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At-home Breast Oncology care Delivered with EHealth solutions (ABODE) study protocol: a randomised controlled trial

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ABSTRACT

Introduction The COVID-19 pandemic disrupted healthcare delivery for patients with breast cancer. eHealth solutions enable remote care and may improve patient activation, which is defined as having the knowledge, skills and confidence to manage one's health. Thus, we developed the Breast Cancer Treatment Application (app) for patients and practitioners to use throughout the cancer care continuum. The app facilitates virtual assistance, delivers educational resources, collects patient-reported outcome measures and provides individualised support via volunteer e-coaches. Among newly diagnosed patients with breast cancer, we will compare changes in patient activation, other patient-reported outcomes and health service outcomes over 1 year between those using the app and Fitbit, and those receiving standard care and Fitbit only.

Methods and analysis This randomised controlled trial will include 200 patients with breast cancer seen at a tertiary care cancer centre in Ontario, Canada. The intervention group (n=100) will use the app in addition to standard care and Fitbit for 13 months following diagnosis. The control group (n=100) will receive standard care and Fitbit only. Patients will complete questionnaires at enrolment, 6 and 12 months post-diagnosis to measure patient activation (Patient Activation Measure-13 score), distress, anxiety, quality of life and experiences with their care and information received. All patients will also receive Fitbits to measure activity and heart rate. We will also measure wait times and number of visits to ambulatory care services to understand the impact of the app on the use of in-person services.

Ethics and dissemination Ethics approval was obtained on 6 January 2023. Protocol version 2.0 was approved on 6 January 2023. The trial is registered with ClinicalTrials.gov. Study findings will be disseminated via publication in a peer-reviewed journal and shared with participants, patient programmes and cancer awareness groups. The app has also been approved as a secure communication method at our trial institution, thus we are well-positioned to support future integration of the app into standard care through collaboration with our hospital network.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A key strength of this study is its use of a randomised controlled trial design to demonstrate the ability of the Breast Cancer Treatment Application (app) to increase patient activation.
⇒ In addition to measuring patient activation, we compare numerous patient-reported outcome measures from both the intervention and control groups to demonstrate the app's ability to deliver educational resources specific to patients' management pathways and provide patients with one-on-one support.
⇒ This study provides a unique opportunity to examine how service outcomes at a tertiary care centre in Canada may benefit from the implementation of a virtual platform.
⇒ A limitation of this study is the exclusion of patients undergoing neoadjuvant chemotherapy and patients who did not have surgery as part of their treatment pathway (stage 4/metastatic breast cancer).
⇒ This is a single-centre trial at a tertiary cancer centre in Canada, thus, findings from this study may not be generalisable.

Trial registration number NCT05989477.

INTRODUCTION

The COVID-19 pandemic has significantly disrupted healthcare service delivery, highlighting the need for virtual care options. eHealth or electronic communication-based interventions allow patients to access care remotely while providing healthcare professionals with relevant health information.[1–3] eHealth benefits patients with breast cancer, as it enables convenient access to support throughout every stage of the cancer care

continuum.[4–9] eHealth reduces unplanned visits to the hospital; platforms that collect patient-reported outcome measures (PROMs) and conduct remote symptom monitoring have been found to improve symptom control and quality of life, leading to reduced acute care visits.[10 11]

Digital solutions also allow for improved multidisciplinary care. Breast cancer care involves collaboration between multiple specialties, including genetics, medical, radiation and surgical oncology, physiotherapy, and social work. Virtual tools allow for increased participation from all team members regardless of geographical limitations, inclusion of specialist expertise and scheduling flexibility.[12 13] The ability to remotely communicate with patients and healthcare teams also reduces existing gaps in care delivery between rural and urban settings.[14]

eHealth interventions also provide opportunities for patient education and assistance with service navigation, empowering patients with the knowledge and confidence to take part in managing their health.[15–17] Patient activation or the ability to self-manage health is important for patients with breast cancer; patients who are more involved in monitoring their health are more likely to understand their diagnosis and experience improved quality of life.[18–21] Tailored information delivery for patients with cancer via eHealth tools supports self-management and encourages healthy behaviours, leading to improved symptom control and wellness.[18 20–22]

To increase access to breast oncology care and to improve patient activation, we developed the Breast Cancer Treatment Application (app) for patients with newly diagnosed breast cancer to use during the diagnostic, treatment and follow-up periods. To evaluate the app, this randomised controlled trial will compare changes in patient activation, other patient-reported outcomes (PROs) and health service outcomes over 1 year between patients with breast cancer using the app and Fitbit, and those receiving standard care and Fitbit. While previous studies have examined the use of eHealth in different patient populations and treatment settings, no study has investigated the outcomes of a tailored digital application across all aspects of the treatment pathway of a patient with breast cancer.[23–25] This trial will provide important evidence for the clinical utility and implementation of this tool into standard practice within breast cancer programmes.

OBJECTIVES

Primary objective: To compare changes in patient activation (assessed by Patient Activation Measure (PAM-13)) over 1 year among newly diagnosed patients with breast cancer between those using the app and Fitbit, and those receiving standard care and Fitbit only.

Secondary objectives:

- To compare PROs (cancer-related distress, anxiety, quality of life, experience of cancer, quantity of treatment information received, patient education programme benefits) between patients using the app and Fitbit, and those receiving standard care and Fitbit only.
- To describe health service outcomes between patients.
- To explore experiences of patients and healthcare professionals with using the app.

Through the use of the app, we anticipate the following outcomes:

- Increased patient activation and health-related quality of life.
- Decreased in-person health service utilisation, including hospital clinic visits, emergency department visits and phone calls from patients to the most responsible physician's office and breast triage line.
- Satisfaction with the app customised for patients with breast cancer undergoing surgery.

METHODS

This protocol used the Standard Protocol Items: Recommendations for Interventional Trials.[26] The trial is registered with ClinicalTrials.gov, NCT05989477.

Design

This trial is a randomised, controlled, single-centre, superiority trial with two parallel groups and a primary objective of comparing changes in patient activation as measured by the PAM-13 scale over 1 year. A total of 200 newly diagnosed patients with breast cancer from the largest Canadian cancer centre will be randomised; the intervention group will have access to the app in addition to standard care and Fitbit (n=100), and the control group will receive standard care and Fitbit only (n=100). We selected a timeframe of 1 year, as change in patient activation over time is typically measured by comparing baseline PAM-13 scores to scores taken 6–12 months later.[27]

Setting

Participants will receive care at our hospital, an urban research centre specialised in cancer treatment. Our hospital network has previously employed similar eHealth applications in other disease sites for sharing educational materials with patients and collecting PROMs.

