The Shrewsbury and Telford Hospital NHS Trust

UNIVERSITY OF BIRMINGHAM

Understanding the offer and uptake of support for lifestyle behaviour change following breast cancer treatment

STUDY PROTOCOL

Short title: Support for lifestyle behaviour change after breast cancer treatment

Version 3.0 1st August 2024

IRAS ID: 332207

ABBREVIATIONS

BME:	Black and Minority Ethnicities
BMI:	Body Mass Index
CI:	Chief Investigator
COM-B:	Capability, Opportunity, Motivation, Behaviour
CRN:	Clinical Research Network
GCP:	Good Clinical Practice
GDPR:	General Data Protection Regulation
HRA:	Health Research Authority
IAHR:	Institute of Applied Health Research
ICD10:	International Classification of Disease 10
ICF:	Informed Consent Form
JISC:	Joint Information Systems Committee
NDRS:	National Disease Registration Service
NHS:	National Health Service
NICE:	National Institute for Health and Care Excellence
NIHR:	National Institute for Health and Care Research
PAG:	Patient Advisory Group
PIS:	Participant Information Sheet
PPIE:	Patient and Public Involvement and Engagement
REC:	Research Ethics Committee
RDN:	Research Delivery Network
QoL:	Quality of life
TDF:	Theoretical Domains Framework

STUDY SPECIFIC DEFINITIONS

BCN: Breast Cancer Nurse (specialist nurse for people with breast cancer)

BCS: Breast Cancer Survivors (those who have been diagnosed with a breast cancer)

LBCS: Lifestyle and Behaviour Change Support (interventions comprising dietary advice, physical activity recommendations and psychological wellbeing support

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KEY STUDY CONTACTS

Chief Investigators	Mrs Blossom Lake Shrewsbury and Telford Hospital NHS Trust blossom.lake@nhs.net Dr Sarah Damery Institute of Applied Health Research University of Birmingham s.l.damery@bham.ac.uk
Sponsor	Research and Innovation Department Shrewsbury and Telford Hospital NHS Trust
Funder	NIHR206118 National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme
Key Protocol Contributors	Dr Laura Jones, University of Birmingham Dr Laura Kudrna, University of Birmingham Professor Kate Jolly, University of Birmingham Mrs Mandy Wilson, Shrewsbury and Telford Hospital NHS Trust Mrs Rebecca Wilcox, Shrewsbury and Telford Hospital NHS Trust Miss Louise Stevens, Shrewsbury and Telford Hospital NHS Trust
Research Fellow	To be appointed
Approval reference IDs	IRAS: 332207 REC ref: 24/WA/0201 (Wales5 REC)
Chief Investigators Signature	 

SCIENTIFIC ABSTRACT

Research question: What physical activity, dietary advice and wellbeing support or Lifestyle Behaviour Change Support (LBCS) is currently offered to and taken up by people who have had breast cancer, and what are the barriers and facilitators to both offer and uptake?

Background: Breast cancer is the most common cancer, with around 500,000 breast cancer survivors (BCS) in the UK currently. Half of BCS live with being overweight or obesity at diagnosis, and 50-80% gain weight following diagnosis. People living with excess weight at or after breast cancer diagnosis have poorer outcomes than those with a normal weight. They may also have poorer response to endocrine treatment and systemic chemotherapy; greater risk of cancer recurrence or secondary cancers and increased overall and cancer-specific mortality. Promoting weight loss and maintaining a healthy lifestyle may improve disease prognosis, outcomes and reduce disparities between groups of BCS.

Aims and objectives: This project aims to describe what LBCS (physical activity, dietary advice and wellbeing support) is currently offered to BCS following diagnosis or during treatment and understand service/patient barriers and facilitators to offer and uptake. Objectives are to:

- Understand what lifestyle and behaviour change support is offered to and taken up by BCS
- Describe barriers and facilitators to service providers offering lifestyle and behaviour change support to BCS
- Describe barriers and facilitators to BCS participating in/engaging with lifestyle and behaviour change support

Methods: Mixed methods study combining quantitative data collection via national survey of Breast Care Nurses/Cancer Navigators (~n=300), survey of BCS across five purposively sampled NHS Trusts (~n=400); semi-structured interviews with a) Breast Care Nurses/Cancer Navigators (n=20) and b) purposively sampled BCS (n=20), and data integration and synthesis followed by a stakeholder workshop.

The survey for Breast Care Nurses and Cancer Navigators will be publicised and made available through an electronic link within the monthly Breast Cancer Now ebulletin. The BCS survey will be disseminated across five NHS Trusts and via the networks available through Breast Cancer Now. Both surveys will be analysed descriptively. Semi-structured interviews will explore barriers and facilitators of LBCS offer and uptake, and will be analysed using the Theoretical Domains Framework and COM-B. The research team and patient advisory group will then synthesise the qualitative and quantitative data to determine the headline study findings. This will inform a half-day stakeholder event (including healthcare professionals, commissioners and BCS) to discuss the findings and develop recommendations for practice.

Timelines: Duration: 18 months beginning June 2024. Milestones: Study set-up/ethical approvals (Pre-award); surveys (months 2-6); patient and practitioner interviews (months 6-10); synthesis and stakeholder workshop (months 11-14); dissemination and reporting (months 15-18).

Anticipated impact and dissemination: Results will be shared with participants, the Association of Breast Surgery Nursing Committee and the West Midlands Clinical Research Network Alliance and published in the Breast Cancer Now newsletter. Academic outputs will include submission for publication to the Breast Journal and presentation at the Association of Breast Surgery and Health Services Research UK annual conferences. Patient-facing resources will include ‘bite-sized’ results summaries, infographics and an animated video.

PLAIN ENGLISH SUMMARY

What is the problem?

Breast cancer is the most common cancer. More than half of people who have breast cancer weigh more than a healthy weight. When people weigh more than a healthy weight, cancer treatments may not work as well, and breast cancer is more likely to return after treatment. It is recommended that patients with breast cancer do regular exercise and eat healthy foods. For those who have excess weight it is suggested that they try to lose between 5% and 10% of their body weight.

Activities which help people lose weight can improve quality of life and mental health. Examples of these activities are eating healthily, exercising and accessing psychological (therapy) support. However, there is no clear way to help people with breast cancer do this, and different activities are provided in different places. We also need to know more about what people with breast cancer do if they are offered support.

