BMJ Open

Digitally distributed Yoga Intervention in Breast Cancer Rehabilitation (DigiYoga CaRe): protocol for a randomised controlled trial

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To cite: Ohlsson Nevo E, Arvidsson-Lindvall M, Hellerstedt Börjeson S, *et al*. Digitally distributed Yoga Intervention in Breast Cancer Rehabilitation (DigiYoga CaRe): protocol for a randomised controlled trial. *BMJ Open* 2022;**12**:e065939. doi:10.1136/bmjopen-2022-065939

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-065939).

Received 23 June 2022
Accepted 10 October 2022

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ABSTRACT:

Introduction Breast cancer is the most prevalent cancer among women. The treatment is extensive; in addition to surgery, various combinations of radiation therapy, chemotherapy and antibody and endocrine treatment can be applied. Cancer-related fatigue (CRF) is high in patients with breast cancer, peaking during chemotherapy, but may persist for several years. Physical activity has proven to be effective in reducing CRF in breast cancer rehabilitation, but many patients tend to be less active after the diagnosis. Yoga has a previously demonstrated effect on energy levels and digitally distributed yoga intervention can potentially increase accessibility in pandemic times and facilitate participation for patients susceptible to infection and those living far from organised rehabilitation opportunities. The purpose of this study, Digital Yoga Intervention in Cancer Rehabilitation (DigiYoga CaRe) is to investigate whether a 12-week digitally distributed yoga intervention can reduce CRF and stress, improve health-related quality of life (HRQL) and affect pro-inflammatory and metabolic markers in patients with breast cancer.

Methods and analysis This multicentre study will adopt a randomised controlled design including 240 persons after their breast cancer surgery. They will be randomised to a 12-week digitally distributed yoga intervention or to a control group. The intervention group practice yoga two times a week, one yoga class live-streamed to the patient's computer or mobile device and one prerecorded video class for self-training. The controls receive standardised care, gift cards for flowers and access to yoga video links after the data collection has ended. The primary analysis will be performed following the principle of intention to treat. Data will be collected by questionnaires, blood samples, accelerometers and interviews.

Ethics and dissemination The DigiYoga CaRe study was approved by the Regional Ethical Review Board in Lund. The final results of this study will be disseminated to conference, patient and public involvements and peer-reviewed publications.

Trial registration number NCT04812652.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The overall strengths of the Digital Yoga Intervention in Cancer Rehabilitation (DigiYoga CaRe) study is in the randomisation and multimethod approach of collecting data including validated standards for reporting.
⇒ The digital format of this multicentre study enhances the fidelity to the intervention since all 120 participants will be instructed by the same team of yoga instructors.
⇒ The digitally distributed yoga intervention developed within the DigiYoga CaRe study is inclusive, innovative and highly relevant in the 20th century.
⇒ The pilot study gave the research team valuable information regarding the design of the yoga program, intervention fidelity and technical issues that were improved before the main study started.
⇒ A limitation is that adherence to the home training by video will be self-reported.

INTRODUCTION

Breast cancer is the most prevalent cancer among women, with more than 1.7 million cases each year.[1] The treatment is extensive; in addition to surgery, various combinations of radiation therapy, chemotherapy, antibody and endocrine treatment can be applied. Cancer-related fatigue (CRF) is a subjective state of overwhelming, sustained of physical, emotional and cognitive tiredness exhaustion related to cancer that is not relieved by rest.[2]

The prevalence of moderate to severe fatigue in persons treated for breast cancer is approximately 50% and more than 25% continue to experience severe fatigue following primary cancer treatment.[3]

Fatigue levels in breast cancer peak during chemotherapy[4] but may persist for several years.[5 6]

The underlying causes of CRF are unclear,[7] although proinflammatory cytokines appear to have an important role.[7]

Exercise and non-pharmaceutical therapies have been shown to be effective in reducing CRF.[8 9] Stress may reduce the engagement in exercise[10] and could explain inactivity of patients with cancer. The barriers for exercise that may hinder adoption and adherence to cancer rehabilitation programmes are low confidence in the benefits of exercise and lack of experience prior the diagnosis.[11]

Yoga can be beneficial in relieving fatigue, an health-related quality of life, both during and after cancer treatment[9 12] and has proven to be a sought-after form of rehabilitation in women treated for breast cancer.[13]

