

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)

Exploring support needs of women with secondary breast cancer.Version1

1. Is your project research?

☒ Yes ☐ No

2. Select one category from the list below:

- ☐ Clinical trial of an investigational medicinal product
- ☐ Clinical investigation or other study of a medical device
- ☐ Combined trial of an investigational medicinal product and an investigational medical device
- ☐ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- ☐ Basic science study involving procedures with human participants
- ☐ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- ☒ Study involving qualitative methods only
- ☐ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- ☐ Study limited to working with data (specific project only)
- ☐ Research tissue bank
- ☐ Research database

If your work does not fit any of these categories, select the option below:

☐ Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? ☐ Yes ☒ No
- b) Will you be taking new human tissue samples (or other human biological samples)? ☐ Yes ☒ No
- c) Will you be using existing human tissue samples (or other human biological samples)? ☐ Yes ☒ No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

- ☐ England
- ☐ Scotland
- ☒ Wales
- ☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ☐ England
☐ Scotland
☒ Wales
☐ Northern Ireland
☐ This study does not involve the NHS

4. Which review bodies are you applying to?

- ☒ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☒ Research Ethics Committee
☐ National Information Governance Board for Health and Social Care (NIGB)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- ☒ Yes ☐ No

6. Do you plan to include any participants who are children?

- ☐ Yes ☒ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- ☐ Yes ☒ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- ☐ Yes ☒ No

9. Is the study or any part of it being undertaken as an educational project?

- ☒ Yes ☐ No

Please describe briefly the involvement of the student(s):
The project is for Mrs Ann Baker's Master's dissertation in Counselling Practice

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

- ☐ Yes ☒ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

☐ Yes ☒ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

☐ Yes ☒ No

Integrated Research Application System
Application Form for Research involving qualitative methods only**Application to NHS/HSC Research Ethics Committee**

The student should complete this form on behalf of the Chief Investigator. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Exploring support needs of women with secondary breast cancer.Version1

Please complete these details after you have booked the REC application for review.

REC Name:

South West Wales REC

REC Reference Number:

13/WA/0241

Submission date:

25/07/2013

PART A: Core study information**1. ADMINISTRATIVE DETAILS****A1. Full title of the research:**

A focus group study of the experiences of women diagnosed with secondary breast cancer and their preferences regarding their needs for counselling and information.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mrs	Ann	Baker
Address	c/o of Psychology & Counselling Dept. Swansea Metropolitan University Swansea		
Post Code	SA2OUT		
E-mail	mbaker.013102@students.smu.ac.uk		
Telephone			
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Masters in Counselling Practice

Name of educational establishment:
Swansea Metropolitan University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title Forename/Initials Surname
	Dr Ceri Phelps
Address	Psychology Department Swansea Metropolitan University Townhill
Post Code	SA2OUT
E-mail	ceriphelps@smu.ac.uk
Telephone	01792482084
Fax	

Please state which academic supervisor(s) has responsibility for which student(s):

Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
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Student 1 Mrs Ann Baker

☐ Dr Ceri Phelps

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ☐ Student
☒ Academic supervisor
☐ Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Dr Ceri Phelps
Post	Senior lecturer
Qualifications	BA(Hons), MPhil, PhD, CPsychol, HPC registered Health Psychologist, AFBPsS.
Employer	Centre for Psychology & Counselling
Work Address	Swansea Metropolitan University Townhill Campus Townhill
Post Code	SA2 OUT
Work E-mail	ceriphelps@smu.ac.uk

* Personal E-mail
Work Telephone 01792482084
* Personal Telephone/Mobile 07977051203
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

Title Forename/Initials Surname
Carol Hughes
Address Centre of Psychology & Counselling
Swansea Metropolitan University
Swansea
Post Code SA2 OUT
E-mail carol.hughes@smu.ac.uk
Telephone 01792481000
Fax

A5-1. Research reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Version 1

Protocol Date:

23/07/2013

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number	Description	Reference Number
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Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

☐ Yes ☒ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.

