had stage I (36%)or stage II(36%) breast cancer. Most of experimental group (60%) and control group (45%) participants were suffering from Invasive Ductal Carcinoma. Most experimental group (80%) and control group (81%) participants breast cancer was detected through Breast Self-examination. Most of experimental group (80%) and control group (91%) participants had no family history of cancer and the relation of experimental group who was suffering from cancer was sister while that of control group was brother. Most of experimental group (50%) and control group (45%) participants had no history of suffering from any Co-Morbid Conditions.

Table 5: Frequency distribution of Breast cancer Survivor's according to Treatment and Management

Sr.no.	SECTION II: Treatment and Management	Experiment Group (N=10)		Control Group (N=11)	
		Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
1.	Current treatment status:				
	☐ Undergoing	10	100%	11	100%
	☐ Completed	0	0%	0	0%
	☐ Planned	0	0%	0	0%
2.	Treatment modalities received				
	☐ Surgery	9	90%	9	81%

	☐ Chemotherapy	8	80%	6	54%
	☐ Radiation therapy	1	10%	1	9%
	☐ Hormone therapy	0	0%	0	0%
	☐ Targeted therapy (e.g., HER2-targeted drugs)	0	0%	1	9%
	☐ Immunotherapy	0	0%	0	0%
3.	Type of Surgery (if applicable):				
	☐ Lumpectomy	2	20%	0	0%
	☐ Mastectomy	6	60%	9	81%
	☐ Breast Reconstruction Surgery	1	10%	1	9%
	☐ Not applicable	2	20%	2	18%
4.	Side effects of treatment Experienced				
	☐ Yes	10	100%	8	73%
	☐ No	0	0%	3	27%
	If Yes, specify:				
	☐ Fatigue	7	70%	5	45%
	☐ Hair loss	8	80%	5	45%
	☐ Nausea/Vomiting	4	40%	2	18%
	☐ Skin changes	2	20%	3	27%
	☐ Pain	5	50%	6	54%
	☐ swelling	0	0%	0	0%
	☐ Reduced blood cell count	2	20%	0	0%
	☐ Other (Specify): _____	0	0%	0	0%
5.	Previous knowledge about breast cancer				
	☐ Yes	0	0%	3	27%
	☐ No	10	100%	8	73%
6.	Primary source of Previous Knowledge on breast cancer				
	☐ Family and Friends	0	0%	0	0%
	☐ Healthcare Professionals (Doctors/Nurses)	0	0%	1	9%
	☐ Virtual Media (Internet, Social Media, YouTube)	0	30%	1	9%
	☐ Written Media (Books, Newspapers, Pamphlets)	0	30%	2	18%
	☐ Television/Radio	0	0%	1	9%

Table 5, indicates that most of the breast cancer survivors both in experimental (100%) and control (100%) group participated in the study were undergoing treatment for breast cancer. Most of experimental(exp.) group (90%) & control(con.) group (81%) participants received surgical treatment, chemotherapy (exp.=80%, con.= 54%) while only 10% experimental group& 9% control group participants received radiation therapy. 9% control group participants also received Targeted therapy. Most of experimental group (60%) and control group (81%) participants had undergone Mastectomy surgery while only 10 % in experimental group and 9% in control group had undergone Breast reconstructive surgery. Most of experimental group (100%) and control group (73%) participants had experienced side effects of cancer treatment. Most of experimental group participants experienced side effects like fatigue (70%), Hair loss (80%), Nausea/Vomiting (40%) and pain (50%) while most of control group participants experienced side effects like fatigue (45%), Hair loss (45%), skin changes (27%) and pain (50%). 100% participants in Experimental group had no Previous knowledge about breast cancer while 27% participants in control group had Previous knowledge about breast cancer from Written media (18%), Healthcare professional (9%) and television/Radio(9%).

III) Descriptive Analysis of Variables knowledge, stress and QOL of breast cancer survivors.

Table 6. Descriptive Statistics of Outcome Variables Among Participants in the Intervention Group

Variable	Time Point	Mean ± SD	Median (IQR*)
Knowledge	T0	5.00 ± 2.65	5.00 (3.00–8.00)
	T1	10.73 ± 5.42	13.00 (11.00–14.00)
	T2	9.64 ± 5.08	11.00 (9.00–13.00)
Stress	T0	35.27 ± 14.70	38.00 (27.00–41.00)
	T1	21.18 ± 12.91	22.00 (13.00–29.00)
	T2	21.45 ± 13.80	21.00 (12.00–34.00)
Quality of Life	T0	83.09 ± 30.41	89.00 (72.00–102.00)
	T1	71.64 ± 36.42	89.00 (70.00–95.00)
	T2	73.00 ± 26.91	79.00 (69.00–88.00)

*IQR = Interquartile Range (25th–75th percentile).

