Submitted in partial fulfilment of the Lancaster University Doctorate in Clinical Psychology, November 2015

Doctoral Thesis:

The Experiences of Women Undergoing Therapeutic and Prophylactic Mastectomy

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Word Counts

Section	Main Text	Appendices (including tables, figures and references)	Total
Main Abstract	268	-	268
Literature Review	7808	3528	11336
Research Paper	8000	9594	17594
Critical Appraisal	3578	695	4273
Ethics Section	Protocol 3375	12738	16113
Total	23029	26555	49584

Abstract

This doctoral thesis explores the impact and experiences of both therapeutic and prophylactic mastectomy. The first aim of the thesis was to provide an in-depth understanding regarding the intrapsychic effects of mastectomy upon the various dimensions of a woman's sexuality. Therefore, a literature review of twelve qualitative studies utilising a meta-synthesis approach was undertaken. Three overarching themes were identified: 'Changes to femininity, body-image and attractiveness'; 'The impact of mastectomy upon desirability within intimate and sexual relationships'; and 'The changed relationship and the importance of support in adapting to mastectomy and facilitating acceptance'. The review highlights how alterations to a woman's sense of femininity after mastectomy generates feelings of undesirability and impedes sexual activity within intimate relationships. Clinical implications and ideas for future research are discussed.

The second aim of the thesis was explore the experiences and decision-making process of women considered low-to-moderate risk of Contralateral Breast Cancer (CBC) undergoing Contralateral Prophylactic Mastectomy (CPM). Six interviews with women considered low-to-moderate risk were conducted and the data were analysed using Interpretative Phenomenological Analysis. Five themes were derived and highlighted that women's decision-making factors were based upon their subjective evaluation of risk and perceived vulnerability to CBC, cosmetic, pragmatic, and psychological reasons, individual experiences, familial and age-related circumstances. The research highlights the importance of interventions that support both women and their families who are challenged by a single mastectomy, and the need for specific national guidelines for clinicians to ensure equity of care in the availability of CPM.

The final section of the thesis provides considerations and personal reflections on the research process, as well as methodological issues that were experienced.

Declaration

This thesis records work undertaken for the Doctorate in Clinical Psychology at the Division of Health Research at Lancaster University from September 2013 to November 2015.

The work presented here is the author's own, except where due reference is made. The work has not been submitted for the award of a higher degree elsewhere

Name: Fehmida Natha (nee. Patel)

Signature:

Date:

Acknowledgements

Firstly, I would like to thank all the participants of the research who shared their stories and experiences with me, without which the compilation of this thesis would not have been possible. I would also like to thank my supervisors Dr Craig Murray and Dr Ailyn Garley who provided me with guidance, feedback and encouragement throughout. I would like to give special thanks to Dr Stephen Weatherhead and Dr Anna Daiches for their invaluable support and reassurance.

To my husband and son, I thank you for providing lots of love, care and cuddles and enabling me to hold onto what's important. Thank you for being so patient. To my wonderful in-laws who cared for my son when I couldn't.

Most importantly, I would like to thank my mother. Though she is not here to see the end of this journey, she has been an incredible force and instilled within me a hard work ethic and taught me the importance of remaining independent. Mum, I could not have got here without you and your constant sacrifices. I owe my success to you. You continue to inspire me and I hope I have made you proud today and forever more. I love and miss you dearly.

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When poets speak of death, they call it the place "without breasts".

Ramon Gomez De La Serna, 1917

Section One: Literature Review

The Impact of Mastectomy upon a Woman's Sexuality: A Qualitative Meta-synthesis

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Prepared for submission to Journal of Qualitative Health Research[1]

[1] See Appendix 4-J for 'Author Guidelines'

Abstract

It is well established mastectomy affects a woman's sexual functioning. However, there is growing recognition that the intrapsychic effects of mastectomy, such as changes to one's body-image and physical integrity can threaten embodied experiences and gendered identity. This is seen to alter how a woman appraises her sense of femininity; influencing her engagement in sexual activity and impacting upon intimate relationships. Accordingly, the aim of this review was to explore and elaborate the impact of mastectomy upon a woman's sexuality through a synthesis of relevant qualitative literature. A systematic literature search of five databases (Academic Search Complete, CINAHL, PsychARTICLES, PsychINFO, and MEDLINE) was undertaken using terms for mastectomy, sexuality, and qualitative data. A meta-synthesis was conducted on the data from the twelve studies obtained. Three overarching themes were derived highlighting how mastectomy impacts upon a woman's femininity, sense of personal attractiveness and desirability within intimate relationships, and the importance of an intimate partners support in enabling women to adjust to their altered bodies. Findings have important practice implications. Particularly, the need for clinicians to offer interventions that aim to maintain the relationship between a woman, her altered body, and partner after mastectomy.

Keywords: Femininity, Identity, Intimacy, Mastectomy, Relationship

The Impact of Mastectomy upon a Woman's Sexuality: A Qualitative Meta-synthesis.

Breast cancer is the most widespread cancer in women worldwide and is the second largest contributor towards cancer death after lung cancer (Gilbert, Ussher, & Perz, 2010). However, advances in detection methods and effective treatments have decreased mortality rates, with breast cancer now considered chronic rather than necessarily terminal (Kudel, Edwards, Raja, Haythornwaite, & Heinberg, 2014).

Despite the advancing techniques in the treatment of breast cancer, such as chemotherapy and hormone therapy, many women undergo mastectomy (Fallbjork, Rasmussen, Karlsson, & Salander, 2013). Mastectomy rates have been shown to vary at hospital, geographical, national and international level (Caldon et al., 2005) with the highest rates of mastectomy procedures undertaken in Central and Eastern Europe (Roder et al., 2013). However, mastectomy can cause various physical and psychosocial problems. One specific area of interest is the impact of mastectomy upon sexuality. Defining sexuality is complex as it extends beyond material sexual function, can vary between individuals, and is often a complex interaction between mind, body and spirit (Huber, Ramnarace, & McCaffrey, 2006). Breasts in particular are positioned as 'sexual' and considered important in the expression of sexuality for women (Manderson & Stirling, 2007). Research indicates mastectomy can cause a loss in personal attractiveness, reduced self-esteem, diminished body-image, depression, and anxiety, (Andrzejczak, Markcoka-Mackza, & Lewandowski, 2013; Didier et al., 2009; Garrusi & Faezee, 2008). As such, mastectomy causes psychological distress and impacts upon a woman's Quality of Life (QoL) (Kalaitzi et al., 2007; Perry, Kowalski, & Chang, 2007).

The Material Effects of Mastectomy upon Sexuality

One of the most commonly cited set of difficulties experienced by women after breast cancer are issues relating to sexuality (Dizon, Suzin, & McIllvenna, 2014). Studies have demonstrated the material effects of mastectomy upon sexuality, such as fatigue (Fobair et al., 2006), reduced sexual stimulation due to the loss of nipple sensation (Kneece, 2003), and a general decline in libido (Meyerowitz, Desmond, Rowland, Wyatt, & Ganz, 1999). These difficulties can cause adverse consequences within intimate relationships. For example, Rowland and Metcalfe (2014) performed a systematic review of men's experiences towards their partner's mastectomy. They found mastectomy led to a reduction in the frequency of intimacy regardless of the length of time they had been together. This was associated with a profound sense of loss.

Moreover, many women suffer from low self-esteem and body-image distress (BID) after mastectomy (Baucom, Porter, Kirby, Gremore, & Keefe, 2006). Negative reactions, such as distancing and rejection from partners can exacerbate these issues and further impede sexual intimacy (Figueieredo, Fries, & Ingram, 2004). Accordingly, research suggests support provided by an intimate partner through providing reassurance and empathy (Wai-Ming, 2002), emotional involvement (Loaring et al., 2015), and verbal intimacy (Helgeson, Snyder, & Seltman, 2004), during a woman's cancer trajectory is associated with improved psychosexual outcomes and better emotional adjustment.

The Breast: From a Symbol of Womanhood to Diminishing One's Femininity

The impact of mastectomy upon sexuality is not limited to material dimensions (Gilbert et al., 2010). Mastectomy alters a woman's perception of her breasts as it eliminates the psychological symbols of what women attribute their 'femininity' and attractiveness to (Boehmke & Dickerson, 2005; Parton, Ussher, & Perz, 2015; Skrzypulec, Tobor, Drosdzol, & Nowosielski, 2008).

Mastectomy causes a profound loss to a woman's physical integrity, confidence and body-image (Fobair et al., 2006; Wilmoth, 2001). These 'indirect' and 'intrapsychic' effects of mastectomy are thought to affect sexual functioning and threaten one's embodied, gendered, and sexual identity (Gilbert et al., 2010; Loaring, Larkin, Shaw & Flowers, 2015; Parton et al., 2015; Wimberly, Carver, Laurencaeau, Harris, & Antoni, 2005) leading a woman to feel less sexually desirable within intimate relationships. Women consider breasts form an important part of their sense of selves and what constitutes their female identity (Huber, Ramnarace, & McCaffrey, 2006). Accordingly, mastectomy has been described as being "*half a woman*" by those undergoing the procedure (Manderson & Stirling, 2007, p. 82). These experiences and difficulties are associated with emotional challenges which a woman has to manage on a daily basis (Fallbjork et al., 2013). Even with the use of an external breast prosthesis which may conceal the mastectomy to others, it does not tackle issues around a woman's sense of disfigurement and cannot be integrated into a woman's body-image (Al-Ghazal, Fallowfield, & Blamey, 2000).

The Importance of Facilitating Communication and Information-Giving

It is evident from the literature that mastectomy places strain upon intimate relationships, as well as how a woman construes her femininity. This indicates the need to discuss and prepare women and their partners for the negative consequences of mastectomy. However, research suggests healthcare professionals often overlook or avoid discussions pertaining to sexuality after breast cancer treatment. For example, Kneece (2003) found 87% of the 126 women within their study reported they were not sufficiently informed of the sexual changes after treatment. There are a number of barriers that hinder such discussions. This includes time-constraints within appointments, the uncomfortable nature of these discussions, as well as a lack of knowledge due to the limited guidelines on the matter (Hordern & Street, 2007).

Communication about sexuality is essential as it further allows women to appraise the information regarding the impact of mastectomy which helps inform treatment choices (Flynn et al., 2012).

Mastectomy vs. Breast Conserving Surgery

Breast Conserving Surgery (BCS) is proposed as an alternative treatment as it produces comparable survival rates to mastectomy, and presents as a less disfiguring procedure, thus having fewer implications upon one's body-image and sexuality (Al-Ghazal et al., 2000). A meta-analytic review of the psychosocial outcomes of breast cancer surgery supports this as the most robust effect size highlighting the benefits of BCS over mastectomy for body-image was established (Moyer, 1997). Similarly, Arndt, Stegmaier, Ziegler, and Brenner (2008) found although the benefits of BCS on overall QoL was most apparent after several years, women reported better satisfaction with their body-image and improved sexual function within the first year of BCS. Despite this, research suggests BCS is an underused procedure relative to mastectomy (MacBride et al., 2013).

Research indicates women who place more value on their body-image and consider mastectomy as more likely to affect their femininity, and assert this to the surgeon, are more inclined to opt for BCS (Sivell, Elwyn, Edwards, & Manstead, 2013). This highlights the importance of establishing a woman's values and attitudes at the pre-surgery consultation. Specifically, this would indicate that where there are no absolute contraindications to pursue BCS, this should be considered as a viable treatment option as opposed to mastectomy.

Breast Reconstruction after Mastectomy: To Feel Whole Again?

In response to the disfigurement and loss of a breast after mastectomy, breast reconstruction has become an increasingly available option for women (Ditsch et al., 2013; Isern, Tengrup, Loman, Olsson, & Ringberg, 2008). However, the literature regarding breast reconstruction and its benefits is equivocal. Some research suggests breast reconstruction

can improve overall QoL and the sexual lives of women after mastectomy. For example, Neto et al. (2013) compared the sexual function of women who underwent mastectomy alone with women who underwent breast reconstruction. They found women within the breast reconstruction group reported improved sexual function relative to the mastectomy alone group. It is likely that reconstruction increases self-esteem and enhances one's body-image, allowing a woman to feel more confident and feminine, which partially explains the results. Correspondingly, Brandberg, Malm, & Blomqvist (2000) found breast reconstruction increased women's confidence within intimate situations and enabled them to feel more whole.

Contrastingly, other studies suggest mastectomy, with or without breast reconstruction, can reduce sexual desire (Raggio, Butryn, Arigo, Mikorski, & Palmer, 2014). Fallbjork et al. (2013) found women who underwent breast reconstruction still reported feelings of discomfort during sexual intimacy, as well as lower levels of sexual attractiveness. It is possible that although breast reconstruction gives the appearance of a 'normal' body, it seldom overcomes the psychological impact of the loss of a breast (Fallbjork et al., 2013). This indicates mastectomy often extends beyond a physical loss; the meaning and interpretation of which can vary for women which reconstruction may or may not overcome.

Scope of the Current Review

Although quantitative research has identified aspects of a woman's sexuality that can be affected after mastectomy, these studies do not adequately explicate a woman's lived experience of losing a breast and the meaning of this in relation to her sexuality. Quantitative research has privileged the positive-realist paradigm, focusing on the material aspects of a woman's sexuality, framing women's sexuality within physical dimensions only. However, as discussed, mastectomy causes disruption to a woman's sexual subjectivity and causes changes at the intrapsychic level as it alters a woman's sense of self, gendered and sexual

identity which reconstruction may not always negate. A more detailed understanding encapsulating women's own meaning-making is required that outlines the various dimensions of sexuality that are affected after mastectomy.

Although a review has been undertaken exploring the impact of breast cancer treatment more generally upon sexuality (see Gilbert et al., 2010), an in-depth understanding regarding the impact of mastectomy specifically upon sexuality is required. Breasts are considered a crucial aspect of a woman's sexual-self, identity, and body-image; with mastectomy presenting unique characteristics due to the disfigurement it causes as compared to other breast cancer treatments, which warrants a specific review.

Meta-syntheses aim to amalgamate individual qualitative studies and provide new perspectives, making them greater than the sum of its parts (Walsh & Downe, 2004). No meta-synthesis currently exists in the area of mastectomy and sexuality. Therefore, the current review is timely and will contribute additional knowledge to the evidence base. Individual qualitative studies are of value, however aggregating the findings are essential in order to provide a new higher-order understanding and interpretation (Sandelowski, Docherty, & Emden, 1997), as opposed to a simple aggregation and description of the studies. This will elucidate the meaning and impact of mastectomy upon one's sexuality producing findings that can identify the clinical implications for the services that attempt to meet the needs of this population. With these aims in mind, the research question identified for the current review was "What is the impact of mastectomy upon a woman's sexuality?

Method

Search and Selection

An exhaustive search in May 2015 was conducted for published studies relating to the impact of mastectomy upon one's sexuality. The decision to search and include peer-

reviewed, full-text articles in English was made prior to searching due to the cost constraints of the current study and to ensure a minimum threshold of 'quality' of the studies reviewed.

A systematic search was conducted using computerised databases Academic Search Complete (1984-2015), Cinahl (1981-2015), PsychARTICLES (1980-2015), PsychINFO (1958-2015), and Medline (1977-2015). For all databases, three key search terms were used: 'Mastectomy', 'Sexuality' and 'Qualitative', connected utilising the Boolean operator 'AND'. Extensive word variants were utilised for the three concepts and were used interchangeably. The search included the following terms for mastectomy: breast cancer, breast tumor/tumour, breast neoplasm/s, BRCA1/BRCA2, metastatic breast cancer, contralateral mastectomy, contralateral prophylactic mastectomy, and bilateral mastectomy. Word variants for sexuality were: sex, body-image, intimacy, relationship/s, femininity, marriage, attractiveness, and desirability. Word variants for qualitative were: experience, interviews, thematic analysis, grounded theory, narrative, and interpretative phenomenological analysis/IPA. The reference sections of the identified papers were also examined for other relevant studies; although none were identified. This resulted in the initial identification of 924 papers (see Figure 1). All abstracts were inspected and studies potentially meeting the inclusion criteria were retrieved and examined more extensively.

INSERT FIGURE 1 HERE

Studies within the present review were all qualitative studies examining the impact of mastectomy upon a woman's sexuality. Specific criteria for inclusion were: (a) female participants only with a diagnosis of breast cancer who had undergone a mastectomy with or without breast reconstruction (single and double mastectomy/therapeutic and prophylactic mastectomy); (b) studies interviewing participants individually or within focus groups; (c) mixed-method studies if the study also met the other inclusion/exclusion criteria; and (d) peer-reviewed articles available in English.

Excluded studies were: (a) articles based upon women who had any BCS prior to mastectomy, or BCS alongside or following mastectomy of the contralateral breast; (b) non-peer reviewed articles including case studies, editorials, special issues, and forum/boardroom studies; and (c) couple interviews unless participant and partner views were clearly separated within the paper. Following this process, 12 studies remained for purposes of the present review. The details of these studies are outlined in Table 1. Despite the debate regarding the utility of comparing studies with differing methodologies and epistemological positions, it is thought this can add to the depth and integrity of the research (Bondas & Hall, 2007).

INSERT TABLE 1 HERE

Study Characteristics

Twelve studies were identified for the current meta-synthesis. All were published between 2000-2013. Participant ages ranged from 21-69 years. The studies retrieved recruited women who identified themselves as heterosexual, although this was not part of the inclusion criteria set for the current review. Nine studies used European samples (three in Sweden, two in Turkey, two in the UK, one in Spain, one in Norway). Two studies used a Middle Eastern sample (one in Iran and one in Syria) and one study used a sample in China. All studies presented a form of thematic analysis of their findings. Six studies used thematic analysis or a thematically informed approach, three content analysis, two grounded theory, and one Interpretative Phenomenological Analysis (IPA). Research questions varied from exploring the psychological reactions and experiences of women who had undergone mastectomy, the meaning women placed on the loss, the experience and changes in perception of their selves, identity, and intimate relationships, reflections on reconstruction, as well the impact of mastectomy upon women's embodiment and corporality. All the studies focused on the language used by the participants as denoting their thoughts, opinions and experiences.

Quality Assessment

All 12 studies were subject to a quality appraisal utilising the Critical Appraisal Skills Programme (CASP: 2010) in order to assess the rigour of the studies. Key dimensions of the CASP upon which the studies were appraised included the appropriateness of the research design, recruitment strategy, and methodology, as well as the rigour of the analysis process and consideration of ethical issues. No studies were excluded on the basis of the quality ratings, as the purpose of the quality appraisal was to evidence that the themes derived as part of the synthesis were not developed exclusively upon methodologically weaker studies. Additionally, there is no agreement within the literature regarding the measures of quality within qualitative research (Dixon-Woods, Booth, & Sutton, 2007), and it is thought excluding studies can lead to the dismissal of important findings (Sandelowski & Barroso, 2003). The studies were scored using a 3-point Likert scale for each of the domains, considering whether the research was of weak (1), moderate (2) or strong (3) quality. The total possible score attainable was 24. Studies within the current review ranged from 15-23 indicating the studies included in the review were of moderate to high quality. (see Table 2).

INSERT TABLE 2 HERE

Data Analysis

The meta-synthesis was conducted in accordance with Noblit and Hare's (1988) meta-ethnographic approach which provides a framework for synthesising qualitative research. Although initially developed for ethnographic studies, the framework can also be used for other qualitative research (Bondas & Hall, 2007). The process involves amalgamating the findings of all the studies and considering them as a whole with the aim of producing higher-order themes, whilst still preserving the original accounts of participants.

Initially, the studies were read repeatedly and thoroughly. Themes and their associated concepts were extracted and notations were made of the concepts and ideas which

represented aspects of participants' experiences. The relationship between the findings of the studies were considered and combined by comparing the key themes of individual studies and determining the similarities between them in a process referred to as reciprocal translation.

The researcher remained aware of the possible emergence of new themes. Throughout this iterative process, a 'sense' of each study was retained and a second level of interpretation was held (Britten et al., 2002). This second level of synthesis allowed for a more coherent explanation of the impact of mastectomy upon a woman's sexuality. This resulted in three overarching themes offering a "new, integrated, and more complete interpretation of findings that offers greater understanding in depth and breadth than the findings from individual studies" (Bondas & Hall, 2007, p.115). The synthesis was expressed in both written and visual form. Table 3 provides an indication of how each of the original themes within the studies contributed towards the development of themes identified for the current review.

INSERT TABLE 3 HERE

Findings

Although the aims of the individual studies varied, they all explored some aspect of the psychosocial impact of mastectomy upon a woman's body and her sexuality. The analysis led to the development of three overarching themes: 'Changes to femininity, body-image and attractiveness'; 'The impact of mastectomy upon desirability within intimate and sexual relationships'; and 'The changed relationship and the importance of support in adapting to mastectomy and facilitating acceptance'. These themes are discussed below.

