Mobile Application based Healthcare Programme for Occupational and Psychosocial Rehabilitation of Breast Cancer Survivors: A Research Protocol

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ABSTRACT

Introduction: Breast Cancer (BC) survivorship requires continuous management of various physical, functional, and psychosocial challenges that survivors often experience. Long-term care compliance is frequently compromised due to the demands of time and financial investment, and most available care systems in India are still predominantly in-person. Technology-based interventions can be a viable solution to help survivors attain a better quality of life.

Need of the study: There is a notable lack of comprehensive research focused on the use of telehealth services in rehabilitative management, education, and awareness initiatives for Breast Cancer Survivors (BCS) in India. This gap highlights the need to investigate how telecommunication technologies can effectively support these individuals in managing their health, receiving educational resources, and increasing awareness about their condition. By exploring the benefits and challenges associated with telehealth services, one can develop tailored support systems that address the unique needs of BCS in the Indian context.

Aim: To design a mobile Healthcare Program (m-HCP) and determine the efficacy of this newly developed text message-based m-HCP in managing fatigue, life satisfaction, and occupational performance.

Materials and Methods: A quasi-experimental study will be conducted at Amity University, Noida, Uttar Pradesh, India, from June 2023 to December 2025. Patients will be recruited from NGOCansupport, New Delhi, India. Participants will receive educational messages for nine weeks and will have pre- and postintervention assessments for the levels of fatigue, occupational performance, and life satisfaction, along with feedback on the effectiveness and utility of the text-message-based m-HCP. Statistical analysis will be conducted using a paired t-test (parametric test) or a Wilcoxon signed-rank test (non parametric test), with a statistically significant difference defined as a p-value≤0.05.

Keywords: Breast cancer survivorship, Compliance, Fatigue, Functionality, Quality of life, Telehealth

INTRODUCTION

BC is the second most common cancer globally, with approximately 2.3 million new cases reported, making it a leading cause of cancer-related mortality, accounting for 6.9% of all cancer-related deaths among women, according to reports from Globocan [1]. The National Cancer Registry Programme (NCRP) has projected that the cancer burden in India will reach 29.8 Disability-Adjusted Life Years (DALYs) by 2025, with BC being the most common among all female-related cancers [2]. With this alarming rise in the number of cases, our focus needs to be on risk factors, screening and early detection, prevention, drug delivery, and awareness for disease control. However, significant challenges also arise, particularly regarding the increase in disability and psychological complications among BCS. The National Cancer Institute (NCI) in the USA integrates physical, emotional, social, and financial aspects to enhance the health and wellbeing of cancer survivors, beginning at the time of diagnosis and continuing throughout life [3].

The challenges faced by BCS are related to physical disabilities, including fatigue, menopause-related issues, and other local and regional physical and psychological changes due to mastectomy, lymphoedema, chemotherapy-induced infertility, pregnancy-related concerns, and cardiac complications [4-6]. Cancer-related fatigue and psychological distress can persist even up to ten years post-diagnosis/treatment and may be expressed by patients in various ways, such as feeling tired, sleepy, having difficulty working, decreased strength or vigour and an inability to focus [7,8].

Various occupational performances/functions related to daily activities—including areas of self-care (e.g., personal hygiene, grooming, eating), work/productivity (e.g., inner drive, inability to return to work, irregularity in work, driving, traveling, homemaking, studying), and recreation (e.g., socialisation, active and passive recreation)—may also be negatively affected [9-14]. These multiple complications undoubtedly impact the quality of life, which largely depends on the survivors' ability to cope with their situation.

Managing BC-Related Challenges

Managing BC-related physical, psychosocial, and functional aspects is a significant challenge. Personalised and regular care services are often overlooked and less explored in the Indian context. Since most available care systems in India still operate primarily in a face-to-face mode, survivors often demonstrate poor compliance due to the demands of time and financial investment. Given that mobile devices have become indispensable in daily life, communication through mobile platforms may encourage compliance and feasibility, enabling patients to adhere to regular symptom management and become more aware of their health conditions.

REVIEW OF LITERATURE

Health Information and Communication Technology (ICT) can serve as a convenient solution for accessing health-related services, especially among those with chronic health conditions. Recent studies have focused on utilising technologies, including apps like BENECA, WhatsApp, EMPOWER-SMS, and Owise-BC Support, for managing diet, nutrition, medication, social networking, weight management, shoulder rehabilitation, and psychological issues to enhance quality of life and self-efficacy. These studies report improved self-efficacy, medication compliance, weight management, and upper limb movement [15-17].

