

A Protocol for a Systematic Review on Psycho-social Interventions for Psychological Distress and Quality of Life among Women with Breast Cancer

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I. Background of the condition

Breast cancer is the second most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012. This represents about 25% of all cancers in women¹. In India cancer has become one of the ten leading causes of death². It is estimated that there are nearly 2 to 2.5 million cancer cases at any given point of time in India³. In India breast cancer represents 18% of all cancers of women which ranks second to cervical cancer. The peak occurrence of breast cancer in developed countries is above the age of 50 whereas in India it is above the age of 40⁶. In India the age standardized incidence rate of breast cancer varies between 9 to 32 per 1,00,000 women⁴.

Dakshina Kannada, a district of Karnataka state with a population of 2,089,649 as per 2011 census with a density of 430 people per sq.km, released by directorate of census operations in Karnataka⁵. Over 7 to 9 lakh new cases and 3 lakh deaths occur annually in India due to cancer⁶, whereas in Karnataka there are about 1.5 lakh prevalent cases of cancer as per 2009 studies and about 35,000 new cases are added to this every year⁷. As per ICMR-PBCR data, breast cancer is the commonest cancer among women in urban register of Delhi, Mumbai, Ahmedabad, Kolkata and Trivandrum where it constitutes more than 30% of all cancers⁹.

Breast cancer is a cancer that develops from breast tissue. Signs of breast cancer may include a lump in the breast, a change in breast shape, dimpling of the skin, fluid coming from the nipple, or a red scaly patch of skin. In those with distant spread of the disease, there may be bone pain, swollen lymph nodes, shortness of breath, or yellow skin. Risk factors for developing breast cancer include: female sex, obesity, lack of physical exercise, drinking alcohol, hormone replacement therapy during menopause, ionizing radiation, early age at first menstruation, having children late or not at all, and older age. About 5–10% of cases are due to genes inherited from a person's parents, including BRCA1 and BRCA2 among others. The treatment includes surgery, hormonal therapy, chemotherapy, radiation according to the severity of the disease.¹⁰

Breast cancer is a serious, stressful and life-threatening disease. It is assumed that the diagnosis of cancer evokes far greater distress than many other diseases, regardless of prognosis. Several studies have documented the significant disruptions in the patient's quality of life during the initial phases of the breast cancer diagnosis and its subsequent treatment. Patients undergoing a mastectomy have been observed to experience significant QOL changes at various levels: physical, functional, emotional domains of QOL and well-being. Studies have also identified the relationship between mastectomy and poor sexual adjustment and body image. Post-operative patients have been found to become more fearful and anxious, develop sleep difficulties, and experience a reduction in interest and pleasure. Their concerns involve feelings of threat to life, fear of pain, fear of recurrence, cosmetic concerns, sexual attitudes, feelings of devaluation, and loss of femininity.¹¹

The emotional impact of cancer diagnosis, symptoms, treatment, and related issues can be severe. Larger hospitals are associated with cancer support groups which provide a supportive environment to help patients cope and gain perspective from cancer survivors. Not all breast cancer patients experience their illness in the same manner. Factors such as age can have a significant impact on the way a patient copes with a breast cancer diagnosis. Premenopausal women with estrogen-receptor positive breast cancer must confront the issues of early menopause induced by many of the chemotherapy regimens used to treat their breast cancer, especially those that use hormones to counteract ovarian function.¹²

Health-related quality of life is now considered an important endpoint in cancer clinical trials. It has been shown that assessing quality of life in cancer patients could contribute to improved treatment and could even be as prognostic as medical factors could be prognostic. Above all, studies of quality of life can further indicate the directions needed for more efficient treatment of cancer patients. Among the quality of life studies in cancer Patients, breast cancer has received most attention for several reasons.¹¹

A study conducted at Warangal, India on the quality of life of breast cancer survivors shows that they have poor quality of life due to various factors related to physical function, role function, insomnia, body image, future perspective, breast symptoms and arm symptoms. Several studies on prevalence rates have found that one-third of the cancer population experiences distress and may profit from early psychosocial intervention. Between 10% and 50% of cancer patients have been found to have depression, depending on the stage of disease and the methods used to assess depression. Most studies report the prevalence of major depression in cancer patients to be 20% to 25%, increasing with higher levels of physical disability, advanced illness, and pain¹⁴.