What is our aim and how will we do this?

We will explore what activities to lose weight and help with lifestyle change are offered to people with breast cancer. We will also look at what activities they do. We will do this by sending surveys to nurses and people with breast cancer. We will also talk to around 20 nurses and 20 people with breast cancer in more detail about their experiences. We will ask what helped nurses when offering activities and what prevented them offering. We will ask people with breast cancer what was helpful in being able to do an activity, or what stopped them doing these activities.

We will bring this information together and have an event to discuss our results with people working in health services and patients, to learn what works well and what does not work well for breast cancer patients and services.

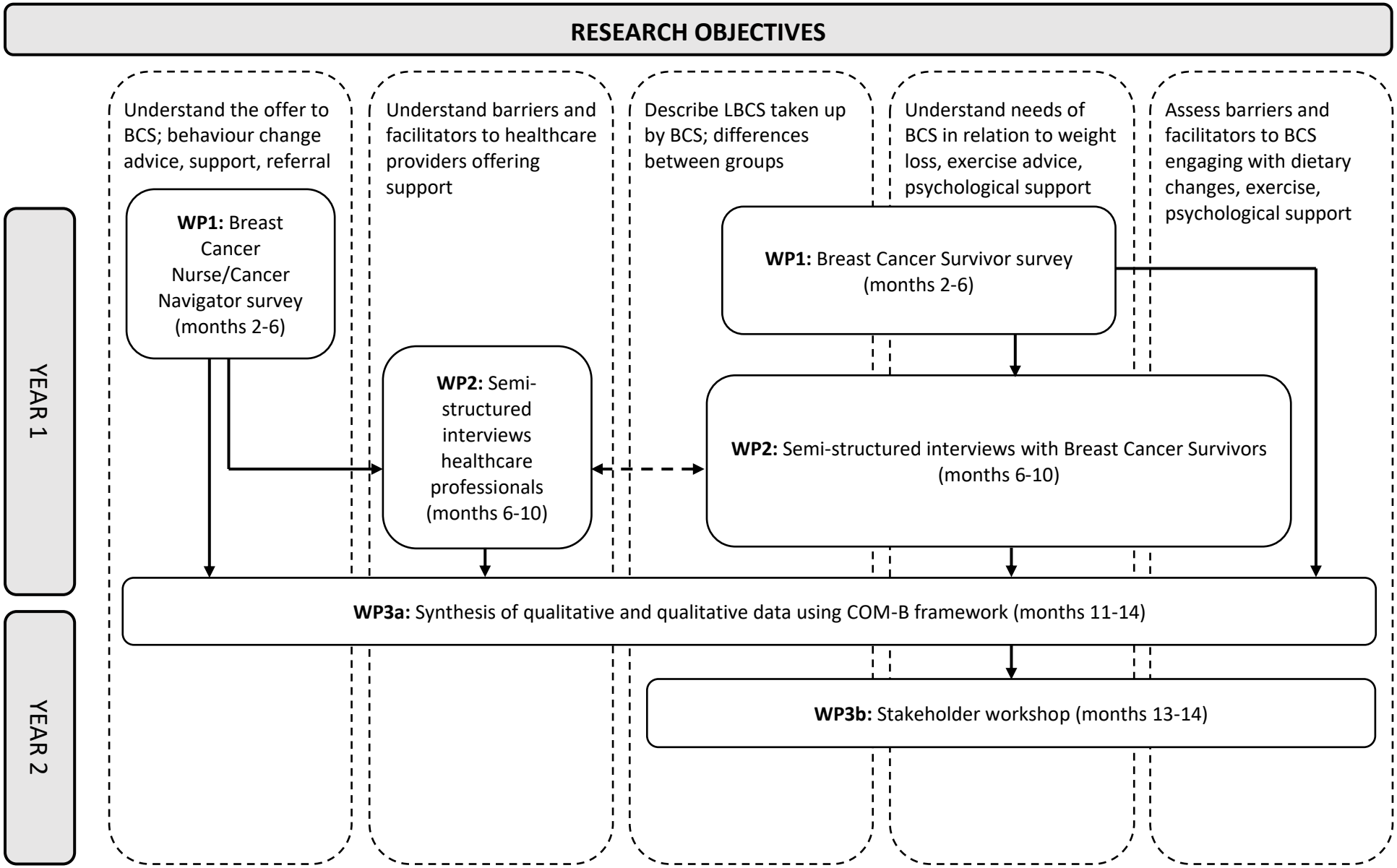
How have we involved the patients and the public?

We worked with people who have had breast cancer, breast cancer nurses and the charity Breast Cancer Now to develop our research questions. We also worked with community leaders to learn the views of people from ethnic minority backgrounds. Our patient co-applicant and Patient Advisory Group will bring lived experience to all parts of the research such as advising on surveys, interview questions, understanding results and helping us share them.

How will we share what we find?

We will share our results with professional networks, patient groups, at conferences and in medical journals. We will create an animated video, infographic and short, easy to understand summaries for patients. We will then apply for further research funding to learn how we can provide a clear patient pathway to help people with breast cancer follow a healthy lifestyle.

STUDY OUTLINE



STUDY TIMELINES

		2024										2025											
Tasks					Year 1													Year 2					
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M		J	J	A	S	O	N
	Duration	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12		13	14	15	16	17	18
Preparation and approvals																							
Protocol development	1 month																						
NHS ethical approval	3 months																						
NHS Trust R&D approvals	3 months																						
Recruit research fellow	3 months																						
WP1: Surveys of BCS and healthcare professionals																							
Survey design using literature	1 month																						
Survey co-design meeting with patient advisory gp	1 month																						
Survey administration: BCNs and cancer navigators	4 months																						
Survey administration: BCS	4 months																						
Survey data cleaning	1 month																						
Survey data analysis	2 months																						
WP2: Interviews with BCS and healthcare professionals																							
Interview topic guide development	1 month																						
Topic guide development meeting with PAG	1 month																						
BCN/Cancer navigator interviews (n=20)	4 months																						
BCS interviews (n=20)	4 months																						
Interview analysis	4 months																						
WP3a: Synthesis of qual and quant data																							
Data synthesis	4 months																						
WP3b: Stakeholder event																							
Stakeholder event - synthesis, recommendations	1 month																						
Outputs																							
Dissemination	3 months																						
Final report	3 months																						
Meetings																							
Patient Advisory Group meetings	x5																						