Yoga

The three main tools of yoga-based practices are body, breath and mind.[14] Typically, they involve a combination of movement sequences, conscious regulation of the breath and various techniques to improve attentional focus.[14] Yoga is often used in prevention and treatment with the main goal of optimising health and reducing stress. Yoga holds potential to improve autonomic, emotional and cognitive regulation and thereby generate measurable changes in physiological parameters, perceived emotional states and cognitive functioning.[14] For stressed, physically inactive adults, yoga has been proven to increase general health, self-efficacy and energy and to decrease fatigue and perceived stress.[15] Slow breathing increases a state of mental relaxation and harmonises the functions of several brain regions related to emotions, cognition and movement.[16 17] Hormonal functions and the state of arousal are also influenced by conscious breathing, and therefore, regular yoga practice may improve the quality of sleep and reduce fatigue by balancing the brain processes that regulate sleep and arousal.[16 17] Yoga has also been shown to have an anti-inflammatory effect, both in general[18] and in cancer.[19–21]

For patients with breast cancer, yoga has significant effects on fatigue,[22] sleep and health-related quality of life (HRQoL)[23 24] and better effect on anxiety and fatigue compared with other psychosocial interventions.[24] A possible mechanism for these effects are the breath, movement and attention components in yoga that may engage the vagal afferent system, basal ganglier and cerebellar circuits, with a possible effect on autonomic, emotional and cognitive regulation.[14]

There are hitherto only few studies that evaluate the effect of yoga in patients with breast cancer where the instructions have been digitally distributed.[25–27] The conclusions of the studies were that accessibility increased, but that there were technological barriers to overcome.

Rationale

The prevalence of CRF is high in patients with breast cancer, providing motivation to find suitable interventions that can reduce fatigue and increase the level of physical activity. A digitally distributed yoga intervention can potentially increase accessibility for patients susceptible to infection and those living far from organised rehabilitation opportunities.

The purpose of this randomised controlled study, Digital Yoga Intervention in Cancer Rehabilitation (DigiYoga CaRe), is to investigate whether a 12-week digitally distributed yoga intervention can reduce CRF and improve HRQoL.

The primary aim is to investigate the effect of digitally distributed yoga compared with results for a control group receiving standard care regarding CRF.

Secondary aims are to

1. Investigate the effect of digitally distributed yoga compared with a control group receiving standard care regarding physical activity level, HRQoL and stress.
2. Investigate the effect of yoga on systemic inflammatory responses.
3. Evaluate the cost effectiveness of digitally distributed yoga intervention from a societal perspective, including number of sick days and time to return to work.
4. Investigate compliance as receipt of planned cycles of chemotherapy and early discontinuation of the initial adjuvant endocrine therapy within 2 years after start.
5. Describe the feasibility of a digitally distributed yoga intervention regarding attendance, technical solutions and procedures.
6. Describe the subjective experience of participating in the digitally distributed yoga intervention from home.

METHOD AND ANALYSIS

Study design and setting

DigiYoga CaRe is a randomised controlled multicentre study where the patients are randomised to a 12-week digitally distributed yoga intervention in addition to standard care (intervention group) or to standard care alone (control group). The DigiYoga CaRe study adheres to the standard methodology of interventional research and this protocol is conducted according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.[28] The study will be reported according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines[29] and the COREQ (Consolidated Criteria for Reporting Qualitative Research).[30]

Patient and public involvement statement

A patient representative with personal breast cancer experience has been a member of the research group since the start of the project. She is involved in design of the yoga programme, in educating the yoga instructors, recruiting patients and participating in the monthly project meetings for DigiYoga CaRe. The relevance of the study and the design was enhanced by capturing the views of the patients that participated in the pilot test of the intervention. They provided additional input leading to adjustment of design and data collection.

Characteristics of participants

Patients diagnosed with breast cancer and who have undergone surgery are consecutively recruited from the hospitals in three cities in Sweden, started October 2021. From January 2022, recruitments through national social media and traditional advertising were possible. The recruitment is ongoing and expected to continue throughout 2023.

Inclusion criteria

Adult women who are literate and understand Swedish and have been diagnosed with breast cancer and undergone breast cancer surgery with curative intention without any signs of metastatic disease (axillary clearance is acceptable). The inclusion take place within 60 days after the surgery and after the regular follow-up visit after the surgery, before the start of chemotherapy.