Anxiety in cancer survivors is attributed to fear of recurrence¹⁵, additional treatment, and the potential for adverse effects¹⁴. Anxiety is sometimes difficult to assess in the cancer survivor population. Stark and colleagues found that 48% of a sample population with a variety of cancer diagnoses had an anxiety disorder when assessed by questionnaire¹⁵. However, when reassessed by diagnostic interview, only 18% of the group fulfilled the criteria for anxiety disorders. Even when the most stringent criteria are used, 5% to 15% of patients with cancer meet the criteria for major depression; another 10% to 15% present with less severe depressive symptoms¹⁶.

II. Description of the intervention

Although at least one-third of the cancer population experiences some variety of distress, only about 10% receive any psychosocial therapy¹⁷. Research focus is returning to the psychological status and quality of life of women with breast cancer, and to the identification of interventions that favorably influence their psychological and social functioning. The report by Kissane and colleagues of a randomized, controlled trial of cognitive-existential group therapy for women with early breast cancer found that the women in the intervention group showed significantly lower anxiety, and improved family function compared to the control group¹⁸.

A literature review of psychosocial interventions concluded that interventions can help people with cancer to cope better with very distressing situations, can improve their affective state, and can help to reduce the adverse effects of disease or its treatment while positively affecting quality of life¹⁹. The author identified five types of effective intervention, best used in combination: education about the disease; behavioral training such as relaxation, yoga, and hypnosis; stress management; cognitive-behavioral therapy.

A number of excellent reviews of psychosocial interventions in cancer in general, have been published which concluded that there are important benefits associated with the use of psychological interventions of various types in various cancer settings, including breast cancer²⁰.

Why it is important to do this review

It is not a coincidence that breast cancer receives so much attention as it is the most common invasive cancer among women worldwide, affecting 1.6 million new women each year. Early detection through the use of mammography screening in combination with sophisticated treatment has substantially contributed to improvement in survival rates. The sheer number of women diagnosed with breast cancer indicates that the disease has grown to become a public health concern mainstream society is unable to avoid. With a growing number of women who live with the aftermath of breast cancer for relatively long periods, it is clear that the need to understand its treatment effects and quality of life (QOL) issues becomes paramount.²¹

Despite a massive amount of research on quality of life after a breast cancer diagnosis, the evidence-based knowledge gap of when, how, in what form, and what the women themselves desire to receive support about, leaves the health care professionals with very limited hands-on guidance for their everyday clinical practice. Quality of life can be studied as a multidimensional construct. It comprises broad concepts that affect global life satisfaction, including good health, adequate housing, employment, personal and family safety, education, and leisure pursuits. For matters related to healthcare, the concept of quality of life has been adapted to focus on those concepts that are most affected by health or illness, hence the term "health-related quality of life"²². Today, there is a fair consensus as to what dimensions health-related quality of life entail.

Immediately upon diagnosis, women's psychological distress may be understood in the context of complex decision-making regarding family and professional life as well as one's treatment options. This is an extremely stressful period for younger women in particular, as all demands of everyday life are the most intense while for example caring for a family with small children²³. Intense treatment may result in an increased sense of vulnerability and a threat to one's self, uncertainty for the future, and existential concerns²⁴.

Understandably, depression and anxiety have been repeatedly documented in this population. Depressive symptom and reactions among breast cancer-diagnosed women have repeatedly been shown. Likewise, although the prevalence of significant anxiety disorder has been less consistently documented, symptoms of anxiety have also been reported in studies with women diagnosed with breast cancer. The Hospital Anxiety and Depression Scale has been used in research to diagnose depression and anxiety²⁵.