This is a proposed qualitative study to explore the experiences of women with secondary breast cancer in terms of their information and support needs. Two separate focus (discussion) groups with a maximum of 6-8 women in each, will be conducted. The women will have secondary breast cancer, meaning that the cancer has spread to other parts of the body away from the breast. The focus groups will be held in Maggie's Caring Centre Swansea. Specific research objectives are: 1. To explore the patients' experiences regarding their secondary breast cancer diagnosis. 2. To gain an understanding of the women's needs for emotional support and information since their diagnosis. 3. To discover whether the women feel their needs have been met. The discussions will be digitally recorded and transcribed. The researcher will use the recordings to analyse the life experiences of the women with a diagnosis of metastatic breast cancer using Interpretative Phenomenological Analysis.

A6-2. Summary of main issues. Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

CONFIDENTIALITY: Confidentiality is paramount because the participants would discuss their experiences (British Association of Counselling and Psychotherapy, 2010). After the focus group has ended the recording would be uploaded to a computer ready for transcribing. The computer is password protected and kept in a secure room in a University building.

ANONYMITY: The participants will be informed that their names would be changed so to protect their identity and to give them anonymity. Each of the two groups would be allocated a code and each participant would be identified by a coded number. The codes would be kept in a locked filing cabinet that would be locked with a key kept in a separate room to the transcript and computer.

CONSENT: The participants will give written consent to take part in the study which will include the transcribing of the digital recording and permission for Ms Dillion (clinical supervisor) to have access to medical notes and radiology reports to confirm eligibility into the study.

POTENTIAL FOR DISTRESS: It is the intention of the student researcher a qualified nurse 32 years to ensure that no intended harm or distress is caused to the women in the study. The researcher will abide by her NMC Code of Professional Conduct and BACP. Every aspect of this research will be conducted in accordance with the BACP Ethical Principles (BACP, 2010). The women would be informed that if during the focus group they feel upset or wish to have a break they can do so. They also have the opportunity to withdraw from the study during the focus group. The co-moderator (Dr Phelps) would be present to monitor any triggers that may create vulnerability.

The women need to feel they are in a safe environment and the researchers need to be sure the women are emotionally safe to leave the facility of study to return home. The participants would be in Maggie's Caring Centre and there would be the availability for them to make an appointment with the psychologist based in Maggie's. Also a Secondary Breast Cancer Care Resource pack which contains the contact number to professional Secondary Breast Specialist Nurses would be offered. The participants would be offered refreshments at the end of the focus group and a toilet break. The work contact number of student researcher would be given in case the women had any queries and also the contact numbers on an information sheet would be handed out for Maggie's and Breast Cancer Care if the women needed help and advice.

A6-3. Proportionate review of REC application The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.

☐ Yes - proportionate review ☒ No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☒ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

The research objectives for this study are as follows:

1. To explore the patients' experiences regarding their secondary breast cancer diagnosis.
2. To gain an understanding of the women's needs for emotional support and information since their diagnosis.
3. To analyse the data and discover whether these needs have been met and how the stakeholders can address any gap in theory to practice.

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

n/a

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

Breast Cancer Care (2009) conducted a UK wide cross – sectional survey representing 276 CNS (clinical nurse specialists) in breast care and revealed 57% believed specialist nursing care provision for secondary (metastatic) breast cancer patients to be inadequate. In practice there is not the same level of a seamless service of allocation of a CNS for support when a patient is diagnosed with secondary breast cancer compared to the well established support at initial primary diagnosis (Reed et al., 2010). There have been significant advances in the treatment and management of secondary breast cancer in particular the availability for entry into clinical trials and targeted therapies such as trastuzumab. These have resulted in the overall survival rates increasing when combined with chemotherapy (Slamon et al, 2001). This has impacted on service provision with the original role of the breast CNS being established to meet the needs of the patient with primary breast cancer. It is now acknowledged women with secondary cancer have a chronic condition and in some health trusts no designated CNS to support them.