However, the available apps have limitations, as they focus only on certain aspects of BC-related complications and are not

programmed for comprehensive care. They require patients to be highly motivated to explore the app, which demands a high level of compliance. Consequently, problems may remain unaddressed by survivors, potentially leading to a cascade of unresolved secondary physical and psychological issues. To the best of our knowledge, there is limited documented evidence of a mobile text-message-based care program for BCS in India that offers a comprehensive approach covering physical, psychological, and functional domains. Existing mobile applications primarily focus on raising awareness, early detection, and screening, yet their efficacy remains unexplored [18].

Thus, there is a pressing need to develop a comprehensive care model tailored to the needs of Indian women with BC, addressing physical, psychological, and functional quality of life. The present study involves the design and development of a tele-mode comprehensive care model through a m-HCP, in which automated mobile text messages will be transmitted to BCS participants, incorporating a web-based instruction platform.

Objectives:

1. Design and develop a tele-mode comprehensive care model through m-HCP.
2. Determine the effectiveness of the m-HCP in the occupational and psychosocial rehabilitation of BCS.

Null hypothesis: The m-HCP is not effective in changing the levels of fatigue, occupational performance, and life satisfaction among BCS.

Alternate hypothesis: The m-HCP is effective in changing the levels of fatigue, occupational performance, and life satisfaction among BCS.

MATERIALS AND METHODS

This quasi-experimental study will be conducted at Amity University, Noida, Uttar Pradesh, India, from June 2023 to December 2025. Patients will be recruited from the NGO CanSupport in New Delhi, India. Ethical clearance has been obtained from the Institutional Ethical Committee of Amity University, Noida (AUUP/IEC/AUG/2021/05), and the CanSupport research committee (IEC CanSupport-1/2022). The study protocol will adhere to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), the National Ethical Guidelines for Biomedical Research involving Human Participants (2017), and the revised Helsinki Declaration (2013).

Inclusion criteria: Postsurgical female BCS aged between 25-65 years, with Stage I, II, or IIIa breast cancer, within three months post-diagnosis to 12 months. Participants must have subjective complaints of fatigue and should be recruited from private clinics, communities, and NGOs. Participants must have completed at least 10 years of schooling in an English-medium institution and be able to read and comprehend English, as the text messages will be in English. Patients must also possess SMS-capable mobile phones those will be included in the study.

Exclusion criteria: Participants with advanced-stage breast cancer, metastatic breast cancer, those who have undergone reconstruction surgery, or those with any other cancer, neurological, or orthopaedic conditions will be excluded from the study.

Sample size and setting: The sample size is calculated through power analysis, accounting for a 20% dropout rate, a variable incidence of fatigue during survivorship estimated at 30%, and an anticipated incidence during survivorship of 15%, with a type I error rate of 5% and 95% power [19]. Therefore, a sample of 120 patients will be required for the study.

Due to practical and ethical constraints, including limited resources, time, and population size, it is not feasible to recruit a matched control group of 120 patients. High refusal rates and compliance issues observed during the pilot trial further complicated recruitment, as many patients were coping with psychological trauma and were unwilling to engage in research discussions.

Mobile Health Care Programme (m-HCP) - Message Development

Content of the text messages: The content of the text messages is developed based on existing literature and evidence-based guidelines for breast cancer rehabilitation [20]. Additionally, opinions from a group of five BCS and eight experts in oncology, psychology, rehabilitation, occupational therapy, and physiotherapy were obtained to understand the core areas of concern for BCS residing in India.

All four key dimensions of self-care—emotional, physical, psychological, and spiritual health—are focused on while developing the messages. The main areas of concern include:

- Limitations in shoulder movement
- Fatigue
- Scarring
- Musculoskeletal pain due to poor posture
- Issues related to managing activities of daily living
- Return to work
- Feeling overwhelmed and stressed
- Fear of recurrence
- Self-esteem
- Body image
- Difficulty in maintaining friendships and intimate relationships
- Decreased libido
- Decreased social participation

Consequently, the text messages are developed based on clinical guidelines for breast cancer rehabilitation, energy conservation, and work simplification principles [Table/Fig-1]. A week-wise protocol for the m-HCP for BCS has been developed [Table/Fig-2]. A good level of agreement among the panel of experts has been established, with a Content Validity Ratio (CVR) of 0.8 [21].

