



BMJ Open Study protocol for a nationwide questionnaire survey of physical activity among breast cancer survivors in Japan

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ABSTRACT

Introduction A major concern is that few cancer survivors meet the guidelines for recommended levels of physical activity. No studies have investigated physical activity among breast cancer survivors nationwide in Japan. Therefore, the aims of this study are to identify the levels of physical activity among breast cancer survivors, to examine factors-related physical activity among breast cancer survivors and to identify breast cancer survivors' preferences for and interest in exercise programmes in order to inform the future programme development.

Methods and analysis We will administer a cross-sectional survey using a self-report questionnaire to breast cancer survivors. At each of 50 facilities selected to include a variety of institutional backgrounds according to the population distribution of different regions throughout Japan, we will consecutively distribute the questionnaire to 30 outpatients who have completed initial treatments, except for hormone therapy. The target sample size is 1500 survivors. We will calculate descriptive statistics for each measurement item and perform univariate and multivariate analyses using outcome measures (eg, physical activity and quality of life) related to physical, psychological, social and environmental factors.

Discussion This is the first nationwide survey of physical activity levels among breast cancer survivors in Japan. Identifying the factors associated with physical activity will help us to develop, disseminate and implement programmes that encourage more survivors to adhere to physical activity guidelines.

Ethics and dissemination The protocol was approved by the Institutional Review Board (IRB) of the National Cancer Center on 11 January 2019 (ID: 2018–295). In addition, many of the participating facilities required ethical approval from their local IRBs, while others did not. Accordingly, approval from the local IRBs of individual facilities was obtained when required. The findings will be disseminated through peer-reviewed publications and conference presentations.

INTRODUCTION

Achieving substantial survivorship is a priority in Japan's cancer countermeasures. Currently, more than 85 000 women are newly diagnosed with breast cancer each year¹, and with the significant improvements

Strengths and limitations of this study

- This is the first nationwide survey in Japan on levels of physical activity among breast cancer survivors.
- Because we selected the facilities according to the population distribution of different regions throughout Japan, the results will reflect regional characteristics throughout Japan.
- We chose facilities with a variety of local area population sizes and institutional backgrounds (size, private or public, general or specialised and teaching affiliation); thus, we expect to identify various factors associated with physical activity among breast cancer survivors.
- Physical activity levels may be overestimated because participants who are more interested in physical activity may be more likely to participate in this study.

in early detection and treatment, the 10-year survival rate is about 80% overall and exceeds 90% in patients with localised breast cancer.¹ Among the growing number of survivors with localised breast cancer, improvement of health-related quality of life (HRQOL) after treatment and prevention of recurrence have become a higher priority.

Some healthy behaviours, such as moderate physical activity, a healthy diet and maintenance of a healthy body weight, may lower the risk of recurrence and improve survival.² In particular, a high level of physical activity is related to the extension of healthy lifespan^{3–9} and improvement of HRQOL among breast cancer survivors.^{3–9} Thus, international and Japanese clinical practice guidelines strongly recommend that survivors maintain high levels of physical activity.^{8 10} Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure.¹¹ American Cancer Society guidelines recommend at least 150 min per week of moderate-intensity physical activity (eg, moderate walking or light jogging sufficient

to induce sweating) or at least 75 min per week of vigorous physical activity (eg, jogging or resistance training).¹⁰ 'The Japan Breast Cancer Society Clinical Practice Guidelines for Breast Cancer' recommend at least 60 min per week of moderate-to-vigorous intensity physical activity in addition to the physical activity necessary for daily living.⁸ The reason for the apparent disparity between the recommendations of these two national cancer societies is that the method of setting the standard is group based in the Japanese guidelines and individual based in the American Cancer Society guidelines. For the Japanese general population, the Exercise and Physical Activity Reference for Health Promotion published by the Ministry of Health, Labour and Welfare recommends at least 60 min per week of moderate-to-vigorous physical activity.