Eligibility criteria

Patients must provide written, informed consent to participate in the study (online supplemental appendix 1).

Inclusion criteria:

- Assigned female at birth.
- Newly diagnosed with primary invasive breast cancer.
- Must have surgery as their first step in the treatment pathway.
- Age 18 or older.
- Access to an electronic device with an internet connection.
- Valid email address.
- Can communicate in English.

Exclusion criteria:

- Assigned male at birth.
- Diagnosed with non-operable breast cancer.

- Stage 4/metastatic cancer.
- Those with hearing or visual challenges.
- Patients undergoing neoadjuvant chemotherapy (NAC).
- Enrolled in any other study using an eHealth application.
- Breast cancer surgery is scheduled within five business days after enrolment.

We consider sex as a biological variable and gender as a sociocultural factor. This study will only include patients assigned female at birth, as breast cancer predominantly affects females.[28] Since breast cancer risk is sex-related and based on physiological values, our inclusion criteria are based on sex.[28] Patients receiving NAC were excluded, as patients must have surgery as their first step in their treatment pathway to be included in the study. Patients must have surgery as their first step in their treatment pathway, as the app was designed to administer PROMs pertaining to postoperative care. The app also does not provide educational materials or support specific to patients undergoing NAC prior to surgery.

Intervention

The app is approved by our hospital network as a secure communication method. The app requires users to create a username and password to log into their personal account. The app enforces strong passwords, supports two-factor authentication and detection of compromised passwords to improve user account security. All data on the app are encrypted in transit and at rest. The app is hosted in highly secure Tier IV data centres managed by a cloud provider which maintains an industry-leading array of security and privacy certifications, including Systems and Organization Controls (SOC) 2 Type 2 as well as the International Organization of Standardization 27000 family of certifications. NexJ Health, which is the platform that the app is hosted on, maintains SOC 2 Type 2 certification. We use the Template for Intervention Description and Replication to report the development of the app.[29]

Patients in both arms of the study were provided with a Fitbit wearable health tracker, which can be worn around the wrist. The dashboard of the Breast Cancer Treatment Application includes a tracker section, which displays information that is collected from their Fitbit device, allowing patients to view their health tracker data within the app. The Fitbit continuously collects information regarding activity level, sleep and fluctuations in heart rate. The provision of Fitbits is not part of standard care at our institution.

Items 1 and 2: intervention name and rationale

The Breast Cancer Treatment Application (app) was developed to increase access to breast oncology care and improve patient activation among patients with newly diagnosed breast cancer. Virtual platforms allow for improved access to multidisciplinary care and patient-centred education, empowering patients with knowledge and confidence to take part in managing their health.[12 13 15–17] The app includes features that support patient education on breast cancer management, measure PROs which inform healthcare providers and encourage patient activation, and allow patients to connect with emotional and social support.

Items 3 and 4: materials and procedures

The app features include a virtual library, to-do list, workbooks, administration of PROMs and ability to connect with the Clinical Research Assistant (CRA), Clinical Research Coordinator (CRC) and a volunteer e-coach.

The app includes a virtual library of resources from our institution and other vetted websites, which eliminates the need for distributing printed handouts and allows for centralised updating of resources. Patients in the intervention group can access this library freely, and specific resources are pushed on-app during applicable treatment phases. The resources include information on different types of breast surgeries, breast imaging, chemotherapy, endocrine therapy, radiation oncology, psychosocial and mental health, genetic counselling, breast reconstruction and survivorship. These resources are publicly available on websites created by our institution (uhn.ca), and the app organises them in a central location for patients to conveniently access.

The app has a to-do list feature on the main dashboard that is automatically updated with important reminders according to the patient's treatment plan (eg, appointments, postoperative reminders). The app also includes various *workbooks* that will be made available to participants based on their treatment schedule. These *workbooks* were created by our interdisciplinary research team and include the following topics: preparing for surgery, postsurgery recovery, genetic testing, radiation, chemotherapy, endocrine therapy and survivorship (available on contacting the corresponding author). The app will administer automatic reminders to patients in the intervention group to complete workbooks and surveys. The surveys are detailed in the Outcomes section. One of these surveys is in the postoperative period. The app's automatic reminders also include links to REDCap for PROM questionnaires and other outcome measures.

Throughout the study period, the CRA and CRC will check the app dashboard daily for any messages and reply to these accordingly. This may include calling or text messaging the patient within the app, assisting with finding information or resources within the app or directing the patient to contact their care team for clinical concerns. The CRA and CRC are both research employees and have completed training mandated by our institution regarding patient safety, confidentiality and indications for triaging patients to their clinical team. The CRA will monitor the app Monday to Friday from 09:00 to 16:00, and patients can expect a reply within 24 hours. It will be made clear to patients in the intervention group that they can still access the standard methods of communication at any time, and that they should go to the emergency department for urgent concerns.

Our institution has established the Care and Connect Programme, which pairs patients undergoing cancer therapy with e-coaches, who provide one-on-one emotional and social support (uhn.ca). All volunteer e-coaches are screened and undergo a 6-month training process through this programme at our hospital network, and may be healthcare professionals or former patients. All patients in the intervention group will have the option to connect with an e-coach on a one-on-one basis for 6 months. E-coaches supporting patients have received additional training from our clinical teams to provide support through the app. The frequency of contact between the e-coach and participant will be jointly determined. E-coaches have access to information about the participants to whom they are providing coaching, which includes the patients' profile and their to-do list of appointments and workbooks.

Item 5: who provided

The app's virtual library, workbooks and PROMs were developed and selected with input from all disciplines involved in breast cancer care at our institution, including surgical oncology (DM, EK, AO, RF, AE, WL, MR, TDC), radiation oncology (CAK), medical oncology (EA), prehabilitation oncology (DSM), genetics (RK, JM, LP, ET), cancer education (JP, FW), breast reconstruction (TZ, SH) and psychosocial oncology (ML, GR). Our team also included three patient partners who provided input on app features and design (AI, SJ, DS). The CRA (MK) and CRC (ER) will be involved in supporting patients who are using the app, as outlined under item 4. The number of e-coaches who will support patients in this study is not predictable, as this will depend on the number of patients who are interested in connecting with an e-coach, and the number of patients each e-coach is willing and able to support. The Care and Connect Programme ensures that volunteer e-coaches are available and appropriately trained to provide compassionate and inclusive support for interested patients at our institution (uhn.ca). The Care and Connect Programme is available for all patients at our institution (both intervention and control groups); patients in the intervention group (the app users) will have the ability to access and converse with their e-coach on the app (calling or text message).