Theme 1: Changes to Femininity, Body-Image and Attractiveness

This theme encapsulates participants' altered body-image and femininity; causing a profound sense of loss, a decline in erotic value, and changes to their sexual-self and identity. Across the studies, participants described the overwhelming sense of losing their femininity

and the alteration to their self-perception; impeding their sexuality (Arroyo & Lopez, 2011; Fallbjork, Salander, & Rasmussen 2012; Fouladi et al., 2013; Hatcher & Fallowfield, 2003; Karaoz, Aksu, & Kucuk, 2010; Klaeson, Sandell, & Bertero, 2011; Landmark & Wahl, 2002; Lloyd et al., 2000; Nizamli, Anoosheh, & Mohammadi, 2011; Piot-Ziegler, Sassi, Raffoul, & Delaloye 2010): "They had removed my femininity and my sexuality, at least a part of it" (Fallbjork et al., 2012, p. 45). The loss of a breast was inextricably linked to losing one's femininity and sexuality: "I miss the sex, I miss the lust; I miss my womanliness" (Klaeson et al., 2011, p734).

Participants' altered body-image was described as overcoming their whole personality and complete self (Arroyo & Lopez, 2011; Klaeson et al., 2011), leading to a critical view of the body and themselves: "my breast is not worthy, my body is not worthy, I am not worthy" (Arroyo & Lopez, 2011, p. 3). Additionally, mastectomy impacted upon participants' identity and how they recognised themselves; describing feelings of abnormality and estrangement from their bodies (Klaeson et al., 2011; Piot-Ziegler et al., 2010). It was felt mastectomy induced depersonalisation experiences: "I didn't recognise myself – it wasn't me – it was quite grotesque" (Fallbjork et al., 2012, p. 44), and "I thought I'd never be the same anymore. I felt weird, it was an enigma to me where I was or who I was" (Arroyo & Lopez, 2011, p. 5).

Mastectomy was also defined as a form of mutilation and handicap (Landmark & Wahl, 2002; Piot-Ziegler et al., 2010) where a once cared-for breast was now something to be disregarded. Participants described the importance of the areola as central to intimacy, sensuality, and femininity (Piot-Ziegler et al., 2010) with one participant utilising a powerful metaphor "half-finished cake" (Lloyd et al., 2000, p. 479) to describe her sense of incompleteness after the loss of her nipples. This was connected to the grief participants experienced. Despite surviving breast cancer, the alterations to participants' sexuality and the

loss associated with this was described as an experience likened to mourning (Fouladi et al., 2013; Karaoz et al., 2010; Piot-Ziegler et al., 2010). The mutilation to the body and the changes to participants' sexuality challenged their sense of belonging to womanhood and humanity, emphasising the importance of breasts and how they are inextricably linked to a woman's identity: "I feel that I'm not a complete woman…I am not sexually aroused. I used to be, but now I'm completely dead" (Karaoz et al., 2010, p. 119). Similarly, another participant stated: "I was lamenting in the way that if you saw me you'd think I had lost a beloved" (Fouladi et al., 2013, p. 2082). For some participants, mastectomy was appraised as so body-modifying; it equated to being male, transforming their gendered identities:

> I'm not ready to be like a boy. I was born a girl, I grew up as a girl. It's not that the breast is the centre of all that, but it's a whole, it's my femininity, it's all organised around it (Piot-Ziegler, 2010, p. 494).

Accordingly, mastectomy was a constant reminder of a former female-self: "When I wake up, certainly I'll bury my past life. For sure, it will change a lot of things" (Piot-Ziegler et al., 2010, p. 490). Piot-Ziegler et al. (2010, p. 495) considered the sociocultural aspects of identity within the context of mastectomy, and the parallel between this and participants' own reality. They narrated how the idealised feminine image within the media, as well as negative responses from others were irrelevant in relation to breast cancer itself for some participants. Therefore, within some of the studies participants resisted the embodied discourses of femininity; being less concerned with their bodily changes and physical appearance (Fallbjork et al., 2012; Fouladi et al., 2013; Piot-Ziegler et al., 2010). For example, older participants within one study considered breasts were not integral to their female identity and felt insulted that this was even suggested:

> She asked me if I didn't lose my femininity, and I thought, what on earth is she talking about! Does she think that this so-called 'femininity' is more important than life itself? (Fallbjork et al., 2012, p. 45).

However, the idealised feminine image within social discourse was seen to highlight some participants' physical change and diminished femininity. This was reinforced in the context of other women:

> No it is that what I want – I want to be like all the others, a little. It isn't me any longer, this woman with only one breast. She isn't me; I don't feel like that. As I said, I feel that I have left that a little bit behind... (Klaeson et al., 2011, p.734).

Participants also described the difficulty in adjusting to a new self and how mastectomy provoked a sense of feeling unattractive (Arroyo & Lopez, 2011; Fouladi et al., 2013; Hatcher & Fallowfield, 2003; Nizamli et al., 2011): "When I see myself, I do not feel I have any charm, and this is a huge problem for me. I try to accept it, but I cannot" (Arroyo & Lopez, 2011, p.3). Likewise, participants described the anguish when confronting their altered body at both a visual and sensual level (Fouladi et al., 2013; Lloyd et al., 2000; Piot-Ziegler et al., 2010): "I cannot really explain how you feel, but I must admit a certain aversion. It seems as though it [the body] was not yours, because first of all you have no sensations anymore" (Piot-Ziegler et al., 2010, p. 491). Accordingly, some participants avoided looking at themselves due to the humiliation and shame they experienced (Arroyo & Lopez, 2011; Fallbjork et al., 2012; Fouladi et al., 2013; Hatcher & Fallowfield, 2003), hindering the process of acceptance (Fallbjork et al., 2012).

In order reconcile the shame and sense of disfigurement some participants concealed their mastectomy by dressing modestly or through aesthetic techniques. Participants

considered breast reconstruction was a necessary pre-requisite (Fallbjork et al., 2012; Fouladi et al., 2013; Landmark & Wahl, 2002) for being reinstated as a woman and a person: "I would die without breasts; I could never live without breasts" (Fallbjork et al., 2012, p. 45). The use of prosthesis, reconstruction and bra-filling was utilised as a means to restore the ideal feminine appearance (Fallbjork et al., 2012; Fouladi et al., 2013; Klaeson et al., 2011; Landmark & Wahl, 2002; Piot-Ziegler et al., 2010). Participants viewed prosthesis and reconstruction as integral in the adaptation to breast cancer and the reorganisation to one's body-image after mastectomy (Fallbjork et al., 2012; Fouladi et al., 2013; Landmark & Wahl, 2002; Piot-Ziegler, et al., 2010). Strikingly, for one participant breast reconstruction was associated with the successful treatment of breast cancer: "I have never thought about getting my breast reconstructed until now. Getting better is the most important goal" (Landmark & Wahl, 2002, p. 117), alluding to the importance of breasts in regaining the self as a person and one's sexual identity. However, other participants considered breast reconstruction would be difficult to integrate into their sense of self and body-image (Arroyo & Lopez, 2011; Hatcher & Fallowfield, 2003; Piot-Ziegler et al., 2010). Participants explained reconstructed breasts would feel foreign: "Like they're not me" (Hatcher & Fallowfield, 2003, p.4), 'strange' and 'different': "Yes, but *your* breast won't be there anymore" (Piot-Ziegler et al., 2010, p. 499).

Theme 2: The Impact of Mastectomy upon Desirability within Intimate and Sexual Relationships

This theme refers to participants' reduced sense of desirability within intimate and sexual relationships. All studies reported on the sexual dysfunction after mastectomy, for example: "until my wounds were healed and following chemotherapy, we did not have sexual activity…" (Cebeci, Yangin & Tekeli, 2010, p. 259). However, in a broader sense the sexual problems experienced were linked to the alterations in body-image which participants'

appeared overwhelmed and self-critical of. This impeded their ability to engage intimately with their partners: “Breast cancer treatment changed the way I looked and I constantly catch myself having critical thoughts about my looks. Our sex life has totally died” (Nizamli et al., 2011, p.483).

Participants commented on how mastectomy appeared to not only undermine the aesthetic of the body but also undermined their sense of self; leading to inwardness, insecurity (Hatcher & Fallowfield, 2003; Klaeson et al., 2011) and detachment from oneself due to the physical transformation that had taken place: “One part of my uneasiness was that I was feeling like a monster, Frankenstein”. (Piot-Ziegler et al., 2010, p. 493). Arroyo and Lopez (2011, p. 5) state this form of detachment from oneself can deter women from engaging intimately; referring to this as “asexuality”. Participants described how undesirable they felt which related to how desire was reciprocated: “If I’m desirable, then I feel desire...I desire him because he desires me” (Arroyo & Lopez, 2011, p.4). Accordingly, participants actively avoided intimacy (Cebeci et al., 2010) in order to avoid possible humiliation and rejection within intimate relationships: “Well, as for me, I don’t dramatise [I hide] the situation, also to protect myself…and to protect others” (Piot-Ziegler et al., 2010, p.496). Arroyo and Lopez (2011) state that this can be understood as a way to circumvent receiving a negative image from others and avoiding a “mirror” (p. 3) of themselves, which would make difficult the gaze of their partners (Piot-Ziegler et al., 2010). This was associated with the diminished sense of womanliness experienced by participants: “But it’s not him that’s got the problem, it’s me. I don’t feel as if I’m a woman, or attractive anymore…” (Lloyd et al., 2000, p. 479). Similarly, one participant stated: “Now I have a feeling of losing something on one side of my chest. I feel uncomfortable if my husband touches my chest. It has considerably influenced my interest in sexual activity” (Wang et al., 2013, p. 4).

For many participants, how they perceived themselves related to others' interpretation of them (Arroyo & Lopez, 2011; Piot-Ziegler et al., 2010). Specifically, participants' appraisal of themselves was directly associated to inter-subjectivity: "I felt people had changed their perception of me" (Arroyo & Lopez, 2011, p. 4). Participants felt their body-image was reflected within their surroundings, with their appearance being described through the evaluation of others (Klaeson et al., 2011). This induced feelings of degradation in relation to others: "You are caught. When you don't like and can't stand yourself, you can't imagine that others can stand you either. I feel rotten" (Landmark & Wahl, 2002, p.116). One participant commented on the sense of repulsion she felt from her partner: "There is a difference between my love life before and today…My husband can't seem to touch me above the waist – that's how I feel, but he says that he doesn't touch me because he's afraid of hurting me" (Karaoz et al., 2010, p. 119).

Participants considered breasts were pivotal in the "games of attraction between men and women" (Arroyo & Lopez, 2011, p.6). As such, mastectomy altered the dynamics and interactions with other men and felt 'less flirtatious' as sexual attraction and participants' capacity to seduce was impeded (Arroyo & Lopez, 2011; Klaeson et al., 2010). Accordingly participants felt certain this would disadvantage them in pursuing relationships: "You can't help but imagine staying alone for the rest of your life...I felt disadvantaged compared to other women, It gives me a certain feeling of insecurity for my life in the future (Piot-Ziegler et al., 2010, p. 497). Equally, another participant stated: "But I felt that if it would go to hell with my husband – who else would want me? Nobody wants someone like me" (Klaeson et al., 2011, p.734).

In light of this, some participants felt reconstruction would be the only way they would remain intimate (Fouladi et al., 2013; Landmark & Wahl, 2002; Fallbjork et al., 2012): "[If reconstruction were not possible] I would certainly have nobody in my bed anymore"

(Piot-Ziegler et al., 2010, p. 497). However, this was not a shared experience amongst all (Fallbjork et al., 2012) with some participants considering reconstruction or prosthesis as a form of deception:

> I was walking down the street and several men were looking at my breasts, I thought I was wearing the prosthesis. A man looks at two boobs as it's feminine. They look at you but you know they're looking at something inexistent; it's a lie and you feel bad (Arroyo & Lopez, 2011, p.5).

Theme 3: The Changed Relationship and the Importance of Support in Adapting to Mastectomy and Facilitating Acceptance.

This theme refers to the ensuing difficulties and changes within intimate relationships, as well as the role of a supportive partner in facilitating adaptation to mastectomy and participants' altered body-image. Participants were very self-aware and sensitive within intimate relationships, fearing "not being able to attract him" (Arroyo & Lopez, 2011, p. 4). Mastectomy placed challenges during intimacy where participants were less spontaneous or would 'keep the room dark' (Cebeci et al., 2010; Fallbjork et al., 2012). Participants were also reluctant to expose themselves: "I had sex with my husband wearing a shirt and a bra. I could not allow him to see so. I did not like me" (Arroyo & Lopez, 2011, p.4; Lloyd et al., 2000). For many participants, an altered body-image and changes in sexual well-being caused conflict and breakdown within relationships (Fallbjork et al., 2012; Klaeson et al., 2011; Wang et al., 2013). Within one study, partners refused to touch participants' reconstructed breasts, or discuss their emotions and thoughts with them which interfered with their sex life (Hatcher & Fallowfield, 2003). One participant stated:

> Well for my part…I suppose it was less and less lust from my side. And then Alan said one evening: Why do I have to seduce you? Why is it up to me to turn you on?

> Probably it is a thing you must accept, that if you get turned on, you must turn me on. I don't get turned on by myself (Klaeson et al., 2011, p. 733).

Within two studies it appeared breasts were integral in maintaining a marriage, as well as the prospect of marriage (Cebeci et al., 2010; Nizamli et al., 2011), thus generating feelings of failure in their feminine role. This even led some participants to encourage their partners to consider extra-marital relations: "I was telling my husband that he could do that with another woman at the times when I was very sick" (Cebeci et al., 2010, p.259).

Across many studies (Arroyo & Lopez, 2011; Fallbjork et al., 2012; Fouladi et al., 2013; Hatcher & Fallowfield, 2003; Klaeson et al., 2011; Lloyd et al., 2000; Piot-Ziegler et al., 2010), the response of an intimate partner was pivotal in how participants adjusted to their altered bodies. Specifically, the role of a supportive partner through providing emotional support and affirming responses validated participants' femininity and sense of attractiveness (Fallbjork et al., 2012; Lloyd et al., 2000): "I'm still a woman, and I guess that's very much thanks to my husband...He likes me despite what I've been through...He loves me as I am and looks upon me as a woman though I have only one breast left (Fallbjork et al., 2012, p. 45). This was seen to facilitate the reorganisation to one's sense of self after mastectomy and participants adjustment to their altered bodies: "My husband supported me well that I could find myself sooner than you can imagine" (Fouladi et al., 2013, p. 2083). This led to a change in the way participants expressed intimacy with their partners after mastectomy (Fouladi et al., 2013; Hatcher & Fallowfield, 2003; Klaeson et al., 2011; Landmark & Wahl, 2002; Piot-Ziegler et al., 2010) and appeared accepting of this: "I have felt we have lived life as retired people now (laughs). We are laying, holding hands, hugging and yes, yes it has been improved" (Klaeson et al., 2011, p. 734).

Contrastingly, disapproving responses from partners were seen to further contribute towards a vulnerable self-image: “But when [husband] saw it, it was like, he just couldn’t believe it. You know, he sort of, ‘Oh my God, what have you done, it’s awful, it looks terrible’, blah, blah” Lloyd et al., 2000, p. 479). This was seen to devalue participants’ sense of self (Arroyo & Lopez, 2011).

However, the greatest lack of support experienced appeared in relation to health professionals (Karaoz et al., 2010; Landmark & Wahl, 2002; Lloyd et al., 2000; Wang et al., 2013). Some participants stated they were unaware of how mastectomy would affect their sexuality and felt unprepared. Participants also described the isolation they encountered and felt professionals avoided discussions pertaining to sexuality: “When we visit the clinics, neither doctors nor nurses actively give suggestions on sex to us…we are ashamed to talk about sex with other people as we are afraid they will laugh at us” (Wang et al., 2013, p. 5).

Discussion

The aim of the current meta-synthesis was to understand and provide a comprehensive understanding regarding the impact of mastectomy upon a woman’s sexuality. This understanding was achieved through the higher-order interpretations of twelve qualitative studies from which three overarching themes were obtained. These themes captured the impact of mastectomy upon a woman’s physical integrity, the meaning of this in relation to her sense of self, as well as how mastectomy poses a challenge to one’s gendered identity and sense of femininity. Moreover, the themes also described the undesirability and diminished feelings of attractiveness women experienced due to their altered body-image, leading to inwardness and insecurity and adverse consequences upon intimate relationships. The themes also encapsulate how a woman appraises her sexuality both intrapersonally and interpersonally after mastectomy. Overall, the findings of the current review highlight how sexual functioning is affected by the indirect experiences a woman undergoes after

mastectomy and has demonstrated the importance of an intimate partner's support and acceptance of a woman's altered body after mastectomy. Moreover, the meaning and experience of mastectomy upon one's sexuality appeared inseparable from what it means to be identified as a woman.

Despite the apparent consequences of mastectomy on the material aspects of sexuality, the findings of the current synthesis emphasise the erotic value of breasts and how integral they are in validating 'the female position', sexuality and womanhood. The meaning associated with the body after mastectomy altered (which was once considered 'sexual'), triggering experiences of repulsion. Specifically, the findings suggest that the disruption to a woman's sense of self and femininity leads to a successive cycle of thoughts regarding her undesirability and unworthiness; hindering her ability to remain intimate. That is, how a woman perceives and appraises herself after mastectomy facilitates intimacy. The findings indicate an intimate partner can facilitate this process of adaptation to an altered body positively through support and understanding. This can assist the reorganisation to a woman's identity and confirm her attractiveness and sense of femininity after mastectomy, as well as exploration of changes to ways in expressing sexuality.

Research suggests alterations to one's body-image after breast cancer poses as one of the most difficult challenges after mastectomy (Al-Ghazal et al., 2000). The profound sense of loss, the challenge to a woman's physical integrity and femininity, self-esteem and confidence considerably affected women's body-image within the current review. This highlighted how a woman's body-image is fundamentally associated with self-appraisal and self-concept. The loss women experienced within the current review resulted in them devaluing themselves as a whole. A reduction in self-esteem led to introversion and personal discomfort, thus negatively altering a woman's experience of and conflict within sexual relationships.

Furthermore, literature indicates gender-role socialisation can influence the construction of body-image which is then integrated into self-concept (Carlock, 1999). Gender-role socialisation refers to the 'standards' of beauty and behaviour. Overt and covert sources of information influence societal ideals regarding what constitutes 'beauty' in order to gain approval and instil feelings of worth within women (Boquiren, Esplen, Wong, Toner, & Warner, 2013). Within the current review, this appeared to be quite salient with some women appraising and constructing their body-image around the evaluation of others and hegemonic discourses. As such, they reported their altered bodies challenged the hegemonic discourses that prevailed in society regarding femininity and sexuality which resulted in avoiding the male gaze and feeling devalued. For these women, reconstruction was integral in restoring the ideal feminine image. Additionally, a woman's mental image of her body was directly associated with inter-subjectivity. This supports social psychology literature, which proposes self-concept and one's own perspective is often positioned within the other person (Decety & Sommerville, 2003). Conversely, others (namely older participants) resisted the societal ideals of femininity by positioning survival over bodily appearance. It is possible this finding reflects cultural and medical discourses pertaining to the ageing female body which positions older age as a time of sexual inactivity and a loss of femininity (Ussher, Perz, & Parton, 2015).

Despite this, many women within the current review viewed mastectomy as an attack on their femininity. It was apparent that the 'intact' body was pivotal in the disposition of the body in relation to feeling attractive, feeling connected to humanity and women's sense of belonging. These interpretations were thought to be crucial in feeling confident and desirable towards a man. The body destruction following mastectomy was considered to provoke negative feelings and identity transformation in women; disrupting the view of themselves and causing a breakdown within relationships.

In addition, the concept of identity was associated with a woman's physical integrity. Similarly, the body and self are thought be closely intertwined, as one feminist theorist states: "to be present in the world implies strictly that there exists a body which is at once a material thing in the world and a point of view towards the world" (Beauvoir, 1949, as cited in Moi, 2008, p. 180). The body is considered to represent one to the world and is therefore subject to meanings, symbols and messages (Gilleard & Higgs, 2013). This compelled women within the current review to question various dimensions of their identities at the physical, relational, social and symbolic level (Piot-Ziegler et al., 2010).

Erikson (1968) proposed a model of female identity development which suggests a woman's identity is attained through intimacy which is integral in feeling worthy and complete. Therefore, a woman's identity is based upon her relationship with her partner. However, the ramification of this is that a woman's sense of self and worth is reliant upon this intimate relationship. Within the current review, women placed their sense of desirability in the context of the 'other' (her partner) supporting this and highlighted the role of an intimate partner in validating a women's sense of self.

The cultural context of the current findings appears to place great importance upon the female body and sexuality, overriding other aspects of femininity (Parton et al., 2015). This again reflects the societal discourses in which women in the current study placed their experiences within casting themselves as 'asexual' (Arroyo & Lopez, 2011). These discourses create obstacles for women socially which are often difficult to negotiate (Perz & Ussher, 2008) and further complicates how a woman adjusts to her altered body after mastectomy.