However, few breast cancer survivors meet the recommended levels of physical activity. Previous studies in the USA have found that less than half of survivors meet the recommended levels of physical activity in the American Cancer Society guidelines.¹² In Japan, less than half of gynaecological cancer survivors visiting outpatient departments at four hospitals engage in any physical activities in their leisure time.¹³ Approximately 70% of the general population also does not regularly exercise.¹⁴ Exercise is a subset of physical activity that is planned, structured

and repetitive and has the improvement or maintenance of physical fitness as a final or intermediate objective.¹¹ Thus, we assume that few breast cancer survivors exercise regularly and maintain high levels of physical activity. However, no studies have systematically investigated actual activity levels in breast cancer survivors in Japan.

It is important to identify the actual physical activity of breast cancer survivors throughout Japan, including those residing in urban and rural areas, as well as the factors that can promote or impede such activity, because some previous studies outside Japan have shown that whether breast cancer survivors can maintain and improve exercise habits is affected by cultural, environmental and personal factors.^{15 16} In Japan, no studies have identified factors related to the maintenance of exercise habits in breast cancer survivors.

Accordingly, we created a conceptual model (figure 1) based on the PRECEDE-PROCEED model which stands for the Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation - Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development model, a framework used globally in the field of health promotion and public health.^{17 18} This study is a preliminary step in the development of an exercise programme designed to