Item 6: modes of delivery

The app will be available to all patients in the intervention group (n=100). The app requires an internet connection. Patients using the app will initiate contact with the CRA, CRC and e-coach as needed. The app will administer reminders for completing PROMs and workbooks.

Item 7: location of the intervention

The app was developed for use by patients at a tertiary cancer centre in Ontario, Canada, and in this study, the app will only be available to patients at our centre. The app requires a CRA and/or CRC to monitor for any messages from patients using the app. The app also requires patients to have an internet connection to access the app's resources, surveys and communication functions.

Item 8: frequency and time period of intervention delivery

The intervention group will receive access to the app and create an account on the app after consenting to the study; the consent process is detailed in the Ethics and dissemination section. On receiving access to the app, the app can be used as frequently as app users (intervention group) desire until the end of the study period.

Item 9: tailoring

The app reminds users to complete PROMs and workbooks according to their treatment plan and schedule. For example, if a patient is receiving endocrine therapy, they will be prompted by the app to complete a survey specific to their experience with endocrine therapy. The surveys and their indications are detailed in the Outcomes section. We tailor the administration of PROMs and workbooks to app users to prevent patients from becoming overwhelmed and ensure that patients engage with app activities that are relevant to their management plan. Each patient's account on the app is automatically set up according to their treatment plan; this is done when patients first log in to their account on the app and are prompted to answer questions about the treatment they will receive. Patients are asked whether they received genetic testing and/or endocrine therapy. This information is used by the app to ensure that patients are prompted to answer surveys and workbooks that are relevant to them.

Item 10: modifications

During the course of the study, we do not foresee that modifications to the app will be made. App users can reach out to their e-coach, CRC or CRA in the app if they encounter technical difficulties while using the app or to provide feedback. At the end of the study, patients can also provide formal feedback regarding the app via the Breast Cancer Treatment Application Review Survey (detailed in the Outcomes section). Feedback regarding the app will be instrumental in informing future modifications to the app after the completion of this trial. We also plan to conduct a future substudy to inform any potential app modifications; this is detailed in the Outcomes section.

Items 11 and 12: planned and actual intervention fidelity

We will assess adherence to using the app for patients in the intervention group by noting if patients complete their surveys and workbooks. App reminders, as detailed under items 3 and 4, will be administered to support intervention fidelity. In the event that patients in the intervention group exhibit poor adherence to using the app, we will discuss this and potential reasons in our future paper detailing the results of this trial.

Standard care

Patients in the control group will receive standard care only and use the Fitbit. At our centre, standard care includes in-person outpatient consultation and appropriate follow-up, either in-person or virtual, with disciplines involved in breast cancer treatment, as indicated (breast surgery, plastic surgery, medical oncology, radiation oncology). Patients in the control group also have access to the Care and Connect Programme at our centre. However, patients in the control group will not have the option to connect or communicate with their e-coach via the app and can only do so via other means (email, phone call, in-person). Patients in the control group will receive reminders to complete questionnaires via email.

Modifications

Participants can discontinue their involvement in the study at any time if requested. If a participant in the intervention group wishes to discontinue their involvement in the study, their app account will be deactivated. Information collected prior to a participant's discontinuation will be used in data analysis, and no new information will be collected without their permission.

Outcomes

Primary outcome measure

Our primary objective is to compare changes in patient activation over 1 year among newly diagnosed patients with breast cancer between those using the app and Fitbit, and those receiving standard care and Fitbit only.

- We will assess the difference between the intervention and control groups for the change observed in patient activation over time, as measured by the PAM-13 at baseline (time of diagnosis), 6 and 12 months post-diagnosis. The PAM-13 is a PROM that measures self-reported knowledge, skills and confidence for self-management of one's health and healthcare.[27 30–33] Patient activation is particularly important for patients with breast cancer, who must often decide between multiple treatment options, adhere to complex treatment regimens and eventually adjust to a 'new normal'.[34]

Secondary outcome measures

Our first secondary objective is to compare additional PROs between patients using the app and Fitbit, and those receiving standard care and Fitbit only.

- We will assess the difference between the intervention and control groups for the change observed in the following additional PROs over time.
  - Cancer-related distress, as measured by the Impact of Events Scale at baseline, 6 and 12 months post-diagnosis. Patients indicate how frequently a cognition was true for them during the past week with respect to their experience with cancer, and the level of distress caused by that cognition.[35]
  - Anxiety, as measured by the General Anxiety Disorder Screener (GAD-7) at baseline, 6 and 12 months post-diagnosis. GAD-7 screens for generalised anxiety disorder and assesses its severity.[36] The scale has been validated as an accurate measure of emotional distress in oncology patients.[37]
  - Quality of life, as measured by the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaires—Core-30 and Breast-23 at baseline, 6 and 12 months post-diagnosis. Both questionnaires are valid and reliable tools to assess quality of life in patients with breast cancer and involve assessments of physical, emotional, cognitive and social functioning.[38–41]
  - Experience of cancer care in terms of their receipt of useful and relevant information about cancer, assistance with service navigation and support from their care team, as measured by the Clinical Evaluation Questionnaire (CEQ) at 6 and 12 months post-diagnosis. The CEQ is a self-reported measure that assesses the perceived benefit of interactions with healthcare providers for patients with cancer.[42]
  - Quantity of treatment information, as measured by the European Organisation for Research and Treatment of Cancer Information Module (EORTC-INFO25) at 9 months post-diagnosis. This tool assesses the information received by patients regarding aspects of their disease and treatment by asking patients how much information they received on various topics, including their diagnosis, extent of their disease, possible causes, expected benefit of treatment and possible treatment side effects.[43 44]
  - Experience with patient education, as measured by the Health Information Questionnaire (heiQ) at baseline and 9 months post-diagnosis. The heiQ was developed and validated with patients who have a wide range of chronic conditions to provide insight on patient education programme benefits.[45]
  - Frequency of use of other eHealth applications, as measured by the Other Health App Questionnaire at 6 and 12 months post-diagnosis (online supplemental appendix 2).
- We will assess the following PROs for the intervention group only. These surveys are administered to the intervention group only, as the collection of data via these surveys is a feature of the app. Through completing these surveys, patients are encouraged to engage with their care by being aware of and recording their symptoms and experiences, and to interact with educational resources that are relevant to their treatment plan (the following surveys display answers for patients to review once they have completed them).
  - Impact of result disclosure after genetic testing, as measured by the Multidimensional Impact of Cancer Risk Assessment (MICRA) 1 week after genetic test results are received. This will only be administered to patients who receive genetic testing in the intervention group. The MICRA is a 25-item