BACKGROUND AND RATIONALE

Breast cancer is the most common cancer[1], with around 500,000 breast cancer survivors (BCS) in the UK currently.[2] Half of BCS live with overweight (Body Mass Index (BMI) 25-29.9 kg/m2) or obesity (BMI >30 kg/m2) at diagnosis, and 50-80% gain weight following diagnosis.[3,4] People living with excess weight at or after breast cancer diagnosis have poorer outcomes than those with a normal BMI (<25 kg/m2).[5,6] They may also have poorer response to endocrine treatment and systemic chemotherapy; greater risk of cancer recurrence or secondary cancers5,[7,8], and increased overall and cancer-specific mortality.[9]

Both obesity and breast cancer incidence vary by ethnicity.[10] BCS of Black African or Black Caribbean heritage are more likely to be living with excess weight and typically experience more unfavourable tumour characteristics.[11] Obesity and breast cancer are also more common among sexual minority groups[12] and vary by socioeconomic status.[13] Promoting weight loss and maintaining a healthy lifestyle may improve disease prognosis, outcomes and reduce disparities between groups of BCS.[14]

The National Institute for Health and Care Excellence (NICE) guidelines recommend physical activity and dietary changes for BCS to ensure a healthy lifestyle[15], and leading cancer organisations suggest that BCS with a BMI >25kg/m2 should aim to achieve weight loss of 5 to 10% following diagnosis.[1] Our systematic review of reviews of the effectiveness of lifestyle and behaviour change support (LBCS – term used throughout this proposal to describe interventions comprising dietary advice, physical activity recommendations and psychological wellbeing support) for BCS synthesised data from 17 systematic reviews, showing that multicomponent LBCS can significantly reduce weight, BMI and body fat.[16] LBCS was also associated with significantly improved health-related quality of life, mental health, emotional wellbeing and physical functioning. Interventions were effective for people with different ethnicities, varying socioeconomic status and educational backgrounds. There is no evidence yet that LBCS can impact cancer recurrence, but ongoing trials seek to address this (results anticipated 2024).[17]

Personalised care for patients with cancer, including needs assessment, care planning and health and wellbeing information, is central to the National Health Service (NHS) Long Term Plan.[18] Understanding specific lifestyle changes which help patients living with and beyond cancer to restore health and improve quality of life is also a James Lind Alliance priority.[19] Whilst the negative impacts of excess weight on breast cancer outcomes are known and the effectiveness of LBCS for BCS has been established, there is no clear pathway to provide personalised support to BCS and the current LBCS offer across the NHS is unknown.[16,20]

Wellbeing support is an essential component of LBCS. Breast cancer diagnosis, treatment and longer-term sequelae typically have substantial psychological impacts on BCS' perception of self, awareness of mortality and changes in body image. Undertaking physical activity can positively impact quality of life in BCS by enhancing self-esteem, improving mood and feelings of control, alongside physical benefits.[21] The main barriers to effective engagement with physical activity include fatigue, pain, work and caring responsibilities.[22,23] Despite known benefits of physical activity for BCS, patients identify a lack of direction about the optimal exercise regime structure

(e.g. type, intensity, duration, frequency), dietary advice, and other support that should be offered. Best practice exemplars exist: the Clinical Oncology Society of Australia recommends that exercise is embedded as standard practice within cancer care and viewed as adjunctive therapy.[24] In the United Kingdom, the Royal Marsden Hospital is developing an 'Active Hospital' strategy, integrating lifestyle changes into cancer care and providing dietician advice for all patients with cancer.[25]

NICE recommends 150 minutes of moderate intensity physical activity per week for patients living with cancer, and for healthcare providers to promote exercise to patients.15 However, research reports that only 43% of breast clinicians may give physical activity advice corresponding with guidelines.26 UK Cancer Alliances advocate personalised care for BCS.27 Similarly, Macmillan Cancer Support's 'Recovery Package for Cancer Care', includes health needs assessment, wellbeing events, and access to '*Let's Get Moving'* and '*Walking for Health'* programmes. However, these services are not widely available, and most users are White British.[28]

An exploratory survey of Breast Care Nurses (BCN) (n=10) at five West Midlands NHS Trusts conducted to support development of this study showed substantial practice variations in offering LBCS to patients, from dedicated consultations, to resource signposting or leaflet dissemination. Sixty percent of BCNs were unsure whether LBCS was/should be part of their role, and 80% felt there was rarely adequate time/opportunity to address lifestyle change issues with BCS. A national patient survey by Macmillan Cancer Support reported that around half of patients with cancer were not told that exercise was beneficial and were not advised how to reduce their risk of recurrence through lifestyle changes.[29] Similarly, a patient survey completed by 113 primary breast cancer patients and 47 secondary breast cancer patients at Shrewsbury and Telford NHS Trust showed that only 5.6% of primary breast cancer patients and 6.8% of secondary breast cancer patients felt they had been offered any information about weight loss activities following their diagnosis or treatment, and only 12% of primary breast cancer patients and 17.8% of secondary breast cancer patients reported that they had been offered advice about diet. Although small-scale, these data suggest that BCS may not be aware of or understand the importance of LBCS offered by health services.

RESEARCH PLAN

Aim and objectives

This study aims to describe what LBCS (physical activity, dietary advice and psychological wellbeing support) is currently offered to BCS following diagnosis or during treatment, and understand service/patient barriers and facilitators to offer and uptake. Specific objectives are to:

1. Understand what lifestyle and behaviour change support is offered to and taken up by BCS

2. Describe barriers and facilitators to service providers offering lifestyle and behaviour change support to BCS

3. Describe barriers and facilitators to BCS participating in/engaging with lifestyle and behaviour change support

Variation in offer/uptake by key patient characteristics such as ethnicity, age, gender/sex and socioeconomic status will be assessed within each objective.