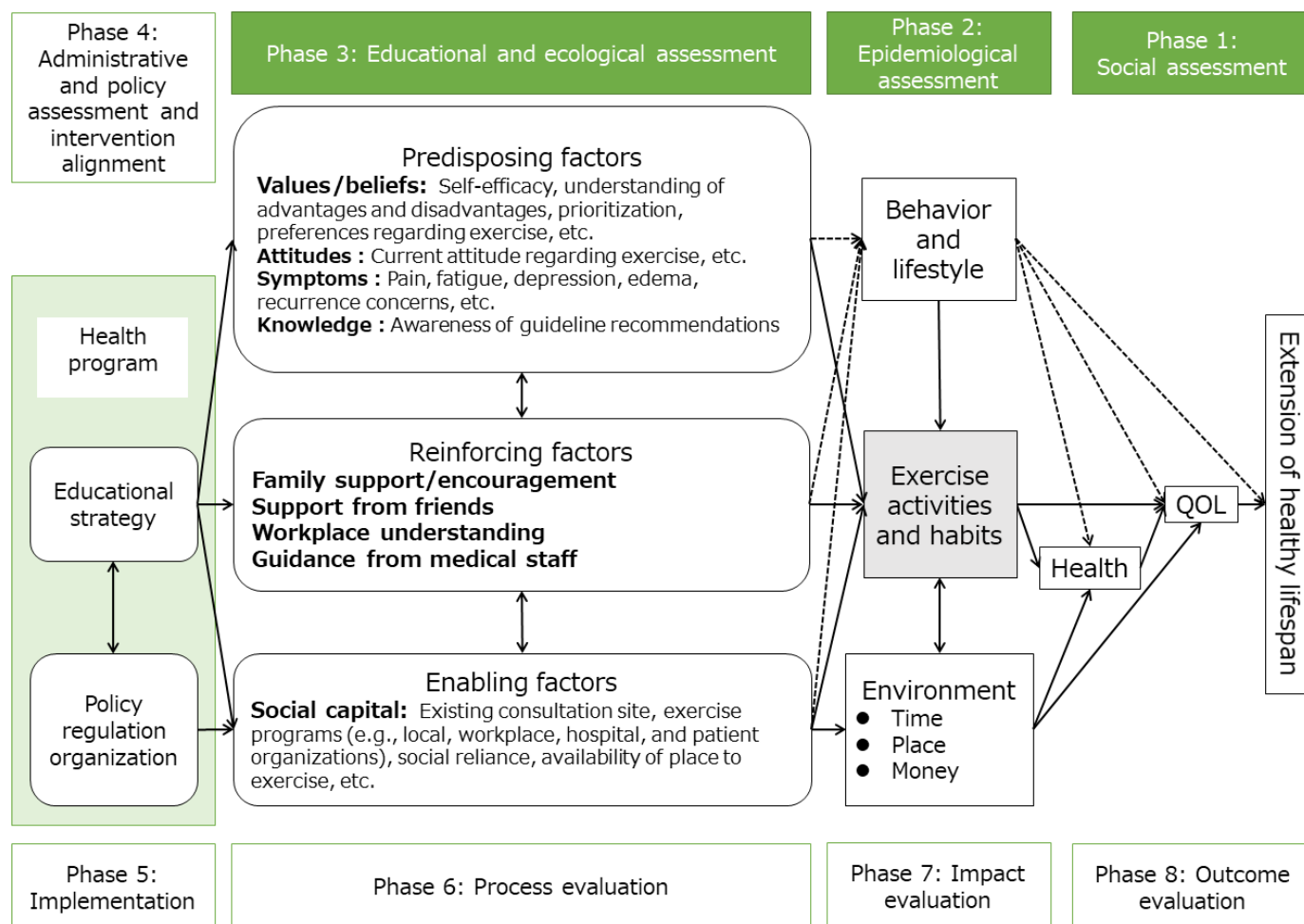


Figure 1 Framework for the study based on the PRECEDE-PROCEED model. Source: Green and Kreuter.¹⁸

empower breast cancer survivors to maintain high levels of physical activity and to determine a pathway for its dissemination and implementation. The study falls under the first to fourth steps of the PRECEDE-PROCEED model. To develop, disseminate and implement-related programmes, it is necessary to identify the factors that impede breast cancer survivors' ability to maintain high levels of physical activity and the factors that make this more likely, in addition to understanding survivors' preferences and interests related to physical activities.

The aims of this study are to identify the levels of physical activity among breast cancer survivors, to examine factors-related physical activity among breast cancer survivors, and to identify breast cancer survivors' preferences for and interest in exercise programmes in order to inform the future programme development.

METHODS AND ANALYSIS

In this study, we will administer survey questionnaires to breast cancer survivors without recurrence or metastasis within 5 years after treatment for breast cancer. Fifty facilities were selected from among the Japanese Breast Cancer Society accredited facilities¹⁹ that conduct more than 100 breast cancer surgeries per year. At the outpatient clinic of each facility, we will consecutively deliver the survey forms by hand to 30 breast cancer survivors who are undergoing outpatient care from the survey start date. The target sample size is 1500 survivors. If they complete the forms, they will send them to the research office by mail.

Operational definitions of terminology

Cancer survivor

According to the National Cancer Institute in the USA, a cancer survivor is 'a person who lives after being diagnosed with cancer. Family members, friends and loved ones are also included as 'survivors', as they too are affected'.²⁰

The American Cancer Society guidelines offer recommendations regarding physical activity levels divided into three stages: the period during treatment, the period immediately after treatment and the period between the immediate post-treatment period and a stabilised state.²¹ The level of physical activity is expected to differ during each of these stages. Consequently, we focus on the post-treatment period, which is expected to be the main target group for the exercise programme that we intend to develop. Thus, we define a breast cancer survivor as 'a person who has completed treatment for breast cancer, other than hormone therapy among their initial treatments performed for curative purposes, without local progression or recurrence (stage 0–IIIa)'.

Maintaining high levels of physical activity

The Breast Cancer Clinical Practice guideline published by the Japanese Breast Cancer Society recommends that breast cancer survivors maintain high levels of physical

activity, which is defined as reporting at least 60 min of moderate-to-vigorous intensity physical activity a week.⁸

Study sites

We selected 50 Japanese Breast Cancer Society accredited facilities that conducted more than 100 breast cancer surgeries from April 2016 to March 2017.¹⁹ Based on the sampling method²² for the public opinion survey on cancer countermeasures by the Japan Cabinet Office, we set 22 stratified categories according to the 11 regions (Hokkaido, Tohoku, Kanto, Hokuriku, Tosan, Tokai, Kinki, Chugoku, Shikoku, KitaKyushu and Minami Kyushu) and population sizes (more than 200 000 people and fewer than 200 000 people) of the cities (and the 23 wards in Tokyo) where facilities are located and decided the number of facilities within each category to match the population distribution. From the list of medical facilities corresponding to each stratified category, facilities were chosen to include a wide variety of institutional backgrounds (size, private or public, general or specialised and teaching affiliation). We will ask each facility to collaborate with this study and to arrange for participants to take the survey.

