

# A prospective, multicenter, cohort study to evaluate the long-term quality of life and psychological factors among patients with breast cancer, 5-year follow-up: a study protocol

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## Study protocol

**Keywords:** Breast neoplasms, Cohort, Depression, Follow-Up study, Iran, Quality of life, Study protocol

**Posted Date:** February 13th, 2023

**DOI:** <https://doi.org/10.21203/rs.3.rs-2349479/v2>

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# Abstract

**Background:** Breast cancer is the most commonly occurring cancer among women worldwide. Quality of life and psychological status of patients with breast cancer could be affected after diagnosis, especially during treatment. The main objective of this study is investigation of long-term influence of breast cancer on quality of life's dimensions and mental health status.

**Methods:** This is a multicenter, ongoing longitudinal prospective cohort study which administered in national institute for medical research development in May 2018 in Iran. 1250 patients with breast cancer who were completed their treatments, will be recruited from 5 referral medical centers located in Tehran, to be followed for 5 years. Questionnaires for evaluating the primary and secondary outcomes will be complete by trained investigators during face-to-face interviews with each participant in three phases: immediately after treatment, 1 year and 5 years later. Data will be collected on socio-demographic, quality of life, body image, hope, psychological problems such as anxiety, depression and mood, also sexual function and physical activity. Data will be analyzed in each phase and at the end of the project by SPSS version 22.

**Discussion:** It is the first nationwide, prospective, cohort study with large sample size, long-term follow-up and broad research aims which will evaluate quality of life-related factors in Iranian breast cancer population to justify the existing gap in literature.

**Trial registration number:** National Institute for Medical Research Development (NIMAD) (IR.NIMAD.REC.1397.322) July 1th, 2018.

## Background

Breast cancer (BC) is the most commonly occurring cancer among women with 2.3 million new incidence and 684,679 deaths globally per year. BC incidence and mortality rates are high in developed and developing countries (1). The incidence rate of BC in Iran had a significant upward trend and it's also considered as a major reason of death in Iranian females (2-4).

Advances for BC detection and treatment lead to the longer expected survival time of patients (5) that's why the QoL is one of the major concerning health issues among them. QoL can be important in predicting the outcomes of patients' disease and could consider as a prognostic factor along with other medical parameters.

Patients might experience several side-effects including sleep disturbance, psychosocial distress and depression after being diagnosed and treated for BC which could detrimentally affect QoL (6-8). So, QoL assessment could determine how BC diagnosis and related treatment could affect QoL.

Based on previous studies, QoL among BC patients is related with several psychological factors such as depression, anxiety (9), sleep disturbances (10), spiritual (11, 12), sexual (13-16), and cognitive

disorders (17, 18). Furthermore, some of physical aspects including pain (19, 20), hot flashes, night sweats, vaginal dryness (21), lymphedema (22), fatigue (23-25), peripheral neuropathy and gastrointestinal problems (26). BC patient's life style behaviors (27-29) and fear of cancer recurrence (30) could also be considered as crucial determinants of QoL.

Recent studies showed high prevalence of anxiety and depression in patients with BC (7, 31). Furthermore, sexual dysfunction (32-34) which exist due to fear of rejection (35, 36) or feeling sexually unattractive (35, 37) and body image dissatisfaction (38-43) should be considered as other problems which could occur in this population.

On the other hand, QoL could depend on some demographical features like age (44), educational (45) and marital status (46). Recent study had demonstrated that women with BC who were before 50 years old experience lower QoL in compared with older patients (47).

Actually, women play a crucial role in family life and their overall wellbeing after BC diagnosis could definitely affect other family members lives (48), Therefore assessing QoL is essential since it could significantly affect the process of treatment and survival (49-51). The shock of BC diagnostic, mental and physical disorders made by side effects of cancer treatments and fearing of recurrence after completion of treatments could have deteriorate influence on patients' QoL which made the beginning, during and the end of cancer treatment as three crucial time points , when we choose for assessing outcomes among BC patients (52, 53).

While early and immediate screening and monitoring after BC diagnosis could improve QoL in survivors, the primary purpose of current study is collecting and evaluating the impact of BC diagnosis on long term QoL, psychological and physical activity status, which is an essential step towards addressing this paucity of knowledge. Moreover, the data of this cohort could also be used to obtain approaches for BC survivorship care over time.

## Methods

### **Study design:**

This prospective cohort study was designed to evaluate a cohort of 1250 women with BC, during a 5-year follow-up (Fig 1).