The women with a diagnosis of secondary breast cancer have complex needs reporting a higher level of psychological distress compared to that at receiving a primary diagnosis (Mahon et al. 1990) with themes of uncertainty and lack of control (Hanson-Frost et al. 2000). Breast Cancer Care's 'Spotlight on secondary breast cancer' (2012) have produced standards of care for people with secondary breast cancer and includes women should have their emotional well being regularly assessed and have access to the appropriate level of psychological support at need, at diagnosis, at progression or when treatment changes occur. NICE (2004) made recommendations regarding needs assessment,

information provision and access to psychological support recognising that these guidelines should significantly improve the care of women with metastatic breast cancer. From this document came the recommendation patients with a cancer diagnosis should be allocated a key worker to coordinate the patient's care and whom they can contact at any time. Breast Cancer Care in their standards state this person should be a Clinical Nurse Specialist (CNS) who has the knowledge regarding the disease, treatments and support needs acting as advocate and as a link between the woman and the multidisciplinary team (MDT). This study aims to obtain rich narrative data regarding the women's feelings and views since their diagnosis in relation to their need for counselling, social, financial and health information support.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The study would be a qualitative focus group study.

Methodology:

Two focus groups with a maximum of six-eight women in each will be convened in Maggie's Caring Centre at Singleton Hospital. Focus groups discussions are an ideal way of obtaining rich narrative information on the lived experiences of a group of people that share something in common and may find themselves in a minority group.

The researcher believes interpretative phenomenological analysis (IPA) will enable the focus on 'how people perceive an experience, or rather what an experience means for them: a focus on the life world' (Langdridge, 2007). McLeod (2011, P71.) notes the use of 'focus groups allows a group of research informants to interact with each other and generate useful qualitative data not only in response to the researcher's questions, but through spontaneous dialogue with each other'. The researcher believes this form of data collection will be suited to the health care environment to be a source to aid in the planning for meeting the future needs of the women with a diagnosis of metastatic breast cancer. The information gathered can assist in decision making and planning for the implementation of a policy and care packages (Kruger & Casey, 2000).

Sample:

The study will involve women who have been diagnosed with secondary breast cancer who are under the care of the oncology department at Singleton Hospital, Swansea. A purposive sample of women with secondary breast cancer as this group would be the best available to provide the data for the area of study (Parahoo, 1997).

This study will run two focus groups with a maximum of six-eight women in each; the focus groups would be convened on different days.

The groups will consist of:

Focus group 1: six-eight women with a diagnosis of secondary breast cancer.

Focus group 2: six-eight women with a diagnosis of secondary breast cancer.

The aim of the small number would be to create an environment in which the women would feel comfortable and at ease to share their views regarding their experiences.

Recruitment:

The researcher would not be directly involved in recruiting women into the study. She would not directly approach her own patients however if her patients became aware of the study through the posters and they decided they would like to take part they should be allowed to do so.

A poster advertising the focus group study with an invitation to take part would be placed on an information board in the breast, oncology clinic and Maggie's Caring Centre by a superintendent radiographer / nurse working in each of these departments whom are not involved directly with the study. There would be contact numbers for the women if they were seeking more information regarding possibly taking part in the study. The work contact numbers on the information sheet of the student researcher including her student email address, the academic supervisor and a breast care nurse (The nurse would not be involved with the study).

If interest was expressed then an information sheet and consent form would be posted out. The consent form explains the study would be recorded and the participant's identity would be confidential. It would state the participants have the right to withdraw from the study at any time and the decision whether to take part or not would not influence their treatments. The consent form would state that permission is sought to view information in the medical notes by the clinical supervisor. The women who consent to take part in the study will be asked to retain a copy of the information sheet and to sign and return the consent form to the student researcher in a pre-paid envelope within two weeks of the

consent form being sent out.

Once the consent forms are returned the researcher will then make arrangements to confirm the venue of the focus groups, date and time to take place and then contact the group members to arrange a suitable date to attend the focus groups. The splitting of the participants into two focus groups would be with the help of the clinical supervisor taking age and site of metastases into account to try and balance the focus group.

