

Investigating the effects of a supported self-management pathway in people who have completed treatment for breast cancer

Submission date 20/12/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/05/2024	Condition category Cancer	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

As more people survive cancer, the NHS is prioritising support pathways to help survivors live well beyond their diagnosis. Traditional breast cancer follow-up involves clinic visits that may be impractical for many women. Supported self-management pathways allow patients to report symptoms when necessary, meaning less time spent attending appointments.

The 24-month PRAGMATIC study will describe the Surrey and Sussex breast cancer supported self-management pathway in terms of patients' experiences, quality of life, self-efficacy, confidence and ability to recognise and report symptoms related to breast cancer. A health economic evaluation will assess costs.

Who can participate?

Women or men who had their breast cancer treatment at a hospital in Surrey or Sussex, who have completed hospital treatment for breast cancer and are about to join the supported self-management pathway

What does the study involve?

Participants have the choice of either completing questionnaires at 3-month intervals for a period of 12 months, or completing the questionnaires and taking part in interviews about their experiences on the supported self-management pathway.

What are the possible benefits and risks of participating?

There will be no direct benefit for research participants, although taking part in this type of research can be a positive experience for some, allowing them to air their views and reflect. Some take satisfaction from being able to contribute to research that they feel may impact on the lives of other patients in the future.

The main disadvantage of taking part is that the study takes time for completing questionnaires and/or participating in interviews. There is a small risk that those taking part in the interview sub-study asking about their experiences of being on the pathway might become distressed when reflecting back about their treatments.

If any participants do become distressed the interviewer will act with care and compassion.

Participants will have control over how much they share. They can decline to answer any questions they wish and can choose to stop the interview at any time. The researchers at SHORE-C are very experienced at conducting interviews with patients and managing interviews in such a way as to reduce distress. If in discussion with a participant, the researcher feels they would benefit by talking to either a support group or an appropriate professional, the researcher would, with (and only with) their permission refer them to the appropriate department.

Where is the study run from?

Sussex Health Outcomes Research and Education in Cancer (SHORE-C), part of Brighton and Sussex Medical School at the University of Sussex (UK)

When is the study starting and how long is it expected to run for?

August 2019 to December 2021

Who is funding the study?

The Surrey and Sussex Cancer Alliance (UK)

Who is the main contact?

Miss Lucy Matthews, l.matthews@sussex.ac.uk

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

272971

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 44180, 064/JEN, IRAS 272971

Study information

Scientific Title

PRAGMATIC: Patients' experiences of a supported self-management pathway in breast cancer

Acronym

PRAGMATIC

Study objectives

As more people survive cancer, the NHS is prioritising support pathways to help survivors live well beyond their diagnosis. Traditional breast cancer follow-up involves regular clinic visits that may be impractical for women who have returned to work/caring duties. Large numbers of patients attending follow-up clinics mean there is increasing pressure on the resource limited NHS.

The National Cancer Plan recognises the importance of personalised care and support, and recommended the implementation of follow-up and supported self-management (SSM) pathways for patients who have completed secondary care treatment for their cancer. SSM pathways allow patients to manage their health and report signs and symptoms as and when necessary, meaning less time spent attending follow-up clinic appointments. In the field of breast cancer, the proposal was for an open access policy to enable GPs or other healthcare professionals to refer patients back to the breast care team immediately if they suspect recurrent cancer or problems related to treatment.

There are obvious benefits in terms of clinical time saving, but few data on patients' experience at managing the pathway, how confident they feel in reporting and receiving advice about suspicious symptoms in a timely manner, and how self-management effects their emotional and psychosocial well-being.

The Surrey and Sussex Cancer Alliance (SSCA) have funded the PRAGMATIC study and it will be conducted in hospitals in the Surrey and Sussex area who have implemented the SSM pathway. Patients who have completed hospital treatment for their breast cancer and are about to join the SSM are eligible. PRAGMATIC will assess the SSCA breast cancer SSM programme from the view of the patients, and measure its impact on NHS costs. The study will run for 24 months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/01/2020, London – Chelsea Ethics Committee (Board Room, Royal Marsden Hospital, The Royal Marsden NHS Foundation Trust, Fulham Road, London SW3 6JJ; +44 (0)207 972 2561; NRESCommittee.London-Chelsea@nhs.net), ref: 19/LO/1966

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Breast cancer

Interventions

The SSM pathway in breast cancer is delivered by the healthcare professionals usually via workshops or a one-to-one appointment. The aim is to provide patients who have finished their hospital treatment with the knowledge, skills, confidence and support to manage any breast-related concerns, including reporting and managing any suspicious symptoms. Those who do have any issue or feel that they need extra support will phone a telephone helpline to enable them to be referred back to the breast care team if they suspect recurrent cancer or problems related to treatment.