METHODOLOGY

This study will used mixed methods (see study outline) and will follow an explanatory sequential design[30] to combine:

1. Quantitative data collection via surveys of BCNs/Cancer Navigators and BCS (WP1)
2. Semi-structured interviews with BCNs, Cancer Navigators and BCS (WP2)
3. Data integration and synthesis and a stakeholder workshop to identify targets for action (WP3)

The Theoretical Domains Framework (TDF) and Capability, Opportunity, Motivation, Behaviour (COM-B) model[31] will inform the development of the surveys and interview topic guides, support the interpretation of the qualitative and quantitative data, and the integration/synthesis of our findings. COM-B identifies the capability, opportunity and motivational factors that may act as interrelated barriers to, and facilitators of behaviour. COM-B maps onto the TDF, which is an integrated theoretical approach to explaining change, such as shaping knowledge or goals.

Work Package 1

Work package 1 will comprise a national online survey of healthcare professionals (Breast Cancer Nurses and Cancer Navigators), and a survey of breast cancer survivors across five purposively sampled NHS Trusts in England.

HEALTHCARE PROFESSIONALS SURVEYS (months 2-6)

Setting/participants

The healthcare professional survey will be sent to BCNs and Cancer Navigators currently working in the NHS across England. BCNs are specialist nurses caring for people diagnosed with breast cancer; Cancer Navigators work closely with BCNs and were introduced as part of the Macmillan Recovery Package as the first point of contact for patients as they progress through the stages of their cancer journey.

Survey development

The BCN/Cancer Navigator survey design will draw on key TDF and COM-B domains, and will be co-designed by the study research team and study Patient Advisory Group (PAG).

Survey content

The healthcare professional survey will assess a number of aspects of lifestyle and behavioural change support (LBCS) for people with breast cancer, including:

1. What LBCS is offered to BCS (activities covered);
2. When in the pathway LBCS is offered (e.g. at or after diagnosis/treatment);

3. Who LBCS is offered to (e.g. to identify specific patient groups that healthcare professionals perceive to face challenges with engagement or who may require additional support);
4. How LBCS is offered (e.g. discussed during consultations, information leaflets, signposting);
5. How LBCS is delivered and in what settings (e.g. remotely or in-person).

Regional differences and good practice will be identified. Data will also be collected on respondents' perceived barriers and facilitators to providers offering lifestyle support; their role characteristics (e.g. NHS Trust, role, length of time working in breast cancer services), and basic demographic information (sex, age group, ethnic group).

Survey participants will also be asked to indicate whether they would be willing to take part in a semi-structured interview to explore issues surrounding the offer of LBCS for people with breast cancer in more detail (as part of WP2). Survey respondents who wish to participate in an interview will be asked to provide their name and preferred contact email address so that the research team can contact them directly once the interview phase of the study begins.

The BCN/Cancer Navigator survey will be designed to be easily completed so as to minimise burden on participants (estimated time for completion 20 minutes), and will use short, tick-box style questions and Likert scales, with optional free text boxes to allow participants to provide additional information to substantiate their responses if they wish. The healthcare professional survey will be piloted for comprehension and readability prior to dissemination with 2-3 staff from Shrewsbury and Telford Hospital NHS Trust who will not be invited subsequently to complete the survey when disseminated, and by members of the study Patient Advisory Group (PAG).

Recruitment and survey administration
All BCNs/Cancer Navigators currently working in NHS Trusts in England, who provide care for people with breast cancer will be eligible to participate in the survey. Surveys will be created by, and administered using the Joint Information Systems Committee (JISC) Online Surveys tool (formerly Bristol Online Surveys), for which the University of Birmingham holds an institutional licence. Online Surveys was chosen as the survey platform because it is designed to protect respondent anonymity – the system does not use cookies for survey completion, and information about respondents' IP addresses cannot be accessed. Survey respondents will be able to take part in the survey from any location, at a time of their choosing, minimising any potential inconvenience associated with research participation. Online Surveys also allows participants to save their answers at any point during completion and return to it at any point.

BCNs and Cancer Navigators will be approached via several pathways. A study profile and survey weblink/QR code will be published in the monthly Breast Cancer Now ebulletin, which is sent to 2000 recipients, around 1600 of whom work in the breast cancer field. This has been agreed by the editor of the ebulletin. The weblink will be published again in a subsequent bulletin to maximise reach and to act as a reminder for those who have yet to complete the survey. The survey will also be publicised via professional networks, appropriate social media platforms, and advertised at multiple breast cancer meetings and in staff newsletters to maximise survey reach and potential uptake.

Potential respondents will have the option to provide contact details (name and email address) to receive a £20 voucher in recognition of their time spent completing the survey.

Consent

Written informed consent will not be obtained, and submission of the survey will be taken as consent to participate. The front page of the survey (before any survey questions) will include a summary Participant Information Sheet (PIS) and a weblink to the full PIS which will be hosted on the Shrewsbury and Telford Hospital NHS Trust website. There will also be a mandatory tick box embedded within the survey for respondents to acknowledge that they have read and understood a series of statements assuring them of the confidential handling of any information they provide in their response; their right to refuse to answer specific survey questions; that they can opt out of submitting a survey response at any time, but that once their survey has been submitted, their response cannot be removed. Participants will not be able to progress into the main body of the survey until the consent box has been checked. They will also be required to type their name into a mandatory text box underneath the consent statements, which acts as a simple form of signed consent.

Sample size and justification

There is no national database of BCNs; however, a 2017 census by Macmillan Cancer Support identified 650 BCNs nationally. If the annual increase in BCN roles from 2014 to 2017 has continued since 2017, we would expect there to be c.880 BCNs in England currently. Cancer Navigators do not exist in all NHS Trusts, however the Cancer Alliance estimates 80% of 219 Trusts offer the Recovery Package, which would equate to c.175 Cancer Navigators nationally. Therefore, we estimate around 1100 potential respondents to the healthcare professional survey. Based on evidence that 43% of clinicians discuss lifestyle behaviour with patients[26], to estimate this proportion to +/- 5% at 95% power, 268 completed surveys would be required (response rate 24%). A previous survey of breast care oncology nurses about metastatic breast cancer achieved a 65% response rate.[32]

Data analysis

Healthcare professional survey data will be analysed descriptively to map the offer of LBCS and its specific components, as well as when and how such services are offered/delivered. The analysis will identify key features of LBCS offered and how they are offered to people with breast cancer (broken down to cover physical activity, dietary advice and psychological wellbeing support). Respondents' views about the barriers to, and facilitators to specific service offers for people with breast cancer will be analysed to describe commonalities and differences in practice. Free text responses will be coded using TDF and COM-B domains to capture key facilitators and barriers related to capability, opportunity and motivation for healthcare professionals in offering lifestyle change support to BCS.