The researcher would need to consider access for special mobility requirements and style of chairs or furniture and the use of cushions to aid positioning. This would be discussed with the staff at Maggie's Caring Centre who has various seating arrangements and cushions.

Data Collection:

Following receipt of the consent forms, the participants will be invited by telephone to one of the two focus groups. The focus groups would be organised so they would not take place on the same day. Each focus group will last between 60 – 90 minutes and will be held at Maggie's Caring Centre, Sketty Lane, Swansea. Ann Baker researcher will facilitate the groups, with the help of a co-moderator (Dr Ceri Phelps – Chief Investigator).

Data Analysis:

The researcher would transcribe the recordings of the focus group and analyse the transcript using interpretive phenomenological analysis (IPA). The researcher would use interpretive phenomenological analysis (IPA) to analyse the life experiences of the women with a diagnosis of metastatic breast cancer to make sense of their making sense of their situation. Smith (2004) recognises focus groups could be used to collect data for IPA. Indeed there is 'no theoretical reason why IPA could not be used to analyse data gathered through group discussions' (Langdridge, p110, 2007).

The researcher is aware of needing to bracket her own experience and knowledge of being a CNS in breast care and her encounters of women with metastatic breast cancer as this would possibly give an expectation of outcome themes.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☒ None of the above

Give details of involvement, or if none please justify the absence of involvement.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

- The women would have a definite diagnosis of metastatic breast cancer made by either cytology or tissue biopsy or by radiological investigation to allow entry into the study.
- Women with bone, brain, liver and lung metastases would be included in the study.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

- The woman becomes an oncological emergency (For example develops a spinal cord compression, hypercalcaemia, cerebral oedema or neutropenia warranting urgent hospital admission for appropriate treatment. This would apply if

the focus group date was during the woman being an inpatient in hospital.

- Any patient considered too psychologically vulnerable by the clinical team to participate in the study (e.g., recognised mental health or other problems causing significant distress).

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
-consent form to be signed and posted back.	1	n/a	14 days to return	student will post out information sheet and consent form to participants.
- Attend a focus group	1	n/a	90mins	student will conduct focus groups hosted at Maggies' Caring Centre Swansea.

A21. How long do you expect each participant to be in the study in total?

We envisage a maximum duration between consent and being sent a summary of the results and thankyou letter to be six months for each participants.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is the intention of the student researcher a qualified nurse 32 years to ensure that no intended harm or distress is caused to the women in the study. While it is hoped that participants will welcome the opportunity to talk about their experiences and their needs of living with metastatic breast cancer there is a need to be aware that some women may find the sensitive nature of the topic under discussion distressing. The researcher will abide by her NMC Code of Professional Conduct and BACP.

Every aspect of this research will be conducted in accordance with the BACP Ethical Principles (BACP, 2010). It is recognised that there is the potential for distress when exploring the lived experience's of women with secondary breast cancer.

In order to minimise any potential distress during the course of the focus groups:

.The women would be informed that if during the focus group they feel upset or wish to have a break they can do so. They would also be informed their participation is voluntary and they are not obliged to answer any questions.

. They will also be informed they have the opportunity to withdraw from the study during the focus group.

. The co-moderator (Dr Phelps) would be present to monitor any triggers that may create vulnerability.

. If, at any time during the course of the focus group, the moderator or assistant perceives that the conversation is beginning to create distress or stress for one or more of the participants involved, the researcher/co - moderator will stop the discussion and introduce a small break in the proceedings, before returning to a more general topic of discussion.

. The participants would be in Maggie's Caring Centre and there would be the availability for them to make an

appointment with the psychologist based in Maggie's.

. Also a Secondary Breast Cancer Care Resource pack which contains the contact number to professional Secondary Breast Specialist Nurses would be offered.

The participants would be offered refreshments at the start of the focus group and a toilet break.