Clinical Implications

The findings of the current review provide important information in facilitating clinicians and healthcare professionals to understand the needs of this population. Breast

cancer services should remain aware of the couple as a mutual system upon which mastectomy can have adverse effects. Services should ensure the routine provision of information regarding the adverse effects of mastectomy upon a woman's sexuality to better prepare couples for these changes, as this is considered helpful in facilitating one's psychological adjustment to cancer (Gotcher, 1995). Clinicians need to enquire and probe cautiously for sexual concerns with women (Schover, 2008). Critical to this is the importance of clinicians in maintaining their clinical skills in matters concerning the discussion of sexuality within consultations sensitively. Moreover, it is important for professionals to establish a woman's values prior to surgery which can help inform treatment choices; considering more conservative procedures which are considered to preserve a woman's femininity and sexuality.

The findings also highlight the importance of an intimate partner in validating a woman's sexual desirability and femininity. Access to therapeutic support and recognising where specialist psychosexual therapy and services may be warranted is also vital which would enable couples to maintain interpersonal discussions and also encourage dialogue between a woman, her altered body, and her partner (Loaring et al., 2015). Equally, referring couples to sexual discovery courses (forums that explore the expression of human sexuality) to explore alternative ways of engaging in sexual activity after mastectomy should also be considered. Specific advice on how to resume intimacy would be useful, including how couples feel regarding nudity after mastectomy, or how to disguise mastectomy with breast prosthesis or lingerie.

Moreover, psychological interventions should also include approaches that target altered body-image and feelings of estrangement for women after mastectomy. Interventions that aid women to redefine standards of attractiveness and feminine ideals that are achievable within the context of mastectomy, and less focused on hegemonic discourses may reduce the

negative self-concept women may assume after surgery. This could promote identity reorganisation after mastectomy. Providing a forum for women to express their concerns and distress can also enhance their ability to cope with sexual changes (Carlick & Biley, 2004).

The current findings also emphasise the need to consider the option of reconstruction at an individual level, based upon a woman's values, attitudes and the meaning associated with breasts, as reconstruction was not consistently shown to overcome a woman's sense of loss within the current review. It is equally vital to manage the expectations of reconstruction as the results can often be less than optimum.

Study Limitations and Recommendations for Future Research

Within the current review, three studies were conducted within the Middle East (Cebeci et al., 2010; Karaoz et al., 2010; Nizamli et al., 2011). Interestingly, these studies focused predominantly on the lack of sexual activity as opposed to the personal impact of mastectomy upon women's femininity. This may reflect the cultural discourses that pervade within these cultures where women may conceptualise their sexuality and breasts within the 'female duty' and fertility/motherhood frameworks. Moreover, within the Cebeci et al. (2010) study women reported on how they would refrain from initiating sexual activity. However, the cultural constraints these women live amongst consider women should remain reserved and modest with their sexuality. Therefore, it is possible that even in the absence of mastectomy; these women would not initiate sexual activity.

Additionally, the studies reviewed included women who had undergone other treatments after mastectomy (chemotherapy or radiation therapy) and did not take into consideration the length of time post-mastectomy. In relation to the latter, it is possible the women interviewed soon after the procedure may not have adjusted to the reorganisation that ensues after mastectomy. Therefore the results may be time-specific and not accurate of women's experiences over a longer period of adjustment and acceptance. With regard to the

former, it is possible that additional treatments can further complicate how and if a woman engages in sexual activity.

The relatively small sample of studies included within this review can be considered as a limitation, however, Sandelowski, Docherty and Emden (1997) argue that considering a larger sample size can prevent the depth of analysis required within qualitative research. Therefore, the sample has been considered as suitable in allowing the researcher to immerse herself within the data to produce a sufficiently rich level of analysis.

Future researchers may wish to explore the sexual experiences of women who undergo bilateral/contralateral prophylactic mastectomy. In the context of a genetic disposition it is possible that these women are better prepared for the changes after mastectomy. Moreover, research in this area focuses predominantly upon heterosexual women and couples, however there is a growing national health interest to understand the impact of mastectomy upon one's sexuality within sexual minority women (lesbian and bisexual). Female sexuality should be understood outside of the heterosexual view.

Conclusions

The current meta-synthesis has explored beyond the physical implications of sexuality after mastectomy. The review provides a higher-order understanding which elucidates the impact of mastectomy upon one's gendered identity, the personal meaning and experience of this, as well as the impact of this upon intimate relationships. It is the impact upon the loss of a woman's femininity which is seen to generate feelings of undesirability in women and impede sexual activity. The review highlights the importance of an intimate partner's support and the value of breasts in maintaining intimacy and confirming a woman's sense of self.

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* Denotes the studies that have contributed towards the meta-synthesis

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Table 1

Summary information of the studies selected for the meta-synthesis

Study	Research Question/Aim	Methodology	Participants
Arroyo & Lopez (2011)	To analyse the psychological effects of a mastectomy.	Face-to face interviews. An unidentified form of thematic analysis.	Sample size: n = 46; Age: not stated; Sex: 46 women. Setting: Spain Breast cancer treatment details/reconstructive surgery: All women underwent mastectomy.
Cebeci, Yangin, & Tekeli (2010)	To identify the changes in the sexual lives of women after breast cancer treatment.	Semi-structured face-to-face interviews. Content Analysis.	Sample Size: n = 8; Age: 33-42; Sex: 8 females. Setting: Turkey Breast cancer treatment details/reconstructive surgery: Either modified, radical, partial, or total mastectomy. All women receiving some form of adjuvant therapy (chemotherapy, radiotherapy, homonotherapy).
Fallbjork, Salander, & Rasmussen (2012)	Investigate women's narratives about the impact of mastectomy on their lives and their reflections on breast reconstruction.	Face-to-face interviews. Thematic analysis.	Sample Size: n = 15; Age: 39-69 Sex: 15 females. Setting: Sweden Breast cancer treatment details/reconstructive surgery: all mastectomy; six women underwent breast reconstruction.
Fouladi et al. (2013)	To investigate the process of coping with mastectomy in patients with breast cancer.	Semi-structured face-to-face interviews. IPA.	Sample Size: n = 20; Age: 33-71; Sex: 20 women. Setting: Iran Breast cancer treatment details: all mastectomy.

Hatcher & Fallowfield (2003)	Explore attitudes and beliefs of women at high risk of developing breast cancer who either declined or accepted bilateral prophylactic mastectomy (BPM).	Semi-structured face-to-face interviews. Qualitative Analysis using NU-DIST Vivo software.	Sample size: n = 80; Age: 28-57; Sex: 80 women, 60 women who accepted BPM and 20 women who declined BPM. Setting: UK Breast cancer treatment details/reconstructive surgery: all 60 women underwent BPM.
Karaoz, Aksu, & Kucuk (2010)	To evaluate the information needed and received by Turkish women with breast cancer regarding contraception, early menopause, infertility, fertility preservation, and sexuality.	Face-to-face semi structured interviews. An unidentified form of thematic analysis.	Sample size: n = 20; Age: 21-50; Sex: 20 women. Setting: Turkey Breast cancer treatment details/reconstructive surgery: all mastectomy. All women receiving some form of adjuvant therapy (chemotherapy, radiation therapy, or, Tamoxifen).
Klaeson, Sandell, & Bertero (2011)	To explore how middle-aged women treated for a breast cancer experience their sexual identity connected to the community norms and values in the society	Three focus groups. Qualitative content Analysis	Sample size: n = 12; Age: 39-45; Sex: 12 women. Setting: Sweden Breast cancer treatment details/reconstructive surgery: Either total or partial mastectomy. 2 women underwent breast reconstruction. All women receiving some form of adjuvant therapy (Chemotherapy, Radiation therapy, or homonotherapy).
Landmark & Wahl (2002)	To explore how women living with breast cancer experience the disease.	Face-to-face in depth interviews Grounded Theory	Sample size: n = 10; Age: 35-69; Sex: 10 women. Setting: Norway Breast cancer treatment details/reconstructive surgery: All women underwent mastectomy of which some were receiving hormone treatment at the time of interview.

Lloyd et al. (2000)	To obtain a detailed understanding of the personal experiences of women undergoing prophylactic mastectomy.	Face-to-face semi structured interviews. Grounded theory	Sample size: n = 10; Age: 31-51; Sex: 10 women. Setting: UK Breast cancer treatment details/reconstructive surgery: All women underwent bilateral prophylactic mastectomy, 9 of which underwent reconstructive surgery.
Nizamli, Anoosheh, & Mohammadi (2011)	To explore the experiences of women with breast cancer regarding chemotherapy after mastectomy.	Semi-structured face-to-face interviews. Content analysis.	Sample size: n = 17; Age: 30-45; Sex: 17 women. Setting: Syria Breast cancer treatment details/reconstructive surgery: All women underwent mastectomy and received chemotherapy.
Piot-Ziegler, Sassi, Raffoul, & Delaloye (2010)	To understand the consequences of mastectomy on corporality and identity in women with breast cancer.	Three semi-structured face-to-face interviews. One at the time of mastectomy, one before reconstruction, and one after reconstruction. Thematic analysis	Sample size: n = 19; Age: 37-62; Sex: 19 women. Setting: Sweden Breast cancer treatment details/reconstructive surgery: All women underwent mastectomy, of which 9 had breast reconstruction.
Wang et al. (2013)	To evaluate changes to one's sexual well-being after breast cancer.	Mixed method study (qualitative and quantitative). Face-to-face in-depth interviews An unidentified form of thematic analysis.	Sample size: n = 20; Age: 36-50; Sex: 20 women. Setting: China Breast cancer treatment details/reconstructive surgery: All women underwent mastectomy and were receiving some form of adjuvant therapy (chemotherapy or hormone therapy).

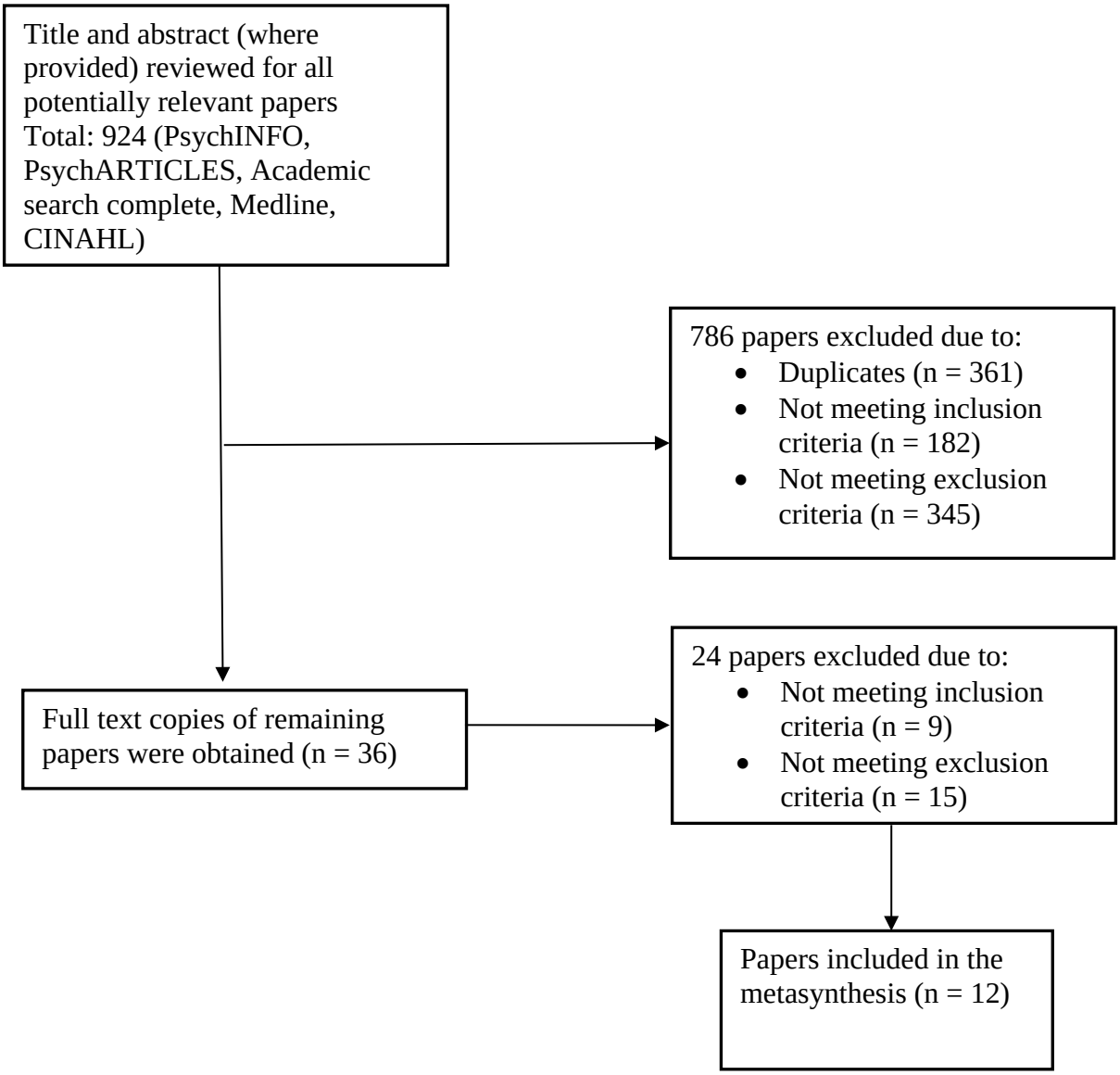

Figure 1

Flow diagram for inclusion of papers in the meta-synthesis

Table 2

Quality assessment of studies included in the meta-synthesis using the Critical Appraisal Skills Programme (CASP, 2006).

Study	Research Design	Recruitment Strategy	Data Collection	Reflexivity	Ethical Issues	Data Analysis	Findings	Value of the Research	Total Score (out of 24)
Arroyo & Lopez (2011)	3	2	3	1	1	2	2	3	17
Cebeci et al. (2010)	3	2	2	1	3	2	2	3	18
Fallbjork et al. (2012)	3	3	3	1	2	2	2	2	15
Fouladi et al. (2013)	3	2	3	1	2	2	2	2	17
Hatcher & Fallowfield (2003)	3	1	3	1	1	2	3	3	17
Karaoz et al. (2010)	3	2	3	1	1	2	2	3	17
Klaeson et al. (2011)	3	3	3	3	3	3	3	2	23
Landmark & Wahl (2002)	3	3	3	1	3	3	3	3	22
Lloyd et al. (2000)	3	3	3	1	1	3	3	3	20
Nizamli et al. (2011)	3	2	3	1	3	2	3	2	19

Study	Research Design	Recruitment Strategy	Data Collection	Reflexivity	Ethical Issues	Data Analysis	Findings	Value of the Research	Total score (out of 24)
Piot-Ziegler et al. (2010)	3	3	3	3	2	3	3	3	23
Wang et al. (2013)	3	2	2	1	2	3	3	2	18

Table 3.

Contribution of Studies to Overarching Themes

	Theme 1: A Violation to the Integrity of the Body: The Impact of Mastectomy upon Femininity, Body-Image and Attractiveness	**Theme 2: The Impact of Mastectomy upon Desirability within Intimate and Sexual Relationships**	**Theme 3: The Changed Relationship and the Importance of Support in Adapting to Mastectomy and Facilitating Acceptance**
Arroyo & Lopez (2011)	Theme: *The fracture of the "imaginary body"* Theme: *The problem of "femininity" in the masectomised woman* Theme: *Mutilation of "the real" of the body*	Theme: *The fracture of the "imaginary body"* Theme: *The problem of "femininity" in the masectomised woman*	Theme: *The fracture of the "imaginary body"*
Cebeci et al. (2010)	No directly observable themes or comments	Theme: *Intermittent penile-vaginal intercourse* Theme: *Sexual dysfunction*	Theme: *Sexual initiative by the male*
Fallbjork et al. (2012)	Theme: *Losing a breast is no big deal: No motives for reconstructive surgery* Theme: *Losing a breast means losing oneself: Reconstructive surgery is a necessity for being restored as a person* Theme: *Losing a breast means a wounded femininity: reconstructive surgery will make it easier to look and feel like a woman*	Theme: *Losing a breast means losing oneself: Reconstructive surgery is a necessity for being restored as a person*	Theme: *Losing a breast means losing oneself: Reconstructive surgery is a necessity for being restored as a person*
Fouladi et al. (2013)	Theme: *Reactions and problems after loss* Theme: *Reconstruction of evaluation system*	Theme: *Reactions and problems after loss*	Theme: *Compatibility with changes and reorganisation*
Hatcher & Fallowfield (2003)	Theme: *Reconstruction*	No directly observable themes or comments	Theme: *Sexual Impact* Theme: *Support, Personal*

Karaoz et al. (2010)	Comment: *"I feel I'm not a complete woman..."*	Comment: *"But I'm all dry during intercourse..."*	Comment: "*they stated that healthcare personnel did not talk about subjects such as sexuality..."*
Klaeson et al. (2011)	Theme: *To feel different* Theme: *The unruly body* Theme: *Re-evaluating*	Theme: *Eroticism is not what it used to be*	Theme: *Eroticism is not what it used to be*
Landmark & Wahl (2002)	Theme: *The body broken and torn – experiences related to bodily, physical change* Theme: *Loss of breast – experiences related to female identity*	Theme: *Loss of breast – experiences related to female identity*	Theme: *For better and worse – experiences related to social support*
Lloyd et al. (2000)	Theme: *Experiencing surgery and recovering – Maintaining womanliness, Loss of womanliness, existing construct of womanliness*	Theme: *Sexuality*	Theme: *Showing others* Theme: *Isolation and being supported* Theme: *Qualities of supportive others* Theme: *Moving on: Relationship*
Nizamli et al. (2011)	Theme: *Psychological discomfort: Body-image*	Theme: *Failure in the family role: Sexual relationship*	Theme: *Social dysfunction: Lack of marriage opportunities*
Piot-Ziegler et al. (2010)	Theme: *Illness and mastectomy: A challenge to body integrity and corporality* Theme: *Body deconstruction: experiencing mutilation* Theme: *Body deconstruction: a challenge to a woman's identity*	Theme: *Body deconstruction and relationship to others* Theme: *Body reconstruction: An identity challenge*	Theme: *Re-evaluating existential priorities and re-position one's identity*
Wang et al. (2013)	Theme: *Body-image changes*	Theme: *Lack of sexual interest* Theme: *Decrease in sexual frequency*	Theme: *Marital relationship* Theme: *Misconceptions about sex* Theme: *The need for professional consultation*

Section Two: Research Paper

The Experience and Decision-Making Process of Women with Low-to-Moderate Risk of Contralateral Breast Cancer (CBC) who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM)

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Prepared for submission to Journal of *Qualitative Health Research*[1]

[1] See Appendix 4-J for 'Author Guidelines'

Abstract

Rates of contralateral prophylactic mastectomy (CPM) are increasing in women who are considered low-to-moderate risk of contralateral breast cancer, with little known regarding the decision-making process. Accordingly, the aim of the current study was to explore the experiences and decision-making process of women identified as low-to-moderate risk who have undergone CPM. Six women recruited from two breast units within the UK were interviewed utilising semi-structured interview schedules and the data were analysed using Interpretative Phenomenological Analysis (IPA). Five themes were identified and highlighted that women's decision-making factors were based upon their subjective evaluation of risk and perceived vulnerability, cosmetic, pragmatic, and psychological reasons, embedded within various individual experiences, familial and age-related circumstances. Clinical implications are discussed, particularly the importance of healthcare providers considering the roles of the aforementioned factors within assessments to ensure women's individual needs are being addressed.

Key Words: Breast Cancer, Contralateral Risk-Reducing Mastectomy, Psychosocial Aspects

The Experience and Decision-Making Process of Women with Low-to-Moderate Risk of Contralateral Breast Cancer (CBC) who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM)

Breast cancer is the most prevalent form of cancer worldwide, with approximately 13 million women diagnosed annually (Yang, Zhu, & Gu, 2015). Women with unilateral breast cancer, who present with risk factors such as mutations to the BRCA1/2 genes and have a significant family history of breast cancer, are considered high-risk of developing contralateral breast cancer (CBC) (Davies, Canton, & Brewster, 2015; Narod, 2010). To minimise this risk, contralateral prophylactic mastectomy (CPM), the removal of the non-cancerous breast after primary breast cancer is proposed as an effective prophylactic procedure (Rebbeck et al., 2004). A recent Cochrane review (Lostumbo, Carbine, & Wallace, 2010) supports this stating CPM is only justified for women considered high-risk as there is no confirmed survival advantage for lower-risk category women.