Domains →	Physical complications	Functional complications	Psychosocial complication
Subdomains →	1. Pain 2. Fatigue 3. Restricted movements 4. Swelling, cording and lymphoedema	1. Selfcare dependence level- bathing, dressing, toileting, grooming 2. Instrumental activities dependence- driving, shopping, home management, kitchen tasks, child-care 3. Return to work 4. Leisure participation	1. Body image disruption 2. Motivation 3. Coping methods 4. Fear of reoccurrence 5. Social participation 6. Anxiety of unknown 7. Level of distress

[Table/Fig-1]: Domains and subdomains of the message content.

Week 1	Baseline assessment	1. Consent and information sheet, demographic information 2. Brief Fatigue Inventory (BFI) 3. LiSat 11 4. Canadian Occupational Performance Measure
	Activity domain	**Message content**
Week 2	Physical activity	1. Tips for pain and first set of shoulder ROM exercises 2. Second set of shoulder ROM exercises 3. Scar management 4. Lymphoedema awareness
Week 3	Energy conservation	1. Tips for pacing, planning methods and using aids 2. Tips on posture, back and importance of rest 3. Activities to do and not to do 4. Reminder message of exercises- first set and second set

Week 4	Activities of daily living	1. Easy dressing methods 2. Checking on driving readiness 3. Return to work tips 4. Reminder message - energy conservation and physical activity
Week 5	Physical activity	1. Tips for pain and first set of shoulder ROM exercises 2. Lymphedema management 3. Scar management 4. Reminder message-Second set of Shoulder ROM exercises
Week 6	Energy conservation	1. Tips for pacing, planning methods and using aids 2. Tips on posture, back and importance of rest 3. Activities to do and not to do 4. Reminder message of exercises- first set and second set
Week 7	Body image	1. Tips of emotional self-care 2. Tips for physical self-care 3. Tips for social self-care 4. Tips for spiritual self-care
Week 8	Body image and self-esteem	1. Tips on self-compassion 2. Manging self-esteem related issues 3. Reminder message-energy conservation and physical activity
Week 9	Relaxation methods	1. Breathing exercises 2. Breathing exercises and sensitisation on meditation 3. Sensitisation on supervised yoga based methods for stress management 4. Reminder message - energy conservation and physical activity
Week 10	Closure and Summary	1. Summary on self- esteem related techniques 2. Summary on emotional, physical, social, and spiritual self-care 3. Summary for return-to-work tips 4. Summary for physical activity and energy conservation methods
Week 11	Re-assessment and survey	1. m-HCP feasibility questionnaire 2. BFI 3. LiSat 11 4. Occupational and psychosocial complications questionnaire

[Table/Fig-2]: Week-wise protocol for the mobile-Health Care Programme (m-HCP) for Breast Cancer Survivors (BCS).

For reliability assessment of the developed protocol, a pilot study was conducted, which included 45 participants. These subjects will not be included in the final study. The pilot study is registered under the Clinical Trial Registry - India: CTRI/2023/03/050529 dated 09/03/2023.

Software Development for the Transmission of Text Messages

The development of software and an automated messaging system has been completed with the assistance of an IT professional. The functional scope of the web-based system included:

- Developing an admin panel
- Creating a login system
- Managing users and their assessments
- SMS gateway integration
- Cron Job integration for sending SMS at scheduled times

The SMS content template has been approved by Vilpower, a telecom services provider in India, and the SMS messages adhere to the regulations set by the Telecom Regulatory Authority of India (TRAI). An automated messaging system has been developed by scheduling deliveries through the SMS delivery web interface. The software named m-HCP has been created for registering participants in the study. This software allows for the addition of demographic details along with baseline assessment data and is linked with the SMS delivery web interface "Velocity SMS" to send bulk messages automatically as scheduled.

Participant Recruitment and Study Protocol

Participants will be recruited from CanSupport NGO, through referrals from physicians, oncologists, gynaecologists, pain clinics, and community-based private physiotherapy and rehabilitation clinics via voluntary participation. Convenient sampling will be utilised to recruit participants for the study. Informed written consent will be obtained before the initiation of the study, and an information sheet will be provided to all participants. Participants have the right to withdraw from the study at any time by informing the researchers via telephone.