PATIENT SURVEYS (months 2-6)

Setting/participants

The BCS survey will be disseminated across five purposively sampled NHS Trusts representing rural/semi-rural/urban localities, and reflecting socioeconomic and ethnic diversity. Participating Trusts will also be drawn from around the country to ensure geographical diversity across London, the Midlands, South West and North of England.

The selection and recruitment of NHS Trusts has been undertaken using data from the National Disease Registration Service (NDRS) (https://digital.nhs.uk/ndrs/) which provides searchable data about disease diagnoses and treatments, identified by International Classification of Disease 10 (ICD10) codes. Data can be broken down by NHS Trust, and for each Trust the volume of diagnoses for a given condition can be assessed by year, including aggregate data on sex, age group, ethnicity and socioeconomic deprivation. The NDRS data were searched across England, region by region, to identify the Trusts within each region with: a) high volumes of patients being treated for breast cancer annually, b) diversity in terms of patient ages, ethnicity and socioeconomic deprivation. Trusts were also divided into urban/semi-rural and rural categories within each region. This process created a long-list of Trusts to approach for recruitment to the study, which were contacted via the Trust research governance office to gauge interest in participation as a study site. If a site expressed interest in participating, a meeting took place between key research governance/clinical staff at the site and the study CIs to explain what participation would involve before securing agreement in principle (subject to local research governance approvals being granted). The five NHS Trusts recruited were:

1. Shrewsbury and Telford Hospital NHS Trust (lead site): Midlands
2. Macclesfield Hospital (East Cheshire NHS Trust): North West
3. Nottingham University Hospitals NHS Trust: Midlands
4. Royal Devon University Healthcare NHS Foundation Trust: South West
5. Guy's and St Thomas' NHS Foundation Trust: London

These sites will ensure that patient surveys include a diversity of patient characteristics, with broad regions of England represented in participating NHS Trusts.

Survey development

The patient survey design will draw on key TDF and COM-B domains, and will be co-designed by the study research team and study PAG.

Survey content

The BCS survey will ask which physical activity, wellbeing support, dietary advice and/or weight loss programmes had been offered to participants, how/when these were offered, and whether participants chose to engage with these activities. Survey structure will broadly follow that used for the healthcare professional survey, including:

1. Whether they had been offered LBCS
2. What LBCS they had been offered (activities covered);
3. When in the pathway LBCS had been offered (e.g. at or after diagnosis/treatment);
4. How LBCS was offered (e.g. discussed during consultations, information leaflets, signposting);

5. How LBCS was delivered and in what settings (e.g. remotely or in-person)
6. Whether patients had accepted the offer of LBCS and what activities/support was accessed

Patient survey questions will also address potential barriers to, and facilitators of accessing LBCS. Patient respondents will be asked to provide brief demographic data (age group, sex, ethnic group, education and socioeconomic status) alongside information on their pre-diagnosis lifestyle (e.g. previous exercise history).

Patients completing the survey will be asked to indicate whether they would be willing to take part in a semi-structured interview as part of WP2. Those who are interested in participating in an interview will be asked to provide their name and preferred contact email address/telephone number so that the research team can contact them directly to discuss their participation in more detail once the interview phase of the study begins. Respondents who are interested in participating in an interview will also be asked to identify any support they might require (e.g. language preferences) to facilitate their participation in an interview. Survey respondents will also have the option to provide contact details to receive a £20 voucher in recognition of their time spent completing the survey.

Patient surveys will be designed so that they can be easily completed, so as to minimise burden on participants. The estimated time for completion will be 20 minutes. Survey questions will use short, tick-box style questions and Likert scales, with optional free text boxes for participants to provide additional information to substantiate their responses as appropriate. The patient survey will be assessed for comprehension and readability prior to dissemination by members of the study PAG and the charity Breast Cancer Now.

Recruitment and survey administration
The primary route of recruitment and administration of the patient survey will be through the NHS. Eligible BCS will be identified at each of the five participating research sites by Trust staff following a search of Trust information systems to identify all patients diagnosed with early or locally-advanced breast cancer within the previous 12 month period who will be between 6 and 12 months post-diagnosis at the time the survey is administered. This time period has been chosen as most breast cancer patients will have completed treatment by this time, thus representing an appropriate point to ask about offer and uptake of LBCS. There will be no restrictions on eligibility based on any characteristics such as ethnicity, gender identity, socioeconomic status, sexuality or disability, although clinical staff at participating sites will screen the lists of potentially eligible patients to remove any that they feel should not receive a survey on clinical grounds or because they may be unable to consent to take part in the study. Each Trust will also apply national opt-out and their local opt-out procedures to ensure that patients who have formally requested not to be involved in research do not receive a survey.

Patient surveys will be disseminated as paper copies by post only (there will be no option for alternative electronic completion so that duplicate responses can be avoided). Survey packs, comprising paper copies of the survey, a PIS, a covering letter and a reply-paid envelope for survey return will be put together by members of the direct care team on Trust premises at the five

participating sites. Clinical staff at each site will produce a list of patient names so that they can personalise the covering letter, and a list of addresses or a pre-printed set of address labels so that envelopes can be addressed for mailing. These activities will be done by clinical staff at each site.

The footer of each survey will have the Trust name, so that the number of surveys returned from each site can be determined and a response rate calculated. Once the survey packs have been collated and addressed, they will be posted from the mail room at each participating site. No information about the patients to whom surveys have been sent will be seen by members of the research team, as all activities relating to the survey mail out will be undertaken by members of the clinical team at each site. There will be no reminder mailing, so patients will receive a single survey only.

Whilst it is not practical to make the survey available in multiple languages, the PIS that accompanies the survey will include a contact telephone number for a member of the research team so that any patient that does not feel confident to complete the survey without support can complete it over the telephone.