questionnaire used to capture positive and negative psychological effects of receiving test results regarding their breast cancer polygenic risk score.[46 47]
  - Knowledge of genetic testing, as measured by the KnowGene Scale 3 months after receiving genetic test results. This will only be administered to patients who receive genetic testing in the intervention group. A higher number of correct responses on this survey indicates greater knowledge regarding the interpretation and clinical impact of genetic test results, and cancer inheritance and risk.[48]
  - Postoperative measures at 1–10 days after surgery, as assessed by our study-specific postoperative survey (online supplemental appendix 3). This survey is administered daily on postoperative days 1–10. This survey will ask patients on the app to report and rate symptoms that they may experience after surgery, including pain, numbness, fever, shortness of breath, tenderness around the incision site, fatigue and anxiety.
  - Symptoms of distress, as measured by the Distress Thermometer (DT) at baseline, 6 and 12 months post-diagnosis. The DT is a self-reported tool that asks patients to identify and rate sources of distress from a problem list, which includes practical, family, emotional, spiritual, religious and physical concerns.[49]
  - Impact of endocrine therapy for those who are receiving endocrine treatment for breast cancer, as measured by the Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES) at 2–3 months after starting endocrine treatment. FACT-ES assesses the effects of receiving hormonal therapy for cancer on physical, social/family, emotional and functional well-being.[50]
- We will assess the difference between the intervention and control groups for the change observed in the following variables over time collected from the Fitbit. These measurements will be collected continuously for the duration of the study. Fitbits or wearable activity trackers are effective for measuring health-relevant physical activity in clinical practice and research.[51]
  - *Activity level*: as measured by the number of steps and exercise sessions per day. This will provide information on trends in physical activity level and whether the provision of exercise resources via the app supports and maintains physical activity.
  - *Sleep*: as measured by the number of hours of sleep per night. This will provide information on levels of distress experienced by patients, which may reduce their sleep quantity.[52]
  - *Heart rate*: fluctuations, particularly sustained increases, in heart rate will provide information on periods of stress experienced by patients.[53]

Our second secondary objective is to describe health service outcomes among app and Fitbit users in comparison to those receiving standard care and Fitbit.

- We will assess changes in the following health service outcomes to understand the impact of the app on the use of health services. We will compare the utilisation of health services between the app users and patients in the control group. Health services utilisation will be measured at the end of the study.
  - Number of hospital emergency department visits, as measured by the Discharge Abstracting Database (DAD) and National Ambulatory Care Reporting System (NACRS).
  - Wait times, as captured by the Wait Times Information System (TIS), which is a web-based system that allows Ontario hospitals to capture wait time information related to surgery, diagnostic imaging and alternate level of care.
  - Number of calls and emails to the breast clinic, as captured by auditing the breast triage line and email.
  - Number of visits to the breast clinic, as captured by auditing our booking system and conducting a chart review at 3, 9 and 15 months.

Our third secondary objective is to explore experiences of patients and healthcare professionals with using the app.

- We will assess the usability of the app by administering the System Usability Scale (SUS) to the intervention group at 12 months post-enrolment. Participants rate items pertaining to their experience as an end-user: desire to use the app frequently, complexity, need for support from a technical person, integration and consistency within the platform and confidence with using the platform.[54]
- We will also assess the usability of the app by administering the Breast Cancer Treatment Application Review Survey to the intervention group at 12 months post-enrolment in the study (online supplemental appendix 4).
- We will monitor user activities of patients in the intervention group, which are tracked in the clinician dashboard: number of clicks on library resources, dates of workbook completion and Fitbit variables viewed most frequently. This anonymised data will be used to determine the most-used features of the app.
- In a future substudy related to this clinical trial, we plan to conduct a qualitative analysis to understand the experiences of patients and healthcare professionals with using this app. This qualitative study will explore the impact of the app on accessibility to and quality of breast cancer care, and assess patient and healthcare professional satisfaction with using the app.

Other measurements

To better understand all participants, patient and disease-specific information will be collected at baseline and multiple time points throughout the study.

- A Self-Identification Survey will be completed at baseline by all patients to collect demographic variables:

gender identity, sexual orientation, age, ethnicity, disability status, language preference, education level, family history and marital status.

- A chart review will be conducted to collect diagnostic, surgical, pathological and treatment-related information for all patients at baseline, 3, 9 and 15 months. The data will be anonymised according to the steps outlined in the Data management section. Data collected from medical records will include diagnostic imaging and pathological staging data, surgical, systemic, radiation therapy, morbidity and mortality outcomes, recurrence and survival information.

Given that the app is a tailored eHealth platform that aims to provide individualised support and education specific to each patient's needs, patients in the intervention group will also complete the following surveys at baseline. These surveys will ensure that the app administers PROMs according to each patient's treatment schedule, and inform e-coaches as they provide individualised support to patients.

- The Duke Activity Status Index (DASI) will be used to assess the functional capacity of patients in the intervention group at baseline. The DASI is a self-reported questionnaire that assesses exercise capacity based on answering 'yes' or 'no' to 12 questions related to daily activities.[55]
- Patients in the intervention group will complete the Surgery Information Survey at baseline, a survey that our team created to assess the knowledge of patients regarding their surgery (online supplemental appendix 5). The survey includes questions that will help our team ensure that the app provides information tailored to patients; it will ask patients to identify their surgery type and date(s) of their surgery(ies).