Table 6 indicates that the intervention group demonstrated a marked improvement in knowledge scores following the KEP, with the mean knowledge score increasing from 5.00 at baseline to 10.73 at post-test and remaining elevated at 9.64 during follow-up. Stress scores decreased substantially from a baseline mean of 35.27 to 21.18 at post-test and remained relatively stable at follow-up (21.45), indicating a favorable trend toward stress reduction. Quality-of-life scores showed fluctuations over time, with a mean score of 83.09 at baseline, 71.64 at post-test, and 73.00 at follow-up. These findings suggest that the intervention primarily enhanced knowledge and may have contributed to reduced stress among breast cancer survivors.

Table 7. Descriptive Statistics of Outcome Variables Among Participants in the Control Group

Variable	Time Point	Mean ± SD	Median (IQR*)
Knowledge	T0	5.18 ± 3.03	4.00 (3.00–8.00)
	T1	5.82 ± 3.34	6.00 (4.00–9.00)
	T2	5.55 ± 3.17	6.00 (4.00–8.00)
Stress	T0	34.64 ± 8.35	36.00 (28.00–41.00)
	T1	21.09 ± 13.39	24.00 (7.00–27.00)
	T2	22.18 ± 15.24	24.00 (13.00–33.00)
Quality of Life	T0	85.36 ± 13.06	83.00 (79.00–94.00)
	T1	76.91 ± 38.24	93.00 (87.00–97.00)
	T2	85.27 ± 13.01	83.00 (79.00–94.00)

*IQR = Interquartile Range (25th–75th percentile).

Table 7 indicates that the control group exhibited minimal changes in knowledge scores across all assessment periods, with mean scores remaining relatively stable between baseline (5.18), post-test (5.82), and follow-up (5.55). Although stress scores decreased from baseline to post-test, the reduction was comparable to that observed in the intervention group, suggesting potential influences from routine care or natural adaptation. Quality-of-life scores showed variability over time but returned close to baseline values at follow-up. Overall, the control group demonstrated limited improvement in knowledge compared with the intervention group.

Table 8: Part B: Classification of knowledge Scores of breast cancer survivors
Prefatory Note: Classification was based on Mean± Standard Deviation

		Experiment Group						Control Group					
S.N	Overall knowledge	Pretest (N=10)		At 4 weeks (N=9)		12 Weeks (N=9)		Pretest(N=11)		At 4 weeks (N=9)		12 Weeks (N=9)	
		F	%	F	%	F	%	F	%	F	%	F	%
1	Poor knowledge (0-5)	2	20%	1	11%	1	11%	0	0%	1	11%	1	11%
2	Average	5	50%	6	67%	6	67%	9	82%	5	56%	6	67%

3	knowledge Good Knowledge	3	30%	2	22%	2	22%	2	18%	3	33%	2	22%
Total		10	100%	9	100 %	9	100%	11	100%	9	100%	9	100%

Table 8, indicates that maximum, 50% of breast cancer survivors had Average knowledge at Pre-testand at 12 weeks it became maximum (67 %) Average knowledge in experimental group. However the maximum (82%) of breast cancer survivors had Average scores at Pre-test which became less that is 67% average at 12 weeks. Baseline increased scores may be because of guess work.

Table 9: Classification of Stress Scores of breast cancer survivors
Prefatory note: Classification was based on Mean± Standard Deviation

		Experiment Group						Control Group					
S.N	Overall Stress level	Pretest (N=10)		At 4 weeks (N=9)		12 Weeks (N=9)		Pretest (N=11)		At 4 weeks (N=9)		12 Weeks (N=9)	
		F	%	F	%	F	%	F	%	F	%	F	%
2	Mild Stress (20-38)	2	20%	1	11%	1	11%	2	18%	1	11%	1	11%
3	Moderate Stress(39-57)	6	60%	7	78%	8	89%	7	64%	7	78%	6	67%
4	Severe Stress(58-76)	2	20%	1	11%	0	0%	2	18%	1	11%	2	22%
Total		10	100%	9	100 %	9	100%	11	100%	9	100%	9	100%

Table 9; indicates that maximum people in experimental group (60 %, 78%, 89%) as well as in Control Group (64%, 78%, 67%) had average stress scores at Pre-test, 4 weeks and 12 weeks respectively. However the percentage of participants having average score was more in experimental group.