Eleven questionnaires will be used in three phases including; baseline (immediately after treatment) and at 1 and 5 years after enrollment. Data will be collected up to five years post BC diagnosis through semi-structured interviews in order to accurately document the subsequent outcomes of patients within the follow up period. In each center, trained interviewers or clinicians obtain information by filling questionnaires through personal interview (face-to-face) (Fig 1).

### **Selection of participants:**

This study takes place at 5 main referral centers including Rasoul Akram, Imam Hossein, Mahdiye and Imam Khomeini Hospitals and Motamed Cancer Institute. The study team attempt to engage with these centers for case identification.

The originally-planned start was delayed due to COVID-19 health and safety protocols. Our study team postponed planned in-person recruitment activities until 2021.

Women should have following conditions in order to participate in this cohort:

1. Women aged 18 years or older
- 2- Histological confirmed BC diagnosed
- 3- Within the first month after active BC treatment completion (chemotherapy, radiation, surgery)
- 4- capable of understanding the purposes of the study and willing to collaborate

Also participants were excluded if they develop metastatic cancer in any stages.

After explaining the purpose of this cohort by researchers, written consent form will be signed by persons who want to participate. Participants will be informed that they could chose to withdraw from the study at any time. Since transportation to and from hospitals may be difficult for several participants and they might not be able to get there for our study, we will set the date for face to face intervention in accordance with their oncologist or surgeon checkup date to minimize the possible discomfort. This approach will be continued as the same in the next phases. Researchers ensure participants to protect their identity throughout recruitment and dissemination process, and to promote clear and honest research reporting.

### **Study questionnaires:**

Participants will receive questionnaires that should be filled out by face-to-face interview at baseline and at different stages of follow-up. Socio-demographic and clinical characteristics information (age, marital, educational, economic and occupational status, family history of cancer, history of mental disease, date of diagnosis, tumor characteristics (grade, stage, hormone receptor status), type of cancer treatment (chemotherapy, surgery, radiation therapy, hormone therapy), physical, mental or cognitive side effects of treatment) will be collected through researcher-made questionnaire and patients' medical records at the beginning of the study. Other outcomes will evaluate by questionnaires which validated for the Iranian population. These instruments will assess QoL (54-57), anxiety (58), depression (58, 59), mood (60), sexual function (61), body image (62), hope (63), physical activity (64). The detailed of these questionnaires described in Table 1.

### **Data analysis and sample size:**

All statistical analysis will be performed using SPSS 22.0. Demographic characteristics and medical history of patients will be described by using Mean and SD, median, lower and upper quartile values and

frequencies (%) depending on the type of variables.

Chi-square test will be used for categorical variables in order to evaluate the association between socio-demographic, clinical characteristics and symptoms with the dependent variables. Also t-test will be used to identify relevance of variables.  $P < 0.05$  would be considered as statistically significant.

Sample size was calculated 1250 women that will be selected 200-250 individuals in each centers.

## Discussion

The survival of patients with BC could remarkably be affected by their QoL and psychological status. Despite the high prevalence of BC in our country and the critical role of QoL, emotional, psychological, and social well-being on this population, no population-based cohort survey have been carried out to assess the longitudinal QoL and other related characteristics among women with BC in Iran.

This prospective, multicenter, cohort study is the first nationwide project with large sample size, long-term follow-up and broad research aims that is investigating health-related QoL dimensions, psychological factors, sexual and physical activity status during 5 years among Iranian breast cancer survivors after completing active cancer treatment to justify the existing gap in literature.

High quality evidence that will be provided by this cohort could play a critical role for investigating effective lifestyle approaches for improving QoL, psychological status and overall survival among our target population.

Furthermore, developing standard valid questionnaires and guidelines for long term screening and monitoring of patients after BC diagnosis is the other goals of this project. We could also identify the main predictors and risk factors of poor health-related QoL or mental disorders after completion of BC treatment until 5 years among this population.

One of the main strengths of this protocol is that in this study participants recruit from 5 main referral centers for cancer treatment in Iran where located in Tehran province and high percentage of patients from other provinces are also referred to these centers for initiation of their cancer treatment annually and this could help us evaluate outcomes among BC patients with different lifestyle, geographic and socioeconomic status. Moreover, the interviewing method in this study is face-to-face (in-person) interview which is effective, feasible and flexible data collection method in obtaining accurate information and higher response rate, especially among the patients after active treatment who may not immediately able to response or understand the questions. Other than that The findings of this study will help physicians, oncologists, psychologists and nutritionists to design instructions for the management and care of patients with BC and training their families. A major limitation of this study is that BC specific death will not be assessed as the primary outcome. Therefore, the power of this study may not be adequate to show a clinical significance. Furthermore, since this is a cohort study, inaccessibility of all participants in the second or third phase due to non-assistance or death could consider as a limitation.