Participants

We will consecutively recruit 30 breast cancer survivors who meet the selection criteria from designated dates at the outpatient clinic of each of the 50 facilities. The target sample size is 1500 survivors. Eligibility criteria are as follows: (1) diagnosis of primary breast cancer without distant metastasis, (2) no recurrence, (3) ≥ 20 years old, (4) completion of initial treatments other than hormonal therapy for curative purposes and (5) the patient has been informed of a diagnosis of breast cancer. Those who cannot respond to the self-reported questionnaire (written in Japanese) are excluded.

Data collection

In the outpatient clinics of the facilities, attending physicians will hand out a set of materials containing explanatory documents and a survey form to potential participants who meet the selection criteria from the study start dates. They will briefly explain the following: (1) that they should carefully read the letter of intent, (2) that they should not hesitate to contact the research office if they have any questions, (3) that they should tick the agreement column in the questionnaire form if they are able and willing to participate in the survey and (4) that consent is voluntary. If they tick the agreement column, it is considered that appropriate informed consent is obtained. A potential subject will complete questionnaire items independently and send it to the research office. It will take about 40 min to complete the questionnaire.

Survey items

In the questionnaire survey, we will measure background information, physical activity levels, factors related to physical activity levels, awareness of the physical activity recommendations in the breast cancer clinical

practice guidelines, and preferences regarding exercise programmes.

During the preparation of the self-reported questionnaire, we reviewed previous studies and our study group, which consisted of 13 medical personnel and 1 breast cancer survivor, discussed the survey items and our conceptual model (figure 1). We conducted focus group interviews and in-depth personal interviews several times with both medical personnel and breast cancer survivors to explore the associated factors related to breast cancer survivors' physical activity and their preferences for exercise programmes. First, we conducted a focus group interview with medical personnel (two physicians, three nurses and two physical therapists), who had been providing breast cancer survivors with medical care for at least 1 year. Second, we conducted three focus group interviews (two or three breast cancer survivors in each group) and five in-depth semistructured interviews with breast cancer survivors. After recording the interview contents, written transcripts were created. We selected survey items based on the results from qualitative content analysis of these interview data.

After developing the questionnaires, we conducted cognitive checks with five breast cancer survivors to evaluate whether the questions were measuring the construct we intended.

Outcomes

Physical activity

The Global Physical Activity Questionnaire (GPAQ) was developed in 2002 as an internationally standardised questionnaire to investigate levels of physical activity and is widely used in policy development by WHO^{23–26} (table 1). The face validity of the Japanese version of GPAQ has been confirmed.^{27 28} The primary outcome of this study is whether patients' physical activity levels meet the guideline recommendation.

We will also ask about participants' recognition of changes in physical activity levels after diagnosis with a 5-point scale ranging from 'significantly reduced' to 'significantly increased'.

Quality of life

EuroQol 5 Dimension (EQ-5D) is a comprehensive evaluation scale developed by the EQ group established in 1987 to measure HRQOL.^{29 30} We will use the 5-level EQ-5D version, which has improved the instrument's sensitivity and reduced ceiling effects³¹ (table 1). The reliability and validity of the Japanese version have also been confirmed.³² The scale consists of five items, and complete health can be converted to 1 and death to 0 as standardised utility values based on the results.³²

Absenteeism and presenteeism

We will measure absenteeism and presenteeism with the Japanese equivalent of WHO Health and Work Performance Questionnaire Short Form^{33–35} (table 1). The

linguistic face validity of the Japanese version has been confirmed.³⁵

Anticipated factors related to physical activity

Subject background

The following attributes of breast cancer survivors will be examined in the questionnaire: age, sex, height, weight, postal code, educational history, employment status, household income, household composition, child care and long-term care situation, free time, treatment history, years since surgery, history of diseases other than breast cancer, use of oral sleeping pills and use of anxiolytics related to relapse concerns. These questions will all be self-reported.

We will ask about participants' past history of exercise at six different ages. Answers range from 'I did not play sports' to 'I exercised 3 or more times a week.' We will also ask about their healthy lifestyle behaviours. For drinking, smoking and eating habits, we created questions based on questions in the lifestyle questionnaire of the National Health and Nutrition Survey.¹⁴

Symptoms

Fatigue: Cancer Fatigue Scale

The Cancer Fatigue Scale (CFS) is a questionnaire designed to measure fatigue in cancer patients, comprising 15 items regarding the patient's sense of fatigue rated on a 5-point scale, from 'not at all' to 'very much.' The scale consists of three subscales: physical malaise, mental fatigue and cognitive fatigue. The reliability and validity of the CFS have been verified³⁶ (table 1).