Exclusion criteria

Patients receiving neoadjuvant treatment, patients with advanced metastatic breast cancer, those with unstable cardiovascular disease and patients who are unable to complete the questionnaires due to reduced physical or cognitive capacity. Patients having any physical condition that hinders participation in yoga, or an unstable medical condition that might be aggravated by yoga, will also be excluded.

Sample size estimation

The sample size calculation is based on the primary outcome of CRF as will be measured by *Multidimensional Fatigue Inventory*. The target main effect size is determined to be an improved fatigue score of 2[31] on a scale between 4 and 20,[32] in accordance with the minimally clinically important difference. For a two-sided test with α=0.05 and 1 – β=80% to detect a factorial effect of 2 under the null hypothesis of no effect, 64 individuals in each group will be needed. To compensate for a potential 30% dropout, the sample size will be increased with an additional 39 participants, giving a total sample size of 167 patients. To detect interaction effects, which are usually smaller than the main effect, the original sample size will be increased by 73 patients. This gives a total of 240 patients divided into two arms by a 1:1 randomisation ratio of intervention to control.

Randomisation

The patients are randomised in a web-based digital portal ('Smart Trial') to either the yoga intervention or control group (figure 1). The randomisation is stratified according to if adjuvant chemotherapy used (yes vs no), use of adjuvant endocrine therapy (yes vs no). The allocation is given the participants by email.

Yoga intervention

The digitally distributed yoga intervention will start after the regular follow-up visit after surgery, within 60 days from the surgery.

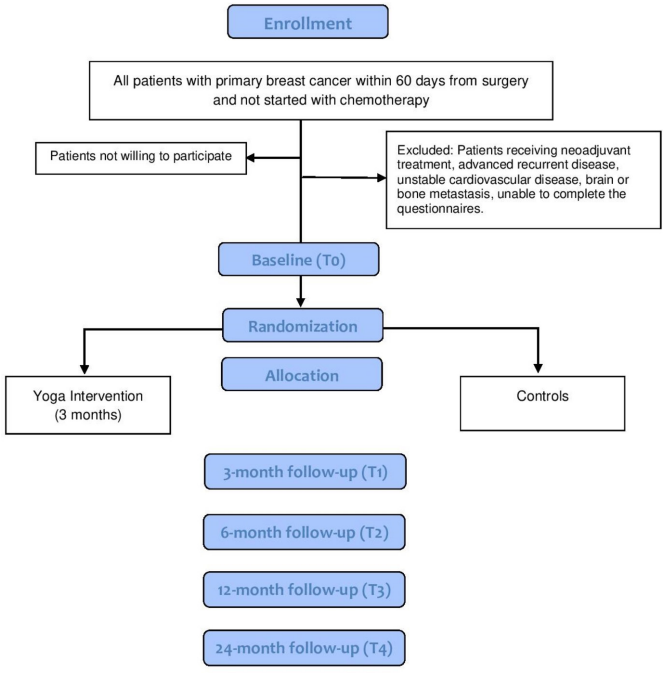

Figure 1 Trial profile (CONSORT). Enrolment, allocation and time for follow-up. CONSORT, Consolidated Standards of Reporting Trials.

To minimise the ambiguities in design found in previous studies, the yoga intervention is designed according to Sherman's recommendations.[33]

The yoga postures and movements are chosen specifically to address this group of patients.

1. Type of yoga: Physical yoga sequences proven to be effective and relevant for the target group, ending with relaxation and time for reflection (see table 1).
2. Dose: Two times a week for 12 weeks; one yoga class live-streamed via Zoom (videoconferencing software) to the patient's computer or mobile device, and one prerecorded video for self-training.
3. Components of yoga: The yoga class will follow standardised programmes with yoga sequences designed to increase energy levels, reduce fatigue, increase calmness and improve focus and acceptance. During the 12-week intervention period, two different programmes will be offered for 6 weeks each, programme 1 and programme 2, as described in table 1.
4. Sequences: The yoga class (in both programmes) will be 60 min including 10 min of relaxation. After the yoga practice at the live-streamed sessions, the instructor will open up for a short voluntary reflection in the group, approximately 5 min. Each live-streamed group will include 2–15 participants.
5. Modifications: Alternatives and modifications of yoga movements will be offered by the instructors at the live-streamed yoga class, based on the individual needs of the participants in the group. In the prerecorded videos, the instructors present several levels of modifications throughout the programmes whenever relevant.