Experiencing difficult events, such as receiving a breast cancer diagnosis, may significantly impact the social and emotional well-being of the woman, her family, and her friends. Thus, intervening to minimize the

emotional trauma through psychosocial support may increase the coping ability of the woman and, as a result, promote her enhanced psychological well-being. So far, with the exception of cognitive behavioral therapy, suggesting it may improve women's adjustment to diagnosis and treatment; results on the 9 systematic reviews showed effectiveness of psychosocial support on quality of life measures specifically during the treatment phase have been inconclusive²⁶.

As such, even though there is some evidence that psychosocial support is helpful, until more solid evidence is available of its effectiveness, humanitarian and ethical values provide the basis and guide for the provision of professional psychosocial support. However, regardless of whether effects on any quality of life measures are detectable or not, psychosocial support and its availability may nevertheless hold a value for those women who desire it.

Even though the challenges to improve psychosocial support for the women may seem daunting and at times overwhelming, we must never despair. Rather, in order to deliver quality care during and after treatment, we have to focus on what is important and what we are actually able to achieve. Psychosocial support is not only important because it aims at improving women's well-being, but also because the women themselves tend to report psychosocial support needs²⁷.

With the help from a strong evidence-base from research, we may likely have to focus on developing time and cost-effective group oriented techniques that essentially help the women help themselves. Essentially, we need to become better at providing them with an early emotional foundation they can stand more firmly on throughout the disease trajectory and for the future. Our job will be to help them maximize their chances at successful rehabilitation. In order to achieve this, however, we will need to find ways to work smarter in a system where the level of psychosocial support provision will have to become routine and should not be left to each clinic.

I believe that we may be able to accomplish that by focusing on getting them better prepared for what lies ahead when first diagnosed as well as when finishing the medical/surgical treatment. In other words, we need to investigate if a proactive healthcare team is helpful for the women in the long run. Also, we will need to be able to track psychosocial services provided for women with breast cancer to deal with their psychological distress and maintaining a better quality of life.

Objectives

1. To assess the effects of psycho-social interventions on psychological distress and Quality of life among women breast cancer.

III. Methods

Criteria for considering studies for this review:

Types of studies

Randomized controlled trial (RCT) designs, and clinical controlled trials (CCTs), Quasi experimental, pre-test-post-test designs, cohort studies (prospective & retrospective) which are made some attempt to address the psychosocial interventions for breast cancer cases will be studied

Type of participants

Women with a histologically confirmed diagnosis of breast carcinoma of an early non-metastatic stage (Grade I-III) as defined by the TNM (tumour, lymph nodes, metastasis) staging system

The studies conducted on breast cancer survivors during the period 2005 to 2016, irrespective of their age will be included in this review.

Inclusion criteria:

- a. Women diagnosed with breast cancer and who are undergoing treatment (surgery, chemotherapy, radiation therapy) will be eligible.
- b. The Studies which are addressed any kind of psychosocial interventions for breast cancer cases will be included
- c. The studies which are conducted exclusively among breast cancer subjects irrespective of the duration of their disease will be included

Exclusion criteria:

- a. Women with metastatic breast cancer will not be included.
- b. Studies including participants with other cancer types will be excluded unless the outcomes for the breast cancer subgroup are reported separately.
- c. The studies with other interventions such as surgical, physical, etc. will be excluded

Types of interventions

The review exclusively assessed psychosocial interventions such as:

- Interpersonal therapy,
- cognitive behavioral therapy,
- group therapy
- yoga,
- meditation
- Guided imagery.
- Counseling
- Psycho-education
- Music therapy
- And any other therapies reported in the studies

We will be comparing these interventions to an inactive control intervention; that is placebo, standard care or waiting list control: 'a group that is assigned to a waiting list to receive an intervention after the active treatment group does', or with an active control intervention (for example another form of psychological intervention). Studies with multi-interventions will be excluded unless data were extractable.

Types of outcome measures

Primary outcome

1. Quality of life (QoL): QoL score measured using any validated questionnaire
2. Psychological distress: Psychological distress measured using any validated questionnaire

Search methods for identification of studies

The search strategy for identification of relevant studies is highlighted below.

- **Electronic Search:** Computerized database searches will be conducted. Search terms and search strategies will be modified to fit individual databases.