Recurrence concerns: Concerns about Recurrence Scale Japanese Version

Respondents' fear of breast cancer recurrence will be measured by the Concerns about Recurrence Scale (CARS). The CARS consists of 30 items and is used to measure the fear of recurrence in breast cancer patients.³⁷ In this study, only four items (overall fear), which are scored on a 6-point scale, will be used as evaluation items. The total score is 4–24 points, and the higher the score, the higher the recurrence fear. The validity of the Japanese version has been confirmed³⁸ (table 1).

Insomnia: Japanese version of the Athens Insomnia Scale

To assess sleep, we will use the Athens Insomnia Scale (AIS), which is an insomnia assessment created by WHO as part of the 'World Sleep and Health Project' that is used globally.³⁹ The answers to the eight questions are digitised, with a total score of 24 points, and a score of 6 points or higher is judged to indicate suspicion of insomnia. The validity of the Japanese version (AIS-J) has been confirmed⁴⁰ (table 1).

Other symptoms related to physical activity: US National Cancer Institute Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events, Japanese Version

Because outcome assessment by patients themselves has become more important, the Patient-Reported

Table 1 Summary information about measurement items

Description	Scale	No of items	Domain/ dimension/attribute	Scaling	Scores to be used in this study	Measurement property
Physical activity level	GPAQ ²³	16 items	Domains 1. Activity at work 2. Travel to and from places 3. Recreational activities 4. Sedentary activity	1. Yes/no question about exercising 2. Free response about time spent exercising	1. Percentage of respondents not meeting guideline recommendation on physical activity 2. Mean or median physical activity using MET-mins per week 3. Time spent in sedentary activities on average per day (mins)	Agreement between GPAQ and accelerometer was moderate for MVPA mins/day ($r=0.48$) and poor for SB ($r=0.19$). ²⁴ Correlations of total questionnaire scores against accelerometer measures were inconsistent ($r=-0.02-0.49$) for women. ²⁶
HRQOL	EQ-5D-5L ^{29,30}	6 items	Dimensions 1. Mobility 2. Self-care 3. Usual activity 2. Pain/discomfort 3. Anxiety/depression	1. 5-point Likert scale of perceived problem 2. VAS	1. Index value converted from EQ-5D-5L descriptive system 2. EQ-VAS score (0–100)	EQ-5D-5L is a valid extension of the 3-level system and improves on the measurement properties, reducing the ceiling, improving discriminatory power and establishing convergent and known-groups validity. ³¹
Lost work productivity: absenteeism and presenteeism	WHO-HPQ ³³	8 items	Domains 1. Absenteeism 2. Presenteeism	1. Semantic differential scale (0–10) 2. Free response about time	1. Combining relative absenteeism and presenteeism 2. Absolute absenteeism/relative absenteeism 3. Absolute presenteeism/relative presenteeism	Comparing WHO-HPQ self-reported presenteeism with independent employer records of job performance showed statistically significant monotonic associations across a range of occupations. Data are presented on the accuracy of WHO-HPQ measures, showing that WHO-HPQ has excellent reliability, validity and sensitivity to change. ³⁴
Cancer-related fatigue	CFS ³⁶	15 items	Domains 1. Physical fatigue 2. Affective fatigue 3. Cognitive fatigue	5-point Likert scale (1–5)	1. Total score (0–60) 2. Scores of each domain	Construct validity, confirmed by repeating factor analysis, was good. Convergent validity, confirmed by a correlation between CFS and a VAS for fatigue, was also good ($r=0.67$, $p<0.001$). The CFS had good stability (average test–retest reliability $r=0.69$, $p<0.001$) and good internal consistency (Cronbach's α for all 15 items was 0.88). ³⁶
Fear of cancer recurrence	Overall fear subscale of CARS-J ³⁸	4 items	N.A.	Semantic differential scale (1–6)	Total score (4–24)	Correlation between CARS-J and Hospital Anxiety and Depression Scale was 0.39–0.60. Cronbach's α was 0.86–0.94. ³⁹
Insomnia	AIS-J ⁴⁰	8 items	Domains 1. Nocturnal sleep problems 2. Daytime dysfunction	4-point Likert scale (0–3)	1. Total score (0–24) 2. Percentage of respondents whose total score was 6 points or higher	Cronbach's α was 0.78–0.88. Correlations between the AIS-J and the Pittsburgh Sleep Quality Index and Insomnia Severity Index were 0.81 and 0.85, respectively. Scores on the AIS-J were significantly higher for the insomnia group than for the control group. ⁴⁰
Symptoms related to cancer treatments	PRO-CTCAE-J ^{43,44}					