. The work contact number of student researcher would be given in case the women had any queries and also the contact numbers on an information sheet would be handed out for Maggie's and Breast Cancer Care if the women needed help and advice.

- It will be emphasised to participants that they are free to take a break or leave the session at any time without providing any explanation;

- During the discussions, if participants find any of the topics raised distressing, they will be given the opportunity to discuss their concerns with the researchers in private.

- The Breast Cancer Care support number will be provided in the participant information sheets and in the Secondary Breast Cancer information pack, if participants decide they would like to talk to somebody after the study has ended.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

☒ Yes ☐ No

If Yes, please give details of procedures in place to deal with these issues:

The women would be informed that if during the focus group they feel upset or wish to have a break they can do so. They also have the opportunity to withdraw from the study during the focus group. The co-moderator would be present to monitor any triggers that may create vulnerability. The women need to feel they are in a safe environment and the researchers need to be sure the women are emotionally safe to leave the facility of study to return home. The participants would be in Maggie's Caring Centre and there would be the availability for them to make an appointment with the psychologist based in Maggie's. Also a Secondary Breast Cancer Care Resource pack which contains the contact number to professional Secondary Breast Specialist Nurses would be offered. The participants would be offered refreshments at the end of the focus group and a toilet break. While it is hoped that participants will welcome the opportunity to talk about their experiences and their needs of living with metastatic breast cancer there is a need to be aware that some women may find the sensitive nature of the topic under discussion distressing. The work contact number of student researcher would be given in case the women had any queries and also the contact numbers on an information sheet would be handed out for Maggie's and Breast Cancer Care if the women needed help and advice.

A24. What is the potential for benefit to research participants?

There is no direct clinical benefit for participants taking part in this study. It is hoped that the participants may benefit from having the opportunity to explore their feelings surrounding their diagnosis of secondary breast cancer and to have an awareness of support networks and counselling organisations.

A26. What are the potential risks for the researchers themselves? (if any)

There are minimal risks involved for the researcher in this study, as participants will be attending Maggie's Caring Centre in Swansea and the researcher will not be travelling to the participants' homes. The researcher recognises the role of nurse versus researcher during the focus group discussion. The nurse feels she is professional, experienced and grounded to accept that whilst it is important to remain objective the emotional impact of hearing the women's stories may have some impact. The nurse is skilled and is able to practice self care when working with women with secondary breast cancer in her daily work. At the end of the focus group the researcher and co moderator will make

time to discuss any aspects they found upsetting.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Ms Marianne Dillon Consultant Oncoplastic Breast Surgeon (Singleton Hospital) will provide clinical support and monitor breast/cancer services. For the purpose of this study Ms Dillon would view the medical notes and radiology reports (permission taken on the consent form) confirming the participants' eligibility into the study. She would also help to split the final number of participants into two groups, age and site of metastases would be considered to try and balance the focus groups. The notes will be requested by Ms Dillon secretary.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

☒ Yes ☐ No

Please give details below:

Medical notes will be viewed by Ms Dillon Consultant Oncoplastic Breast Surgeon after consent had been gained to verify that the potential participants have a confirmed diagnosis and meet the inclusion criteria.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

☐ Yes ☒ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

☒ Yes ☐ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

A poster advertising the focus group study with an invitation to take part would be placed on an information board in the oncology clinic and Maggie's Caring Centre by a superintendent radiographer / nurse working in each of these departments whom are not involved directly with the study. There would be contact numbers for the women if they were seeking more information regarding possibly taking part in the study. The work contact numbers on the information sheet of the student researcher including her student email address, the academic supervisor and a breast care nurse (The nurse would not be involved with the study).

A29. How and by whom will potential participants first be approached?

Potential participants will contact the student researcher on the telephone number or email address provided on the poster to express their interest in taking part in the discussion group. The student researcher will post out or email information sheet and consent forms to the potential participants.

A30-1. Will you obtain informed consent from or on behalf of research participants?