Databases to be searched will include the following databases (and others may be added):

1. PUBMED
2. SCIENCE DIRECT
3. COCHRANE LIBRARY
4. CTRI (clinical trials registry – India)
5. CONFERENCE REPORT or DISSERTATIONS published in SHODHGANGA

It will include literature published from 2005 to 2016. The search of databases will use four sets of keywords that pertain to the population, intervention, outcomes, and study design. Search strings' keywords will be customized to the particular thesaurus of each database. Keywords will be connected with "and"/"or" when searching titles and abstracts. Search terms will also be truncated to include variations in word endings, spellings, and database indices. Studies in English language only will be considered.

Key words:

- "Quality of Life" and "Breast Cancer"
- "Quality of Life" and "Breast Carcinoma"
- "Psychosocial distress" and "Breast Cancer"
- "Psychosocial distress" and "Breast Carcinoma"
- "Psychosocial intervention" and "Quality of Life"
- "Psychosocial intervention" and "Breast Cancer"
- "Psychosocial intervention" and "psychosocial distress"
- "Inter- personal therapy" and "Breast Cancer"
- "Inter- personal therapy" and "Breast Cancer"
- "Inter- personal therapy" and "Quality of life"
- "Inter- personal therapy" and "Psychosocial distress"
- "Cognitive behavioral therapy" and "Breast Cancer"
- "Cognitive behavioral therapy" and "Psychosocial distress"
- "Cognitive behavioral therapy" and "Quality of life"
- "Group Therapy" and "Breast Cancer"
- "Group Therapy" and "Quality of life"
- "Group Therapy" and "Psychosocial distress"

- “Yoga” and “Breast Cancer”
- “Yoga” and “Psychosocial distress”
- “Yoga” and “Quality of life”
- “Meditation” and “Breast Cancer”
- “Meditation” and “Quality of Life”
- “Meditation” and “Psychosocial distress”
- “Guided imagery” and “Breast Cancer”
- “Guided Imagery” and “Quality of Life”
- “Guided Imagery” and “Psychosocial distress”
- “Counseling” and “breast cancer”
- “Counseling” and “Quality of life”
- “Counseling” and “Psychosocial distress”
- “Psycho-education” and “Breast Cancer”
- “Psycho-education” and “Quality of life”
- “Psycho-education” and “Psychosocial distress”
- “Music Therapy” and “Breast Cancer”
- “Music Therapy” and “Quality of life”
- “Music Therapy” and “Psychosocial distress”
- “Quality of life” and “Breast cancer” or “ Breast carcinoma”
- “Psychosocial distress” and “Breast cancer” or “ Breast carcinoma”
- “Psychosocial intervention” and “Breast cancer” or “ Breast carcinoma”
- “Inter- personal therapy” and “Breast cancer” or “ Breast carcinoma”
- “Cognitive behavioral therapy” “Breast cancer” or “ Breast carcinoma”
- “Group Therapy” “Breast cancer” or “ Breast carcinoma”
- “Yoga” “Breast cancer” or “ Breast carcinoma”
- “Meditation” “Breast cancer” or “ Breast carcinoma”
- “Guided imagery” “Breast cancer” or “ Breast carcinoma”
- “Counseling” “Breast cancer” or “ Breast carcinoma”
- “Psycho-education” “Breast cancer” or “ Breast carcinoma”
- “Music Therapy” “Breast cancer” or “ Breast carcinoma”

PATIENT	INTERVENTION	OUTCOME
Breast Cancer	Psychosocial intervention	Quality of Life
Breast Carcinoma	Inter- personal therapy	Psychosocial distress
Women	Cognitive behavioral therapy	
Woman	Group Therapy	
Females	Yoga	
Breast neoplasm	Meditation	
	Guided imagery	
	Counseling	
	Psycho-education	
	Music Therapy	
	Social intervention	

IV. Data collection and analysis

- **Selection of studies**
- ✓ Titles and abstracts of studies identified during the literature search will be screened by two investigators. Potentially eligible studies will be read in full by the review author to determine whether or not they meet the eligibility criteria. Any clarifications will be discussed with a third author until consensus is reached.
- ✓ Excluded studies will be recorded in the 'Characteristics of excluded studies' table.
- ✓ The study selection process will be documented in a PRISMA flow chart.
- ✓ Articles which are published in English language only will be included

Data extraction and management

Data from all relevant studies will be extracted and entered into the 'Characteristics of included studies' table in RevMan 5.3 (RevMan). All studies will be appraised independently by two review authors. Any disagreement was resolved by discussion. Extracted data will include the following.