Participant timeline

The intervention group will have access to the app for 13 months. Access will commence within 1 week of randomisation, which occurs after study entry at diagnosis. All participants will be sent survey REDCap links via email, and participants in the intervention group will additionally receive automatic reminders through the app to complete these questionnaires, which include the REDCap link to the survey (figure 1). Completion of all surveys is estimated to take 30 min at each time point.

Sample size

The primary outcome is the between-group difference in the change from baseline to 12 months of the PAM-13 score. The sample size calculation was based on a clinically relevant difference of 4 points of PAM-13 change and an SD of 10.0.[56] We opted to use the change in PAM-13 from baseline to 12 months, rather than the raw scores in the PAM-13, to account for the within-sample variation and provide a better understanding of the study endpoint. Based on the power calculation, 156 patients are needed to have 80% power to identify a significant difference between the two arms, with a two-sided significance level α=0.05. We have assumed a 10% participant attrition rate based on previous eHealth application studies[57] in our sample size and power calculations. We have also assumed an additional 10% of potential patient drop-off. Therefore, if we account for a total attrition rate of 20%, the total required sample size is 196 (98 patients in each arm). We have rounded up our sample size to 200 (100 patients in each arm).

Recruitment

The planned recruitment rate for this trial is based on patient acceptance and adherence from other sites using a similar application clinically[58 59] and the number of potentially eligible subjects at our cancer centre. We estimate there will be 96 eligible patients per month, based on breast centre volumes. These numbers have remained stable throughout the COVID-19 pandemic. Thus, we expect to recruit our sample size of 200 participants by our proposed recruitment completion date of 22 April 2025. Recruitment began on 22 June 2023. The number of participants accrued thus far is 76.

Allocation

Participants will be randomly assigned to either the control or intervention group with a 1:1 allocation as per a computer-generated randomisation schedule using simple randomisation. Participants will be randomised using REDCap, which is an online central randomisation service. The study team is blinded to this allocation process.

Blinding

Given that patients and their practitioners will know whether they have access to the app, it is not possible to blind participants to their allocation to the intervention or control group. It is also not possible to blind the CRA or CRC to the allocation of participants, as the CRA or CRC will need to communicate with patients in the intervention group via the app. However, data analysts will not be involved in patient care and will be unaware of the allocation sequence and group assignment throughout the study.

Data collection

Online supplemental file 1 displays the reliability of each assessment tool used to collect our outcome measures. Each participant will be given a Fitbit activity tracker to wear during the study period. All participants will be asked to download the Fitbit application on their device. For the intervention group, the app will automatically pull the variables from the Fitbit app and display them on the patient dashboard for easy viewing. The control group will be able to view their data in the Fitbit app throughout the study.

For health service outcomes, we will collaborate with the Decision Support Team at our hospital to request data for the patients included in our study from the following sources:

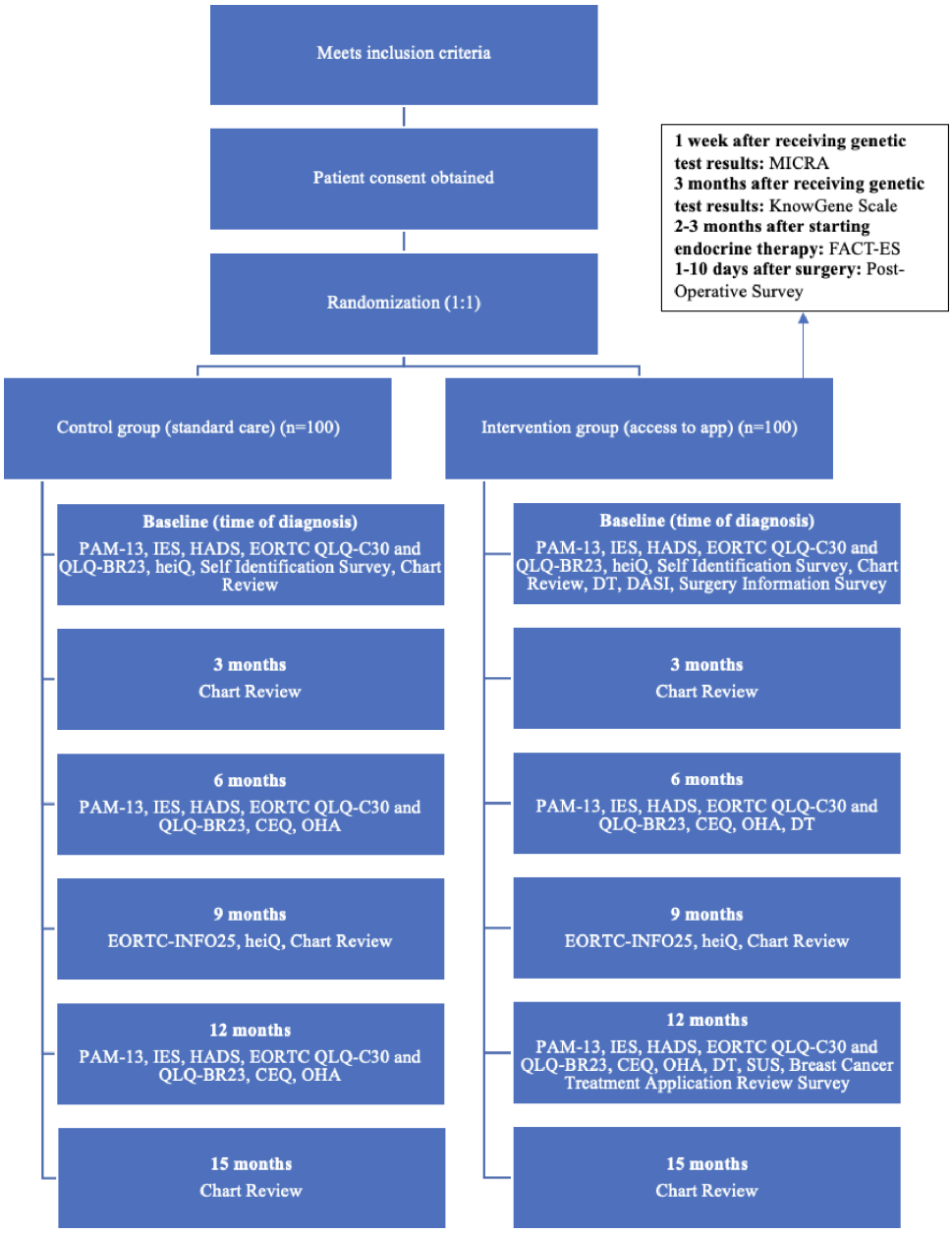

Figure 1 Timeline of study. Fitbit variables and app user activities are collected continuously throughout the study duration, and health service outcomes are collected at the end of the study. CEQ, Clinical Evaluation Questionnaire; DASI, Duke Activity Status Index; DT, Distress Thermometer; EORTC, European Organisation for Research and Treatment of Cancer; FACT-ES, Functional Assessment of Cancer Therapy-Endocrine Symptoms; GAD, General Anxiety Disorder Screener; heiQ, Health Information Questionnaire; IES, Impact of Events Scale; INFO-25, Information Module; MICRA, Multidimensional Impact of Cancer Risk Assessment; OHA, Other Health App Questionnaire; PAM, Patient Activation Measure; QLQ-BR23, Quality of Life Questionnaires—Breast- 23; QLQ-C30, Quality of Life Questionnaires—Core-30; SUS, System Usability Scale.

- TIS: this is a web-based system that enables Ontario hospitals to capture wait time information related to surgery, diagnostic imaging and alternate level of care.
- NACRS: this database includes ambulatory clinical activity.
- DAD: this database is used to capture acute clinical activity and data will be requested from the Decision Support Team.

Data management

The survey responses from the control and intervention groups will be collected and securely stored using REDCap. Participant profile data on the app is securely stored on a Canadian-hosted IBM data cloud and only those who are part of the patient's care team and members of the study team will have access to this data. Chart review data will be entered into a REDCap database where each patient will be identified with a unique participant ID. A separate REDCap consent database will be kept as a linking log that matches the participant ID to the patient. The study files will be stored securely in REDCap and SharePoint software, which are both approved by our hospital network. All

Table 1 Outcome measures and methods of analysis for comparing between intervention and control groups

Outcome measures	Hypothesis	Methods of analysis
Change in PAM-13 score from baseline to 12 months	Intervention increases score	Paired t-test
Change in IES score from baseline to 12 months	Intervention decreases score	Paired t-test
Change in GAD-7 score from baseline to 12 months	Intervention decreases score	Paired t-test
Change in EORTC QLQ-C30 and QLQ-BR23 score from baseline to 12 months	Intervention decreases score for symptom scales and increases score for functional scales	Paired t-test
Change in CEQ score from 6 months to 12 months	Intervention increases score	Paired t-test
EORTC-INFO25 score	Intervention increases score	Paired t-test
Change in heiQ score from baseline to 9 months	Intervention increases score	Paired t-test

CEQ, Clinical Evaluation Questionnaire; EORTC, European Organisation for Research and Treatment of Cancer; GAD, General Anxiety Disorder Screener; heiQ, Health Information Questionnaire; IES, Impact of Events Scale; INFO25, Information Module; PAM, Patient Activation Measure; QLQ-BR23, Quality of Life Questionnaires—Breast-23; QLQ-C30, Quality of Life Questionnaires—Core-30.

records and documents pertaining to the study will be retained by the study trial site for 15 years from the completion of the study.

Statistical methods

Table 1 outlines the analyses that will be conducted for outcome measures collected from all patients; the intervention group will be compared with the control group for all analyses. Table 2 outlines the analyses that will be conducted for outcome measures collected from the intervention group only. SAS and SPSS will be used to conduct analyses. For all tests, we will use two-sided p values with an alpha ≤0.05 level of significance. The statistician (YZ) at our centre is blinded to study groups, and will conduct all analyses.

Descriptive statistics will be used to summarise MICRA, postoperative survey, FACT-ES, SUS, DASI and Breast Cancer Treatment Application Review Survey scores, all baseline measures, and Self-Identification Survey and chart review results. Linear regression will be performed for Fitbit variables and all health service outcomes. Demographic and clinical characteristics from the Self-Identification Survey and chart review will be compared using Kruskal-Wallis tests for continuous variables and Fisher's exact tests for categorical variables.

Patient and public involvement

Patient partners were involved in the design, reporting and dissemination plan of this research, including the development and publication of this protocol.

ETHICS AND DISSEMINATION

This protocol has been reviewed and approved by the sponsor and applicable institutional review boards (ID#20-6232). Any protocol amendments will be approved by the ethics committee prior to implementation and uploaded to the trial registry.

Consent

Eligibility will be assessed by the CRA using the Study Screening Form (online supplemental appendix 6). There will also be a poster (online supplemental appendix 7) on the wall in the clinic that directs patients to contact the study team directly. Eligible participants will be asked if they are interested in meeting with the CRA to learn the details of the study. This conversation will occur after the patient's appointment, during which they consented to receive surgical treatment for their breast cancer. Interested participants will be introduced to the CRA for a brief overview of the study or directed to scan a QR code to give consent to contact (online supplemental appendix 8). The CRA will give them a copy of the consent form (online supplemental appendix 1) to review and will facilitate a meeting either virtually or in person to answer any questions about the study as soon as the participant is available during a mutually agreeable time to meet. This could happen during the clinic visit if time permits. On receiving verbal confirmation of the patient's willingness to participate in the study, the CRA will register the patient in the REDCap study database using their email address. A link to the online consent document will be automatically emailed to the patient.

Table 2 Outcome measures collected from the intervention group only and methods of analysis

Outcome measures	Hypothesis	Methods of analysis
KnowGene Scale score	Intervention increases score (in comparison to average score)[48]	Paired t-test
Change in the Distress Thermometer (DT) score from baseline to 12 months	Score decreases from baseline to 12 months	Paired t-test

Dissemination policy

Results will be shared through peer-reviewed publications and presentations at conferences. The app was designed to integrate with our hospital network's health information system and has been customised with representation from all departments in the breast clinic. We will continue to work with the digital platforms team at our hospital network who will lead the implementation of the app. Our clinical trial team, including the CRA and CRC, will continue to be involved with implementing our app into standard care practices at our institution. Future plans to integrate the app at other cancer care centres will involve training healthcare staff at these centres to undertake the roles of the CRA and CRC (ie, responding to messages from patients within the app).

DISCUSSION

This study will provide evidence for using the app to support patients with breast cancer throughout all aspects of their treatment journey. eHealth interventions such as the Breast Cancer Treatment Application allow patients to access information and resources specific to their care plan, while also providing convenient and continuous access to care services. We anticipate that this trial will demonstrate the potential that eHealth solutions have for effectively supporting patients with breast cancer throughout their continuum of care, by improving patient activation through patient-specific education, and supporting patient–provider interactions via remote care delivery and collection of PROMs.