Table 10: Classification of Quality of Life (QOL) Scores of breast cancer survivors
Prefatory note: Classification was based on Mean± Standard Deviation

		Experiment Group						Control Group					
S.N	Overall Stress level	Pretest (N=10)		At 4 weeks (N=9)		12 Weeks (N=9)		Pretest (N=11)		At 4 weeks (N=9)		12 Weeks (N=9)	
		F	%	F	%	F	%	F	%	F	%	F	%
2	High QOL	2	20%	4	45%	0	0%	2	18%	2	22%	1	11%
3	Moderate QOL	6	60%	2	22%	7	78%	8	73%	5	56%	7	78%
4	Low QOL	2	20%	3	33%	2	22%	1	9%	2	22%	1	11%
Total		10	100%	9	100%	9	100%	11	100%	9	100%	9	100%

Table 10; indicates that maximum people in experimental group had moderate (60%) QOL at Pre-test, High QOL (45%) at 4weeks and again Moderate QOL (78%) at 12 weeks while in Control Group maximum participants (73%, 56%, 78%) had moderate QOL at all-time series.

Table 11. Comparison of Within-Group Effect Sizes (Cohen's d) for Outcome Variables in the Intervention and Control Groups

Outcome Variable	**Intervention Group (T0–T1)**	**Control Group (T0–T1)**	**Intervention Group (T0–T2)**	**Control Group (T0–T2)**
Knowledge	1.35 (Large)	0.20 (Small)	1.15 (Large)	0.12 (Negligible)
Stress	-1.02 (Large)	-1.22 (Large)	-0.97 (Large)	-1.02 (Large)
Quality of Life	-0.34 (Small)	-0.30 (Small)	-0.35 (Small)	-0.01 (Negligible)

Interpretation of Cohen's d: Negligible (<0.20), Small (0.20–0.49), Medium (0.50–0.79), Large (≥0.80).

Table 11 indicates that a large effect of the Knowledge Enhancement Program (KEP) was observed on participants' knowledge scores in the intervention group, with effect sizes of **1.35 at post-test** and **1.15 at follow-up**, indicating substantial and sustained improvement in knowledge following the intervention. In contrast, only small to negligible effects were observed in the control group (d = 0.20 and d = 0.12), suggesting minimal change in knowledge over time.
For stress, large reductions were observed in both the intervention and control groups at post-test and follow-up. The effect sizes ranged from **-0.97 to -1.22**, indicating a considerable decline in stress levels irrespective of group allocation. This finding suggests that factors other than the intervention, such as routine treatment, adaptation to survivorship, or study participation effects, may have contributed to the observed reduction in stress.
Regarding quality of life, only small changes were observed in the intervention group (d = -0.34 and d = -0.35), while negligible to small changes were noted in the control group (d = -0.01 and d = -0.30). These findings indicate that the Knowledge Enhancement Program had limited short-term influence on quality of life during the pilot study period.

Section B: Inferential statistics using Intension to treat analysis:
Instructions: Inferential statistics were interpreted at Significance level of $p < 0.05$.
Abbreviations:T0 = Baseline assessment; T1 = Immediate post-test; T2 = Follow-up assessment; are used to represent the data .

Table12: Test of Normality Using Shapiro–Wilk Test

Variable	W Statistic	df	p value	Interpretation
Knowledge T0	0.944	22	0.242	Normal distribution
Knowledge T1	0.902	22	0.033	Not normal
Knowledge T2	0.933	22	0.140	Normal distribution
Stress T0	0.925	22	0.095	Normal distribution
Stress T1	0.898	22	0.027	Not normal
Stress T2	0.950	22	0.321	Normal distribution
QOL T0	0.752	22	0.000	Not normal
QOL T1	0.631	22	0.000	Not normal
QOL T2	0.776	22	0.000	Not normal

Table 12, indicates that the Shapiro–Wilk test was used to assess the normality of the study variables. A p-value greater than 0.05 was considered indicative of normal distribution.
The results showed that Knowledge at T0 and T2, and Stress at T0 and T2 followed a normal distribution ($p > 0.05$). However, Knowledge at T1, Stress at T1, and all Quality of Life (QOL) variables (T0, T1, T2) significantly deviated from normality ($p < 0.05$).