Continued

Table 1 Continued

Description	Scale	No of items	Domain/ dimension/attribute	Scaling	Scores to be used in this study	Measurement property
Pain in joints (elbows, knees, shoulders)	Pain in joints (elbows, knees, shoulders)	3 items	Attributes 1. Frequency 2. Severity 3. Interference	5-point Likert scale (0–4)	Presented descriptively	Mean (SD) ICC of overall reproducibility for the Japanese PRO-CTCAE was 0.63 (0.02). Correlation coefficient for the corresponding items in the EORTC QLQ-C30 and the Japanese PRO-CTCAE was high (Pearson $r=0.56-0.76$). Responsiveness analysis revealed significant dose–response trends (Jonckheere–Terpstra test, $p<0.001$). ⁴³
Numbness in limbs	Numbness in limbs	3 items	Attributes 1. Frequency 2. Severity 3. Interference	5-point Likert scale (0–4)	Presented descriptively	
Swelling of arms	Swelling of arms	2 items	Attributes 1. Severity 2. Interference	5-point Likert scale (0–4)	Presented descriptively	
Feeling depressed no matter what	Feeling depressed no matter what	3 items	Attributes 1. Frequency 2. Severity 3. Interference	5-point Likert scale (0–4)	Presented descriptively	
Stage of change in the trans-theoretical model	Stages of change scale for exercise behaviour ^{46,47}	1 item	N.A.	5-point scale (1–5)	Presented descriptively	Scale has good 2 weeks test–retest reliability ($\kappa=0.75$, $n=136$). ⁴⁷ As the stage of change progressed, self-reported levels of physical activity and exercise practice tended to increase. ⁴⁷
Perceived social support for exercise habits	Exercise-related social support scale ⁴⁸	5 items	N.A.	5-point scale (1–5)	Total score (5–25)	Reliability (Cronbach's $\alpha=0.86$) and construct validity (AGFI=0.93, RMSEA=0.07) have been confirmed in Japanese adults. ⁴⁸
Perceived support from formal relationships (exc. medical staff)	Scale measuring human support from formal relationships ^{49,50}	6 items	Domains 1. Encouragement 2. Inhibitory 3. Intervention	5-point scale (1–5)	Scores of each domain (5–15 in each domain)	Cronbach's $\alpha=0.65-0.72$. Scale's construct validity (AGFI=0.98, RMSEA=0.03) has been confirmed in elderly Japanese adults. ^{49,50}
Degree of psychological resilience	RS 14 ⁵²	14 items	N.A.	7-point scale (1–7)	Total score (14–98)	Japanese version has psychometric properties with high internal consistency (Cronbach's $\alpha=0.88$) and test–retest reliability (ICC=0.84). ⁵³

AGFI, adjusted goodness of fit; AIS-J, Japanese version of the Athens Insomnia Scale; CARS-J, Concerns about Recurrence Scale Japanese Version; CFS, Cancer Fatigue Scale; EQ-5D, EuroQol 5 Dimension; EQ-5D-5L, Euro-QOL-5 Dimensions-5 Levels; EQ-VAS, EuroQol Visual Analogue Scale; GPAQ, Global Physical Activity Questionnaire; HRQOL, health-related quality of life; ICC, intraclass correlation coefficient; MET, metabolic equivalent; MVPA, moderate-to-vigorous physical activity; N.A., not applicable; PRO-CTCAE-J, Japanese version of the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events; RMSEA, root mean square error of approximation; RS 14, Resilience Scale 14; SB, sedentary behaviour; VAS, Visual Analogue Scale; WHO-HPQ, WHO Health and Work Performance Questionnaire Short Form.

Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) has been developed, and its reliability and validity have been confirmed.^{41 42} The validity of the Japanese version of the PRO-CTCAE (PRO-CTCAE-J) has also been confirmed^{43 44} (table 1). PRO-CTCAE-J consists of 78 adverse event items, but it is possible to use adverse events partially as needed, and for this study, a relationship has been observed between physical activity in breast cancer survivors and ‘pain in joints (elbows, knees, shoulders)’, ‘numbness in limbs’, ‘swelling of arms’ and ‘feeling depressed no matter what’.⁴⁵

Subject characteristics of exercise behaviour

Stages of change scale for exercise behaviour

The reliability and validity of the scale developed to measure the stages of change in exercise behaviour based on the transtheoretical model of behavioural change has been confirmed.^{46 47} The patient is instructed to consider personal experiences of and attitudes towards exercise over the past 6 months and choose from a range of options: ‘1. I currently exercise regularly; I have been doing so for more than 6 months’ to ‘5. I am not exercising, and I will not do so in the future.’ Results are classified as a ‘period of indifference’, ‘period of interest’, ‘preparation period’, ‘execution period’ and ‘maintenance period’ (table 1).

Exercise-related Social Support Scale

The Exercise-related Social Support Scale consists of five items (one factor), such as ‘family and friends give advice and guidance on how to exercise,’ scored on a 5-point Likert scale from ‘completely agree (5)’ to ‘completely disagree (1)’ and its reliability and construct validity have been confirmed in Japanese adults⁴⁸ (table 1).

Scale measuring human support from formal relationships

This is a scale measuring the support received from formal relationships, such as with physicians and nurses, that participants have experienced in the past year. The scale consists of six items scored on a 5-point scale from ‘not at all’ to ‘very much.’ The scale’s reliability and construct validity has been confirmed in elderly Japanese adults^{49 50} (table 1).

Self-efficacy for some exercise programmes

We will examine the degree of participants’ confidence that they can perform possible future exercise programmes. They will choose from ‘(1) I do not think so’ to ‘(5) I very much think so.’

Preferences for exercise programmes

Questions about existing programmes and consultation sites

We will ask about questions about participation in existing programmes and consultation sites in free-response form. We will also ask questions using items similar to those in past overseas studies^{16 51} about participants’ preferences for exercise programmes.

Others

Questions regarding the Japanese Breast Cancer Clinical Practice guidelines

We will ask if they know about the recommendations and the level of evidence for physical activity in Japanese breast cancer clinical practice guidelines.

Resilience Scale 14 Japanese version

Resilience Scale consists of 14 items that are rated on a 7-point Likert scale to measure degree of psychological resilience.⁵² The Japanese version has psychometric properties of reliability and validity⁵³ (table 1).

Beliefs about healthy lifestyles

We will ask about the participants’ beliefs about healthy lifestyles and risk of cancer recurrence through four items, which have been prepared with reference to the question items⁵⁴ in the Health Information National Trends Survey (HINTS Survey), regularly conducted by the Division of Cancer Control and Population Sciences of the National Cancer Institute of the USA. These items are reported on a 4-point Likert scale from ‘strongly agree’ to ‘strongly disagree’.

Data analysis

Statistical analysis

We will calculate descriptive statistics for the physical activity levels of breast cancer survivors and each measurement item. To identify factors related to meeting the physical activity recommendations, we will perform logistic regression analysis using whether the participants meet recommended physical activity levels as an outcome variable. After performing univariate logistic analysis for each potential-related factor as an explanatory variable, we will perform logistic regression analysis with all related factors as explanatory variables using backward technique by the F-test to identify the significant factors.

Additionally, multiple regression analysis will be also performed with physical activity levels, symptoms and background information as explanatory variables and absenteeism/presenteeism and HRQOL as outcome variables using backward elimination by the F-test to identify significant factors.

A $p < 0.05$ for two-sided tests will be considered significant, and we will perform the analysis using SAS V.9.4 (SAS Institute). We will use multiple imputation to handle missing values.