Table 1 The 60 min yoga intervention in the DigiYoga CaRe study: programmes 1 and 2

Minutes	Sanskrit (reference)	Description
Programme 1		
8	Savasana[20 41–43] Deerga Swasam[20]	Corpse pose Conscious breathing: Three-part breath
4	Supported Setu[20 41–43]	Supported bridge/shoulder bridge Modification: Setu Bandha Sarvangasana, half bridge pose
5	Pavana Muktasana[20]	Wind relieving pose Modification: One or two legs
3	Paschimottanasana[20 41]	Seated forward bend Modification: On chair
1	Tadasanak[20]	Mountain pose
10	Adho Mukha Svanasana[20] Chaturanga Dandasana[20] Urdhva Mukha Svanasana[43]	Downward-facing dog Four-limb staff pose at wall Upward-facing dog at wall or chair Modification: Different positions possible for this sequence: on the mat, on a chair or standing facing a wall
5	Vrksasana[41]	Tree pose: Balance Modification: Foot position variations
3	Balasana[20]	Child's pose Modification: Arms in different poses
3	Bhujangasana[20]	Sphinx pose Modification: Forearms/hands to floor
8	Shava Udarakarashasnana[20 43]	Universal spinal twist (left and right) Modification: Jathara Parivartanasana
10	Savasana[20 41–43]	Corpse pose; Relaxation
5		Reflection (voluntary)
Programme 2		
6	Savasana[20 41–43] Deerga Swasam[20]	Corpse pose Conscious breathing: Three-part breath
2	Supported Setu Bandasana[20 41–43]	Supported bridge/shoulder bridge Modification: Setu Bandha Sarvangasana, half bridge pose
2	Active Setu Bandha[20]	Half bridge pose, progression with hands over head Modification: Rest the arms
8	Ardha Matsyendrasana[20 42 43]	Sitting half spinal twist (left and right)
6	Marjarasana[20 41]	Cat and cow
4	Marjariasana[41]	Diagonal static yoga cat
3	Balasana[20]	Child's pose Modification: Arms along the body
1	Tadasana[20]	Mountain pose
6	Urdhva Hastasana[42] Urdhva Baddhanguliyasana[42]	Raised hands pose, arms parallel, hands facing each other Raised hands pose, if possible palms together overhead Modification: On toes
4	Prasarita Padottanasana[20]	Wide-legged forward bend Modification: Use chair
4	Viparita Karani[20 42 43]	Legs up the wall
4	Supta Badha Konasana[42]	Reclining bound angle pose (butterfly)
10	Savasana[20 41–43]	Corpse pose; Relaxation
5		Reflection (voluntary)

Also, as a more advanced alternative, the participants can chose a video without modifications.

6. Selection of instructors: The yoga instructors have previous experience of teaching yoga; they are registered yoga teachers with 100–200 hours of training. They have attended a 1 day course led by the research team, consisting of lectures and seminars about breast cancer and breast cancer treatment; the aim and design of the study; theory and instructions regarding the yoga programmes, including modifications and technical aspects regarding digital distribution of the intervention.

7. Home practice: The participants are expected to practice the yoga programme individually once a week in addition to the instructor-led group yoga class. The intervention comprises yoga at home two times a week; one live-streamed session in group and one individual session following a prerecorded video. The participants will not receive instructions of extra home practicing in addition to these two sessions but have access to the video-links and self-registered number of sessions weekly during the intervention will be evaluated.
8. Presence over time: Adherence to the live-streamed yoga intervention is noted by the instructors and reported to the research team, and adherence to the video home training will be self-reported by questionnaire. Adherence to activity will be calculated as the number of patients fulfilling 65% of the sessions, divided by the total number of patients in the group. Attendance rate over the intervention period will be calculated as a mean of the individual percentage.

Participants are expected to use their own computers or mobile devices. The streaming is arranged through Zoom, with end-to-end encryption (E2EE). Written basic information together with instructions on how to connect to the streamed live yoga class are provided. Participants will be given an opportunity to test the digital connection before start. aPersonal guidance and support is available by phone twice a week and before the start of each yoga session. The yoga practice does not require any special equipment but the participants are encouraged to use a soft mat (yoga mat if they have), blankets, pillows and if needed a chair and a big book (or yoga block if they have). When the 12 weeks have ended, the intervention participants will receive a letter with encouragement to keep practicing two times a week to the videos if they wish to.