Table13: Mann–Whitney U Test Comparing Outcomes Between Groups

Variable	Mann–Whitney U	Wilcoxon W	Z value	p value (2-tailed)	Interpretation
Knowledge T0	58	124	-0.166	0.868	Not significant
Knowledge T1	20	86	-2.676	0.007*	Significant
Knowledge T2	21	87	-2.609	0.009*	Significant
Stress T0	50.5	116.5	-0.658	0.511	Not significant
Stress T1	56.5	122.5	-0.264	0.792	Not significant
Stress T2	60	126	-0.033	0.974	Not significant
QOL T0	51	117	-0.625	0.532	Not significant
QOL T1	44	110	-1.088	0.277	Not significant
QOL T2	42	108	-1.217	0.224	Not significant

Table 13indicates that the Mann–Whitney U test was used to compare outcome variables between the intervention and control groups. There was no statistically significant difference at baseline (T0) for knowledge, stress, and quality of life, indicating group homogeneity.
However, a statistically significant difference was observed in knowledge scores at T1 (U = 20, p = 0.007) and T2 (U = 21, p = 0.009), suggesting that the intervention was effective in improving knowledge among participants.No significant differences were observed in stress and quality of life scores at any time point ($p > 0.05$), indicating that the intervention did not produce a measurable change in these variables during the study period.

Table14: Within Group Comparison of Knowledge, Stress, and Quality of Life Scores of Intervention group across Time Intervals Using Wilcoxon Signed Ranks Test

Variables	Comparison	Median (IQR)*	Z value	p value	Interpretation
Knowledge	T1 vs T0	13 (11–14) vs 5 (3–8)	-2.504	0.012*	A statistically significant increase in knowledge scores was observed immediately after the

					intervention compared to baseline.
	T2 vs T0	11 (9–13) vs 5 (3–8)	-2.560	0.010*	Knowledge scores remained significantly higher at follow-up compared to baseline, indicating sustained improvement.
	T2 vs T1	11 (9–13) vs 13 (11–14)	-1.409	0.159	No statistically significant difference was observed between post-test and follow-up knowledge scores, suggesting retention of knowledge over time.
Stress	T1 vs T0	22 (13–29) vs 38 (27–41)	-2.549	0.011*	Stress scores significantly decreased immediately after the intervention compared to baseline.
	T2 vs T0	21 (12–34) vs 38 (27–41)	-2.395	0.017*	Stress levels remained significantly lower at follow-up when compared to baseline.
	T2 vs T1	21 (12–34) vs 22 (13–29)	-0.059	0.953	No statistically significant difference was found between post-test and follow-up stress scores, indicating maintenance of reduced stress levels.
Quality of Life	T1 vs T0	89 (70–95) vs 89 (72–102)	-1.377	0.169	No statistically significant improvement in quality of life was observed immediately after the intervention.
	T2 vs T0	79 (69–88) vs 89 (72–102)	-2.803	0.005*	A statistically significant difference in quality of life scores was observed at follow-up compared to baseline.
	T2 vs T1	79 (69–88) vs 89 (70–95)	-1.174	0.241	No statistically significant difference was observed between post-test and follow-up quality of life scores.

*IQR = Interquartile range.

Table 14 indicated that, the Wilcoxon Signed Ranks Test demonstrated that the intervention significantly improved participants' knowledge and reduced stress levels from baseline to post-test and follow-up assessments. The absence of significant differences between post-test and follow-up scores indicates that these beneficial effects were sustained over time. For quality of life, a statistically significant change was observed only between baseline and follow-up assessments, suggesting that improvement in quality of life may require a longer duration to become evident.

Table15: Comparison of Knowledge, Stress, and Quality of Life Scores across Three Time Periods Using Friedman Test among Intervention Group participants.

Variables	Time Points	Mean Rank	χ^2 value	df	Kendall's W	p value	Interpretation
Knowledge	T0	1.27	10.947	2	0.498	0.004*	A statistically significant difference was observed in knowledge scores across the three assessments. The increase in mean ranks from baseline to post-test and follow-up indicates improvement and retention of knowledge following the intervention.
	T1	2.55					
	T2	2.18					
Stress	T0	2.59	6.684	2	0.304	0.035*	A statistically significant difference was found in stress scores across the three time points. The reduction in mean ranks at post-test and follow-up suggests that the intervention effectively reduced stress levels among participants.
	T1	1.73					
	T2	1.68					
Quality of Life	T0	2.55	8.600	2	0.391	0.014*	A statistically significant difference was observed in quality-of-life scores across the three assessments, indicating that the intervention had

						a significant impact on participants' quality of life over time.
	T1	2.09				
	T2	1.36				