☒ Yes ☐ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for

children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If interest was expressed then an information sheet (see appendix 1) and consent form (see appendix II) would be posted out. The consent form would explain the study would be tape recorded and the participant's identity would be confidential. It would state the participants have the right to withdraw from the study at any time and the decision whether to take part or not would not influence their treatments. The consent form would state that permission is sought to view information in the medical notes by the clinical supervisor. The women who consent to take part in the study will be asked to retain a copy of the information sheet and to sign and return the consent form to the student researcher in a pre-paid envelope within 2 weeks of the consent form being sent out.

(Returned to:
C/O Dr Ceri Phelps,
FAO Ann Baker,
Centre for Psychology & Counselling,
Swansea Metropolitan University, Townhill Campus, Townhill Road, Swansea.
SA2 0UT.)

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

☒ Yes ☐ No

A31. How long will you allow potential participants to decide whether or not to take part?

Two weeks to return consent form by post.

Return address and stamped envelope will sent out in the post with information sheet and consent form, or can be emailed if requested by the potential participant.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

No arrangements are in place for this student project for individuals with limited understanding of the English language or with special communication needs, and thus they are excluded from the study.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

The student researcher's only language is English therefore the focus groups will be discussed and transcribed in the medium of English.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- ☒ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ☐ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ☐ The participant would continue to be included in the study.
- ☐ Not applicable – informed consent will not be sought from any participants in this research.
- ☐ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be

assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☒ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☒ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☒ Use of audio/visual recording devices
- ☒ Storage of personal data on any of the following:
 - ☐ Manual files including X-rays
 - ☐ NHS computers
 - ☐ Home or other personal computers
 - ☒ University computers
 - ☐ Private company computers
 - ☐ Laptop computers

Further details:

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

The participants would be informed their names would be changed so to protect their identity and to give them anonymity. Confidentiality is paramount because the participants would discuss their experiences (BACP, 2010).

After the focus group has ended the tape would be uploaded to the computer (immediately) ready for transcribing. The computer is password protected and kept in a secure University building. The audio tape of the focus group discussion would then be locked away in a filing cabinet until the end of the study when it when the digital recording will be erased.

Each of the two groups would be allocated a code and each participant would be identified by a unique coded number. The codes would be kept in a locked filing cabinet in a separate filing cabinet to the transcript and consent forms.

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

The researcher (student) and the Clinical Supervisor will be the only individuals with access to the participants' personal data. Written consent will be sought to gain permission for access.

Storage and use of data after the end of the study**A43. How long will personal data be stored or accessed after the study has ended?**

- ☒ Less than 3 months
☐ 3 – 6 months
☐ 6 – 12 months
☐ 12 months – 3 years
☐ Over 3 years

INCENTIVES AND PAYMENTS**A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?**

- ☒ Yes ☐ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Travelling expenses will be reimbursed.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- ☐ Yes ☒ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- ☐ Yes ☒ No

NOTIFICATION OF OTHER PROFESSIONALS**A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

- ☐ Yes ☒ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION**A50. Will the research be registered on a public database?**

- ☐ Yes ☒ No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.

You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- ☒ Peer reviewed scientific journals
- ☒ Internal report
- ☒ Conference presentation
- ☐ Publication on website
- ☒ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☒ Other (please specify)
Dissertation thesis.

A53. Will you inform participants of the results?

☒ Yes ☐ No

Please give details of how you will inform participants or justify if not doing so.

The participants would have indicated on the consent form if they would like to have sight of the research findings. For the participants that wished to view findings they would be sent a copy in the post with an offer to discuss if required.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi-centre research group
- ☒ Review within the Chief Investigator's institution or host organisation
- ☐ Review within the research team
- ☒ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

The proposal was reviewed by the educational supervisors and by the School of Psychology and Counselling Research Ethics Committee, bound by the ethical codes of the British Psychological Society and the British Association of Counselling and Psychotherapy.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 16
 Total international sample size (including UK):
 Total in European Economic Area:

Further details:

Two focus groups with a maximum of 6-8 women in each. Up to eight women will be recruited for each group to allow for the eventuality that not all consenting participants may attend on the actual day of the focus group.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size is considered adequate for a qualitative study of this nature, with the aim to have a small number in each group to create an environment in which the women may feel at ease to share their experiences. There are no definitive guidelines on a number of participants for a focus group, between six and thirteen will work well (Carter & Thomas 1997, Bowling 2002).