Consent
Written informed consent will not be obtained, and submission of the survey will be taken as consent to participate. The survey will be accompanied by a PIS giving a detailed description of the study. The front page of the survey will include a series of statements assuring potential respondents of the confidential handling of any information they provide; their right to refuse to answer specific survey questions; that they can opt out of submitting a survey response by not returning the survey, but that once their survey has been submitted, their response cannot be removed. Respondents will be asked to initial a box linked to each individual statement to indicate that they have read and understood it. They will also be asked to write and sign their name underneath the consent statements to indicate their consent to participate.

Sample size and justification
We estimate inviting c.2000 patients to complete the BCS survey, based on an average sized NHS Trust diagnosing 400 breast cancers per year. An expected 20% response rate would equate to 400 surveys returned (~80 per Trust); sufficient to estimate the proportion with a positive/negative attitude towards LBCS at 95% power (precision+/-5%) (334 surveys needed).

Data analysis
BCS survey data will be analysed descriptively to understand what physical activity, wellbeing, dietary advice and/or weight loss programmes have been offered to patients' post-diagnosis and used by them. Sub-group analyses by ethnicity, locality and socioeconomic status will seek to understand whether there are inequalities in offer and uptake across regions. Free text responses will be coded using TDF and COM-B domains to capture key facilitators and barriers related to capability, opportunity and motivation for patients in engaging with lifestyle change support.

Data handling (BCN/Cancer navigator and patient surveys)

Online Surveys assigns each survey respondent a unique identifying number, and does not record any personal information, cookies, IP addresses or email addresses. BCN/Cancer Navigators will not be asked to provide any personal information apart from basic demographic data (sex, age group, ethnic group) and some brief information about their job (NHS Trust, role, time working in breast cancer services). Patients will not be asked to provide any personal information apart from brief demographic data (age group, sex, ethnic group, education, socioeconomic status). This information will be non-identifiable. If any survey respondents disclose personal information via their free text responses, these will be removed by the research team at the point of exporting survey responses from the Online Survey database to the database that will be kept securely at University of Birmingham for the purposes of analysis (for electronic returns), and redacted from data entry for paper-based survey returns. If respondents have provided any contact details to claim the £20 reimbursement being offered, these details will be removed from the database before analysis. If respondents have provided any contact details so that they can be contacted about participating in an interview, these will be kept in a password-protected document and stored electronically within a secure folder on the IT network for the Institute of Applied Health Research (IAHR), using the University of Birmingham's research drive which provides secure, backed up storage of research data. These details will be retained until the interview stage of the study is complete, then they will be deleted.

The survey database will be password-protected and stored electronically within a secure folder on the IT network for IAHR, using the University of Birmingham's research drive which provides secure, backed up storage of research data. The secure study folder will only be accessible to members of the core research team involved in the management and analysis of the survey data. Data will not be shared outside of University of Birmingham, and anonymised data will be archived under the University of Birmingham's regulations on the management of research data and retained for 10 years, with the study joint CI (SD) as data custodian.

Work Package 2

SEMI-STRUCTURED INTERVIEWS (months 6-10)

Work package 2 will comprise semi-structured interviews with breast cancer survivors (n=20), and BCNs/Cancer Navigators (n=20).

Topic guides

Interview topic guides will be finalised following analysis of the surveys returned in WP1, literature review, and with the input of the research team and PAG. Key domains of the TDF and COM-B will be used to inform the structure of the topic guides, including questions about components of LBCS and the barriers and facilitators to the offer of LBCS (service-related factors), and uptake of LBCS (patient-related factors).

Recruitment and consent

Potential interview participants will be purposively sampled from those who indicated their willingness to be interviewed in their completed survey. BCNs/Cancer Navigators will be purposively sampled to ensure a mix of job roles and that mix of NHS Trusts is included, as well as

targeting survey respondents from NHS Trusts that demonstrated substantial engagement offering LBCS to people with breast cancer and those that demonstrated less substantial engagement with LBCS. Patients will be sampled using maximum variation sampling to ensure that potentially under-represented groups of BCS (e.g. those from ethnic minority backgrounds); those with varying socioeconomic characteristics (e.g. age, socioeconomic status) and a range of pre-diagnosis lifestyles (e.g. previous exercise history) can be included in the interview cohort.

Interviewees from both the healthcare professional and patient groups will be offered a £20 voucher to thank them for their participation. Survey respondents in both groups who indicated on their survey that they would like to be interviewed, but who are not part of the purposive sample selected to participate in an interview will be contacted using the contact information provided on the survey to thank them for their interest and let them know that they will not be required to take part in an interview.

Individuals who have been selected to be approached for interview will be contacted initially by a member of the research team using the contact details provided on their survey return. This initial approach will check that the individual is still willing to be interviewed, and if so, to obtain their preferred contact details so that an interview PIS and informed consent form (ICF) can be sent to them (either electronically or by post with a reply-paid envelope for return of the signed consent form). Once potential interviewees have had time to consider their participation, they will be contacted again by a member of the research team to answer any questions they may have about participating in an interview, and to set a convenient date and time for the interview to take place.

Data collection
All interviews will be conducted by an experienced qualitative researcher fully trained in qualitative research methods and Good Clinical Practice (GCP).

BCN/Cancer Navigator interviews will all take place either online (using a secure videoconferencing platform such as Zoom or Microsoft Teams) or over the telephone. For online interviews, the University of Birmingham Zoom/Microsoft Teams account will be used. Patient interviews will be offered online/via telephone, or in-person at a mutually convenient location, and participants will have the opportunity of participating with or without family/carer support. This will allow participation by BCS with diverse socioeconomic, ethnic and other characteristics. Participants who will be interviewed online or by telephone will be asked to return their signed consent form to the research team at University of Birmingham either electronically or by post before the interview takes place. Participants being interviewed in person will provide their signed consent form to the researcher conducting the interview at the time it takes place.

At the start of each interview (whether taking place online, via telephone or in-person), the researcher will remind the participant of the purpose of the study and will respond to any questions the participant may have. Participants will be informed that they have the right to decline to participate; that participation is voluntary; that all responses given will remain completely confidential, and that they can withdraw from the study at any time without giving a reason.

However, they will be informed that if they withdraw more than two weeks after their interview, any data collected may still be used in the study if analysis is already underway.