Abbreviations:
χ^2 = Chi-square value; df = Degrees of freedom.
Table 15 indicates that, The Friedman test revealed statistically significant differences in knowledge, stress, and quality-of-life scores across baseline, post-test, and follow-up assessments among participants in the intervention group. Knowledge scores showed consistent improvement after the intervention, while stress scores demonstrated a reduction over time. Quality-of-life scores also showed significant changes across the assessment periods. The Kendall's W values indicated a moderate effect size for knowledge (0.498), stress (0.304), and quality of life (0.391), suggesting moderate agreement and intervention effect over repeated measures.

Table16: Within-Group Comparison of Knowledge, Stress, and Quality of Life Scores Using Wilcoxon Signed Ranks Test among Control Group participants.

Variables	Comparison	Median (IQR)	Z value	p value	Interpretation
Knowledge	T1 vs T0	6 (4–9) vs 4 (3–8)	-0.491	0.624	No statistically significant difference was observed in knowledge scores immediately after the intervention compared to baseline.
	T2 vs T0	6 (4–8) vs 4 (3–8)	-0.565	0.572	No statistically significant difference was found between baseline and follow-up knowledge scores.
	T2 vs T1	6 (4–8) vs 6 (4–9)	-0.531	0.595	No statistically significant difference was observed between post-test and follow-up knowledge scores.
Stress	T1 vs T0	24 (7–27) vs 36 (28–41)	-2.045	0.041*	A statistically significant reduction in stress scores was observed immediately after the intervention compared to baseline.
	T2 vs T0	24 (13–33) vs 36 (28–41)	-1.599	0.110	No statistically significant difference was found between baseline and follow-up stress scores.
	T2 vs T1	24 (13–33) vs 24 (7–27)	-0.140	0.889	No statistically significant difference was observed between post-test and follow-up stress scores.
Quality of Life	T1 vs T0	93 (87–97) vs 83 (79–94)	-0.267	0.789	No statistically significant difference was observed in quality-of-life scores immediately after the intervention compared to baseline.
	T2 vs T0	83 (79–94) vs 83 (79–94)	-1.000	0.317	No statistically significant difference was found between baseline and follow-up quality-of-life scores.
	T2 vs T1	83 (79–94) vs 93 (87–97)	-0.312	0.755	No statistically significant difference was observed between post-test and follow-up quality-of-life scores.

Abbreviations: IQR = Interquartile range.

Table 16 indicates that the Wilcoxon Signed Ranks Test revealed no statistically significant improvement in knowledge and quality-of-life scores across baseline, post-test, and follow-up assessments among participants in Control Group 2. However, stress scores showed a statistically significant reduction immediately after the intervention (T1 vs T0), although this improvement was not sustained at follow-up. Overall, the findings suggest that the control group demonstrated minimal changes across the assessment periods compared to the intervention group.

Table17: Comparison of Knowledge, Stress, and Quality of Life Scores Across Three Time Periods Using Friedman Test among Control Group participants.

Variables	Time Points	Mean Rank	χ^2 value	df	Kendall's W	p value	Interpretation

Knowledge	T0	1.77	1.316	2	0.060	0.518	No statistically significant difference was observed in knowledge scores across baseline, post-test, and follow-up assessments, indicating minimal change over time in Group 2.
	T1	2.23					
	T2	2.00					
Stress	T0	2.55	5.590	2	0.254	0.061	No statistically significant difference was found in stress scores across the three assessment periods, although a decreasing trend in stress scores was noted after the intervention.
	T1	1.77					
	T2	1.68					
Quality of Life	T0	2.00	0.235	2	0.011	0.889	No statistically significant difference was observed in quality-of-life scores across the three time points, suggesting that the intervention had no measurable effect on quality of life in Group 2.
	T1	2.09					
	T2	1.91					

Abbreviations: df = Degrees of freedom.

Table 17 indicates that, the Friedman test demonstrated no statistically significant differences in knowledge, stress, and quality-of-life scores across baseline, post-test, and follow-up assessments among participants in control Group. Although stress scores showed a decreasing trend over time, the change did not reach statistical significance. The low Kendall's W values indicated weak effect sizes and minimal agreement across repeated measurements.