Control group

All participants in the study receive standard care, which includes written standardised information in their personal care plan, provided to all patients with breast cancer in Sweden. This includes exercise instructions and information about the importance of physical activity. Participants in the control group receive a gift card for flowers after each completed follow-up, and moreover, get access to the yoga video links after the data collection has ended.

Data collection

Data are collected at baseline and at 3, 6, 12 and 24 months after study inclusion (table 2).

Instruments for patient-reported outcomes

Self-reported data are collected at all follow-up time points.

The *Multidimensional Fatigue Inventory* (MFI) is a 20-item self-reported questionnaire including five subscales: general fatigue, physical fatigue, mental fatigue, reduced activity and reduced motivation.[32] MFI was originally designed for use in patients with cancer. The responses to each item are captured with a five-point Likert scale, ranging from 1 (yes, this is true) to 5 (no, this is not rue). A total score is calculated for each scale by summation of the individual item scores, that range from 4 to 20.

The *Perceived Stress Scale (PSS*) measures general stress and coping capabilities. The instrument is validated on a Swedish population and has 14 questions.[34] PSS measures

Table 2 Enrolment and outcome measurements in DigiYoga Care

	Enrolment	Allocation	Postallocation				
TIMEPOINT**	$-t_1$	0	t_1 3 mon	t_2 6 Mon	t_3 12 Mon	t_4 24 Mon	
Eligibility screen	x						
Informed consent	x						
Randomisation	x						
Yoga intervention		x	x				
ASSESSMENTS:							
Blood samples	Proinflammatory and metabolic markers	x	x	x			
Fatigue	MFI	x	x	x	x	x	
Health economic evaluation	EuroQol-5 (EQ-5D-5L)	x	x	x	x	x	
Health-related quality of life	EORTC-QLQ30 –BR23	x	x	x	x	x	
Stress	PSS	x	x	x	x	x	
Physical activity	Accelerometer	x	x	x	x		
General measurements	Body length, weight and heart rate	x			x		
Medical and clinical background data	Treatment, dose intensity, toxicity, comorbidity, disease recurrence, death, sick days and return to work						x

MFI, Multidimensional Fatigue Inventory; PSS, Perceived Stress Scale.

the degree to which one finds life unpredictable, uncontrollable and overloading. Participants are asked to rate items on a 5-point Likert scale of Never to Very Often.

EORTC-QLQ30-BR23 measures generic HRQoL and comprises 30 items grouped into six functional scales: Global health status, Physical functioning, Role functioning, Emotional functioning, Cognitive functioning and Social functioning, and the symptom scales nausea, pain, dyspnoea, insomnia, loss of appetite, constipation and diarrhoea.[35] The instrument determines which score change magnitude corresponds to change defined by the patient as significant. All scales and single items are transformed into scores ranging from 0 to 100. For functional scales and global QOL, a higher score suggests a better level of functioning, while a higher score suggests more severe problems when it comes to symptoms.[35]

BR-23 is the breast cancer specific module with 23 additional items.

EuroQol-5 (EQ-5D-5L) is a generic standardised instrument to measure HRQoL in health economic analysis. It is instrument for assessing the quality of life in relation to health and covers five aspects: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each aspect has five levels (5L) ranging from no problem to extreme problems.[36 37]

Additional measures/data collection

Assessment of physical activity are conducted at baseline and at 3, 6 and 12 months after study inclusion. The primary analysis will be performed following the principle of intention to treat measured to identify changes in activity level that may be an effect of reduced fatigue and increased energy levels. Measurement is carried out with an accelerometer (advanced pedometer) for 7 days on four occasions. Data on physical activity will be combined with body weight to calculate energy expenditure, complemented with a diary for the same time period that describes the type of activity.

Blood samples (see table 2). The following analyses are planned: proinflammatory and inflammatory markers (IL-1, IL-1β, IL-8, IL-12, serum Hs CRP, TNF-α, sTNFRII, fibrinogen) and metabolic markers (IGF-1, IGF-II, B-HbA1C, leptin, adiponectin). Blood sample will be frozen and saved in a biobank and later analysed by commercially available ELISA kits.