Sample size estimation

The proportion of people with established exercise habits in the National Health and Nutrition Survey in 2008 was 20%–40%¹⁴; thus, the percentage of breast cancer survivors who have recommended levels of physical activity is as assumed to be approximately 20%. We calculated the number of samples required to estimate the proportion with margins of error of $\pm 2.5\%$ ($\alpha = 0.05$, 984 people). Therefore, the questionnaire must be distributed to 1500 people if the effective response rate is assumed to be about 70%. Fifty facilities are scheduled to be contacted

for cooperation and 30 people at each facility will be given the questionnaire.

A sample size of at least 200+ ($20 \times$ number of explanatory variables) is required for multiple regression analysis.⁵⁵ We will perform logistic regression analysis with about 25 explanatory variables and multiple regression analysis with about 15 explanatory variables. We calculated the required sample size as $200 + (20 \times 25) = 700$. Thus, the target sample size (1500 people) is estimated to be sufficient for logistic analysis.

Patient and public involvement statement

We involved a breast cancer survivor in the design of this study protocol as a researcher and coauthor. She discussed issues with other survivors in instances where survivors' preferences and opinions should be considered. In the process of developing the research items, 13 breast cancer survivors informed us of their experiences, priorities and preferences through focus group interviews and in-depth personal interviews. We conducted cognitive checks and a preliminary confirmation of the feasibility, safety and burden of the questionnaires with five breast cancer survivors.

Dissemination

We will present our findings at medical conferences and submit the results obtained for publication in a peer-reviewed international journal.

DISCUSSION

This study is Japan's first nationwide cross-sectional survey of physical activity in breast cancer survivors. This study is intended to identify the physical activity levels and the factors related to those in Japanese breast cancer survivors. Identifying the associated factors will help us to develop, disseminate and implement programmes to encourage more breast cancer survivors to develop exercise habits and to maintain high levels of physical activity.

It is important to identify the actual physical activity of breast cancer survivors throughout Japan, including those residing in urban and rural areas, as well as the factors that can promote or impede such activity. Factors associated with maintaining and improving exercise habits may vary by culture, environment and survivors' backgrounds. According to a qualitative study by Hefferon *et al*, age, cancer treatments, existence of comorbidities, fatigue, occupational status, women's traditional roles (household chores, nursing care, etc), poor access to exercise facilities, and seasonal weather changes are factors that could reduce the likelihood of maintaining exercise habits.¹⁵ In addition, according to a telephone interview survey about barriers to exercise habits carried out by Ottenbacher *et al*, lack of time, lack of motivation, being discouraged by bad weather, hesitance to exercise alone and feeling as if there is no suitable space to exercise have been highlighted as barriers to exercise.¹⁶ There may be factors specific to Japan, in particular, walking distances

in Japan are generally longer due to the development of public transportation facilities in Japan compared with the largely car-oriented societies seen in Europe and the USA. However, while dense urban populations in Japan use public transportation, there are still many situations where people travel by car, particularly in rural areas.

If this study reveals that breast cancer survivors have low physical activity, it will be necessary to develop, disseminate and implement programmes based on the associated factors, which will be identified in order to encourage more survivors to acquire exercise habits and to maintain high levels of physical activity.

This study has several strengths and limitations.

Strengths

The first strength is that participants are recruited according to the population distribution of different regions throughout Japan. Therefore, the results will reflect regional characteristics, including cultural, social, ecological and environmental aspects, throughout Japan. The second is that differences can be evaluated based on both institutional backgrounds (size, private or public, general or specialised and teaching affiliation) and the surrounding environment because we selected facilities with various backgrounds from rural and urban areas.

Limitations

The first limitation is that participants who are interested in physical activity may participate and complete questionnaires more readily than those who are not; thus, the study may overestimate physical activity levels. The second is that use of a self-reported measure of physical activity may overestimate or underestimate participants' physical activity. Previous studies have found that the correlations of total questionnaire scores against accelerometer measurements were inconsistent ($r = -0.02$ – 0.49) for women²⁶ and that there was moderate agreement between GPAQ and accelerometer measurements for moderate-vigorous physical activity (mins/day) and poor agreement for sedentary behaviour.^{24 26} Cleland *et al* reported that the higher validity of GPAQ in higher-income countries was likely due to high education levels.²⁴

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