Table 18: Spearman's Correlation between Knowledge, Stress, and Quality of Life Scores across Three Time Periods among Intervention Group Participants (N = 11)

Variables Compared	Time Points	Spearman's rho (r)	p value	Interpretation
Knowledge and Stress	T0	-0.088	0.798	A very weak negative correlation was observed between knowledge and stress scores at baseline assessment; however, the relationship was not statistically significant.
	T1	0.500	0.117	A moderate positive correlation was observed between knowledge and stress scores during the immediate post-test assessment, but the association was not statistically significant.
	T2	0.610*	0.046*	A statistically significant strong positive correlation was observed between knowledge and stress scores during the follow-up assessment, indicating a significant association between the two variables over time.
Knowledge and Quality of Life	T0	0.405	0.217	A moderate positive correlation was found between knowledge and quality-of-life scores at baseline; however, the association was not statistically significant.
	T1	0.516	0.104	A moderate positive correlation was observed between knowledge and quality-of-life scores during the immediate post-test assessment, though the relationship was not statistically significant.
	T2	0.417	0.201	A moderate positive correlation was identified between

				knowledge and quality-of-life scores at follow-up assessment; however, the association was not statistically significant.
Stress and Quality of Life	T0	0.050	0.883	A negligible positive correlation was observed between stress and quality-of-life scores at baseline, with no statistically significant association.
	T1	0.153	0.654	A weak positive correlation was found between stress and quality-of-life scores during the immediate post-test assessment; however, the relationship was not statistically significant.
	T2	0.219	0.517	A weak positive correlation was observed between stress and quality-of-life scores during follow-up assessment, but the association was not statistically significant.

Abbreviations: r = Spearman's correlation coefficient.

Table 18 indicates that the Spearman's correlation analysis revealed varying relationships between knowledge, stress, and quality-of-life scores across baseline, immediate post-test, and follow-up assessments among participants in Intervention Group. Knowledge demonstrated moderate positive correlations with quality of life at all assessment periods; however, these associations were not statistically significant. Similarly, stress and quality of life showed weak positive correlations throughout the study period without statistical significance. A statistically significant strong positive correlation was observed between knowledge and stress scores during the follow-up assessment ($r = 0.610$, $p = 0.046$), indicating a significant association between these variables over time. Overall, the findings suggest that the intervention influenced the interrelationship among knowledge, stress, and quality of life across repeated assessments.

Table19: Spearman's Correlation between Knowledge, Stress, and Quality of Life Scores across Three Time Periods among control Group Participants (N = 11)

Variables Compared	Time Points	Spearman's rho (r)	p value	Interpretation
Knowledge and Stress	T0	0.146	0.669	A very weak positive correlation was observed between knowledge and stress scores at baseline assessment; however, the relationship was not statistically significant.
	T1	0.486	0.130	A moderate positive correlation was found between knowledge and stress scores during the immediate post-test assessment, but the association was not statistically significant.
	T2	0.463	0.152	A moderate positive correlation was observed between knowledge and stress scores during follow-up assessment; however, the relationship was not statistically significant.
Knowledge and Quality of Life	T0	-0.132	0.699	A very weak negative correlation was identified between knowledge and quality-of-life scores at baseline assessment, with no statistically significant association.
	T1	0.537	0.088	A moderate positive correlation was observed between knowledge and quality-of-life scores during the immediate post-test assessment; however, the relationship did not reach statistical significance.
	T2	0.157	0.644	A weak positive correlation was found between knowledge and quality-of-life scores during follow-up assessment, but the association was not statistically significant.
Stress and Quality of Life	T0	-0.151	0.658	A very weak negative correlation was observed between stress and quality-of-life scores at baseline assessment, without statistical significance.
	T1	0.353	0.287	A weak positive correlation was identified between stress and quality-of-life scores during the immediate post-test assessment; however, the relationship was not statistically significant.
	T2	0.172	0.613	A weak positive correlation was observed between stress and quality-of-life scores during follow-up assessment,

	but the association was not statistically significant.

Abbreviations: r = Spearman's correlation coefficient.

Table 19 indicates that, the Spearman's correlation analysis demonstrated varying relationships between knowledge, stress, and quality-of-life scores across baseline, immediate post-test, and follow-up assessments among participants in control Group. Knowledge and stress scores showed weak to moderate positive correlations across all assessment periods; however, none of these associations were statistically significant. Similarly, knowledge and quality-of-life scores demonstrated a transition from a weak negative correlation at baseline to moderate positive correlations during the post-test and follow-up periods, though these relationships did not achieve statistical significance. Stress and quality-of-life scores also showed weak correlations throughout the study period without statistical significance. Overall, the findings suggest that although positive trends were observed in the relationships among knowledge, stress, and quality of life following the intervention, the associations were not statistically significant among participants in control Group.