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

This is a qualitative study using audio recordings to gather data on the life experiences of women diagnosed with secondary breast cancer. Interpretive phenomenological analysis (IPA) would be used to analyse the participants responses and interactions and to make sense and gain an understanding of their making sense of their situation.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title Forename/Initials Surname

Post

Qualifications

Employer

Work Address

Post Code

Telephone

Fax

Mobile

Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: ☐ NHS or HSC care organisation
☒ Academic
☐ Pharmaceutical industry

Commercial status:

- ☐ Medical device industry
☐ Local Authority
☐ Other social care provider (including voluntary sector or private organisation)
☐ Other

If Other, please specify:

Contact person

Name of organisation University of Wales Trinity St David, Swansea Metropolitan.

Given name Gwyndaf

Family name Tobias

Address Mount Pleasant Campus

Town/city Swansea

Post code SA1 6ED

Country UNITED KINGDOM

Telephone 01792481000

Fax

E-mail

Is the sponsor based outside the UK?

- ☐ Yes ☒ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- ☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☒ No application for external funding will be made

What type of research project is this?

- ☒ Standalone project
☐ Project that is part of a programme grant
☐ Project that is part of a Centre grant
☐ Project that is part of a fellowship/ personal award/ research training award
☐ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

- ☐ Yes ☒ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title Forename/Initials Surname
	Ms Kirsty Price
Organisation	Abertawe Bro Morgannwg University Health Board
Address	Morrison Hospital
Post Code	SA6 6NL
Work Email	kirsty.price4@wales.nhs.uk
Telephone	01792 704056
Fax	01792 545774
Mobile	

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 02/09/2013

Planned end date: 03/03/2014

Total duration:

Years: 0 Months: 6 Days: 2

A71-2. Where will the research take place? (Tick as appropriate)

- ☐ England
- ☐ Scotland
- ☒ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

☐ Yes ☒ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- ☐ NHS organisations in England
- ☒ NHS organisations in Wales 1
- ☐ NHS organisations in Scotland
- ☐ HSC organisations in Northern Ireland
- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Social care organisations
- ☐ Phase 1 trial units

- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent hospitals
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study:

1

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (NHS sponsors only)
- ☒ Other insurance or indemnity arrangements will apply (give details below)

University of Wales Trinity St David, Swansea Metropolitan Insurance will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- ☒ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- ☒ Other insurance or indemnity arrangements will apply (give details below)

For non NHS-staff involved in the project, University of Wales Trinity St David, Swansea Metropolitan Insurance will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- ☒ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- ☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Abertawe Bro Morgannwg University Health Board	Title	Ms
Department name	Breast Care Centre/Department of Oncology	First name/ Initials	Marianne
Street address	Singleton Hospital	Surname	Dillon
Town/city	Swansea		
Post Code			

PART D: Declarations**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
 - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ☒ Chief Investigator
- ☐ Sponsor

- ☐ Study co-ordinator
☐ Student
☐ Other – please give details
☐ None

Access to application for training purposes *(Not applicable for R&D Forms)**Optional – please tick as appropriate:*

☒ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Print Name: Dr Ceri Phelps

Date: 23/07/2013 (dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
3. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
4. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
5. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
6. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature:

Print Name: Mr Gwyndaf Tobias

Post: Pro Vice Chancellor (Finance and Planning)

Organisation: University of Wales Trinity St David (Swansea Metropolitan)

Date: 23/07/2013 (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.
2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.
3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.
4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature:

Print Name: Dr Ceri Phelps

Post: Senior Lecturer and HPC registered Health Psychologist

Organisation: University of Wales Trinity St David (Swansea Metropolitan)

Date: 23/07/2013 (dd/mm/yyyy)