Advances in medicine, namely the administration of Tamoxifen has decreased CBC rates (Swain, 2001). However, USA statistics (currently no UK data available) indicate an increase in CPM as a prophylactic measure across all risk categories (Murphy, Milner, & O'Donoghue, 2013; Tuttle, Habermann, Grund, Morris, & Virig, 2007). Research suggests these women, who are considered low-to-moderate risk, overestimate their risk of CBC (Portschy et al., 2015). In the absence of high-risk factors, CPM appears disproportionate to women's treatment needs. Hence, many physicians view CPM as an excessive procedure as the risk of these women developing CBC is between 0.5-0.7% (Spear, Carter, & Schwarz, 2004; Wood, 2009). CPM is also a controversial procedure, stimulating discussion and raising ethical concerns regarding the removal of a healthy breast in the absence of high-risk factors (Wood, 2009).

There are limited clinical guidelines internationally and nationally (only one recently published UK site-specific protocol [Basu, Ross, Evans, & Barr, 2015]) and no NICE guidance in the UK to offer assistance to physicians for women seeking CPM who fall within the low-to-moderate risk category. This results in a lack of uniformity in care pathways and referral patterns across hospitals and a rise in CPM rates (Murphy et al., 2013). Additionally, the ambiguity concerning the criteria for decision-making regarding which women qualify for the surgery in the absence of high-risk factors, can lead to inequality in the availability of CPM and places added responsibility onto physicians for the decision (Beesley, Holcombe, Brown, & Salmon, 2013).

Factors Influencing the Decision to Undergo CPM

The decision to undergo CPM often ensues over an extended period of time, in which information-seeking, evaluation and various intersecting factors are considered by the women themselves or collaboratively with the physician. The initial diagnosis of primary breast cancer may lead to heightened anxiety and prompt an impulsive request to physicians for CPM (Guth et al., 2012). Women may consider their best chance at survival is by eliminating the potential threat posed by the contralateral breast (Newman, 2014). Research highlights a number of reasons which may influence a woman's decision to undergo CPM. This includes, reducing the anxiety and fear of developing CBC, perceived risk, uncertainty about cancer, and anticipated feelings of regret (Brewster & Parker, 2011; van Dijk, van Roosmalen, Otten, & Stalmeier, 2008). Hallowell (1998) states the decision to undergo CPM is often made based upon the anticipated consequences upon family members, such as their death, and the need to contain fear. However, for other women the psychological benefits of CPM (e.g. reducing anxiety) and aesthetic reasons (e.g. the desire for symmetry) outweigh the possible risks and fear and are integral to the decision-making process (Beesley et al., 2013; Chagpar, 2014; Rendle, Halley, May, & Frosch, 2015).

Psychological factors. Significant psychological benefits of CPM include the decrease in the chronic anxiety of developing CBC and reducing the distress associated with surveillance (Bebbington Hatcher, Fallowfield, & A'Hern, 2001; Katz & Morrow, 2013). The role of anxiety and worry is considered pivotal in prophylactic decision-making (Schwartz, Peshkin, Tercyak, Taylor, & Valdimarsdottir, 2005). For example, Fisher et al. (2012) found the most commonly cited reasons motivating women to undergo CPM was the fear of developing CBC and the belief of improving survival. Moreover, mastery over cancer and feeling in control can also motivate women to undergo CPM (Covelli et al., 2015).

The affect heuristic in relation to cancer worry provides a useful framework for understanding the decision-making process (Slovic, Finucane, Peter, & McGregor, 2004). The theory hypothesises people under duress have limited mental resources and accordingly rely more heavily on their affective responses, as opposed to reasoned judgment whilst making decisions. McCaul and Mullens (2003) state worry may accelerate the process of undertaking health-protective behaviours and can serve to keep an issue more salient. The emotional arousal of worry can encourage proactive coping and provides a cue to action as people are naturally averse to worry. Therefore, a woman who is worried about developing CBC may choose to undertake CPM; reducing negative affect. However, this raises a contentious debate regarding the use of CPM as a psychological coping strategy (i.e. reducing anxiety) particularly for women considered low-to-moderate risk (Murphy et al., 2013).

Moreover, research suggests women can experience ongoing interpersonal and intrapersonal difficulties following CPM (Altshuler et al., 2007; Frost et al., 2005; Patenaude et al., 2008). For example, Rolnick et al. (2007) found women reported feeling less sexually desirable and feminine after prophylactic surgery. They suggest women would benefit from improved understanding of alternative treatment options, as well as better awareness of the possible consequences of CPM. This includes information regarding the pain, scarring and

physical changes resulting after the surgery. Although, the literature indicates 86.5% of women undergoing CPM are generally satisfied with their decision (Geiger et al., 2006; van Dijk et al., 2008), they report some dissatisfaction due to the negative consequences (e.g. alterations to body-image, sense of femininity, and complications related to reconstruction) (Frost et al., 2011).

Patient factors and the availability of breast reconstruction. Research suggests women who opt for CPM are generally younger, white, and of higher educational and socioeconomic status (Guth et al., 2012; Yakoub et al., 2015). It is thought this demographic of women are more body conscious and more aware of the information and awareness of CBC risk (Rippy et al., 2014). It is possible being younger and the availability of breast reconstruction could influence the decision to undergo CPM. Specifically, some women may be motivated to undergo CPM for prophylactic reasons, as well as their readiness to undergo breast reconstruction (Newman, 2014). Ashfaq et al. (2014) reviewed the medical records of over 100,000 women with unilateral breast cancer and found the rise in CPM rates correlated positively with breast reconstruction rates. Improved reconstructive techniques and the increasing view of breast reconstruction as a lifestyle choice renders the option of CPM as a prophylactic measure more acceptable to women (Ashfaq et al., 2014; Guth et al., 2012). Optimal aesthetic results are achieved when breast reconstruction is performed bilaterally allowing women to achieve chest wall symmetry (Murphy et al., 2013). CPM with breast reconstruction is associated with less decision-regret (Isern, Tengrup, Loman, Olsson, & Ringberg, 2008) and can mitigate some of the negative consequences after CPM by retaining one's body-image and sense of femininity (Frost et al., 2005).

Research highlights the importance of managing women's expectations of CPM and breast reconstruction as complications can occur post-surgery. This includes chronic pain, cosmetic issues (e.g. scarring), and numbness and reduced sensitivity to the chest wall or

nipples (Patenaude et al., 2008; Rosenberg et al., 2013). This indicates the importance of education and reasoned decision-making when considering CPM.

Media and social networking influences. There is growing interest in explicating the increasing trend in CPM rates in women considered low-to-moderate risk. High profile figures within the media have raised the public awareness of prophylactic surgery. This may have inadvertently led to the overestimation of CBC risk (Portschy & Tuttle, 2013). Guth et al. (2012) suggest the aggressive advertising of breast cancer within health promotion campaigns may have instilled fear within women. Additionally, medico-social factors such as patient-led webpages and forums actively support CPM. This encourages women to form set opinions about prophylactic surgery which physicians find difficult to alter. However, the discordance between women's perceptions regarding their risk of CBC and reality provides an opportunity for physicians to dispel these perceptions, and facilitate the decision-making process.

The role of the physician. Although women may feel assured in their decision to undergo CPM, physicians may not be as certain regarding why they perform the surgery (Katz & Morrow, 2013). Physicians often act as the gate-keepers to patient-information and many women confirm their decision to undergo CPM within the consultation (Bedrosian & Yao, 2015). It is important physicians equip women with information, attend to women's individual needs and values, and integrate the assessment of anxiety and cosmesis into their assessment, whilst empowering women to make an informed choice.

However, physicians may not concur with the decision for women to undergo CPM but assent to their request due to the implications upon their practice. Potentially, not accommodating for a woman's preferences could compel them to consult with another physician. This could cause a loss of future practice for the physician if the information was made public; impeding their ability to meet national cancer targets (Katz & Morrow, 2013).

Moreover, patient-centered care and granting patients their choices and requests is an increasing priority within health services to ensure equity of care, enhancing Quality of Life (QoL), and treatment satisfaction (Caldon et al., 2010). This challenges physicians; balancing evidence-based practice by avoiding unnecessary surgery whilst managing women's preferences/meeting expectations (Covelli et al., 2015; Rosenberg et al., 2013).

The evidence suggests CPM rates have increased across all risk categories, indicating reducing potential risk for CBC may not be the only influencing factor in the decision-making process (Brewster & Parker, 2011; Tuttle et al., 2009). It is evident that there is a need to better understand the motivations and decision-making process of women undergoing CPM who are considered low-to-moderate risk of CBC who may shed further light on these factors. Although quantitative research has elucidated some of the factors associated with the decision, there is a lack of qualitative research in this area. The latter is important in explicating the meaning, perceptions and experiences of women undergoing CPM and the impact of the decision on one's QoL. Undertaking this research will highlight how physicians can better facilitate the decision-making process and lead to improved understanding and interventions on how to best advise and support these women. This will aid the process of forming guidelines regarding the decision-criteria for CPM and devising helpful information for women within the low-to-moderate risk category of CBC.

Aims of the Current Research

This study aims to investigate the experiences and the decision-making process of women who have undertaken CPM and are considered low-to moderate risk of CBC. This includes understanding the impact of CPM on a woman's QoL, the emotions associated with this, and its impact upon one's psychosocial functioning. Understanding which factors are central to the decision-making process is also crucial. A further aim is to explore how satisfied/dissatisfied women are with the surgery and their decision to undergo CPM. The

study will also elucidate the reasons why some women opt for breast reconstruction after CPM, and others do not.

Method

Design

The current study employed a qualitative design utilising semi-structured interviews. Prior to data collection the researcher consulted with a local service-user public involvement network who provided opinions on the overall design of the project. However, decisions regarding the incorporation of this feedback remained with the researcher.

The data were analysed utilising Interpretative Phenomenological Analysis (IPA); an inductive process which aims to provide an in-depth understanding of lived experiences through the process of interpretation (Biggerstaff & Thomson, 2008; Smith, Flower, & Larkin, 2009). Three concepts: phenomenology, hermeneutics, and idiography underpin IPA. Phenomenology refers to the lived content of experience and how individuals make sense and meaning of this (Smith et al., 2009). The 'double hermeneutic' refers to a two-stage interpretation whereby the researcher interprets the meaning the participant's place upon their own experiences (Smith & Osborn, 2008). Idiography refers to the detailed understanding of a specific sub-set of people, as opposed to generalising across larger populations. Accordingly, IPA is generally characterised by a smaller sample size to allow the researcher to identify commonalities as well as divergences across participants within a specific group (Smith et al., 2009). Ensuring a homogenous sample is important in IPA to enable the researcher's interpretation to be representative of the whole sample. Thus, the current study explored the unique experiences and decision-making process of women considered low-to-moderate risk of CBC who had undergone a CPM. However, IPA also allows the researcher to depict variation in experience; therefore participants' reasons to undergo CPM with or without reconstruction and age varied.

Participants

Participants were recruited from two NHS breast cancer services in the North West of England. Women were considered eligible for inclusion if they were (a) over 18 years old; (b) had undergone CPM with or without reconstruction and considered low-to-moderate risk of CBC; and (c) not undergoing any adjuvant treatment e.g. chemotherapy or hormone therapy. The latter was important to consider as adjuvant treatment is associated with physiological and psychological side effects (van den Ende, 2012) which could negatively impact upon women's experiences and adjustment to CPM. Additionally, it was a requirement that women were at least over the 12 months post-surgery period. This allowed the researcher to balance a reasonably protracted period of experience and reflection with the ability to recall the experiences in sufficient detail. Specific criteria for exclusion were (a) participants who had developed metastasis at the time of interview or any other major illness; and (b) participants who did not speak sufficient English to undertake the interview due to the limited funding available to employ interpreters. Participants' real names were replaced with pseudonyms to ensure confidentiality.

In total, six women were recruited and interviewed for the current study. Three participants underwent CPM at the same time as their therapeutic mastectomy, and was a delayed procedure for the remaining participants. Four women underwent reconstruction. Participants were aged between 42-74 (M = 53 years) years and underwent CPM between 2-4 years prior to interview. Additional demographic information is provided in Table 1 (Appendix 2-A).

INSERT TABLE 1 HERE

Procedure

Recruitment. Psychologists working within the oncology department of the respective sites who routinely assessed women considering CPM conducted a manual file trawl of their

caseloads. Breast surgeons were also consulted by the psychologists, enquiring whether any other patients had undergone CPM. Breast cancer nurses facilitated this process by accessing the patient database to determine eligibility for the current study. A phased approach to recruitment was employed to widen the participant pool. Stage 1, 2, and 3 involved recruiting women from the 12-24, 24-36, and 36-48 month post-surgery bracket respectively. If enough participants were not recruited from Stage 1, women within the following post-surgery brackets were contacted 4 weeks after the initiation of the previous phase. For all phases, the following process was followed.

Psychologists and breast cancer nurses identified the women who met the eligibility criteria and sent out a study information pack containing the participant information sheet (see Ethics Section: Appendix 4-A) and a contact sheet (Appendix 4-B) via post. If participants wished to learn more about the study they were invited to return the contact sheet by post, with their details so that the researcher could contact them to discuss the potential to participate further. A date and time convenient to the participant was arranged for participants who were willing to participate. On this date, participants signed the consent form (Appendix 4-C) highlighting their participation was voluntary and ensuring their anonymity.

Interviews. A semi-structured interview schedule was used to guide the interviews; however, this was tailored according to the specific responses of participants (Appendix 4-D). Questions focused on the decision-making process, the factors contributing towards the decision, as well as the psychosocial impact of CPM. Interviews were conducted in either the respective NHS site (N =1) from which participants were recruited, or at the participant's home (N = 5) if they preferred this. The researcher adhered to relevant lone worker policies. All interviews were recorded using a digital audio device. Following the interviews,

participants were provided with a debrief sheet (Appendix 4-E) together with a conversation regarding the support they could seek if required.

Reflexivity. In order to maintain a reflective stance, a reflective diary was kept by the researcher (Appendix 2-D) to enable thoughts and document the process, reflections and acknowledge the researchers own influences on the data and the themes derived. Whilst the researcher does not have a diagnosis of breast cancer, she has a first-hand family experience of breast cancer. This was not shared with participants, however it was important to note the impact of this upon ensuing interviews with participants.

Data Analysis

Interviews were transcribed verbatim and analysed using IPA. The researcher undertook an iterative process by reading and re-reading the individual transcripts to familiarise herself with each individual's experience. Initial notations were made reflecting the researcher's immediate thoughts and observations which informed emerging themes. This process was repeated across all transcripts and emergent themes were considered across transcripts to establish connections. Emerging themes were clustered together if they were considered to contribute towards a theme development. The principle of 'contextualisation' was utilised where the narrative and temporal features of themes were considered (Smith et al., 2009). Theme clusters for individual participants were named which captured a description of the experience (Appendix 2-B). Recurrent themes were developed into higher-order themes which were compared with other participant's experiences that were considered similar in meaning and content, but also captured variation in experience. This allowed the development of super-ordinate themes which were inclusive of all participants' experiences. These themes were individually titled to capture the essence of the experiences as well as the researcher's interpretation (Appendix 2-C).

Reliability and Validity. IPA acknowledges the active role of the researcher within data collection and analysis due to the 'double hermeneutic' process. However, it is important for the researcher to 'bracket' (Chan, Fung, & Chien, 2013) their own experiences; to be aware of and set aside their own preconceptions about the construct under investigation. This ensures the researcher's interpretation accurately describes the participants' experiences, as opposed to the researcher's own imposed beliefs (Reid, Flowers, & Larkin, 2005). Bracketing is a means of demonstrating the validity of the analysis.

To further confirm the themes derived and interpretations were credible and valid, the researcher consulted with the supervisors of the study. They provided guidance and reviewed the participants' accounts, ensured they corresponded with the themes and reviewed the transcripts (Willig, 2001). Ensuing conversations and comments from supervisors led to the revision of themes and interpretation. This included revisiting original transcripts to further support the developed themes. Furthermore, in order to remain transparent, the researcher provided a paper trail of the data analysis process (Yardley, 2008) (see Appendix 2-B and 2-C).

Ethical Considerations and Approval

Full ethical approval was obtained from the National Research Ethics Committee (REC) for recruitment, as well as local Research and Development approval from the individual NHS sites where participants were recruited from (See Ethics section 4-F for all relevant ethical approval documents). A key ethical issue that was considered was the possibility that participants may feel distressed after the interview due to the emotive nature of the topic under study. However, this was managed as the researcher was also a trainee clinical psychologist trained in managing distress and containing difficult emotions, whilst also offering further sources of support to participants.

Findings

Analysis of participants' experiences and decision-making process of CPM were organised into five overarching themes. Each of these are presented in turn below, supported by relevant data excerpts, highlighting areas of convergence and divergence across participants' accounts.

Theme 1: Responding to Cancer: From Taking Control to Acceptance

Participants' responded to their cancer diagnosis in a variety of ways. Responses ranged from feeling overwhelmed with anxiety and uncertainty to adopting a positive outlook and appearing acquiescent to cancer. The former precipitated the need to regain control by reducing risk and asserting themselves fully to consultants for their decision to undergo CPM.

Some participants described their anxiety of developing another cancer which was pivotal in their decision-making process. Participants immediately felt vulnerable: "I was worried it might come onto the other side and I might not have got it in time" (Tina) and wanted to eliminate this entirely, despite acknowledging their low-risk: "I started to think about things, I started to get quite anxious…and I know people say the chances of recurrence of the other breast are quite low, but that's not nil" (Jillian). Participants' vulnerability and anxiety was heightened due to the lack of assurance in medical team decisions and tests previously: "Nothing had been picked up on the one that was cancerous, so how was I ever going to have a check-up that left me feeling reassured and happy that everything was fine?" (Jane). This convinced participants that medics and tests were unreliable and placed them into a position of further uncertainty.

Living with risk was incongruent with these participants' identities and so they strove to regain control and certainty of their health: "I don't like risk. I am risk averse. I'm rather, I would be proactive than to say let's see what happens" (Hannah). Consequently, some participants were regretful of not having done more in the past to prevent cancer which was

construed as negatively reflecting upon their sense of self: “I felt it reflected on me” (Hannah) and: “I do not want to have any thoughts of I wish I had done that. I have to do everything in power to beat this” (Jane). This, along with anticipated regret motivated participants’ decision to undergo CPM, which for some was construed in their motherly role: “It’s not the same as being three and five and losing your mum and the worse thing about it is and I said this to my Mum…but my boys calling someone else Mum” (Jane) and family context: “[I’m adopted] I don’t know my genetic history, I don’t know anything about me” (Hannah).

Regaining control of cancer was crucial for participants. The importance to participants of regaining control to reconcile anxiety and ensure they defeated cancer meant they were willing to take any measures to guarantee this: “Do whatever you have got to do. And I will do everything I have to do …if there was a question over whether I should have a certain type of treatment, throw it at me anyway” (Jane). One participant initially felt despondent after her consultant refused to oversee her care and offer CPM, however was quickly able to regain her command: “Then I thought, no let’s do something…I took control, thank God I am who I am” (Hannah). Consultants’ responses to participant’s requests for CPM differed. Consultants were on the whole fully accepting of the decision: “No she (consultant) said it was pointless talking [about CPM] because you know what you want and why you want it. She was so supportive, she was just who I needed” (Karen). Others were initially resistant, though acquiesced:

> When I saw the surgeon I told her I made the decision for CPM, and she said we don’t normally remove healthy tissue…[she was] reluctant to do the left. I said to her you may think it may be healthy tissue, but in my view it’s not healthy (Jillian)

For Tina it was “a joint decision between me and my consultant… I said what about the other one? And she said we have to talk about that later on. This is early diagnosis”. For

most participants, being proactive and assertive in the decision for CPM was essential in feeling empowered and ensuring the consultant assented to their decision for CPM. Therefore, consulting with others regarding the decision for CPM was redundant and the consultant's opinion was not always considered necessary: "but even if he had said think about it, I would say it's my body and I had made that decision" (Jillian), and, "So I said would you like me to tell you what should happen? I think you should refer me to the other surgeon [for CPM]" (Hannah). Therefore, instead of rescinding control to the consultant, participants assumed an active role in their treatment decision and took agency over their own bodies as a means to manage their risk.

Contrastingly, Mary and Karen assumed a more hopeful and a less worrisome attitude towards cancer and further risk: "That's one of the things the doctor asked me [fear of secondary cancer]. The consultant asked me and I said no not a scrap" (Mary). They reflected on relatives' experience of cancer and used this as a reference for remaining optimistic: "Yeah, so seeing how the others progressed was, well until anyone told me any different, I had nothing that I had to genuinely worry about" (Karen). Their perception of cancer differed to other participants, considering it could not progress and overcome them, facilitating a positive outlook. Increased awareness through witnessing others with cancer or through having experienced cancer previously enabled resilience: "So it was quite straight forwards really, we just went through the motions again" (Mary). Mary assumed a stoic attitude and appeared acquiescent and resigned to cancer, considering it as an acceptable and usual experience expected with age:

> Well, it's given me an awareness of cancer, right across the board really, and of the elderly. And so it didn't seem...when I was diagnosed, it didn't seem, any different, it could happen to anyone, and I know people who it has happened to. And so it didn't come as, oh why did it happen to me? It was just oh why not?