DISCUSSION:

- **Feasibility findings:** Participant feedback was obtained following the Knowledge Enhancement Program to evaluate the acceptability and feasibility of the intervention. The feedback form assessed participants' perceptions regarding the usefulness, clarity, comprehensibility, and overall satisfaction with the program. The pilot study findings indicated that the study was feasible, the Knowledge Enhancement Program (KEP) was acceptable, and the research procedures were practical for assessing stress and quality of life among breast cancer survivors, thereby justifying the conduct of the main randomized controlled trial.
- **Issues identified:** During pilot study it was identified that the Confounding variables like the status of treatment modalities like whether the patient was taken during the start of chemotherapy or later and the side effects of drugs received by survivors often determined the stress level of participants. For example if the patient was taken during the start of chemotherapy she would not experience the stress of fatigue, stress of body image disturbance etc. hence the effect of KEP on these patients will be questionable.
- **Time required:** Time required to answer the tool again depend upon whether the tool was self-reported or the responses were taken by asking questions by the researcher. Self-reported tool was completed within 20 minutes while the researcher completed tool takes 30 to 35 minutes.
- **Participant response:** Feedback obtained during the pilot study demonstrated favorable participant acceptance of the Knowledge Enhancement Program (KEP). While some breast cancer survivors initially showed hesitation to participate, most reported that the program improved their knowledge regarding breast cancer and its management. Regarding the preferred timing of the intervention, 72% of participants indicated that the educational program should be provided at the time of breast cancer diagnosis, 13% were uncertain, and 13% did not respond. These findings suggest that newly diagnosed patients perceive a substantial need for structured educational support and highlight the feasibility and acceptability of implementing the KEP during the diagnostic phase.

12. Limitations of the Pilot Study:

- The pilot study was conducted with a small sample size, which limits the generalizability of the findings. As the primary purpose of the pilot study was to assess feasibility rather than effectiveness, the results should be interpreted cautiously and cannot be extrapolated to the wider population of breast cancer survivors. The inferential statistics were restricted till the objective of finding correlation and no associations were calculated to determine the factors affecting knowledge, stress and quality of life among breast cancer survivors.

13. IMPLICATIONS FOR THE MAIN STUDY

The findings of the pilot study provide important methodological and procedural implications for conducting the main randomized controlled trial.

The improvement observed in knowledge scores among breast cancer survivors in the experimental group across all three time points indicates that the Knowledge Enhancement Program (KEP) is effective in improving disease-related knowledge. The sustained improvement at 12 weeks suggests that the intervention has a lasting effect, thereby supporting its inclusion in the main study without major modification. The comparatively static knowledge scores in the control group further strengthen the need for a structured educational intervention in this population.

The reduction in severe stress levels in the experimental group, particularly the elimination of severe stress by 12 weeks, highlights the potential of KEP in addressing psychosocial stress among breast cancer survivors. The increase in severe stress in the control group emphasizes the vulnerability of survivors who do not receive structured educational support. These findings indicate that stress-related outcomes should be retained as a primary outcome variable in the main study, with particular attention to domains such as social life, personal life, body image, and self-perception.

Although the quality of life (QOL) scores fluctuated over time, the experimental group demonstrated better domain-specific improvements, particularly in the spiritual domain. This suggests that the KEP may influence coping, meaning-

making, and adjustment to illness. Therefore, domain-wise analysis of QOL will be emphasized in the main study rather than relying solely on overall QOL scores.

The pilot study identified confounding clinical variables, particularly treatment modality, number of chemotherapy cycles, and drug-related side effects, as significant determinants of stress and QOL. To minimize their influence, it is decided that these confounding variables will be systematically identified, recorded, and controlled during data analysis in the main study.

Further, the pilot study revealed that inclusion of additional clinical and reproductive variables such as age at menarche, parity, menopausal status, breastfeeding history, age at first childbirth, height, weight, and obesity status would allow a more comprehensive description of breast cancer survivors. Hence, these variables, which were not collected during the pilot study, will be incorporated into the main study.

Based on feasibility findings, the time points for data collection will be modified to pre-test, 3 weeks, and 12 weeks instead of pre-test, 4 weeks, and 12 weeks. This change aligns with the routine 21-day chemotherapy and targeted therapy cycle, making data collection more feasible for participants and the researcher.