It is anticipated that interviews will last up to 45 minutes. Interviews will be digitally audio-recorded using a University of Birmingham-supported device as issued by University of Birmingham IT services. Even if carried out over a video conferencing platform such as Zoom or Microsoft Teams, interviews will still be audio recorded using an encrypted digital recorder (i.e. the built-in audio or video recording functions within Zoom and Microsoft Teams will not be used). To maintain researcher safety when undertaking in-person interviews, the qualitative researcher will adhere to the University of Birmingham's Code of Practice for the Safety of Social Researchers (https://intranet.birmingham.ac.uk/hr/documents/public/hsu/information/offcampus/sracop.pdf).

Although interviews will not be designed to discuss patient participants' cancer diagnosis or treatment, focusing instead on the lifestyle and behavioural change support they may have been offered by their NHS Trust, there is a risk that patient interviewees could become distressed during their interview. The researcher conducting the interviews will be trained in collecting interview data on potentially sensitive topics. If an interview participant becomes upset during their interview, the interview will be paused, and the participant provided with the opportunity to stop, take a break or continue, as outlined by the Qualitative Research Distress Protocol.[33] If the participant wishes to continue but remains distressed, the researcher will make the decision to bring the interview to a close. The decision as to whether data collected during the interview until that point can still be included in analysis or whether the participant should be withdrawn will be taken by the research participant.

Data collection will continue until no new knowledge is contributed to the analysis (sufficient information power[34]), or the target of 20 interviews in each group is reached.

Data analysis

Data collection and initial analysis will take place iteratively. Individuals will not be identifiable from any quotation cited in reports of the study findings, presentations, academic papers etc. Following each interview, the audio recording will be independently transcribed verbatim by an independent transcription company, and the resulting transcript will be proof-read against the original recording by the researcher who undertook the interview. The original audio recording will be deleted after proof reading is completed. Transcripts will be uploaded to NVivo for data management and coded by the researcher.

Characteristics of interview participants and issues related to the offer and uptake of LBCS will be described. Barriers and facilitators to the offer/uptake of LBCS will be inductively coded using codebook thematic analysis.[35] Following completion of the inductive analysis, themes from the BCNs/Cancer Navigator and patient interviews will be aligned with and further interpreted against the TDF and COM-B domains. Where relevant, themes will be compared between BCS and BCNs/Cancer Navigators, and potential similarities and differences in views explored between BCNs and Cancer Navigators, and between BCS groups. The findings from the qualitative phase of the study will be discussed by the research team and the PAG prior to synthesis in WP3.

Data handling

The research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998 and the General Practice Data Protection Regulations (GDPR) 2018. Healthcare professionals and patients participating in the interview phase of the study will be asked for permission to publish anonymised quotations from their interviews in research outputs. The presentation and reporting of data will remove any information that may lead (either directly or deductively) to the identification of individuals who have participated in the study.

Each interview participant will be allocated a unique identifier so that they will not be identifiable. A document linking participant names and IDs with basic contact details for each participant (name, email address/telephone number) will be retained until the end of the study so that: a) participant data can be retrieved and removed if an individual asks for their study data to be withdrawn within two weeks of their interview, and b) research participants can be sent a summary of the research findings if they indicate they would like one. The linking document will be stored electronically in a password-protected Excel document, within a secure folder of the IT network for IAHR, using the University of Birmingham's secure research drive. The folder will only be accessible to named members of the research team and the document will be deleted after study completion.

Audio recordings of interviews will be transferred from encrypted devices to password-protected computers and network drives at the University of Birmingham immediately after each interview has been carried out. Once transferred to the secure University of Birmingham network, the audio files will be deleted from all recording devices. For the purposes of interview transcription, an independent, University-approved transcription company (Clayton Research Support) will be used. Audio files will be passed to the transcription company via upload to a secure encrypted server. The company is registered with the Information Commissioner's Office (ICO) and all transcribing will be undertaken in full compliance with the Data Protection Act and requirements of GDPR. A confidentiality agreement will be signed between University of Birmingham and Clayton Research Support prior to this work commencing. All study participants will be made aware on the PIS and ICF that data will be transcribed by an external company and will give consent for transcription to take place independently from University of Birmingham.

Interview transcripts and signed consent forms returned to the research team electronically (e.g. scanned PDF or word files) will be password-protected and stored electronically within a secure folder on the IT network for the IAHR, using the University of Birmingham's research drive. The secure study folder will only be accessible to named members of the research team. Any paper files (such as signed consent forms) will contain no identifiable data, and will be stored in locked filing cabinets in a locked office in an area of the IAHR at the University of Birmingham which can be accessed only by swipe card and numerical keycode. No identifiable qualitative data will be shared outside of the University of Birmingham.

As per the University of Birmingham's regulations on the retention of research data, anonymised, analysed data will be retained for 10 years and will be securely archived on University of Birmingham premises, with joint CI SD as data custodian. At the end of the study (with participants'

consent), data in the form of anonymised transcribed interviews will be stored in the University of Birmingham Data repository and made available to bona fide researchers on request. This process is managed by the University of Birmingham Research Governance Office.

The end of the study is defined as the point at which all data have been collected and analysed and the study funding has ended.

Work Package 3

SYNTHESIS AND DISSEMINATION (months 11-14)

Data from work packages 1 and 2 will by synthesised to determine the headline findings of the research and to develop recommendations for practice in relation to the provision of lifestyle and behavioural change support for people with breast cancer within the NHS. WP3 will comprise two parts:

WP3a*:* Results-based convergent synthesis and integration of the quantitative and qualitative data.[36]

WP3b: Synthesised results, headline findings, and unanswered questions will be presented at a stakeholder event attended by healthcare professionals, allied health professionals, patients and commissioners, to enable development of service and patient-informed recommendations on how to tailor advice and provide lifestyle change support to BCS and how to enable BCS engagement with such support.

Setting and participants

WP3a: A half-day event in which the research team and PAG will synthesise data across work packages and determine the headline findings for each study objective. The detailed approach to synthesis will be driven by the nature of the quantitative and qualitative data i.e. survey and interview data may either be integrated thematically then aligned to the appropriate TDF and COM-B domains in a two-stage process, or TDF and COM-B domains may be used as an organising 'umbrella' framework within which survey and interview data are integrated for interpretation.