Interestingly, Mary's consultant reflected on the role of breasts for an elderly woman and asked: "Have you considered the removal of the other one?" (Mary). Overall, participants' responses to cancer and the decision and assertion for CPM to consultants varied according to their disposition and circumstances, which for some appeared to be embedded in their roles as mothers or considering cancer as a usual experience expected with age.

Theme 2: The Breasts as Emotionally and Physically Constraining

In reflecting on the past and an imagined future, participants discussed how they considered their breasts as troublesome and burdensome. They expressed feeling constrained by pain, anxiety, barriers associated with their natural breasts, and the emotional and physical entailments of a single mastectomy due to the asymmetry and lopsidedness.

Participants reflected on the turbulent journey of physical self-examination they had undergone prior to diagnosis which had overshadowed the majority of their lives: "Yes, I had my first episode [of benign tumours] at 30. So it has been from the age of 30 to the age of 52. So that's 22 years of having a lot of stress really" (Jillian). Following the occurrence of cancer in one breast, the prospect of continuing a life of self-examination could be overwhelming with CPM presenting as a method to overcome this: "I didn't want to become obsessive about checking it, I didn't" (Jane).

Participants construed their breasts as a source of pain and anxiety: "I never perceived my breasts as anything other than being trouble" (Jillian). Accordingly, they perceived their future to be impeded by the disfigurement and pain of a single mastectomy which influenced and threatened their perception of themselves in an imagined future: "I couldn't see where I was going. I couldn't envisage wearing these thick big woolly fleeces in a British summer" (Karen). These difficulties were both emotionally and physically restricting so that participants "tended to stay in more rather than go out in a baggy man's fleece" (Karen).

CPM therefore was a means to an end which enabled participants to overcome these barriers and was psychologically freeing: “I was so elated after the operation that they had gone I didn’t feel any pain. I was offered pain relief, but I honestly didn’t need it. I think maybe it was the adrenaline, or the relief or whatever” (Jillian). CPM was also enabling at a physical and practical level:

> It’s just less bother. There was a time when I thought err my breasts were fairly large, they weren’t huge but I had big breasts. And you know the clothes and everything else, erm…it’s simple now, I just wear a t-shirt. Swimming shorts and you’re away!” (Mary).

Participants discussed the detachment they experienced towards their breasts due to the negativity and previous difficulties associated with them: “They have never really been a part of me that I was particularly attached to. I did breast feed both my children and had terrible problems with the second one [child]” (Hannah). Some participants explained that their breasts were: “not a big part of my psyche, so to think about having them removed was not an issue really” (Jillian). This disconnection provoked feelings of redundancy towards their natural breasts: “They were just bits of my body” (Hannah) which facilitated the decision for CPM: “So I just wanted to be rid really…I decided I wasn’t going to be lopsided. Symmetry as in let’s get rid of what we don’t want” (Mary). Hannah described always feeling accustomed to the prospect of prophylactic surgery, contemplating why people would want to retain parts of their bodies that were no longer needed or necessary, which fuelled her decision for CPM: “All the things I use to laugh about, one day you know [I said], I don’t see why you wouldn’t want to have two mastectomies…! But I suppose that says my attitude has always been why not?”. In summary, CPM enabled participants to overcome the sense of

redundancy, psychological and physical constraints some participants felt towards their contralateral breast.

Theme 3: Retaining one's Femininity and Sense of Self

The manner in which CPM, with or without reconstruction, enabled the retaining of one's sense of self was discussed by all participants. The period before undergoing CPM evoked strong emotional reactions: "The state of mind I was in, my mind state, the way I looked" (Karen). The prospect of mastectomy without immediate reconstruction was disconcerting: "I just don't want a hole there, to wake up and see a flat shape" (Hannah) and appeared to lead to feelings of estrangement and disconnection with their bodies: "It wasn't just lopsided, it's like you'd only catch a glimpse in the mirror, it just didn't look right" (Tina).

A single mastectomy threatened some participants' femininity and self-image, resulting in feelings of inadequacy and feeling "Different... I just felt different than other women. I mean like going swimming…little things like that" (Tina) serving to highlight the discrepancy between their pre and post-cancer bodies. Participants described not feeling as feminine and considered breasts were crucial in the definition of being and appearing like a woman: "Not from a beautiful point of view, just a shape point of view" (Hannah). Equally, Jane considered cancer and mastectomy was associated with being elderly. Therefore, embodying a more desirable body through reconstruction enabled the preservation of youth and femininity: "I'm quite, I would not say obsessed, but determined, the cancer and the treatment isn't going to turn me into a old woman before my time" (Jane) and "Because I want boobs, even if they are only small boobs. Yeah, womanliness, it's your shape" (Tina). Reconstruction could not only be reparative of one's identity, but also aesthetically enhancing and facilitative of new identities, affecting participants self-worth: "I like them better. That might sound ridiculous...Yes they're more me, it has enhanced it [body-image and

femininity]…I didn't like my breasts before, to me they were a source of anxiety, they were not integral to me at all" (Jillian).

The discomfort of a single mastectomy was seen as debilitating where participants "didn't want to have to wear clothes that hid the fact that my boobs looked different" (Jane). CPM therefore enabled participants to restore their pre-cancer body and identities by continuing to appear the same and continue leisure pursuits: "I'm back to being me, going out all the time, doing things" (Karen) and "I just feel back to how I was before you know…I am still who I am" (Tina).

In contrast, some participants considered reconstruction was not crucial to their sense of self or considered it integral in the adaptation to a post-cancer identity: "I didn't want anything false inside me…I'm healthy I don't need it'" (Karen). Similarly, Mary viewed the prospect of reconstruction as unnecessary and appeared threatened at the prospect of this: "I just want to be left with my body. Not have any accommodating bits and pieces… I don't want something else, my body is my body". Overall, a single mastectomy was seen as disfiguring and debilitating, with CPM (with or without reconstruction) enabling participants to retain their identity and femininity, and even enhance it.

Theme 4: Preserving Identities within Valued Relationships

Maintaining identities within valued relationships and continuing cherished relationships in the manner they had prior to cancer was important to participants. Participants were very aware of how they were construed and defined after the disfigurement of a single mastectomy by family members: "They'd talk about just having one boob and when you have your new boob put on, it made me more determined to get me the other one" (Tina).

Intimate relationships following mastectomy could be occasioned by feelings of shame and embarrassment: "towards my partner it was a bit like I didn't want to see him and

he didn't want to see me" (Tina). Therefore, CPM with reconstruction was aesthetically and psychologically important in regaining self-worth, and remaining intimate: "Sex life fine, not bothered him at all" (Hannah) and "he tells me looking at them, 'they're 'wonderful' quote" (Jillian).

Conserving family life was pivotal for participants and retaining normalcy. Jane described the importance of being able to fulfill her motherly role in appropriately educating her children:

> I am conscious now where the boys are getting to an age where, I don't want them to think my boobs are normal. I do want them to think they are normal, but I have no nipples so that's not normal. So I, after I had them tattooed I thought I wonder how they will react? The oldest went, 'mummy, what are those big dots on your boobs', and I said oh well they are nipples like you have, and they said oh that's fine then" (Jane).

Separating cancer from family life by creating "Pandora's box…I have a lid firmly on the box and it does not come off" (Jane) to contain emotions, waiting for the "kids to go to bed before I could fall down and break" (Hannah) and shielding them from being labeled by others as "the kids whose Mum's only got one boob now" (Tina) was a means to protect family from the gravity of cancer, the disfigurement of mastectomy, as well as continuing cherished relationships: "You know, one of the proudest things I feel, is how unaffected they [children] are over what we went through" (Jane).

Reducing risk was also seen to provide participants with the capacity to "dismiss thoughts of" (Jane) cancer and enhanced family life: "Strangely the cancer has made that better. I have more time now with my son and grandson" (Jillian). It also enabled participants to continue focus upon and prioritise the family: "Nothing is more important than

the youngsters…because you've got to concentrate on them and you can't afford for that not to happen. You have to realise you've just got to continue with life as good as you can" (Mary). Therefore, CPM was seen as a way to maintain valued identities and relationships by maintaining participants' physical form.

Theme 5: Embracing a Cancer-Free Identity

The experience of participants' bodies appearing cancer-free as a means to express health, avoid being construed as victims, and manage the perception of others was discussed by some participants. Central to their accounts was the pivotal role that CPM, with or without reconstruction (as being lopsided was more indicative of cancer than no breasts), moderated the reactions of others by disguising they had experienced cancer: "I don't feel when I'm dressed now; I don't feel like I'm the person who has had a double mastectomy and wearing prosthesis. I feel me. I feel really comfy in the clothes I wear" (Karen).

Participants reflected on others' reactions to mastectomy and were aware: "[that it] could upset someone… a lot of it was subjecting people to how I looked" (Karen). Mastectomy was experienced as negative, causing others to stare and felt they had to dress in a way that concealed their diminished cleavage to feel comfortable: "I felt I had to wear high tops… I didn't want people looking cause it, they'd look even more if they'd see you know, cause they'd be more intrigued" (Tina). Mastectomy was also considered stigmatising and defining of a sick condition: "people perceive it with pity, which when I was at work, they would be like…'Ohh so sorry', and I would be like what the hell for I am not ill" (Karen). Therefore, the external representation of their bodies as vehicles to express their health and appearing normal was important. This also negated being perceived as a victim and transmitted to others how they felt internally:

> I don't want people to look at me, and think she has had cancer and she...every time I have a cough and a cold, and people think ooh she might have her cancer back. I just

> don't...I refuse to be that person, I do, I'm not a victim, I won't be a victim to it and I won't have people pitying me or seeing me in any other way than just me and who I am (Jane)

Overall, CPM was a way to manage others' perceptions, retain normalcy, appear less evidently ill and not "have a big arrow pointing" (Jane) at them. This was to ensure they were seen as themselves first, as opposed to being defined by cancer and construed as victims. Appearing cancer-free through CPM was seen to facilitate a cancer-free identity and feel psychologically healthy: "Fine, normal. I think 'God did that really happen to me?' It's not an everyday thought" (Jane) and "If I had kept the other breast, it would have been more of a reminder, of the breast surgery [and cancer]" (Jillian).

CPM enabled participants to feel less self-aware in front of others: "If I was to bend down and pick something up it wouldn't shock anyone around. I'm not always having to do that you know, lift me top up" (Tina). CPM with reconstruction was seen as an achievement of a turbulent journey. This highlighted survivorship, as opposed to victimhood and enhanced confidence: "I'm happy to show people. I don't hide them away… they are a symbol of achievement, that I have achieved this hurdle, that I had cancer, it's gone and I'm still here. I am enjoying life" (Jillian). Regardless of whether participants underwent reconstruction, CPM was considered less disfiguring than a single mastectomy and minimised receiving the attention of others: "I buy the style of clothing where you can't tell. If anything I look a bit flat-chested, but so what?" (Karen). Overall, CPM enabled participants to avoid the possible shame, pity and stigma associated with cancer by projecting to others their cancer-free bodies in an attempt to not be defined by this.

Discussion

Previous research has indicated CPM is often undertaken for motives other than risk-reducing reasons (Beesley et al., 2013; Rendle et al., 2015; Soran, Polat, Johnson, & McGuire, 2014) and the current study has provided new and valuable insights into this phenomenon for women considered low-to-moderate risk of CBC. The study highlighted participants' decision-making factors were based upon their subjective evaluation of risk and perceived vulnerability, cosmetic, pragmatic, and psychological reasons, familial and age-related circumstances which influenced the way participants understood and responded to the concept of risk and their decision to undergo CPM. All participants experienced positive changes and converted their cancer experience into an empowered choice with practical, cosmetic, social, and psychological benefits. This is in line with other research which suggests people can experience positive outcomes after breast cancer (Brix et al., 2013; Rendle et al., 2015). However, despite CPM providing an important adjustment to life for participants, the research highlights various clinical and ethical complexities related to the procedure. Specifically, the limited scope for shared-decision making and how surgeons acquiesce to a woman's request for prophylactic surgery that is currently not confirmed as psychologically beneficial.

Despite participants acknowledging their low-to-moderate risk, their perceived vulnerability and worry over future self-examination, and uncertainty regarding the efficacy of medical tests outweighed this and the need to regain control took precedence. How participants responded to their cancer diagnosis and asserted their decision for CPM varied according to their age and familial context. Some participants viewed risk as disempowering and a loss of control, precipitating the need to take action. Lipowski (1970) conceptualised how people coped with illness, identifying 'illness as a challenge' as the category that was most likely to inspire active coping strategies. Participants within the current study construed

living with risk as a challenge to their identities and lives and adopting this meaning enabled them to respond accordingly and regain their sense of selves and pre-cancer lives.

Moreover, the shifting perspectives model of chronic illness (Loerzel & Aroian, 2013) describes how people make sense and place meaning upon their illness. Within the current study ageing and family experiences of cancer facilitated participants' perspectives and adaptation to cancer, considering illness as normal. The former is in line with previous research where older women viewed cancer as a "bump in the road of ageing" (Yoo et al., 2010). Similarly, Paterson (2001) described the 'wellness in the foreground' perspective, illustrating how people reconcile the effects of illness by shifting from "a victim of circumstances to creator of circumstances" (Barroso, 1995, p. 44). Within the current study, it is possible the decision for CPM could be construed within this framework, enabling participants to distance themselves from breast cancer (albeit their low-to-moderate risk) reframe a negative situation, and have an improved sense of selves.

Additionally, living with risk and a single mastectomy was seen as disfiguring and debilitating, affecting participants' identities and interactions with others and placing strain upon valued relationships. CPM, with or without reconstruction had both interpersonal and intrapersonal benefits; conferring the advantage of preserving, enhancing and even reviving participants' identities and valued relationships, by retaining a more acceptable appearance and giving them capacity to dismiss cancer. Moreover, CPM reinstated participants' sense of self-worth by reducing the discrepancy between their post-treatment and desired bodies; representing to others a less cancer-identifying body which facilitated normalcy. In relation to self-objectification theory (Fredrickson & Roberts, 1997) participants construed themselves as objects and viewed their bodies as a means to express how they felt internally and control how others perceived and appraised them. Similarly, in line with sociocultural theory of body-image (Thomson et al., 1999), participants' external representation was

crucial in how socially accepted they felt, considering the visible aspects of breast cancer attracted stigma and prejudices.

Furthermore, sociocultural constructions of femininity and ageing construe women's value in society based upon their physical attractiveness and youth (Ferguson, 2000; Halliwell & Dittmar, 2003). Some participants within the current study considered different-sized and numbered breasts deviated from the social norms of beauty and femininity. Accordingly, CPM with reconstruction was vital for achieving symmetry; restoring participants' femininity, sense of selves, and embodying normalcy. For some participants, their identities were closely entwined with the essence of womanhood, refusing to renegotiate their changed bodies, with breasts considered a definitive part of the self and restoring the physical, psychological and sexual (Crompvoets, 2006). This supports previous research which suggests the psychological and sexual implications for younger women undergoing CPM can be managed with concurrent breast reconstruction (Ashfaq et al., 2014). Conversely, CPM was seen to offer other participants a pragmatic solution, positioning their breasts as dispensable and redundant; considering breast reconstruction would present an obstacle to normalcy. This presents a contradiction between the social constructions of femininity and participants' own experience of recovery and normalcy (Crompvoets, 2006) and highlights the complexity of the varying meanings and experiences of women choosing to undergo CPM.

Clinical Implications

The current findings have important clinical implications that require consideration. It is evident CPM is undertaken for reasons other than reducing risk. Therefore, it is imperative healthcare providers include the role of cosmetic, pragmatic, interpersonal and intrapersonal factors, in the context of the differing meanings and perspectives women place upon their diagnosis and perceived risk into assessments. Most importantly, clinical guidelines are

required for CPM that are applicable to women within the low-to-moderate risk category (Cook, Rosser, Meah, James, & Salmon, 2003). The latter is imperative in minimising the varying and ambiguous responses from physicians to ensure equity of care in the availability of CPM.

Moreover, participant's visible appearance was important in how they were perceived and appraised by others in valued relationships and within their wider social context, as well as how they perceived themselves. Appearance interventions should be considered, including the strategic use of clothing to disguise mastectomy. Reconstruction should also remain a surgical decision, acknowledging that it may not be helpful to all women. Interventions should also include and support partners and family members who are also challenged by a single mastectomy and facilitate a relational dialogue between all parties in the period between the initial mastectomy and CPM (Manne, Siegel, Kashy, & Heckman, 2014). Additionally, psychological interventions focusing on managing the responses of others, issues pertaining to control, altered identities and relationship with one's breasts in light of risk and BC should be considered. Strength-based interventions that promote well-being and cognitive reframing interventions that aim to alter a woman's appraisal of living with low-to-moderate risk of CBC and alter her self-views by focusing on less aesthetic aspects of her body should also be offered.

Limitations and Future Research

As there is currently no unique CPM procedure code within the UK medical databases, this may have inadvertently excluded potential participants. Moreover, the study size and the sociodemographic of participants also pose several limitations. As all the participants within the current study were British, participants' decision to undergo CPM due to their perceived risk may reflect a choice based on culture and the expectation that people must act in the face of impending adversity (Bennet, Laidlow, Dwivedi, Naito, & Gruzelier, 2006). However, as

with other qualitative studies the research design did not set out to provide generalisable data, but rather present both the frequent and nuanced meaning and experiences of the sample. Future research may want to focus upon a larger set of participants from socioeconomically diverse backgrounds. Future research may also want to explore physician's experiences of the decision-making process with women considered low-to-moderate risk of CBC, as well as exploring the psychological outcomes of CPM.

Conclusions

The decision for CPM in women considered low-to-moderate risk of CBC is influenced by various psychosocial factors and the current study highlights the complexity in the meaning and experiences of women undergoing the procedure. National guidelines are required however for women considered low-to-moderate risk of CBC which would ensure equity in the availability of CPM, and physician-patient communication is paramount in ensuring reasoned decision-making.

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Appendix 2-A
Table 1: *Patient Demographic Details*

Participant	Description
1) Mary	74 year old woman, white British. Widowed and retired and lived with daughter and her family. Worked as a nurse previously. Had a diagnosis of ovarian cancer and treated at the age of 44. Diagnosed with breast cancer and underwent CPM 2 years prior to interview. Did not undergo reconstruction. Does have some family history of cancer on the paternal side, but not specifically breast cancer.
2) Jillian	56 old woman, white British. Married with one child and has a grandson. Employed within legal profession and lecturer before taking early retirement. Diagnosed and underwent CPM 4 years prior to interview and underwent reconstruction. No family history of cancer. Has had a history of having lumps (benign) in her breasts and considered her natural breasts to be very 'fibrous'.
3) Karen	53 old woman, white British. Married with no children. Was employed within the police force as a detective before taking early retirement. Diagnosed and underwent CPM 2 years prior to interview and did not undergo reconstruction. Does have second degree relatives with cancer, but not specifically breast cancer.
4) Tina	45 old woman, white British. Married with 5 children (three dependent). Worked within a local grocery store. Diagnosed and underwent CPM 2 years prior to interview. Has a diagnosis of neurofibromatosis which is considered to place women with the condition within the low-to-moderate risk of breast cancer. Mother had a diagnosis of cervical cancer however has been in remission for 30 years.
5) Jane	42 year old woman, white British. Married with two young children. Employed and worked as a director of a large international company, but stated family was very important to her. Diagnosed and underwent CPM 4 years prior to interview and underwent reconstruction. No family history of cancer, but has friends who have had a diagnosis of cancer. Has had a history of having lumps in her breasts which were all benign. However, a newly formed lump 4 years ago was confirmed as cancerous after a biopsy.
6) Hannah	50 year old woman, white British. University lecturer in evidence-based practice. Worked as nurse previous to this. Adopted as a child and no contact with birth family. Raised concern over her genetic history and caused anxiety as declined by professionals for gene testing. Had numerous health conditions. Had a diagnosis of breast cancer 5 years prior to interview and underwent lumpectomy. Recurrence of breast cancer 2 years prior to interview with reconstruction. Also underwent prophylactic hysterectomy.