# Abbreviations

BC: Breast cancer; QoL: Quality of life.

# Declarations

## Ethics approval and consent to participate

The study protocol was approved by Ethics committee of the National Institute for Medical Research Development (NIMAD) with approval ID of IR.NIMAD.REC.1397.322. Written informed consent to participate will be registered for all enrolled patients. The findings of the study will be disseminated through scientific peer-reviewed journals, national and international conference presentations, and also will be accessible for patients, clinicians and public.

## Consent for publication

A signed informed consent will be obtained from each participant.

## Availability of data and materials

The datasets will be available from the corresponding author on reasonable request.

## Competing interests

The authors declare that they have no competing interests.

## Funding

This study is supported by National Institute for Medical Research Development Islamic Republic of Iran with number 964822.

## Author's contribution

MRL, AS, AM participated in the design and coordination of the study. AK and FA are the biostatisticians of the study. RA, RO, NN, LH and MR reviewed the study protocol and made suggestions that improved the design. All of these individuals are involved in the management of the study. MRL and EH drafted the manuscript. All of the authors read, revised and approved the final manuscript.

## Acknowledgements

This research has received a grant from the National Institute for Medical Research Development (NIMAD), (IR.NIMAD.REC.1397.322). The authors would like to thank the oncologists and surgeons who are participating in the follow-up of the patients.

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## Table 1

**Table 1.** Description of instruments used for evaluation of the participants.

<b>Instruments</b>	<b>Description</b>	<b>Domain/Subscales</b>	<b>Score</b>	<b>Validity/Reliability</b>
<b>Iranian version of EORTC QLQ-C30 (65-67)</b>	Scale with 30 questions assessing QoL among patients with cancer during the previous week	Global health status. Functional scales: Physical, role, emotional, cognitive and social functioning. Symptom scales/items: Fatigue, nausea/vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties.	Range: 0-100. Higher scores for the global health status and functional scale represent a better level of QoL and functioning. Higher scores for a symptom scale/item represents a higher level of symptomatology/problems	Montazeri et al. validated the Iranian version of the EORTC QLQ-C30 in cancer patients (57). Cronbach's alpha coefficient for multi-item scales ranged from 0.48 to 0.95 and Validity was checked using two methods: inter-scale correlation and known-groups comparison.
<b>Iranian version of EORTC QLQ-BR23 (68)</b>	Specific breast cancer scale with 23 questions assessing QoL in patients with breast cancer during the previous week and month.	Functional scales: body image, sexual functioning, sexual enjoyment, future perspective. Symptom scales/items: systemic therapy side effects, breast symptoms, arm symptoms, concern about hair loss.	Range: 0-100. Higher scores for a functional scale represent a healthy level of functioning. Higher scores for a symptom scale/item represent a higher level of symptomatology/problems	Iranian version of the EORTC QLQ-BR23 is a reliable tool which was validated by Montazeri et al in breast cancer patients (56). Cronbach's $\alpha$ coefficient for multi-item scales ranged from 0.63 to 0.95.
<b>Iranian version of SF-36 (69-71)</b>	The Short Form Healthy Survey is a generic instrument with 8 subscales for assessing health related QoL.	Physical functioning, Role physical, Bodily pain, General health, Vitality, Social functioning, Role emotional and Mental health. Energy/fatigue, Emotional well-being, Social Functioning, pain, it also provides two summary scales, Physical component summary and mental component summary.	Range: 0-100. Scores ranged from 0 (worst health status) to 100 (best health status) for each subscale that higher scores indicating a better condition.	The Iranian version of the SF-36 is known as a reliable and valid instrument which evaluated by Monrazeri et al. Cronbach's $\alpha$ coefficients ranging from 0.77 to 0.90 ( $\alpha = 0.65$ ) (55).
<b>Iranian version of FACT-B (72, 73)</b>	The FACT-B is a sensitive, disease-specific instrument	Consists of two parts: the general subscale on cancer (FACT-G) and additional concerns on	Range: 0-144. The scoring method of FACT-B is in Likert's scale and responses were recorded on a 5-	The Persian version of the FACT-B is validated by Patoo et al. (54) Internal consistency using Cronbach's alpha was