During data collection, confidentiality will be maintained, with access granted only to the research investigators. Patients will be registered in the m-HCP software to receive educational text messages. The registration will include:

- Name
- Mobile number
- Date of diagnosis
- Date of surgery
- Date of chemotherapy or radiotherapy (if applicable)
- Baseline fatigue score
- Occupational performance and life satisfaction

This registration will be completed in the first week of recruitment. Following this, participants will receive automated educational text messages for nine weeks, with four messages sent each week. In the sixth week, an investigator will follow-up with participants via telephone to ensure consistent delivery of text messages and to address any issues faced.

Outcomes

After the nine-week message period, a postintervention assessment of fatigue, occupational performance, and life satisfaction will be conducted. Along with this, a feedback survey will be administered to evaluate the effectiveness and utility of the m-HCP among BCS.

- **Fatigue measurement:** Fatigue will be assessed using the Brief Fatigue Inventory (BFI), a self-reporting scale with nine items that takes 2-3 minutes to complete. The BFI has strong reliability and is validated for cancer patients. Scoring involves rating from 0 (no fatigue) to 10 (fatigue as bad as you can imagine), with total scores between 1-3 indicating mild fatigue, 4-6 moderate fatigue, and 7-10 severe fatigue [22].

- **Occupational performance:** The Canadian Occupational Performance Measure (COPM) will be administered to identify women's priorities following breast cancer treatment. This semistructured interview will assess self-perceived occupational performance across self-care (e.g., dressing, walking), productivity (e.g., work, shopping), and leisure (e.g., reading, socialising). Participants will list up to five daily activities they want, need, or are expected to do, rating each on a 10-point scale for importance, performance, and satisfaction [23].

- **Life satisfaction:** Life satisfaction will be assessed using the Life Satisfaction Checklist-11 (LiSat 11), a validated questionnaire developed by Fugl-Meyer AR et al., [24]. It includes 11 items gauging the level of life satisfaction across various domains: overall life, vocational situation, financial situation, leisure, social contacts, sexual life, self-care management, family life, partner relationships, somatic health, and psychological health. Each item is rated on a six-point scale from very dissatisfied (1) to very satisfied (6). A score of 5-6 indicates satisfaction, while scores of 1-4 indicate dissatisfaction [24]

- **Feedback survey:** An overall feedback survey will assess the effectiveness and utility of the m-HCP among BCS. This questionnaire aims to gather quantitative feedback from participants regarding ease of use, effectiveness, learning, practicability, and utility of the m-HCP. Responses will involve "Yes," "No," or "Somewhat." Percentages for each item will be calculated based on the number of responses.

STATISTICAL ANALYSIS

The Statistical Program for the Social Science (SPSS) 25.0 will be employed to analyse the data, using the Kolmogorov-Smirnov or Shapiro-Wilk tests, as applicable, to evaluate the normal distribution of the variables. Depending on the distribution status, significant differences in pre- and postintervention scores for fatigue, occupational performance, and life satisfaction will be analysed using paired t-tests. A p-value of <0.05 will be considered statistically significant.

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Authors' contribution

VS: Participated in conceiving the study, designing the mHCP protocol, developing message content, contributing to software development, enrolling study participants, monitoring follow-ups, and writing the manuscript; BCD: Contributed to conceiving and reviewing the protocol, guiding and monitoring the study, editing the manuscript, and facilitating communication; PK: provided significant methodological advice; VS, BCD, PK, JB, and RS: Participated in study design and planned the statistical analysis; JB and RS: Reviewed the protocol and content of the messages.

REFERENCES

[1] Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024;74(3):229-63.

[2] Sathishkumar K, Chaturvedi M, Das P, Stephen S, Mathur P. Cancer incidence estimates for 2022 and projection for 2025: Result from National Cancer Registry Programme, India. Indian J Med Res. 2022;156(4&5):598-607.

[3] National Cancer Institute. The NCI Dictionary of Cancer Terms: Survivorship [Internet]. [cited 2021 Jun 4]. Available from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/survivorship.

[4] Iyer R, Ring A. Breast cancer survivorship: Key issues and priorities of care. Br J Gen Pract. 2017;67(656):140-41.

[5] Galiano-Castillo N, Ariza-García A, Cantarero-Villanueva I, Fernández-Lao C, Díaz-Rodríguez L, Arroyo-Morales M. Depressed mood in breast cancer survivors: Associations with physical activity, cancer-related fatigue, quality of life, and fitness level. Eur J Oncol Nurs. 2014;18(2):206-10.

[6] Khan F, Amatya B, Pallant JF, Rajapaksa I. Factors associated with long-term functional outcomes and psychological sequelae in women after breast cancer. Breast. 2012;21(3):314-20.