The findings of the present pilot randomized controlled trial provide preliminary evidence supporting the feasibility and effectiveness of the Knowledge Enhancement Program (KEP) in improving knowledge, reducing stress, and enhancing quality of life among breast cancer survivors. These findings are consistent with previous studies that have highlighted the benefits of structured educational and survivorship-focused interventions in promoting positive survivorship outcomes. Maly et al. demonstrated that nurse-led survivorship care plans significantly improved the implementation of recommended survivorship care among breast cancer survivors, emphasizing the importance of structured educational support during the survivorship phase[23]. Similarly, Ulloa et al. reported significant improvements in survivors' knowledge regarding cancer history, treatment, and follow-up care following a patient-centered survivorship intervention[24]. Tucholka et al. observed that tailored web-based educational resources enhanced patients' understanding of breast cancer treatment options and facilitated informed decision-making[25]. Likewise, Oswald et al. found that a culturally tailored smartphone-based intervention improved breast cancer knowledge and adaptive coping among survivors[26]. In addition, Shi et al. demonstrated that a Knowledge–Attitude–Practice (KAP)-based educational program significantly improved functional outcomes and quality of life among postoperative breast cancer patients[27]. Together, these studies support the premise that structured educational interventions can enhance survivors' knowledge, self-management abilities, coping skills, and overall well-being, thereby reinforcing the relevance of the KEP implemented in the present study.

The reduction in stress observed among participants in the intervention group is also supported by existing literature. Hu et al. reported that breast cancer survivors experience substantial psychological, physical, economic, and informational stress during survivorship and highlighted the need for interventions that strengthen coping mechanisms and social support systems[28]. Similarly, Dooley et al. found that adaptive coping and psychological resilience play a crucial role in adjustment following breast cancer diagnosis and treatment, suggesting that interventions aimed at improving coping skills may contribute to stress reduction and emotional well-being[29]. Furthermore, Lengacher et al. demonstrated that a mobile mindfulness-based stress reduction program significantly reduced stress, anxiety, depression, fear of recurrence, fatigue, and sleep disturbances among breast cancer survivors[30]. These findings indicate that supportive and educational interventions can effectively address the psychosocial challenges experienced during survivorship, which may explain the positive impact of the KEP on stress reduction in the present study.

The improvement in quality of life among breast cancer survivors following the intervention is also consistent with previous evidence. Mokhtari-Hessari and Montazeri, in a comprehensive review of reviews, concluded that psychosocial interventions, supportive care programs, physical activity, and educational strategies are effective in improving quality of life among breast cancer survivors[31]. Similarly, Costa et al. reported that quality of life is closely associated with functional capacity and symptom burden, particularly pain and fatigue, emphasizing the importance of comprehensive rehabilitation and supportive care interventions (10). Moreover, Lengacher et al. observed significant improvements in overall quality of life following a mindfulness-based intervention, further supporting the role of psychosocial approaches in enhancing survivors' physical and emotional well-being[32]. Therefore, the findings of the present pilot study suggest that the KEP may serve as an effective supportive intervention to improve quality of life by addressing survivors' informational, psychological, and coping needs. Collectively, these findings justify the conduct of a larger randomized controlled trial to establish the long-term effectiveness of the KEP among breast cancer survivors.

14. CONCLUSION OF THE PILOT STUDY

The pilot study demonstrated that the proposed randomized controlled trial is feasible and acceptable among breast cancer survivors. The Knowledge Enhancement Program was well received by participants and showed promising trends in improving knowledge, reducing stress, and influencing quality of life, particularly in psychosocial and spiritual domains.

The research instruments were found to be appropriate, understandable, and practical, with an acceptable time requirement for data collection. Despite initial hesitation among a few participants, overall feedback was positive, with many participants acknowledging the usefulness of the information gained about breast cancer and its management. The

pilot study successfully identified methodological challenges, including the influence of treatment-related confounding variables and optimal timing of data collection, which have been addressed through refinements in the study design. Overall, the findings justify proceeding with the main study with minor modifications, thereby strengthening the methodical objectivity, feasibility, and applicability of the planned randomized controlled trial.

AUTHOR'S CONTRIBUTION:
Primary investigator, Sulaksha Dessai1, reviewed past literature, performed data collection, primary statistical analysis and prepared the pilot study manuscript as a requirement for her Ph. D. study. Dr. Preeti Bhupali2 and Dr. Rajesh Patil3 edited the pilot study report and approved the final manuscript of this article.

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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.

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