	with 5 subscales for measuring the QoL of breast cancer patients.	breast cancer-specific subscale (BCS). The FACT-G includes physical well-being (seven items), social/ family well-being (seven items), emotional wellbeing (six items), and functional well-being (seven items) and the BCS has nine items.	point Likert scale, and a higher score indicates a better QoL of patient. (Ranging from 0 to 4, where 0 represents 'not at all', 1 - a little bit, 2 - somewhat, 3 - quite a bit and 4 - very much).	0.63 to 0.93 for the subscales and 0.92 for the total scale.
<b>Iranian version of HADS (74)</b>	this instrument is a brief scale with 14 questions to measure anxiety and emotional distress in patients during the previous week	Including 14 items in 2 subscales: Anxiety and Depression	Each item is ranked on the 4-point Likert scale (0 to 3). Scores of 11 or more on either subscale are considered to be a significant 'case' of psychological morbidity, while scores of 8-10 represents 'borderline' and 0-7 'normal'.	(58) The Persian version of HADS is an acceptable tool which reliability and validity was confirmed by Montazeri et al. Cronbach's alpha coefficient has been found to be 0.78 for the HADS anxiety sub-scale and 0.86 for the HADS depression sub-scale
<b>Iranian version of BDI (75)</b>	Beck depression inventory-II is a self-reported tool for assessing depression in general population.	BDI-II have 21-items	Range: 0-63 BDI-II have 21-items which are rating on a 4-point Likert scale (0 to 3)  The score of 0-9 was not depressed. From 10 to 15 points are mild depressed states, 16-23 points are moderate depressed, and 24-63 points are severe depressed.	The Persian version of BDI-II has demonstrated acceptable psychometric properties of validity and reliability in different populations (59). The reliability of the instrument is Cronbach's $\alpha = 0.87$ and acceptable test-retest reliability ( $r = 0.74$ ).
<b>Iranian version of Brums-32 (76-78)</b>	The BRUMS-32 including 32 questions evaluated two aspects positive and negative's mood in athletes	It is included 8 Positive dimensions subscales vigor, calmness, happy, also negative dimensions subscales anger, tension, depression, fatigue and confusion	Final score questionnaire can be calculated by taking the sum negative dimensions and then subtracting the sum of positive dimensions. Thus positive scores	Farokhi Ahmad et al. proved reliability and validity of Persian version of the BRUMS-32 for assessing mood among Iranian population (with internal consistency of 0.78 and temporal reliability of 0.88) (60)

reflected distress mood and negative scores represent good mood

<b>Iranian version of FSFI (79, 80)</b>	This instrument consists of 19 questions that evaluate the sexual function in women over the past 4 weeks.	Including 6 dimensions (desire, arousal, lubrication, orgasm, satisfaction and pain.)	The total score is the sum of the scores in all domains. Items 1, 2, 15, 16 are ranking Likert scale from 1-5 and other questions rating Likert scale from 0-5. The maximum score is 36, and scores lower than 28 reveal an undesirable sexual function	In Iran the validity and reliability FSFI questionnaire have been proved in several studies (61). The overall test-retest reliability coefficients were high for each domain of the FSFI (r ranging from 0.73 to 0.86) and the internal consistencies within the acceptable range ( $\alpha$ ranging from 0.72 to 0.90).
<b>Iranian version of BICI (81)</b>	self-report questionnaire which assessing dissatisfaction and shame regarding one's appearance	BICI consists of 19 questions	Questions rating on a 5 point Likert scale from 1 (never) to 5 (always). Total score can range from 19-95, which the lower scores indicate satisfaction body image	Iranian version of BICI is validated by Pooravari et al. (Cronbach's $\alpha = 0.91$ ) (62).
<b>Iranian version of AHS(82)</b>	Instrument consists of 12 questions measuring hope in the general adult population.	Consist of 12 questions with four items measure pathways of thinking, four items measure agency thinking and other four items are expletive.	The scoring is based on 8-point Likert scale including 1 (Definitely False), 2 (Mostly False), 3 (Somewhat False), 4 (Slightly False), 5 (Slightly True), 6 (Somewhat True), 7 (Mostly True) and 8 (Definitely True).	Snyder's Adult Hope Scale (AHS) can be used as a valid and reliable instrument for assessing hope in women with breast cancer (63)
<b>Iranian version of IPAQ (83)</b>	Scale with 27 items as a long form questionnaire assessing physical activity during the past 7 days	5 sections: occupational (7 items), transportation (6 items), household affairs (6 items), leisure-time activities (6 items) and time spent on sitting (2 items)	Results reported in 3 categories low activity, medium activity and high activity level	validity and reliability of Iranian version of IPAQ is confirmed with Cronbach's Alpha coefficient (0.7) and Spearman Brown correlation coefficient (0.9) (64)

QoL; Quality of life, EORTC QLQ-C30: The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30, EORTC QLQ-BR23: The European Organisation for Research and