Appendix 2-B: Examples of process of theme clusters developed for individual participants

Participant 1 Mary annotations, emerging themes and summary narratives

1. 'So it didn't come as, oh why did it happen to me? It was oh why not?': Accepting the aged body		**Supporting Quotes**
• Nursing profession • Diagnosis of ovarian cancer 30 years ago • States she recovered well and things have been 'normal' in the period in between ovarian cancer diagnosis and breast cancer • Worked in palliative care previously • Had an awareness of cancer and what could happen to any old person • Doesn't seem surprised or shocked about breast cancer • Doesn't believe what has happened to her is any different to most old people who become unwell • Considers herself lucky that she had a good life after ovarian cancer • Didn't have chemotherapy or radiotherapy • Considers she has already lived a long life so happy to take medication for cancer • Doesn't feel like she has much life remaining as in her seventies. • Seems un-phased by cancer • Appreciates her life so far and would prefer cancer to neurological disease • worrying about cancer would take away from focusing on family	This theme refers Mary's acceptance of her cancer diagnosis and her very unphased attitude towards it. She had worked previously in palliative care and considered that cancer was quite common and so didn't feel as though she was exclusive in her experience from most other older people. She appeared very accepting of cancer as a usual and general experience for older people. She acknowledges the life she had in between ovarian cancer and breast cancer, and it appears that she is more focused on the life she has had as opposed to the life she may not have going forward with cancer. Overall, it feels as though Mary accepts she is towards the end of her life, despite cancer, has led a fulfilled life and therefore she doesn't feel it necessary to be worried or anxious or fight cancer in the same way. She appears very matter of fact and almost acquiescent to cancer.	'I've just been the normal...It's just been as normal, you know, it's not a physical...' Well, it's given me an awareness of cancer, right across the board really, and of the elderly. And so it didn't seem...when I was diagnosed, it didn't seem, any different, it could happen to anyone, and I know people who it has happened to. And so it didn't come as, oh why did it happen to me? It was just oh why not?' 'I wasn't surprised. Erm, erm, it all happened, it sequentially all happened very quickly. I soon had the surgery for the effected breast' 'So it was quite straight forward really' 'So we just go through the motions again' 'This next one, well for goodness sake I'm in my seventies you know. It's erm...I've been lucky to have been given all those years in the interim period. My daughter was worried obviously' 'I'm more frightened of a neurological disease. Not bothered about cancer really That's a bit stark to say that, I don't want it. I don't want to think about it. Because the chances are I'll be dead before I get it'

2. ‘I didn’t care less about me’: Prioritising the family		**Supporting quotes**
• worrying about cancer would take away from focusing on family • worried about grandson’s accident • didn’t care about her cancer diagnosis • put things into perspective for her • concern over grandson and his life forward • accepting and appreciate of her life so far	Mary considers family as very important. It is felt it is this strong sense of family that enables her to focus less on the gravity of cancer and look outwardly at the positive and more important things around her. Mary referred to the time when her Grandson sustained an injury whilst playing sport and the perspective this gave her on her life so far enabling her to dismiss her cancer and focus on what she considers as more important.	‘Because you’ve got to concentrate on them and you can’t afford for that not to happen. You have to realise you’ve just got to continue with life as good as you can’ ‘And incidents happen that bring home to you, the time I was diagnosed with the cancer, my eldest grandson that came in, had to be rushed into hospital, he has two breaks in the base of his spine’ ‘This was when I was diagnosed. I didn’t care less about me. I was horrified for him. Even now I feel emotional about it’ ‘Nothing is more important than the youngsters. And also I’m lucky in as much I’ve had my life, and you know you make mistakes and live with it. You want the best you can for them’
3. ‘ I just want to be rid really’: Removing what’s not needed and to make life easier		**Supporting quotes**
• Getting rid of what she doesn’t need • Raised children so breasts have no function • Has had previous surgery related to ovarian cancer – seems tired of the ill body. • Has had other body parts removed so seems acceptable to have CPM • Didn’t want any further trouble –	This theme refers to Mary considering her breasts as unimportant; acknowledging they no longer having the function they once served (breast-feeding) as well viewing them as bothersome. A sense of Mary feeling she has had enough of her ailing body is felt due to previous ill health and cancer experience and appears that she	‘So I just wanted to be rid really’ ‘Breasts were no use to me anymore now I’ve got my children’ ‘Well I decided I wasn’t going to be lop-sided... symmetry as in let’s get rid of what we don’t want’

difficulties • Felt CPM was the best and most practical approach • Wanted to make life easier	viewed her body as quite troublesome. CPM was an opportunity to rid herself of something that could pose as bothersome and to put an end to a difficult and troublesome body. She also didn't seem to consider breasts played a vital role in her life anymore and wanted the ease and practicality of CPM. Mary also alluded to how her breasts were quite large previously and how this hindered her. CPM provided her with ease and practicality and it is felt that CPM had freed her from previously troublesome breasts.	'If I'm having a mastectomy, I'm going to lose a breast so I might as well lose the other one' 'I've had various bits of surgery, and I've had various bits and pieces taken off me' 'But I, I just want to have at least trouble as possible, Just to be practical' 'Just practicalities really. Just to make life easier' 'Erm, it was just the practicalities of it, to forget about it' 'Just, everything about me tends to be practical really. It's just less bother. There was a time when I thought err my breasts were fairly large, they went huge but I had big breasts. And you know the cloths and everything else, erm.. it's simple now, I just wear a t-shirt. Swimming shorts and you're away!'
4. 'My body is my body': The evolving relationship with the body		**Supporting quotes**
• Body-image not important • Considers her female shape not important as she is older • Considers how a woman's view of her body can change as one gets older • Didn't think the body-image questions prior to CPM were relevant to her as she is older	This theme refers to Mary acknowledging her evolving perception and relationship with her breasts now that is older. She appeared to consider her breasts as unimportant and didn't feel maintaining the 'female shape' was necessary as she is in her 70's. CPM therefore was an appropriate option as maintaining the ideal feminine shape was not something she connected with.	'By the time your older you realise, most people are mature enough to realise, you know how it was then isn't affecting you now' 'It didn't differentiate between a young person and an old person, You'd had to have had a real problem the way the body image questions seemed to keep coming' 'And I thought the idea of prosthesis, putting

	It appeared Mary's view of her body had evolved as a function of her age and didn't acknowledge her breasts as pivotal to her identity. The thought of accommodating for prosthesis/reconstructed breasts was seen to be taking away from her sense of self and the sense of her own body.	something in, when all my life I've been getting rid of things. I don't want something else, my body is my body' 'And I don't, I just want to be left with my body. Not, not have any accommodating bits and pieces. I can imagine in a young woman you want to be shapely, and that's fine'

Participant 5 Jane annotations, emerging themes and narratives

1. 'I wasn't worried in the slightest' – experiencing symptoms		**Supporting Quotes**
• Has had a difficult journey with breasts pre-diagnosis throughout life due to lumpy/dense breasts. All benign • Considers herself breast aware and conscious. Also has friends diagnosed with breast cancer • Has always had to monitor/survey her breasts • Being proactive about health/breast cancer • Reflects on current lump and dismisses it as believes it would be benign based on previous experience. • Didn't want to appear a hypochondriac/aware of wasting clinical time • Feeling assured and safe it would be ok • Initial tests came back negative • Biopsy however confirmed cancer. Shocked to find out it was cancer	This theme reflects Jane's journey of surveillance and self-examination, being proactive and breast aware and the reassurance she felt from previously clear tests. Accordingly she talked about not being worried about a newly formed lump. She talked about her difficult relationship with her breasts pre-diagnosis, as she always had 'lumpy' dense breasts which she had to monitor. This naturally made her more breast aware and proactive in relation to her health. Fortunately, these had always been benign, which made her somewhat complacent about a newly formed lump and delayed making an appointment to have it assessed. She thought about how she may be perceived by the medical team as her previous tests had come back clear and didn't want to be seen as a nuisance.	'So all the way through my adult life I have always felt various lumps in my boobs, and I have always been very breast aware shall we say. I have two friends... so I guess cancer is something I am very aware of' 'Erm, whenever I have found a lump I always had it checked and had CT scans and what have you to make sure my breasts were clear, so, coming up to three years ago, I noticed a lump on my breast, that felt, didn't feel worrying, I wasn't worried in the slightest, I just kinda thought another one' 'Cause you worry about becoming a nuisance. Or seen as paranoid or hypochondriac. So I always easily forgot about it'
2. 'I do not want to leave any stone unturned' – Taking control of one's body and managing the uncertainty of cancer		**Supporting quotes**
• Biopsy however confirmed cancer. Shocked to find out it was cancer	This theme reflects the importance of Jane managing the possible risk of a secondary cancer and taking control of her body and her	'Do whatever you have got to do. And I will do everything I have to do and throw the book at me because I don't care, I am strong, and I will

• Thinks about children in relation to the prospect of dying • Spurs her into action. Has to do everything/anything for the sake of children. • Doesn't want to be left with regret in relation to not doing enough • Determined cancer would not kill her • Taking control back in the face of cancer • CPM was not up for debate – could not trust any tests • Would never feel content or reassured that she was ever going to be cancer free • Didn't want to embark on a continued journey which continued to be fraught with self-examination • Determined not to be a victim • Asserts her decision – no need to discuss CPM with others • Had to do everything in her power to stick around for children. • Satisfied she took control of her body and choices • Had no reason believe she would get cancer – acknowledges her risk was low • Erring on the side of caution • Invested in every aspect of her body and medical decisions • Reflects on friends who didn't take control and the implications of this for them	choices in relation to her body. The decision – making process was rooted in this and the need to ensure her survival for her children's sake. Initial tests didn't confirm cancer, but surgeon offered a biopsy and unfortunately, this confirmed the lump as cancerous. A sense of regret is felt that Jane didn't respond sooner to the lump and letting cancer take control of her. This spurred her into action, the regret of not doing something sooner or enough. The decision to undergo CPM was not up for debate or question as Jane didn't feel assured in tests or her own ability to recognise a cancerous lump. There is no sense of her consulting with any family members or leaving scope for the surgeon to discuss further. The way in which she asserted her reasons for CPM, the surgeon agreed with. It felt that taking control of her body and ensuring cancer doesn't beat her was important and no-one had the right to question her on that. She acknowledged her low-risk but felt the uncertainty and lack of assurance she had in tests and herself was too much to bear. A sense of empowerment is felt that she is taking control of cancer and having a sense of agency over her body. She didn't want a continued journey of frantic	get through whatever you throw at me, if there was a question over whether I should have a certain type of treatment, throw it at me anyway. You know, throw the book at me, because I do not want to leave any stone unturned. I do not want to have any thoughts of i wish i had done that. I have to do everything in power to beat this' 'But I probably had done that four times, so goodness knows why I didn't think it would be fine again' 'I know Gary is a grown-up he would deal with it and he would move on from it and he would find someone else and be fine, it's not the same as being three and five and losing your mum and the worse thing about it is and I said this to my mum I didn't say it to Gary but my boys calling someone else mum' 'taking control back' 'it was a no brainer. Nothing had been picked up on the one that was cancerous, so how was I ever going to have a check-up that left me feeling reassured and happy that everything was fine? I didn't want to become obsessive about checking it, I didn't...' 'I mean, it was a decision made right at the start. I never waned on it and I never discussed

• Thinking about impact of her death on her family members • Taking control of her life; the thought of her boys losing their mum haunted her	checking and self-examination. It felt CPM provided an opportunity to develop a more positive relationship with breasts as her life prior to CPM seemed to be quite overshadowed by self-examination and she wanted to be free of this. CPM provided a way to minimise her risk of cancer and move forward from a life that was hindered by self-examination and worry, but also not having a reminder of a turbulent relationship with natural breasts. It is felt Jane didn't want to ever have any room for doubt, or feelings of regret of not doing enough to save her life. Not doing enough was seen to be quite personally attacking on her sense of self and her ability to make well-informed decisions.	it with anyone because in my view I didn't need to discuss it with anyone' 'And whilst I feel that erm yes I absolutely had a vested interest in being part of a decision making process for every medical decision I was to do with' 'It's about control and you pointed out for me it's about not being defined, going forward with something that is in my past' 'So, for me, erring on the side caution. At no point did I want to have room to think oh why didn't, I wish, I Just...' 'I was very up front with this, the main driver was I was never going to trust tests that came back clear'
3. 'Not to have this label, or this big arrow pointing at me': Look and feel normal to self and others		**Supporting quotes**
• Not wanting to be defined by cancer • Buying wig to conceal cancer • Thinks about impact on son after seeing her lose her hair • Reconciles pain of cold cap with the	This theme refers to Jane's attempts to appear normal to others to avoid actual and potential stigma of being perceived as a victim, a cancer patient, and to avoid the pity of others, which would contribute towards Jane feeling	'Not being perceived as a victim. The thing I hated when I did go back to work was being 'Jane, the one who had cancer'. Do you know what I mean? I have since moved companies, I mean, I told my boss, but nobody knows I had

‘normal’ period of looking cancer free. • Wanting symmetry, cosmetic reasons did not want to look different and ‘weird’ in clothes. • Determined not to be a victim • Determined to maintain her ideal womanly shape • Doesn’t want to conceal her asymmetrical breasts. • Didn’t want to endure the disfigurement of having no breasts after surgery. • Body-conscious in terms of weight management • Difficult to manage others’ reactions to • cancer • People’s reactions to cancer discouraged her • Convincing others she wouldn’t die • Forced her to convince others she wasn’t going to die • Trying to appear normal and positive in front of others • Reconciles pain of cold cap with the ‘normal’ period of looking cancer free • Wanting symmetry, cosmetic reasons did not want to look different and ‘weird’ in clothes to others.	abnormal and different. Jane also talked about how she made concerted effort to not tell many people about her cancer as she felt discouraged by their responses and didn’t want the cancer to define her. This appeared to be a way to protect her own emotions, maintain her sense of normality to herself and others, as well as a way to continue her efforts to remain strong, motivated and beat cancer. It appears Jane is very concerned about how others perceive her and it was crucial she maintained presenting herself in the normal way, her former self, and not allow cancer to define her.	cancer where I am now. And I love that’ ‘I don’t know, I mean yes, I think so, obviously I look after myself, I have a good figure and i didn’t want…one of the things that I had been very determined was that I was determined it would not make a victim’ ‘The look in people’s eyes, and the way that they react, it almost like, oh my god you’re going to die. And so I felt the thing i needed to do was when I told people was to convince them i wasn’t going to die. And i found it exhausting, I almost had this show that i would put on, ‘but it’s all going to be fine so, it’s all going to be fine’. It’s almost like I wouldn’t let them leave my company thinking oh my god she’s got cancer and she is going to die’ ‘I don’t want people to look at me, and think she has had cancer and she...every time i have a cough and a cold, and people think ooh she might have her cancer back. I just don’t...I refuse to be that person, I do, I’m not a victim, I won’t be a victim to it and I won’t have people pitying me or seeing me in any other way than just me and who I am’ ‘He said mummy take those scarves off I don’t like them. And they freaked him out a bit. So I thought, I am going to do the cold cap, and I heard the cold cap was really painful. But I

		thought if I do that and I keep my hair so when I have the chemo I'll be the cancer patient, but then it will enable me in the three weeks in between chemo, to be normal. And not to have this label of, or have this big arrow pointing at me saying 'having chemotherapy' 'I said to my surgeon was, I was 38, from a cosmetic reason, I want to look symmetrical, I want to be able to wear a bikini and not for it to look weird, and having seen the fabulous job he had done of my left breast, I just want them to look the same' 'It made the remaining three weeks in between so much more bearable cause I didn't look like I was having it'
4. 'A lid on Pandora's box': Preserving valued identities and relationships with family		**Supporting quotes**
• Separating life between treatment and mother/family role and life. • Thinks about impact on son after seeing her lose her hair • Thinks about affect of mastectomy and how it appears to husband – but not as concerned about impact on him • Thinks about how she appears in front of sons • Retaining a stable family • Not disrupting family life • Sharing 'dark thoughts' with best friend	Retaining and preserving Jane's sense of self in valued relationships, mainly family, appeared very important. She made concerted effort to maintain her family life, to ensure cancer journey didn't affect every aspect of her life, to separate it from the things she valued the most – family. To retain a sense of her pre-cancer self/identity was important as she had young children and it appeared Jane did not want her son's perception to change of her. Maintaining her motherly role in the best way possible to ensure her	'I would erm be sick for a few days but knowing the boys didn't like it when mummy had her strong medicine and I couldn't read them their bedtime stories and I couldn't do my normal stuff with them, meant that the very minute that I started to turn a corner and feel ok I would force myself to get back in to the normal routine so that they were affected by it for a short period of time as possible' 'Eating chocolates and being a poorly person because err...I couldn't do that I mean I could have done that but I couldn't do that and I

only • Doesn't want her dark thoughts to affect family members • Doesn't want to worry family • Appearing like a normal, the same, mum to her sons	family were as least affected as possible. She talked about how she didn't want to frighten her children after showers if they saw her naked. She wanted to protect them and believed the reconstructed breasts allowed her children to perceive her as normal. To further ensure least disruption to her family, protecting the family from difficult and emotive aspects of journey was also important. She only difficult things with a best friend, otherwise she continued her life in the most usual way as she had always done so as not to worry others but also ensure relationships and dynamics didn't change. She refers to this as keeping a lid on Pandora's box, and it is felt that doing this allowed her to protect her identity and her family.	believe that any mother with young children would be exactly the same and they do say that women with younger children get through it better for that very reason' 'Were not a prudish family, but I said to Gary that I am conscious now where the boys are getting to an age where, i don't want them to think my boobs are normal. I do want them to think they are normal, but i have no nipples so that's not normal. So I, after I had them tattooed I didn't make a big deal of it. I though i wonder how they will react. The oldest went, 'mummy, what are those big dots on your boobs', and i said oh well they are nipples like you have, And they said oh that's fine then. You know, one of the proudest things I feel, is how unaffected they are over what we went through' 'I had a rule with my best friend, she was the one who got to hear my dark thoughts, that I didn't want to share with mum, dad or Gary as i didn't want them to worry about me anymore than they were, so my friend and I had a deal that if I had really dark thoughts, I would share them with her. But equally we would talk about cancer, if I brought it up, but if I didn't, it was business as usual and not a topic for conversation' 'I have a lid on Pandora's box'

5. 'It isn't going to turn me into an old woman before my time': Preserving her youth and not being changed as a person		**Supporting quotes**
• Thinks about how she became cared for by parents- left work. Construed as retired person • Breast cancer and CPM didn't compromise femininity as had reconstruction • Appearance important • Determined not to look older before her age • Determined to maintain her ideal womanly shape • Important to not feel disfigured • Aesthetic reasons important but not as much as managing risk • Body-conscious in terms of weight management	Jane reflected on how the cancer made her feel old in terms of how her body changed after the medication and chemo treatment and CPM with reconstruction was a way to retain her youth and femininity. The thought of waking up to one breast and the disfigurement and the asymmetry was difficult to imagine. A sense of having gone through cancer, and having one breast was felt to be associated with an older person, and CPM provided an opportunity to detach and move on from the cancer, as reconstruction concealed the loss of breasts and was a way to detach from the loss and the gravity of what happened. Possibly convincing self it didn't happen by restoring the body to its former physical state Jane also talked about how important it is for her to not feel the cancer journey is a part of her and who she is and to not bring that forward or carry that with her post-cancer. It appeared to be functional for Jane to detach and not talk about cancer as a means to not allow cancer to change her both physically or her identity.	'I feel like I was in the little protective bubble and I joke and say I joined my mum and dad's retirement club. Because, I literally, I almost went back, reverted back to being their child' 'I'm quite, I would not say obsessed, but determined, the cancer and the treatment isn't going to turn me into a old woman before my time. so I didn't want to have to wear clothes that hid the fact that my boobs looked different' 'Cause I thought with immediate reconstruction, I knew I would end up looking fine. I never at any point thought 'oh my god' I'm not going to be a woman anymore, it's going to make me feel different, I did joke and say you're going to me look like Frankenstein's bride' 'Fine, normal. I think God did that really happen to me. it's not an everyday thought. Talking to you know has brought up things, I don't talk about it, I don't think about it, I have a lid of Pandora's box. I thought when i got your letter oh god do I want to take the lid of Pandora's box, because I haven't, in the early days I did, but I have not cried and mourned, and felt sorry for myself, like I say, I have got on with it'

Appendix 2-C: The development of super-ordinate themes from the data

Contributing themes	Theme 1: Responding to cancer – from taking control to acceptance	Example Quotes
'So it didn't come as, oh why did it happen to me? It was oh why not': Accepting aged body (Mary) **'And then I started to think about things, I started to get quite anxious': Becoming worried about risk** **'This is what I wanted for a long time now' (Jillian)** **'Yeah, you know get on with it': Not worried about cancer diagnosis (Karen)** **'I was worried it might come to the other side': Worried about risk (Tina)** **'I do not want to leave any stone unturned': Taking control of one's body and managing uncertainty (Jane)** **'You have to find yourself another consultant': feeling rejected but taking control (Hannah)** **'I don't know anything about me': managing uncertainty (Hannah)**	This theme refers to varying ways the participants responded to cancer which appears to relate to participants age and family circumstances. For some participants, being young, mothers, or both, taking control by reducing their risk of secondary cancer and having a sense of agency over their body seemed to be integral in their decision-making process. It is felt this is fuelled by a sense of not having done more in the past and feeling regretful about this in the face of cancer, as well as managing the uncertainness that cancer can pose. The former in particular seemed to be construed as an attack of one sense of self if participants didn't regain control. Participant's lack of trust in medical tests and opinions further heightened participants' need to take control and manage their risk. On the other hand, other participants' experience of responding to cancer differed where Mary considered cancer was acceptable part of elderly life and appeared acquiescent to cancer. Similarly, Karen who had no children also appeared accepting of cancer, however, was buffered by her belief she could survive cancer as her family members had.	'I don't know what's going on with my body. Physiologically something is not right. I have got a very..I don't like risk. I am risk averse. I'm rather, I would be proactive than to see let's see what happens' (Hannah) 'I want everything. I'm going to have the kitchen sink' (Hannah) 'Do whatever you have got to do. And I will do everything I have to do and throw the book at me because I don't care, I am strong, and I will get through whatever you throw at me' (Jane) 'yeah, so seeing how the others progressed was, well until anyone told me any different, I had nothing that I had to genuinely worry about' (Karen) 'When I was diagnosed, it didn't seem, any different, it could happen to anyone, and I know people who it has happened to. And so it didn't come as, oh why did it happen to me? It was just oh why not?' (Mary)