Through collaboration with our hospital network, we are well-positioned to integrate the app, adapted as appropriate with the findings from our study, into standard care at our institution. The app is customised to follow a breast cancer treatment plan with the option of further changes or for certain features to be disabled. Based on the transferability of this type of innovative approach to remote patient care, we anticipate the capacity to extend the use of the app to other sites across Canada in the future.

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Contributors TDC led the development of the concept and design of the study, oversaw all aspects of the study, and edited the manuscript. TDC is the guarantor. AM drafted the manuscript. WX developed the statistical protocol for data analysis. The entire team of listed authors (AM, MK, ER, EA, AI, RK, EK, CAK, ML, DM, KM, AO, JP, SR, GR, WX, TZ, TDC) as well as additional members of The ABODE Study Group (JC, RF, AE, JE, SH, SJ, WL, JM, DSM, LP, MR, SS, DS, ET, FW) contributed to the development and design of the study, reviewed the manuscript, and will contribute to the successful completion of the study.

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REFERENCES

1 Mobasheri MH, Johnston M, King D, *et al*. Smartphone breast applications - what's the evidence? *Breast* 2014;23:683–9.
2 Virtual Care Task Force. Report on virtual care in Canada: progress and potential. 2022. Available: https://www.cma.ca/sites/default/files/2022-02/Virtual-Care-in-Canada-Progress-and-Potential-EN.pdf
3 World Health Organization. Executive summary. In: *WHO guideline recommendations on digital interventions for health system strengthening*. Geneva: World Health Organization, 2019. Available: https://www.ncbi.nlm.nih.gov/books/NBK541888/
4 McGrowder DA, Miller FG, Vaz K, *et al*. The Utilization and Benefits of Telehealth Services by Health Care Professionals Managing Breast Cancer Patients during the COVID-19 Pandemic. *Healthcare (Basel)* 2021;9:1401.
5 Cox A, Lucas G, Marcu A, *et al*. Cancer Survivors' Experience With Telehealth: A Systematic Review and Thematic Synthesis. *J Med Internet Res* 2017;19:e11.
6 Sirintrapun SJ, Lopez AM. Telemedicine in Cancer Care. *Am Soc Clin Oncol Educ Book* 2018;38:540–5.
7 Hazin R, Qaddoumi I. Teleoncology: current and future applications for improving cancer care globally. *Lancet Oncol* 2010;11:204–10.
8 Laughlin AI, Begley M, Delaney T. Accelerating the delivery of cancer care at home during the Covid-19 pandemic. *NEJM Catal* 2020.
9 Steindal SA, Nes AAG, Godskesen TE, *et al*. Patients' Experiences of Telehealth in Palliative Home Care: Scoping Review. *J Med Internet Res* 2020;22:e16218.
10 Nipp RD, Gaufberg E, Vyas C, *et al*. Supportive Oncology Care at Home Intervention for Patients With Pancreatic Cancer. *JCO Oncol Pract* 2022;18:e1587–93.
11 Maguire R, McCann L, Kotronoulas G, *et al*. Real time remote symptom monitoring during chemotherapy for cancer: European multicentre randomised controlled trial (eSMART). *BMJ* 2021;374:n1647.
12 Rajasekaran RB, Whitwell D, Cosker TDA, *et al*. Will virtual multidisciplinary team meetings become the norm for musculoskeletal oncology care following the COVID-19 pandemic? - experience from a tertiary sarcoma centre. *BMC Musculoskelet Disord* 2021;22:18.
13 Bate J, Wingrove J, Donkin A, *et al*. Patient perspectives on a national multidisciplinary team meeting for a rare cancer. *Eur J Cancer Care (Engl)* 2019;28:e12971.
14 Nelson D, McGonagle I, Jackson C, *et al*. A rural-urban comparison of self-management in people living with cancer following primary treatment: A mixed methods study. *Psychooncology* 2022;31:1660–70.
15 Arora S, Ryals C, Rodriguez JA, *et al*. Leveraging Digital Technology to Reduce Cancer Care Inequities. *Am Soc Clin Oncol Educ Book* 2022;42:1–8.
16 Moradian S, Maguire R, Liu G, *et al*. Promoting Self-management and Patient Activation Through eHealth: Protocol for a Systematic Literature Review and Meta-analysis. *JMIR Res Protoc* 2023;12:e38758.
17 Hibbard JH, Stockard J, Mahoney ER, *et al*. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;39:1005–26.
18 Kanu C, Brown CM, Rascati K, *et al*. Are Health Literacy and Patient Activation Related to Health Outcomes in Breast Cancer Patients? *Health Lit Res Pract* 2021;5:e171–8.
19 Basch E, Deal AM, Kris MG, *et al*. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. *J Clin Oncol* 2016;34:557–65.
20 Magnezi R, Glasser S, Shalev H, *et al*. Patient activation, depression and quality of life. *Patient Educ Couns* 2014;94:432–7.
21 Singleton AC, Raeside R, Hyun KK, *et al*. Electronic Health Interventions for Patients With Breast Cancer: Systematic Review and Meta-Analyses. *J Clin Oncol* 2022;40:2257–70.
22 Villani D, Cognetta C, Repetto C, *et al*. Promoting Emotional Well-Being in Older Breast Cancer Patients: Results From an eHealth Intervention. *Front Psychol* 2018;9:2279.
23 Yang S, Bui CN, Park K. Mobile Health Apps for Breast Cancer: Content Analysis and Quality Assessment. *JMIR Mhealth Uhealth* 2023;11:e43522.
24 Cai T, Huang Y, Zhang Y, *et al*. Mobile health applications for the care of patients with breast cancer: A scoping review. *Int J Nurs Sci* 2021;8:470–6.
25 Jongerius C, Russo S, Mazzocco K, *et al*. Research-Tested Mobile Apps for Breast Cancer Care: Systematic Review. *JMIR Mhealth Uhealth* 2019;7:e10930.
26 Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
27 van der Hout A, van Uden-Kraan CF, Holtmaat K, *et al*. Role of eHealth application Oncokompas in supporting self-management of symptoms and health-related quality of life in cancer survivors: a randomised, controlled trial. *Lancet Oncol* 2020;21:80–94.
28 Łukasiewicz S, Czeczelewski M, Forma A, *et al*. Breast Cancer-Epidemiology, Risk Factors, Classification, Prognostic Markers, and Current Treatment Strategies-An Updated Review. *Cancers (Basel)* 2021;13:4287.
29 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:bmj.g1687.
30 Hibbard JH, Mahoney E, Sonet E. Does patient activation level affect the cancer patient journey? *Patient Educ Couns* 2017;100:1276–9.
31 Hibbard JH, Mahoney ER, Stockard J, *et al*. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;40:1918–30.
32 Westman B, Bergkvist K, Karlsson Rosenblad A, *et al*. Patients with low activation level report limited possibilities to participate in cancer care. *Health Expect* 2022;25:914–24.
33 Hellström A, Kassaye Tessma M, Flink M, *et al*. Validation of the patient activation measure in patients at discharge from hospitals and at distance from hospital care in Sweden. *BMC Public Health* 2019;19:1701.
34 O'Malley D, Dewan AA, Ohman-Strickland PA, *et al*. Determinants of patient activation in a community sample of breast and prostate cancer survivors. *Psychooncology* 2018;27:132–40.
35 Salsman JM, Schalet BD, Andrykowski MA, *et al*. The impact of events scale: a comparison of frequency versus severity approaches to measuring cancer-specific distress. *Psychooncology* 2015;24:1738–45.
36 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
37 Esser P, Hartung TJ, Friedrich M, *et al*. The Generalized Anxiety Disorder Screener (GAD-7) and the anxiety module of the Hospital and Depression Scale (HADS-A) as screening tools for generalized anxiety disorder among cancer patients. *Psychooncology* 2018;27:1509–16.
38 Aaronson NK, Ahmedzai S, Bergman B, *et al*. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365–76.
39 Sprangers MA, Groenvold M, Arraras JI, *et al*. The European Organization for Research and Treatment of Cancer breast cancer-specific quality-of-life questionnaire module: first results from a three-country field study. *J Clin Oncol* 1996;14:2756–68.
40 Tan ML, Idris DB, Teo LW, *et al*. Validation of EORTC QLQ-C30 and QLQ-BR23 questionnaires in the measurement of quality of life of breast cancer patients in Singapore. *Asia Pac J Oncol Nurs* 2014;1:22–32.
41 Imran M, Al-Wassia R, Alkhayyat SS, *et al*. Assessment of quality of life (QoL) in breast cancer patients by using EORTC QLQ-C30 and BR-23 questionnaires: A tertiary care center survey in the western region of Saudi Arabia. *PLoS One* 2019;14:e0219093.
42 de Vries FE, Mah K, Malfitano C, *et al*. Clinical evaluation questionnaire in advanced cancer: a psychometric study of a novel measure of healthcare provider interactions. *BMJ Support Palliat Care* 2024;13:e1093–102.
43 Arraras JI, Greimel E, Chie W-C, *et al*. Information disclosure to cancer patients: EORTC QLQ-INFO25 questionnaire. *Expert Rev Pharmacoecon Outcomes Res* 2011;11:281–6.
44 Arraras JI, Greimel E, Sezer O, *et al*. An international validation study of the EORTC QLQ-INFO25 questionnaire: an instrument to assess the information given to cancer patients. *Eur J Cancer* 2010;46:2726–38.
45 Osborne RH, Elsworth GR, Whitfield K. The Health Education Impact Questionnaire (heiQ): an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions. *Patient Educ Couns* 2007;66:192–201.
46 Cella D, Hughes C, Peterman A, *et al*. A brief assessment of concerns associated with genetic testing for cancer: the Multidimensional Impact of Cancer Risk Assessment (MICRA) questionnaire. *Health Psychol* 2002;21:564–72.