Potential participants identified by the clinician as eligible for the study are approached by the nurse or support worker running the workshop or one-to-one appointment about the supported self-management pathway. They will be given an information sheet about the study. A researcher from SHORE-C will obtain written consent from the participant prior to the start of the study.

After signing a consent form patients will complete 5 questionnaires when they join the study, at baseline. These are the Functional Assessment of Cancer Therapy - Breast (FACT-B), Patient Role and Responsibilities Scale (PRRS), General Health Questionnaire - 12 Items (GHQ-12), General Self-Efficacy Scale (GSE), and EuroQoL EQ-5D (EQ-5D-5L). Patients will complete questionnaires at 3, 6, 9 and 12 months. The questionnaires will be sent in the post or completed online, according to patient preference. Completion of these questionnaires will take approximately 30 min.

Participants will also be asked to provide basic demographic information and personal details, such as age, education, family situation, and employment status, as well as details relating to diagnosis and treatment

For those who agree to participate in the interviews, the procedure will be as above together with semi-structured interviews conducted at the same timepoints as the questionnaires (baseline, 3, 6, 9 and 12 months). The first interview will take about 30-40 min and follow-up interviews approximately 15-20 min. These interviews will take place either face to face or via telephone, according to the patient's preference. Interviews will be conducted by an experienced researcher and begin with reiteration of the researcher's independence from other services, the voluntariness of participation, the right to withdraw and anonymity in any report or publication. The researcher will emphasise that the participant can take a break or stop altogether at any time.

Intervention Type

Behavioural

Primary outcome measure

1. Physical, social, emotional, and functional well-being assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B) questionnaire at baseline and 3, 6, 9 and 12 months
2. Breast cancer concerns assessed using the FACT-B sub-scale at baseline and 3, 6, 9 and 12

months

3. Impact of cancer and its treatments on everyday life assessed using the Patient Roles and Responsibilities Scale (PRRS) at baseline and 3, 6, 9 and 12 months
4. Mental wellbeing assessed using the General Health Questionnaire-12 (GHQ-12) at baseline and 3, 6, 9 and 12 months
5. Health-related quality of life assessed using the EuroQol-5D-5L (EQ5D-5L) scale at baseline and 3, 6, 9 and 12 months
6. Self-efficacy assessed using the General Self-Efficacy Scale (GSE) at baseline and 12 months
7. Patient's use of and access to NHS services assessed using a service use questionnaire at 3, 6, 9 and 12 months
8. Participant's views about the supported self-management pathway assessed by interview at baseline and 3, 6, 9 and 12 months

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/08/2019

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Completed hospital treatment for breast cancer and about to join the supported self-management pathway
2. Attended end-of-treatment appointment and supported self-management workshop/one-to-one consultation
3. Able to read and understand English
4. Willing and able to provide consent
5. Aged 18 years or over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 110; UK Sample Size: 110

Total final enrolment

110

Key exclusion criteria

1. Currently inpatient
2. Acutely distressed for any reason
3. From a hospital outside the Surrey and Sussex Cancer Alliance
4. Do not speak/understand English and have no one to interpret/translate

Date of first enrolment

10/02/2020

Date of final enrolment

30/11/2020

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Ashford and St Peter's Hospital**

Ashford and St Peter's NHS Foundation Trust

St Peters Hospital

Guildford Road

Chertsey

United Kingdom

KT16 0PZ

Study participating centre**Royal Sussex County Hospital**

Eastern Road

Brighton

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Study participating centre**Worthing Hospital**

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Sponsor information

Organisation

University of Sussex

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Sponsor type

University/education

Website

<http://www.sussex.ac.uk/>

ROR

<https://ror.org/00ayhx656>

Funder(s)**Funder type**

Other

Funder Name

The Surrey and Sussex Cancer Alliance

Results and Publications**Publication and dissemination plan**

The results will be made available in peer-reviewed scientific journals, an internal report, conference presentations and website publications. Participants will be invited to indicate on their consent forms if they would like a copy of the published results. They will be informed that publication of findings can take a considerable time.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The data are held in the University of Sussex Figshare data repository at <https://doi.org/10.25377/sussex.22925822.v1>

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article	Quality of life and service use results	12/09/2023	09/10/2023	Yes	No
Results article	Patients' views and experiences	27/10/2023	01/11/2023	Yes	No
Dataset			22/05/2024	No	No