Medical and clinical background data will be collected from the medical records covering administered treatment, dose intensity, toxicity and adverse events according to US National Cancer Institute Common Terminology Criteria for Adverse Events 4.0 (NCI-CTCAE) as well as any disease recurrence or death due to any cause. From the statistical and result database (STORE) managed by the Swedish Social Security Agency, data on sick days and return to work will be collected. Comorbidity will be calculated according to the Charlson Comorbidity Index.[38]

General measurements: Body length, weight and heart rate are measured according to standard routines at baseline and after 12 months.

Health economic evaluation

The health economic evaluation will be performed with a societal as well as a healthcare perspective and will consider the time period from baseline to 1 year after the interventions have ended. All relevant costs and benefits of the intervention will be taken into account. Cost effectiveness will be presented in costs per quality-adjusted life years, and also as a probability of cost effectiveness compared with usual care.

Individual interviews

The experience of participating in the digitally distributed yoga intervention will be described using qualitative content analysis in which 20 patients are interviewed about their experience of participating in the yoga intervention. The interviews will be conducted within 1 month after ending the class and will be transcribed verbatim and then analysed with qualitative content analysis. An interview guide will be used, covering experiences of the yoga intervention, reflections on the digital format, structure of home training as well as how the intervention influenced their everyday life. The data collection will take place at a venue of each participant's choice.

Pilot study

In spring 2021, a pilot study with the DigiYoga CaRe concept was conducted. Five patients who had undergone breast cancer surgery in a curative attempt participated for 4 weeks. At the end of the intervention, a focus group discussion explored the experience of participation in the yoga programmes (both live-streamed and prerecorded video), the technical solutions, and the questionnaires.

The pilot study participants comprised both beginners and individuals with previous experience of yoga practice, and baseline data indicated a variation in how the participants reported their t HRQoL. The result of the pilot study show that the intervention was well received by all participants.

Regarding the intervention, the digital format was experienced as convenient and easy to access, even though there were some technical challenges associated with using Zoom for the first time. The problems were overcome during the pilot intervention period. The pilot study participants with previous experience of yoga requested one more prerecorded video class for self-training where the yoga poses were presented in a more advanced flow without modifications. Those without previous experience of yoga requested an opportunity for individual instruction of the yoga poses.

The pilot study participants expressed positive experiences of participating in the yoga intervention. They described feelings of hope connected to the body being able to function despite the breast cancer treatment. They also reported that the yoga sequences enabled them to perceive abilities of movement, which increased physical self-trust despite the new situation after having breast cancer surgery. Participating in the yoga class, both live-streamed and video versions, was described by the

participants as a moment of feeling harmony. The digital group concept both created community with the other participants and also gave an opportunity to focus solely on one's own body. The insight that 'none of the others had time to focus on you' had a calming effect. One of the pilot study participants expressed:

> 'Excellent yoga programs that have given me strength, increased mobility, circulation, and relaxation. Definitely contributed to faster recovery.'

The results of the pilot study will not be included in the main study.

Intervention fidelity

Intervention fidelity are followed and supervised throughout the study. As part of this, the intervention coordinator will communicate with the yoga instructors a regular basis. As a routine, the yoga instructors give a brief information about the yoga class to the intervention coordinator after each session and sends a list of number of patients attending.

Monitoring harms

Patients are told to report any experienced adverse events from participating in the intervention. Any events that occur as a result of the activities of the study trial will be registered by the primary investigator. Patients who experience an adverse event will be referred to their contact nurse for medical assessment.

Data analysis and statistical analysis

The primary analysis will be performed following the principle of intention to treat. The level of significance will be $p \leq 0.05$ and all tests will be two-tailed. The risk for false positive findings in multiple comparisons will be addressed using suitable statistical methods such as the Holm and Dunett methods.[39] If there is a high magnitude of missing values, multiple imputation or full-information maximum likelihood method will be considered.

For the analysis of repeated measures data, multilevel linear, logistic and other forms of regression models will be used.

Missing data will be handled with multiple imputations or within the mixed model.