- (a) Participants: country of origin, sample size, setting, diagnostic criteria, age, ethnicity, date of study and data on baseline psychological morbidity for assessment of effect modifiers.

- (b) Methods: study design, methods of allocation, allocation sequence concealment, blinding, and exclusion of participants after randomization, proportion and reasons for loss at follow up.
- (c) Interventions: type, dose, length and frequency of intervention (for each intervention and comparison group).
- (d) Outcomes: type of outcomes, assessment instruments, assessment time point, and follow-up time point. If mentioned, sources of funding were recorded in the 'Characteristics of included studies'. For studies with more than one publication, the first publication will be considered as the primary reference but data will be extracted from all of the publications.

Assessment of risk of bias in included studies

Two review authors will be graded and assessed each selected trial using a simple contingency form, addressing the seven specific domains discussed in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). The evaluations given by all authors will be compared and any inconsistencies and disagreements will be resolved by discussion. Each domain will be assigned a judgment related to the risk of bias in that domain. Judgments used were: 'low risk of bias', 'high risk of bias', and 'unclear', which indicated unclear or an unknown risk of bias. The domains will be:

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Other sources of bias.

Each domain will be judged as either:

- 'low risk of bias' if the requirements are adequately fulfilled²⁵
- 'high risk of bias' if the requirements are not adequately fulfilled²⁵
- 'Unclear risk of bias' if insufficient data for a judgment are provided²⁵.

Risk of bias will be incorporated in judging the quality of evidence for each outcome according to the GRADE recommendations²⁶

Measures of treatment effect

Primary outcomes will be classified as continuous outcomes and expressed as standardized mean differences (SMD) with 95% confidence intervals (CI) according to the Cochrane Handbook for Systematic Reviews of Interventions, chapter 7, section 7.7.325. If the outcome variable is dichotomous (yes/no) we will be using Risk ratio and if it is continuous mean difference will be used. For discrepancies in scales standardized mean difference will be used.

All measures of effect included 95% CIs, P values, and for pooled measures the I² statistic.

Assessment of heterogeneity

Statistical heterogeneity between studies will be assessed using the Chi² test. A P value ≤ 0.10 will be regarded to indicate significant heterogeneity. Additionally, the I² statistic will be used.

Assessment of reporting biases

If at least 10 studies are included in a meta-analysis, funnel plots of effect estimates against their standard errors (on a reversed scale) will be generated using Review Manager Software. Publication bias will be assessed by visual analysis of funnel plots, with roughly symmetrical funnel plots indicating low risk and asymmetrical funnel plots indicating high risk of publication bias²⁵. Further attempts will be made to avoid publication bias by searching trial registries and conference proceedings for unpublished studies.

Duplicate publication bias will be addressed as studies with more than one publication will be included only once. If there is doubt whether multiple publications refer to the same data, attempts will be made to contact the trial authors by e-mail.

Data synthesis

For continuous outcomes, data will be pooled using a random-effects model (inverse variance method). All analyses will be performed using RevMan 5.3 software. If the studies are found to be homogenous in terms of study designs, participant characteristics, interventions and outcome the extracted data from such studies will be pooled in a meta-analysis using a random effect model, Revman 5.3. If meta-analysis is not appropriate then the results of the studies will be synthesized narratively

Subgroup and moderator analyses

Subgroup/moderator analyses will be conducted for a limited number of independent variables. The approach to the moderator analyses will be dependent on the available data. Meta-regression will be used if the volume of data makes it possible to do regression of multiple factors on to the treatment effect size.

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