WP3b: A half-day stakeholder event will be convened in Birmingham to include healthcare professionals, allied health professionals (e.g. physical activity instructors, nurses, dieticians) and commissioners (n=20) and BCS (n=5) to discuss the findings and develop recommendations for practice. This second workshop will consider the headline findings and use them to develop specific recommendations. The expected output would comprise up to 10 recommendations that may subsequently be used to design a future intervention to address barriers and facilitators to LBCS. The theory of change underpinning each recommendation will also be discussed, in order to identify what the active ingredients are expected to be and how they exert their influence.

DISSEMINATION AND OUTPUTS

The main target groups to which study findings will be communicated include members of the public, patients (including study participants), healthcare professionals, service providers, policy makers and academics. Each group will have its own dissemination plan and tailored outputs.

Members of the public and research participants

Survey and interview findings will be shared with participants and published in the Breast Cancer Now newsletter, with members of the patient advisory group and patient co-applicant contributing to writing this. Patient-specific dissemination will include 'bite-sized' results summaries. To ensure that dissemination is inclusive of seldom heard voices and those whose first language may not be English, we will develop infographics and an animated video of the results for patients.

Healthcare professionals, service providers and policy makers

Clear written reports of the findings will help service providers providing breast care services apply this work to their practice. This will also be supported through sharing the results with the Association of Breast Surgery Nursing Committee via the stakeholder team, the West Midlands Regional Representative and the West Midlands Clinical Research Network (CRN) Alliance.

Academics

Findings will be published in open-access, peer-reviewed journals and presented at academic conferences relevant both the breast cancer as a clinical area, and more generally in relation to health services research. Study results will be submitted for publication in *The Breast Journal* and presented at the Association of Breast Surgery and Health Services Research UK annual conferences.

ANTICIPATED STUDY IMPACT

The anticipated impact of this study will be to provide key information for NHS services on how best to offer/provide LBCS to people who have had breast cancer, including those patients who may be underrepresented within offers and provision of LBCS. A subsequent funding application will seek National Institute of Health and Care Research (NIHR) funding via the Health and Social Care Delivery (HSDR) programme to develop an intervention to optimise the pathway for post-breast cancer care and create a management tool for BCS that incorporates the voices and needs of under-represented groups and the seldom heard.

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT

Patient and Public Involvement and Engagement (PPIE) has been embedded as an integral component of this study. We have established a diverse patient advisory group with eight members. This group includes BCS with varied sociodemographic characteristics, ethnic backgrounds and experiences of LBCS, fostering the inclusion of opinions and views from people with diverse lived experience. The PAG will meet quarterly and/or at key points on the study timeline where patient input and co-creation of resources will be particularly important. BL and SD will attend all PAG meetings, which will be led by LS and RW. Our patient co-applicant has lived experience of breast cancer and will contribute to regular study meetings. PAG members will advise the research team on survey development and development of the interview discussion guides. They will also have input to the interpretation of the research findings and results

synthesis, the design and content of the WP3 stakeholder event, and the dissemination of results, drawing on their own patient networks to ensure a broad range of dissemination routes.

All PPIE representatives involved with this project have been costed to attend meetings, review documents and co-create study resources where appropriate, as well as supporting interpretation, synthesis and dissemination. They will be offered training as required, for example in research methods and qualitative work in particular. Together, our patient co-applicant and PAG will be key in supporting dissemination of project findings. PPIE will be monitored and evaluated throughout the project, using the GRIPP2 guidance for reporting the impact of patient and public involvement in health and social care research.

RESEARCH MANAGEMENT

As study co-leads, BL and SD will be responsible for the day-to-day management of the research, with senior support and mentorship from KJ. The research team consists of all study co-applicants (including LS, our patient co-applicant; RW, our PPIE liaison, and the study research fellow) and will meet on a monthly basis throughout the study to discuss emerging findings and monitor study achievements against key milestones on the timeline and completion of the study objectives as outlined on the Gantt chart.

STUDY TIMELINE

The research will run for 18 months from June 2024 (see Gantt chart page 7 for detailed project timetable). Key milestones include:

1. Study set-up/ethics (to be completed pre-award)
2. Recruitment of half-time study research fellow to support the research team with project delivery, qualitative data collection and qualitative analysis (months 1-3)
3. Healthcare professional and BCS surveys (months 2-6)
4. Patient and healthcare professional interviews (months 6-10)
5. Synthesis of qualitative and quantitative data and stakeholder workshop (months 11-14)
6. Dissemination of findings and final report (months 15-18)

ETHICAL AND REGULATORY CONSIDERATIONS

Ethical approval for this study will be obtained in a single ethics application to the appropriate NHS Research Ethics Committee (REC) and approval of the study by the Health Research Authority (HRA) (IRAS ID 332207). The research team will provide regular reports as required to the REC and any study amendments will be approved by the sponsor (Shrewsbury and Telford Hospital NHS Trust) prior to submission to the REC. Shrewsbury and Telford Hospital NHS Trust is the lead contracting organisation (contracting directly with NIHR), with the involvement of University of Birmingham outlined under a collaboration agreement with Shrewsbury and Telford Hospital NHS Trust. The study will be conducted in accordance with the principles of GCP in research studies and current versions of the UK Policy Framework for Health and Social Care Research.

The study will be adopted onto the NIHR Research Delivery Network (RDN) portfolio (West Midlands) (CPMS ID: 57791).

PEER REVIEW

This study has received external peer review by the NIHR Research for Patient Benefit Programme Committee as part of the application for funding.

PROTOCOL COMPLIANCE

Deviations from protocols and GCP may occur in research studies. The majority of these instances are technical non-compliances that do not result in harm to the study participants, do not compromise data integrity, or significantly affect the scientific value of the reported study results. These technical deviations will be documented and appropriate corrective and preventative actions will be taken by the research team, with responsibility taken by the joint chief investigators (BL and SD).

INDEMNITY AND INSURANCE

The study is sponsored by Shrewsbury and Telford Hospital NHS Trust who will monitor and audit the study according to institutional standard operating procedures. Shrewsbury and Telford Hospital NHS Trust assumes overall responsibility for the initiation and management of the study. Agreements between the sponsor and participating NHS organisations detailing study conduct and the responsibilities of each party will be fully executed before the study can start at participating NHS study sites.

FUNDING

The study is funded by the National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme (NIHR206118). The NHIR is not responsible for the management or governance of the project. The NIHR does not control the final decisions regarding the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

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