47 Yanes T, Meiser B, Kaur R, *et al*. Breast cancer polygenic risk scores: a 12-month prospective study of patient reported outcomes and risk management behavior. *Genet Med* 2021;23:2316–23.
48 Underhill-Blazey M, Stopfer J, Chittenden A, *et al*. Development and testing of the KnowGene scale to assess general cancer genetic knowledge related to multigene panel testing. *Patient Educ Couns* 2019;102:1558–64.
49 Ownby KK. Use of the Distress Thermometer in Clinical Practice. *J Adv Pract Oncol* 2019;10:175–9.
50 Sert F, Ozsaran Z, Eser E, *et al*. Quality of life assessment in women with breast cancer: a prospective study including hormonal therapy. *J Breast Cancer* 2013;16:220–8.
51 Beagle AJ, Tison GH, Aschbacher K, *et al*. Comparison of the Physical Activity Measured by a Consumer Wearable Activity Tracker and That Measured by Self-Report: Cross-Sectional Analysis of the Health eHeart Study. *JMIR Mhealth Uhealth* 2020;8:e22090.
52 Yap Y, Slavish DC, Taylor DJ, *et al*. Bi-directional relations between stress and self-reported and actigraphy-assessed sleep: a daily intensive longitudinal study. *Sleep* 2020;43:zsz250.
53 Kim HG, Cheon EJ, Bai DS, *et al*. Stress and Heart Rate Variability: A Meta-Analysis and Review of the Literature. *Psychiatry Investig* 2018;15:235–45.
54 Brooke J. SUS: a "quick and dirty" usability scale. In: Jordan PW, Thomas BA, McClelland IL, et al, eds. *Usability evaluation in industry*. London: Taylor and Francis, 1996: 189–94.
55 Hlatky MA, Boineau RE, Higginbotham MB, *et al*. A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). *Am J Cardiol* 1989;64:651–4.
56 Hibbard JH, Tusler M. Assessing activation stage and employing a "next steps" approach to supporting patient self-management. *J Ambul Care Manage* 2007;30:2–8.
57 Lidington E, McGrath SE, Noble J, *et al*. Evaluating a digital tool for supporting breast cancer patients: a randomized controlled trial protocol (ADAPT). *Trials* 2020;21:86.
58 Melissant H, Verdonck-de Leeuw B, Lissenberg-Witte I, *et al*. Oncokompas,' a web-based self-management application to support patient. *Acta Oncol* 2018;57:924–34.
59 Vivify Health. What are the provider results. 2019. Available: www.vivifyhealth.com/for/providers/ [Accessed 7 Oct 2020].