[7] Maass SW, Brandenbarg D, Boerman LM, Verhaak PFM, de Bock GH, Berendsen AJ. Fatigue among long-term breast cancer survivors: A controlled cross-sectional study. Cancers (Basel). 2021;13(6):1301.

[8] Campbell KL, Pusic AL, Zucker DS, McNeely ML, Binkley JM, Cheville AL, et al. A prospective model of care for breast cancer rehabilitation: Function. Cancer. 2012;118(S8):2300-11.

[9] Recchia TL, Prim AC, da Luz CM. Upper limb functionality and quality of life in women with five-year survival after breast cancer surgery. Rev Bras Ginecol Obstet. 2017;39(3):115-22.

[10] Jamshidi F, Akbarfahimi N, Hosseini SA, Shayan A, Fazeli A. Determining occupational performance issues in women with breast cancer referred to treatment centers of Hamadan, Iran. Asian Pac J Cancer Prev. 2019;20(4):1113.

[11] de Oliveira NP, Guedes TS, Holanda AM, Reis MA, da Silva CP, e Silva BLR, et al. Functional disability in women submitted to breast cancer treatment. Asian Pac J Cancer Prev. 2017;18(5):1207.

[12] Soria-Reyes LM, Cerezo MV, Molina P, Blanca MJ. Life satisfaction and character strengths in women with breast cancer: Zest and hope as predictors. Integr Cancer Ther. 2023;22:15347354231197648.

[13] Olsson M, Nilsson M, Fugl-Meyer K, Petersson LM, Wennman-Larsen A, Kjeldgård L, et al. Life satisfaction of women of working age shortly after breast cancer surgery. Qual Life Res. 2017;26:673-84.

[14] Phoosuwan N, Lundberg PC. Life satisfaction, body image and associated factors among women with breast cancer after mastectomy. Psychooncology. 2023;32(4):610-18.

[15] Lozano-Lozano M, Martín-Martín L, Galiano-Castillo N, Álvarez-Salvago F, Cantarero-Villanueva I, Fernández-Lao C, et al. Integral strategy to supportive care in breast cancer survivors through occupational therapy and a m-health system: Design of a randomized clinical trial. BMC Med Inform Decis Mak. 2016;16:1-10.

[16] Singleton A, Partridge SR, Raeside R, Regimbal M, Hyun KK, Chow CK, et al. A text message intervention to support women's physical and mental health after breast cancer treatments (EMPOWER-SMS): A randomised controlled trial protocol. BMC Cancer. 2019;19:01-08.

[17] Cruz FO, Vilela RA, Ferreira EB, Melo NS, Reis PEDD. Evidence on the use of mobile apps during the treatment of breast cancer: Systematic review. JMIR Mhealth Uhealth. 2019;7(8):e13245.

[18] Subramanian S, Jose R, Lal A, Augustine P, Jones M, Gopal BK, et al. Acceptability, utility, and cost of a mobile health cancer screening education application for training primary care physicians in India. Oncologist. 2021;26(12):e2192-e2199.

[19] Bardwell WA, Ancoli-Israel S. Breast cancer and fatigue. Sleep Medicine Clinics. 2008;3(1):61-71.

[20] Harris SR, Schmitz KH, Campbell KL, McNeely ML. Clinical practice guidelines for breast cancer rehabilitation: Syntheses of guideline recommendations and qualitative appraisals. Cancer. 2012;118(S8):2312-24.

[21] Gilbert GE, Prion S. Making sense of methods and measurement: Lawshe's content validity index. Clin Simul Nurs. 2016;12(12):530-31.

[22] Mendoza TR, Wang XS, Cleeland CS, Morrissey M, Johnson BA, Wendt JK, et al. The rapid assessment of fatigue severity in cancer patients: Use of the Brief Fatigue Inventory. Cancer. 1999;85(5):1186-96.

[23] Law M, Baptiste S, McColl M, Opzoomer A, Polatajko H, Pollock N. The Canadian Occupational performance measure: An outcome measure for occupational therapy. Can J Occup Ther. 1990;57:82-87. Available from: http://dx.doi.org/10.1177/000841749005700020.

[24] Fugl-Meyer AR, Melin R, Fugl-Meyer KS. Life Satisfaction in 18- to 64-year-old Swedes: In relation to gender, age, partner and immigrant status. J Rehabil Med. 2002;34:239-46. Doi: 10.1080/165019702760279242.

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