Data storage

Electronic data storage

The project is using a web-based system, Smart Trial, to facilitate storage and monitoring of outcomes for the multiple study sites. The database is provided by Region Örebro County, and the security of the system accords with rules and regulations concerning sensitive data. To log in as a researcher to all levels of the system, two passwords are needed. For the participants, only one login is needed to register their answers. All communication with the database is encrypted, and backups are performed on a regular basis to secure the data. The data system will automatically send emails to participants informing them to log on to the portal to complete the questionnaires; it will also issue notices when assessment points are coming up and if a questionnaire is not completed. Notifications are sent by email if questionnaires are not completed within the set time frame. Participants who prefer paper questionnaires will have them sent by post together with an envelope with prepaid postage; these will be stored in a locked facility in the University Health Care Research Center to which only the research team has access.

Blood samples

Blood samples are handled and stored according to certified laboratory routines.

Blinding

As this is a yoga intervention, participants cannot be blinded in this study. However, those collecting and analysing blood samples and conducting physical tests will be blinded to group allocation.

Project organisation

The research team includes researchers with extensive knowledge about developing, testing and evaluating randomised controlled studies involving patients with cancer, yoga, and a health economics.

To increase the clinical relevance of and to facilitate a future implementation, a reference group including clinicians, leaders in healthcare, patient representatives and politicians are affiliated to the research group.

ETHICS APPROVAL AND DISSEMINATION

The DigiYoga CaRe study was approved by the Regional Ethical Review Board in Lund, Sweden, Reference number 2020–06219, 2022-00956-02 and 2021-05994-02.

Informed written consent forms are collected from all participants prior to entry into the study. Participants have the right to withdraw from the study at any point throughout the study. The principles established by the Declaration of Helsinki are followed during the study. To ensure confidentiality, personal data are coded. Participant and study-related information are stored in locked cabinets and digital documents are password protected.

The final results of this study will be disseminated by the research team to participants, healthcare professionals and relevant public and political groups. Presentations will be given at community forums such as patients support groups, in media and at relevant national and international scientific conferences.

DISCUSSION

The DigiYoga CaRe study will provide new insights regarding the effect of digitally distributed yoga intervention on CRF and HRQoL in patients with breast cancer. High-quality randomised controlled studies are needed to clarify the acceptability, feasibility, efficacy and effectiveness of online interventions.

Furthermore, the current study is designed to gain additional information on the role of inflammation in

CRF and to evaluate the cost effectiveness of a digital yoga intervention.

It is unknown whether digitally distributed yoga has an effect, since most studies on patients with cancer performing yoga are evaluated as a group activity in real life. The same yoga postures can be reproduced online, but the experience of the human interaction in a physical room might be different. However, the COVID-19 pandemic might have increased the awareness of the benefits of digital solutions and enhanced the feelings of social togetherness in spite of physical distance. According to Brinsley *et al*,[40] online delivery of yoga constitute a convenient and affordable way to strengthen mental health and holds potential to increase availability for people in remote areas.

If a digitally distributed yoga practice is effective on CRF, the healthcare service will have a mode of rehabilitation to offer, without a need to travel or to be exposed to environments where immunosuppressed patients could be infected. Digitally distributed yoga can reach patients who live far from the hospital and have limited resources to engage in rehabilitation activities to enhance their quality of life. With an increasing number of cancer survivors, the demand for rehabilitation will increase, and digital solutions can be an alternative offer.

Practical and operational issues in the planning and starting phases of the DigiYoga CaRe-study include the logistical and the communicational difficulties connected with multicentre design. However, DigiYoga CaRe has the advantage of offering full control of the intervention, since the same digital yoga classes are distributed to the participants in all sites. Possible challenges to overcome are technical obstacles. Some participants may experience difficulties with the internet connection and the audio and video settings.

The anticipated personal gains of participation in the intervention group, alongside the hypothesised health effects and increase in activity, include an easy-to-access new habit that can, if implemented regularly, have several positive physical and mental consequences. The value for the healthcare system can be a complement to other rehabilitation activities, as a digital rehabilitation has no geographical boundaries and can therefore be an option available to patients in several regions.

We hope that the knowledge gained from this study will contribute to developing effective long-term strategies to improve the health of breast cancer survivors.

This protocol is the first publication related to the DigiYoga CaRe project.

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Funding Regional Research Council Mid Sweden Grant number RFR-940296, regi onalaforskningsradet@regiongavleborg.se funds and support the study after a peer-reviewed process in competition with other project applications.

Disclaimer The study funders did not have any part in study design; collection, management, analysis and interpretation of data; writing of the report or the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. This manuscript is a protocol. Data on design of the study are available.

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