Contributing themes	Theme 2: The Breasts as Emotionally and Physically Constraining	Example Quotes
'I just want to be rid really': Removing what's not needed and to make life easier (Mary) **'I wasn't worried in the slightest' – experiencing symptoms (Jane)** **'But it was a means to stop the back pain and you know...so it was to try and get myself un-lopsided': CPM as a means to an end (Karen)** **'So that's 22 years of having a lot of stress really': The journey before** **'I never perceived my breasts as anything other than being trouble': Wanting to be rid of troublesome breasts (Jillian)** **'I just don't want a hole there. To wake up and see a flat shape': Reconstruction to maintain the female shape** **'Be careful what you wish for': Tempting fate' (Hannah)**	This theme referred to participants' acknowledging difficulties and the negative relationship with their natural breasts. For some participants this related to the difficulties associated with self-examination and worry of cancer, and for others this related to the sense of disconnection they felt towards their breasts as they either felt didn't serve a purpose and considered them troublesome, or that, they associated them with pain and felt indifferent towards them. CPM providing a means to overcome this. Participant's reflected on the ailing body and the turbulent journey preceding cancer and how this overshadowed their life. Some participants perceived their breasts as burdensome and felt disconnected with their breasts and not an integrated part of their bodies. CPM was a means to overcome these difficulties and alleviate them of a burden. It was felt this negative relationship with their natural breasts enabled women to make the decision for CPM.	Well I decided I wasn't going to be lob-sided... symmetry as in let's get rid of what we don't want' (Mary) 'I couldn't wear a bra. So I was suffering back pain and pain in my remaining breast because of nothing being supported' (Karen) 'They have never really been a part of me that I was particularly attached to. I did breast feed both my children and had terrible problems with the second one, they said I might have had cancer for 5 years. I wonder if with the second child...he wasn't latching on properly. I got very sore to the point where I had wounds to the nipples. And erm, I never felt the same about them afterwards' 'They were just bits of my body' (Hannah) 'I hated them. Because of everything they put me through in the past. They were a source of anxiety, I didn't like them, didn't define me, and I were happy that they had gone' (Jillian)

Contributing themes	Theme 3: Retaining one's Femininity and Sense of Self	Example Quotes
'My body is my body': The evolving relationship with the body (Mary) **'I could see where I was going from there, I can get back to normal': Seeing a way forward from the difficulties of single mastectomy (Karen)** **'You'd catch a glimpse in the mirror, it just didn't look right': Not looking like a woman (Tina)** **'It isn't going to turn me into an old woman before my time': Preserving her youth and not being changed as a person (Jane)** **'Perfectly happy. It was the right decision definitely': Feeling content with the decision and reconstructed breasts (Jillian)** **'I just don't want a hole there. To wake up and see a flat shape': Reconstruction to maintain the female shape (Hannah)**	This theme referred to the importance of participant's retaining their sense of self. For some participants, CPM with reconstruction was crucial in order to retain their feminine identity as the loss and disconnection they felt towards their body in the interim period was associated with feeling genderless and unfeminine. It was considered breasts were an integral part of what it means to look and feel like a woman, as well as retaining and regaining their feminine identity and youth. The disfigurement of a mastectomy was seen to be associated with being elderly. For others, reconstruction was interpreted as taking away from their sense of self, construing it as foreign, and didn't consider breasts were pivotal in retaining their femininity. The prospect of having to accommodate for something false appeared to threaten their identity. Therefore retaining an acceptable body-shape (CPM without reconstruction) was important as managing the imbalance of a single mastectomy was seen to impede their lives and concept of themselves in an imagined future.	'And I don't, I just want to be left with my body. Not, not have any accommodating bits and pieces. I can imagine in a young woman you want to be shapely, and that's fine' (Mary) 'The state I was in, my mind state, the way I looked, I couldn't see where I was going. I couldn't envisage wearing these thick big woolly fleeces in a British summer' (Karen) 'Yeah womanliness. It's your shape' (Tina) 'It has enhanced it (body-image and femininity). This is an individual thing' I am happy with these now that my natural ones, yes they're more me' (Jillian) 'yes that was important. Not from a beautiful point of view, just a shape point of view. It mattered to me that i wasn't..i remember saying to the nurse, i just don't want a hole there. To wake up and see a flat shape'. 'Clothes. Femininity doesn't worry me. the shape of clothes and how you look in clothes' (Hannah)

Contributing themes	Theme 4: Preserving Identities within Valued Relationships	Example Quotes
'A lid on Pandora's box': Preserving valued identities and relationships with family (Jane) **'They're not the kids whose mum's only got one boob now': Wanting to preserve identity within valued relationships (Tina)** **'I didn't care less about me': Prioritising the family (Mary)** **'It makes you realise what is important, I spend a lot of time with family': Putting things into perspective (Jillian)**	This theme referred to the importance of maintaining and preserving valued relationships and retaining normality within the family. Specifically, not allowing cancer to overshadow interactions with family, protect family members from the gravity of cancer, or alter others' perception of them. For some participants, they were very aware of how they were perceived and defined by family after cancer and undergoing CPM with reconstruction was a means to retain normality through maintaining their physical form, as a means to preserve their identities within these relationships, both with children and intimate partners. This appeared to be motivated by the need to protect family members from cancer and its impact, and the disfigurement of a single mastectomy and what this could be construed as in relation to others' perception of them. For others, not having to worry about cancer risk enabled them to continue focus and prioritise the family. This appeared helpful in order to maintain and allow relationships to continue as normal. Overall, CPM provided an opportunity to separate themselves from cancer and its associated difficulties and continue cherished relationships.	'No they'd talk about just having one boob and when you have your new boob put on, it made me more determined to get me other one' 'towards my partner it was bit like I didn't want to see him and he didn't want to see me' (Tina) 'I am conscious now where the boys are getting to an age where, I don't want them to think my boobs are normal. I do want them to think they are normal, but I have no nipples so that's not normal. So I, after I had them tattooed I didn't make a big deal of it. I though i wonder how they will react. The oldest went, 'mummy, what are those big dots on your boobs', and I said oh well they are nipples like you have, And they said oh that's fine then. You know, one of the proudest things i feel, is how unaffected they are over what we went through' (Jane) 'This was when I was diagnosed. I didn't care less about me. I was horrified for him. Even now I feel emotional about it.' (Mary) 'But with my family, strangely the cancer has made that better. I have more time now with my son and grandson, it makes you realise what is important' (Jillian)

Contributing themes	Theme 5: The body as a vehicle of health and embracing a cancer-free identity	Example Quotes
Perfectly happy. It was the right decision definitely': Feeling content with the decision and reconstructed breasts. (Jillian) **'I don't feel like I'm the person who has had a double mastectomy': To feel normal and avoid pity** **'But it was a means to stop the back pain and you know...so it was to try and get myself un-lopsided': CPM as a means to an end (Karen)** **'I didn't want people looking cause they'd be more intrigued': not wanting to draw attention to self (Tina)** **'Not to have this label, or this big arrow pointing at me': Look and feel normal to self and others (Jane)**	This theme refers to participants' effort to avoid shame and pity so as not to be perceived as the victim, being labeled the cancer patient and the stigma associated with this. Participants were very aware of how they were perceived by others and the negative impact of this upon them. Cancer and mastectomy was seen to highlight difference and weakness. Some participants were aware of offending or causing intrigue within others. CPM therefore enabled women to feel normal in front of others and avoid pity, shame and embarrassment.	'People perceive it with pity, which when I was at work, they would be like…'ohh so sorry', and I would be like what the hell for I am not ill' 'I didn't want it. I didn't want anything false inside me. It's just, I know it's not totally false but I just thought, I'm healthy I don't need it'. (Karen) 'I was just quite, I was concerned all the time and you know you can't wear anything that you know lower then if I lent over, normally, you lean over and sometimes you'd see a ladies cleavage.. but I was aware, if I was to lean over' (Tina) 'I don't want people to look at me, and think she has had cancer and she ...every time i have a cough and a cold, and people think ooh she might have her cancer back. I just don't..i refuse to be that person, i do, I'm not a victim, I won't be a victim to it and I won't have people pitying me or seeing me in any other way than just me and who I am.' (Jane) 'But a friend or a relative asked me, I have a friend, and I'm happy to show people. I don't hide them away' (Jillian) 'From a distant, they do look like natural breasts' (Jillian)

Appendix 2-D: Excerpt from reflective diary

Reflections after interview with Mary

Very matter-of-fact throughout interview regarding her experience of breast cancer and decision to undergo CPM. Very resilient. Doesn't seem 'bothered' by cancer – Accepted she is old and illness can happen. States she thought the interview would be boring for me as she considers she doesn't have anything 'interesting enough' to offer or anything complicated. Dismissive of self possibly and related to age?

Reflections after interview with Jane

Very emotive and powerful interview. Being a young Mum seems pivotal for Jane and her decision. I also feel emotional – identifying with her as a young mum too possibly? Dominated interview, very assertive and clear about why she chose CPM and experiences: Understand how she also may have asserted herself to surgeon for decision to undergo CPM.

General Reflections

- Disparity in how participants view their breasts – either very much part of their identity or redundant and not needed – different life stages?
- Hannah adopted and has no family history and therefore has been refused a gene test – feels very disappointed about this. Astonishing how someone can be refused a gene test on the basis of no family history, however, can still opt for CPM (an invasive surgery).
- During maternity: Difficulties with breast-feeding. Cannot provide for baby: feeling upset and frustrated towards breasts. Understanding and reflecting on how women's perception of breast can alter.

Section Three: Critical Appraisal

Methodological Considerations and Reflections on the Research Paper

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Introduction

The research paper involved a qualitative exploration of the experiences and decision-making-process of women undergoing contralateral prophylactic mastectomy (CPM) who are considered low-to-moderate risk of contralateral breast cancer (CBC). Semi-structured interviews were utilised with six participants and their accounts were analysed using Interpretative Phenomenological Analysis (IPA; Smith, Flower, & Larkin, 2009). The findings indicated participants' decision to undergo CPM was based upon their subjective evaluation of risk and perceived vulnerability, cosmetic, pragmatic, and psychological reasons, interwoven within various individual experiences, familial and age-related circumstances. The findings provided novel information into the increasingly requested procedure by women considered low-to-moderate risk of CBC and highlighted key clinical implications for healthcare providers working with and supporting these women.

The current critical appraisal will present some of the main considerations that arose during the research process, such as issues relating to the methodology of the study, ethical issues, and personal reflections. In line with the philosophy of IPA, my personal reflections will incorporate the use of relevant interview excerpts where appropriate.

Choosing the Topic

My interest in breast cancer more generally arose after my maternal grandma unfortunately was diagnosed with breast cancer and later died from this. This was a difficult and turbulent time for the family. However, I was very young at the time to recall all aspects of the journey beforehand. Nevertheless, what I do recall is how my Grandma responded to her diagnosis; very distraught and subdued compelling her daughters to take full control of her care and guiding her choices. Retrospectively, I have considered how people's choices

and responses to breast cancer can vary. With the 'Angelina Jolie effect'[1] raising awareness of hereditary breast cancer (Evans et al., 2014) and understandably the request for gene testing and risk-reducing surgery, I have always been left with an interest of what exactly motivates women to undergo CPM in the absence of high-risk factors. Though I cannot dismiss the anxiety and worry regarding the prospect of CBC in women after unilateral breast cancer, I wanted to explore this phenomenon further and contribute towards the limited research and understanding of these particular set of women.

Methodological Issues and Considerations

Homogeneity of Sample

Homogeneity within IPA is recommended (Smith et al., 2009) as it enables researchers to gain a specific understanding of participants' experiences within a particular context. In the development phase of the study, the issue of homogeneity was discussed with supervisors, regarding whether to include participants within a certain post-surgery bracket only, consider women who underwent CPM as an immediate or delayed procedure, and whether or not to include women who had undergone reconstruction. However, these issues had to be considered alongside the practicality of enforcing such specific inclusion/exclusion criteria, as this could have limited the participant pool. Smith et al. (2009) also state homogeneity can differ between studies, particularly when the sample is difficult to recruit and is dependent upon practical and interpretative issues. Moreover, enforcing a strictly homogenous sample is also considered to limit the diversity of the results (Leask, Hawe, & Chapman, 2001). As IPA is underpinned by the concept of idiography, which balances individual accounts within overall themes, and values convergences and divergences in the data (Smith & Osborn, 2008), it was felt that a wider scope of inclusion criteria would be

[1] Phrase referring to how a high-celebrity profiles decision to undergo genetic testing and prophylactic mastectomy has led to more awareness and has increased the number of referrals to breast cancer services.

appropriate. This was particularly important as this was the first IPA study to research women's decision-making process and experience of undergoing CPM within the low-to-moderate risk category.

Accordingly, disparity in the participants' experiences and decision-making process of undergoing CPM may be due to the lack of homogeneity. However, these differences were important to establish as they had important clinical implications. Therefore, taking into consideration that the research was the first IPA study in this area; having a less than homogenous sample was considered acceptable. Moreover, the features of IPA were considered relevant to the research questions; drawing on phenomenology to elucidate participants' lived experiences and enabling me to balance the idiographic and group aspects of the analysis. Future research may want to specifically focus on women who have all undergone reconstruction within a specific time-period post-surgery, or utilise methodologies that better enable the researcher to better compare the accounts of participants according to their contexts.

Recruitment Difficulties

Prior to undertaking this study, I was assured by my field supervisor that recruiting the anticipated 8-10 participants within one site would be easily attainable. However, I experienced recruitment difficulties from the outset which resulted in further ethical approval to recruit from two other NHS-sites (though one of these sites was not utilised for recruitment due to the time constraints of the study) and an amendment to undertake an internet recruitment strategy. The final sample comprised of six participants that were recruited from two NHS-sites.

There were various obstacles to recruitment within the NHS-sites which were not considered prior to undertaking the research. Currently, within the UK medical database

there is no unique procedure code specifying CPM, therefore identifying potential participants required systematic identification of patients who underwent mastectomy, accessing of the records and determining from the notes whether potential participants underwent CPM (and categorised low-to-moderate risk). This understandably presented a mammoth task for the breast care nurses who initially agreed to facilitate recruitment. Many attempts were made to engage the breast care nurses, the 'gatekeepers' to eligible participants, and better situate the study within the department through discussions within multidisciplinary meetings via the field supervisor (also the psychologist within the department) and various emails directly from myself to arrange a meeting with the breast care nurses to discuss the research, to no avail due to busy and heavy workloads. Kennedy, Hicks, & Yarker (2014) explored the challenges oncology researchers encounter, and found the logistics of accessing and recruiting participants due to busy healthcare staff was a key issue. Within the current study, due to these issues a more manualised recruitment strategy was employed where the psychologist who had assessed patient suitability for CPM reviewed her case files and compiled a list of potential names and these were cross-referenced by breast cancer nurses. Moreover, surgeons who had performed CPM also referred patient names onto the psychologist. However, it is possible that potential participants were not identified due to this ad hoc method, which presented as both an ethical issue and an added barrier to gain the intended number of participants.

During the recruitment phase, although I was disheartened by the lack of interest on part of the breast care nurses to be involved in the recruitment process as originally planned, after the interviews I felt conflicted about this. Some participants informed me that they had limited contact with their breast care nurses and found it difficult to establish contact even on the phone. This prompted one participant to volunteer her time to provide assistance:

> "So my experience of the breast care nurses is very negative. The telephone system. You ring up and you leave a message and people don't get back to you. Interestingly, I did ring and left a message and I volunteered to help minding the telephone…Just someone to say 'don't worry I will get someone to ring you back'. Just a person on the phone. And I never got a message back" (Julia)

Accordingly, I identified with participants frustration regarding their inability to contact the breast care nurses, however also came to an appreciation regarding breast care nurses limited time to facilitate student research in a climate of increasing workloads.

Additionally, in order to gain sufficient participant numbers an internet recruitment strategy was also undertaken. Research has indicated social media sites present as a cost-effective means to engage difficult-to-reach populations within health research (O'Connor, Jackson, Goldsmith, & Skirton, 2013). As such, an internet recruitment flyer (Appendix 3-A) was posted on the social media pages (Facebook/Twitter) of various breast cancer organisations; however no participants were recruited via this medium. I attempted to overcome this by contacting the administrators of the organisations in an attempt to have the flyer posted on their main website and forum. However, I was advised by two organisations that recruiting for research went 'against the peer support focus of our site'. This highlighted the increasingly bureaucratic nature of health forums which may have placed additional barriers to recruitment.

Upon reflection, it is possible potential participants may not have identified with the study inclusion criteria via the social media pages, specifically whether they were within the 'low-to-moderate' risk category. As research suggests women's perceived vulnerability to risk can often influence a woman's decision to undergo CPM (Brewster & Parker, 2011), it is possible potential participants did not identify with an objective formal risk category and

therefore excluded themselves from participating. Additionally, the flyer could be considered as having a low readability score, and this may have impeded potential participants' ability to determine whether they met the inclusion criteria.

Ethical and Professional Issues

Managing Boundaries of the Research

During the interviews, though effort was made to focus the discussions on issues relating to the research questions, the semi-structured nature of the interview schedule enabled participants to discuss more general issues related to their care. For example, some participants stated they received little support post-surgery from their breast care nurses and felt disgruntled by this. Though I acknowledged and sympathised with this, it was important for me to maintain my professional boundaries where possible and remind myself of the purpose of the interview and my role within that. As the research was not a service-development project it was not within my remit to action these particular points and I attempted to refocus the interview back to the relevant research-related questions whilst ensuring not to disregard participants' wider experiences.

Experiences of 'The Psychologist' for Participants

Patients considered low-to-moderate risk of CBC who request CPM are often required to undergo a psychological consultation to assess their suitability and highlight any contraindications for the surgery. The field supervisor of the current study, who had assessed some of the participants within the current study, was also identified as a possible contact for participants to speak to if they felt distressed after the research interview. Therefore, this raised an ethical issue as many of the participants appraised the psychological assessment as

an unnecessary formality with some participants unsure as to why they being referred to a psychologist:

> Erm, but what the hell does the psychologist want to see me for? That's how you think. Well, why am I seeing the psychologist that has nothing to do with my treatment? The psychologist doesn't know me, I'm going to sit there for an hour and the psychologist is going to make a decision on me in an hour (Karen)

Acknowledging that some participants experienced the psychological consultation as negative raised some concerns regarding how I was perceived as a trainee clinical psychologist. To overcome this, I clearly defined my role and purpose from the outset of the interview, where participants understood I was working within a research capacity. I also emphasised the distinct nature of my project and role on the information sheet prior to interviews. Moreover, the suitability of the field supervisor/assessing psychologist as a point of contact for the research was also a concern. However, due my dual role as both a researcher and psychologist, I am trained in managing distress and containing difficult emotions, and it was hoped this would have sufficed for participants. Additionally, other contacts and lines of support were also provided to participants via the debrief sheet after the interviews.

My Personal Reflections

My Changed Relationship with my Breasts after Maternity

Whilst undertaking this research, it has raised many thoughts and considerations regarding a woman's breasts, their position, value, and how breast cancer can dramatically alter how breasts are appraised and understood by women. Prior to undertaking the interviews for the current study, initially I struggled to understand how women were able to

make the decision for such drastic surgery and remove what culturally and socially is understood as a woman's 'whole' and feminine entity. Though not likening my experience to breast cancer in anyway, my maternity break (mid-research) and attempted breastfeeding experience gave me insight into some of the struggles associated with breasts and how a woman's perception of her breasts can alter accordingly.

I was often left with sore breasts and developed a breast infection, mastitis, which ultimately meant I could not keep up with feeding demands and resorted to baby formula. This experience was conflicting. On one hand, I felt guilty and incompetent as a mother; frustrated with my breasts and feeling negative towards them as they had given-up on me and my baby. However, I equally felt liberated that I had the option of formula and recovering my sore breasts which hindered me in so many ways. It appeared my experience paralleled in some way with participants' accounts of the altered relationship with their breasts after breast cancer, with CPM providing an option to overcome these difficulties. Yalom (1998) provides a descriptive account of women's breasts throughout history, outlining the powerful and contradictory ideas associated with breasts depicting the 'good' and 'bad' breast. Likewise, I too felt that my relationship with my breasts changed from breasts that were originally considered life-affirming and life-saving to withholding and life-destroying (Yalom, 1998).