Treatment of Cancer Quality of Life Questionnaire Breast Cancer-Specific, SF-36: The Short Form 36 Health Survey Questionnaire, FACT-B : Functional Assessment of Cancer Therapy-Breast, HADS: The Hospital Anxiety and Depression Scale, BDI : beck depression inventory, Brums-32: Brunel mood scale-32 items, FSFI : Female Sexual Function Index, BICI : Body Image Concern Inventory, AHS: Adult Hope Scale, IPAQ: International Physical Activity Questionnaire

## Figures

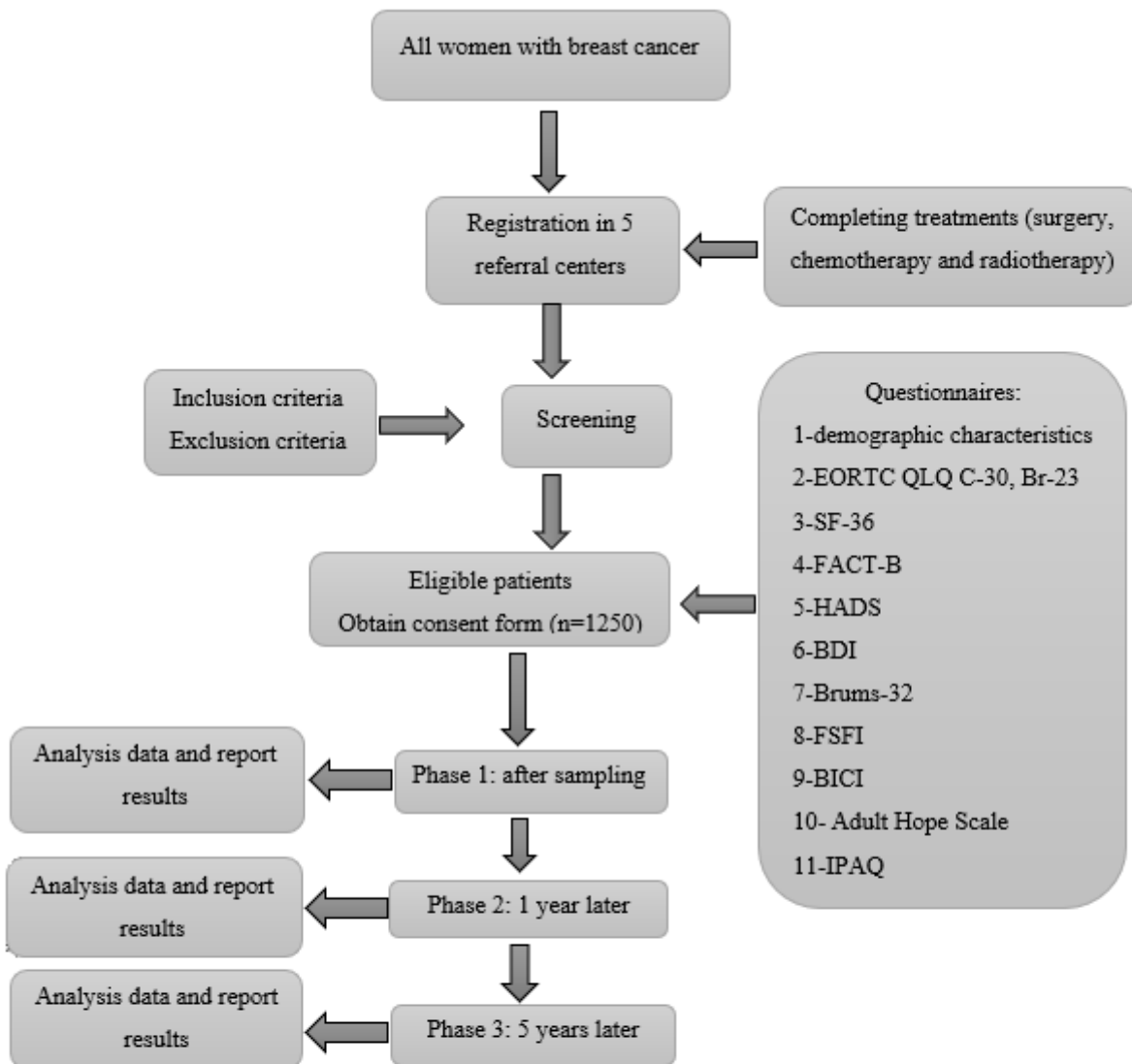


Figure 1

Project overview and timing of baseline and follow-up evaluations in the participants.