Returning to the research after maternity provided me with a new and appreciated understanding of the modified relationship with one's breasts after an illness experience and the attempts made to overcome these difficulties. It was important that I noted these reflections through the use of a reflective diary (see Appendix 2-D) to ensure I 'bracketed' (Chan, Fung, & Chien, 2013) my own experiences and assumptions during the analysis process. This was to ensure interpretations of the data were embedded within the participants' accounts.

Reflections on the 'Exceptional' and 'Assertive' Participants

In my personal experience, I have often found women with breast cancer are often referred to as 'cancer victims'. However, upon speaking to the participants I experienced these women very differently. They presented as very assertive and assured within the 'telling' of their CPM decision-making process and experience; they were survivors and doers. It was refreshing and uplifting to witness this. These women had not only overcome breast cancer but also made a categorical decision for CPM and I have wondered whether there are certain personalities that both exude this sense of survivorship and also opt for CPM. In a recent study, Saita, Acquati, and Kayser (2015) explored the coping styles of women with breast cancer and found women who rated high on assertiveness were more likely to convey a 'Fighting Spirit' characteristic which was activated when they appraised their diagnosis as a challenge/threat. This is in line with the current study findings, as some participants viewed their diagnosis and risk of CBC, despite low-to-moderate, as a threat and motivated their decision for CPM.

Siegel (1988) wrote about the 'exceptional' cancer patient describing the characteristics of the patient who surpasses their diagnosis, stating personality traits such as independence and assertiveness particularly in the patient-doctor relationship enable people to heal as they pursue something they believe in and gives them hope. I consider all the women I interviewed were 'exceptional' in some way; they knew what they wanted, when and why and went outside of the normal circumstances where CPM is offered to women (in cases of high-risk) and gained a lot of solace in their decision. Additionally, their outlook on life was exceedingly positive. Hannah's account was quite significant in relation to this. She exemplified what it meant to be 'exceptional' by seeking another consultant who would acquiesce to her decision for CPM after her original consultant felt overwhelmed by her general manner and request and walked out of the consultation:

> The consultant had been a bit shaky with me over the years, she found me difficult because I asked questions. Not bad questions. Like can I go on aspirin? Will that help? Me and my friend who also had breast cancer at the time did research together. The consultant was doing this (gestures) beating her chest after I asked for CPM and giving me really bad signals. I said 'do you think you can continue with this consultation'? And she said 'no' and walked out. That was the last I saw of her. (Hannah)

In relation to my findings, it appeared there was little scope for shared-decision making between participants and their consultants. I speculated whether this was related to the traits of the 'exceptional' cancer patient who are more likely to be granted their decision for CPM as they assert themselves in such a way that consultants agree to the decision with relatively little consultation.

The Emotional Impact of Interviews

Research has highlighted the importance of researchers recognising the emotional impact of their research (Haynes, 2006). For me, this was particularly striking when interviewing Jane. Her account was very descriptive and rooted in her role as a young mother and wife. I found myself becoming quite emotional during the interview whilst she informed me of how her decision was based upon the need to survive and ensure she was always there for her children. As a new mother, I identified with Jane and naturally this brought up many thoughts about the possibility of illness for me and what this would mean in relation to my maternal role. In order to not detract away from Jane's interview, it was important for me to hold and manage my emotions and not physically display this. This has been referred to as 'emotional labour' (Zapf, 2002); the process of concealing and managing emotions, which is considered an important skill when working in health settings so as to

maintain professionalism. Again, my role as a trainee clinical psychologist also enabled this. I also had to remain aware of how my emotions and connection with Jane translated into my findings. The use of a reflective diary was useful here in order to maintain a reflective stance.

Although it was difficult to hear accounts of breast cancer and participants' harrowing details of the 'cold cap', it has provided me some important developments as a researcher and clinician and opportunity for personal growth. Within my clinical training, I had previously undertaken a placement in oncology, namely with service-users preparing for end of life within a hospice setting. This was a very difficult experience for me at the time, as it brought back many issues relating to my grandma. However, clinical supervision was helpful in exploring these issues and I consider I brought these developments and reflections to the current research in my ability to manage my emotions.

The Complexities of being a Researcher and Clinician

Previous research has outlined the difficulties in both being a researcher and health professional (Kidd & Finlayson, 2006). As this was my first experience in conducting an IPA study, I was unsure of how to conduct an interview within the role of a researcher as opposed to a clinician. My fear was using the semi-structured interview schedule too rigidly to overcome this, and this has been sighted as an issue often experienced by novice researchers (Smith et al., 2009). However, once the interviews ensued I was surprised at my flexible use of the semi-structured interview schedule and allowing the participants to guide the discussions in the way that was meaningful to them.

However, the challenge arose when participants shared particularly emotive aspects of their journey. I felt a 'pull' towards my clinical role and the need to attend to the information more therapeutically and provide summaries/interpretations. However, through supervision

and experience gained over the course of the interviews I learnt to balance empathic listening, checking my own understanding of participants' accounts, and learning to refrain from interpretations.

Taking Away Participants Stories

Although all participants were provided information regarding the nature of the study and its potential impact, after the interview process I did reflect on whether I was justified in placing participants into a position of recalling aspects of their cancer journey which they may have preferred to keep in the past. This was highlighted further when Jane stated:

> Talking to you know has brought up things, I don't talk about it [cancer], I don't think about it, I have a lid of Pandora's box. I thought when I got your letter 'Oh god do I want to take the lid of Pandora's box?', because I haven't, in the early days I did, but I have not cried and mourned, and felt sorry for myself, like I say, I have got on with it. (Jane)

Although it felt somewhat exploitative to record participants' accounts and 'take away' their stories for the benefit of the profession, this was reconciled by the fact that all participants, including Jane, felt they were contributing towards cancer research. This supports the 'trickle down' theory of altruistic participants where it is thought participants gain satisfaction from the belief their accounts will benefit policy, practice and wider communities (Bay-Cheng, 2009).

Conclusion

This critical review has explored further key aspects of the research methodology, ethical and professional issues and potent personal reflections whilst undertaking the research. In doing so, it has also offered some ideas for future research; specifically

examining the influence of personality traits in the decision-making process of CPM, and understanding the differences in experiences of women who may or may not undergo breast reconstruction after CPM separately.

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Appendix 3-A: Internet Recruitment Flyer

The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

- Have you had unilateral breast cancer (primary cancer in one breast) and have chosen to undergo a Contralateral Prophylactic Mastectomy (CPM) of the non-cancerous breast?
- Are you considered to be in the low-to-medium risk group of secondary breast cancer as you do not have a significant family history of breast cancer or a BRCA1/BRCA2 gene carrier?
- Did you have the surgery (with or without reconstruction) more than 12 months ago?
- Are you not receiving any adjuvant treatment such as chemotherapy/radiotherapy?
- Would you be interested in talking to someone about your experiences and decision-making process of undergoing CPM?

If so...I'd like to hear from you!

My name is Fehmida Patel and I am Trainee Clinical Psychologist. I'm carrying out a research project looking at the experiences and the decision-making process of women who are within the low-to-medium risk group of secondary breast cancer (but have had primary/unilateral breast cancer), yet, have chosen to undergo CPM of the non-cancerous breast. Exploring your reasons and experiences of CPM could help other professionals allow better understanding regarding how to support and advise other women contemplating CPM as there is currently limited information within this area. Moreover, the information can also aid understanding of how psychological services can improve to better support women contemplating CPM.

Taking part will involve answering some questions over the phone, then meeting me to complete an interview.

If you think you might be interested in taking part and would like to find out more, please e-mail me on f.patel@lancaster.ac.uk. You can also provide a telephone number via email I can call you to discuss the study further.

Thanks

Fehmida Patel

Trainee Clinical Psychologist

Lancaster University Doctorate in Clinical Psychology

Section Four: Ethics Documents

Word Count: 16,113

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

All correspondence should be sent to:
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Doctorate in Clinical Psychology
Furness College
Lancaster University
Lancaster
LA1 4YT
f.patel@lancaster.ac.uk

Appendix 4-A

Participant Information Sheet

Study Title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

My name is Fehmida Patel and I am training as a Clinical Psychologist on the doctorate course at Lancaster University. This information sheet has been sent by the cancer department at [redacted] on my behalf. I would like to invite you to take part in a study which I am undertaking as part of my training. If you think this is something you would be interested in, please take time to read the information sheet below which may help you decide whether you would like to take part.

What is the purpose of the study?

The purpose of this study is to understand the experience and decision-making process of women within the low to medium risk group of contralateral cancer who have chosen to undergo a Contralateral Prophylactic Mastectomy (CPM). The study is also interested in understanding the psychological effects of the procedure and how it has affected your quality of life. Exploring these issues will allow better understanding regarding how to support and advise other women contemplating CPM as there is currently limited information within this area. Moreover, the information can also aid understanding of how psychological services can improve to better support women contemplating CPM.

Why have I been invited to participate?

You have been invited to participate within this study as you have undergone CPM.

Do I have to take part?

You do not have to take part, and, if you decide not to participate the standard of care you receive will not be affected. However, if you think you would like to take part or would like to talk to me about this, you are invited to return the enclosed contact sheet (with the pre-paid envelope provided) with your telephone number and/or email address so that I can telephone or email you. It is also encouraged that you take at least 24 hours to decide whether you want to take part or not. We can then discuss any further questions you may have and you can either decide to volunteer or decline to take part in the study.

If too many people volunteer I will contact you to thank you for your interest and advise that I will not be asking you for an interview on this occasion.

What will I have to do if I agree to take part?

You will have to be interviewed by the researcher about your experience. The interview is expected to last approximately one hour and fifteen minutes and will be recorded. If during the interview there is potential to going over an hour and fifteen minutes, I will stop the interview and ask if you are happy to continue, or, if you would like another appointment to conclude the interview. If you do not want to continue and do not wish to make another appointment, I will stop the interview and use the data collected from the incomplete interview.

As the interview will be recorded, you may ask for the tape to be stopped, edited, or re-played at any point in the interview. We can stop the interview at any point, or, you can decide not to answer any particular questions.

Where and when will the interview take place?

Once your contact details have been received, I will contact you to arrange a suitable time and place to conduct the interview. This can be either within your home or within a clinic room at [redacted]. A suitable quiet room is required as the interview will be recorded using an audio digital recorder. Prior to the interview commencing, you will be given a consent form to read and then we will discuss your experience of undergoing CPM.

If you decide to be interviewed at [redacted], up to £10.00 travel costs can be claimed back.

What will happen when the interview ends?

After the interview, I will listen to the recording and type out our discussions. I will then attempt to identify themes from our discussion and cross-reference these themes with discussions with other women who have undergone CPM.

The overall data produced by the study will be reported after July 2014. Only summary information and not individual data will be reported, so no individual will be identifiable in the report. However, I may use anonymised direct quotes, with your permission, in writing up the findings. It is possible that some of this data will be published as well as being shared within the research community through conferences and presentations. A summary of the findings will be made available if you request it after this date. The identity of anyone who takes part in the study will not be disclosed at anytime.

Will my participation in this study be kept confidential?

All information collected will be kept strictly confidential. However, if during the interview any information regarding risk to yourself or others is disclosed, this information will be discussed with my academic and field supervisors ([redacted]). However, this will be discussed with you in the first instance wherever possible.

The interview transcripts will be password protected on the computer and will not contain your name (or any names you may mention within the interview) or other identifying information such as your address. Your name and any other identifying information will not be used in any reports and will be kept confidential. Pseudonyms (replacement names) will be used instead. The audio data will be destroyed and transcripts will be stored for 10 years on the Lancaster University electronic database which is password protected and encrypted.

After 10 years the transcripts will be destroyed as NHS policy requires for this type of project.

Can I withdraw after taking part?

If you participate in this study you will be able to withdraw your data from the study for up to two weeks after the interview. A request to withdraw after this point may not be possible as the data collected may have already been analysed and themes elicited. It would therefore be difficult to separate individual data and themes from the overall pool collected.

If I have questions who can I talk to?

If you would like to ask questions about this research you can contact the researcher via the contact details below.

What are the risks and benefits of taking part?

There are no direct benefits of taking part in this study. However, some participants find it helpful to discuss their experiences and views after undergoing CPM. It is hoped that the research will help highlight the information required to better support other women contemplating CPM.

It is possible that talking about your experiences about CPM and the impact it has had on your life may cause distress. If this happens during the interview, we can discontinue, or take a break. You are also welcome to contact me after the interview if you continue to feel distressed and I will direct you to further support. This can include contacting the field supervisor, [redacted] to discuss the impact of the interview. You can also telephone my academic supervisor [redacted] on [redacted]. Some other sources of support are given at the end of this information sheet.

Other information

You will be sent another information sheet after two weeks as a reminder. If you have decided to take part in the study and have already contacted me about this, you will still receive the reminder pack as the staff working in the service (who are sending the packs on my behalf) do not know about your participation. This is to ensure your confidentiality. You will not receive any further information/contact from me thereafter unless you choose to contact me.

Ethical approval

This study has been granted ethical approval by the [redacted]

Complaints

If you are in anyway dissatisfied with how this research is conducted, complaints can be addressed to the research director: Dr Jane Simpson, Lancaster University Doctorate in Clinical Psychology, Lancaster University, Lancaster, LA1 4YG, Tel: 01524 592858, email: [redacted]. You may also contact my academic supervisor: [redacted]

Contact Details

This research is carried out by Fehmida Patel, Trainee Clinical Psychologist, Clinical Psychology, Furness College, Bailrigg, Lancaster, LA1 4YG, email: f.patel@lancaster.ac.uk.

The results

You are very welcome to have a copy of the summary of the results after July 2015 if you indicate this is what you would like.

If you would like to take part:

1. Please read and sign the contact sheet that is enclosed.
2. Please return the contact sheet in the pre-paid envelope provided.

Sources of information and support

Breast Cancer Care	0808 800 6000	www.breastcancercare.org
Macmillan Cancer Support	0808 808 0000	www.macmillan.org.uk
The Haven	0113 284 7829	www.thehaven.org.uk

Appendix 4-B

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Participant Contact Sheet

The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

I am interested in hearing more about the above study and I consent for the researcher (Fehmida Patel) to contact me using the details below (please tick the box of you are happy to be contacted) ☐

My name is _____

My telephone number is _____ and/or

My email address is _____

The best time to contact me is: **Day** **Evening** (please circle)

Day: **Mon** **Tues** **Wed** **Thurs** **Fri** **Sat** **Sun** (please circle)

Please place this sheet in the enclosed addressed envelope (you do **not** need a stamp).

Thank you for your interest.

Appendix 4-C

Participant Consent Form

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Study Title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

Chief Investigator: Fehmida Patel

Please initial box

1	I confirm that I have read and understand the information sheet dated 20th November 2013 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I agree to the interview being audio recorded and then made into an anonymised written transcript.	☐
4	I consent to information and anonymised quotations from my interview being used in reports, conferences and training events.	☐
5	I consent to Lancaster University keeping written transcriptions of the interview for 10 years after the study has finished.	☐
6	I agree to take part in the above study.	☐

7. I understand that data from the study may be looked at by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this study. I consent to these individuals having access to this information ☐

_____	_____	_____
Name of Participant		Date Signature

_____	_____	_____
Researcher	Signature	Date

One copy each to be retained by participant and researcher.

Appendix 4-D

Semi-structured interview schedule

This schedule will be used as a guide, in order to facilitate discussion on the topic interest. The questions are indicative of the types of questions that may be asked but it is not intended to ask all questions to all participants. The questions may be adapted or changed depending on each participant's response.

Introduction/Background

Can you tell me a little about yourself?

Prompts: Age, family composition, occupation

Can you tell me about your diagnosis?

Prompts: How long since diagnosed?

How did you feel when you received the diagnosis?

How did your family react?

Is there anyone else in your family with cancer?

Questions regarding the decision-making process

How did you come to the decision of undergoing CPM?

Prompts: What factors were associated with the decision?

Why did you want CPM?

Did you consult with anyone else about making this decision?

What emotions were going through your mind whilst making the decision?

How long did you think about CPM before informing the consultant this is what you wanted?

What information did you receive, both from the consultant and elsewhere, regarding the procedure?

How did the consultant respond after you requested CPM?

What were you told about the surgery?

Do you think you were advised enough about CPM prior to the procedure?

Prompts: Was there any advice that was given specifically that helped you make the decision?

What information did you receive from the surgeon regarding reconstructive surgery and how did this help you make your decision?

Prompts: Was the surgeon realistic about the look and feel of the reconstructive surgery?

Did the surgeon show you any pictures of reconstruction after mastectomy? Would you have preferred to seen pictures?

What advice would you like to have received prior to the surgery?

Would receiving this information have impacted upon your decision to undergo CPM?

Questions regarding satisfaction and the psychosocial impact of CPM

Are you satisfied/dissatisfied with the decision to undergo CPM? Why?

Are you satisfied/dissatisfied with the reconstructive surgery?

Prompts: Did the surgery meet your expectations?

If dissatisfied: Despite not being satisfied with the reconstructive surgery, are you still happy with your decision to undergo CPM?

What are specifically dissatisfied about regarding the surgery?

Prompts: Do you experience any pain after the implants?

Are you happy with the 'naturalness' of the reconstruction?

Were you left with any unexpected scarring?

What options were you given for reconstruction (Implants/using own tissue)

Were you prepared for the issues that had arisen?

What impact has the procedure had on your life?

How do you feel about yourself?

Has the procedure affected your relationships?

Other Questions

What support did you receive prior and after the surgery?

How would you advise other women considering this procedure? What specific information should be made available for women thinking about CPM?

Appendix 4-E

Participant Debrief Sheet

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

Thank you for your time and taking part in this study. Your participation is much appreciated and I hope you enjoyed sharing your experiences. Your views will allow me to complete the study, but, more importantly may allow services to develop more information regarding how to advise other women contemplating CPM and help improve psychological services to better support women before and after the procedure. Your views will also be integral to this.

If you have any queries after the interview please contact me at the following address: Fehmida Patel, Trainee Clinical Psychologist, Clinical Psychology, Furness College, Bailrigg, Lancaster, LA1 4YG, email: f.patel@lancaster.ac.uk.

Below are other sources of support that you may also find helpful:

Breast Cancer Care	0808 800 6000	www.breastcancercare.org
Macmillan Cancer Support	0808 808 0000	www.macmillan.org.uk
The Haven	0113 284 7829	www.thehaven.org.uk

Thank you very much for taking part in this study.

Appendix 4-F

Research Protocol

DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Study Title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

Chief Investigator: Fehmida Patel
Supervisors: [redacted] (Research supervisor, Doctorate in Clinical Psychology, Lancaster University).
[redacted] (Field Supervisor, Clinical Psychologist at [redacted]

Introduction

Breast cancer is the most prevalent form of cancer within England and Wales, with over 40,000 new cases diagnosed each year (National Institute for Health and Care Excellence, 2009). Advances in genetic testing allows for predictive testing for hereditary cancer and risk factors, such as, mutations to the *BRCA1* and *BRCA2* genes and significant family history of cancer, are associated with the increased risk of developing breast cancer (Narod, 2010). As such, risk-reducing surgery such as prophylactic bilateral mastectomy (removal of both breasts) is considered as an effective treatment intervention and is thought to reduce the risk of breast cancer by 90% (Rebbeck et al., 2004).

Similarly, women diagnosed with unilateral breast cancer (cancer in one breast) and are at high risk of developing cancer within the contralateral (the other) breast may consider contralateral prophylactic mastectomy (CPM) which involves the removal of the non-cancerous breast (Lostumbo, Carbine, & Wallace, 2010). However, in the absence of the aforementioned risk factors, the risk of developing contralateral breast cancer in women within the low-to-medium risk bracket is rare (Herrington, 2005 as cited in Lostumbo et al., 2010). Research suggests women with unilateral cancer are at increased risk of developing secondary cancer within the same breast as opposed to developing cancer within the contralateral breast (Brewster & Parker, 2011). Despite this, women with unilateral breast

cancer, many of whom are good candidates for breast conservation as they are within the low to medium risk category (Helzlsouer, 2005), are increasingly requesting CPM (with reconstructive surgery thereafter) so that they do not have to undergo the 'cancer process again' (Khan, 2011). Oncologists therefore view CPM in this population as an unnecessary 'mutilating' procedure as the risk of these women developing contralateral breast cancer is very rare (Spear, Carter, & Schwarz, 2004). Moreover, there is a lack of evidence to suggest an increased risk of death from secondary cancer and research suggests the procedure does not affect overall cancer-related mortality (Khan, 2011). The lack of information regarding the clinical value, risks, and benefits of CPM for women within the low-to-medium category is considered an important public health concern (Brewster & Parker, 2011). There is also limited information regarding the psychosocial impact of CPM in women with low-to-medium risk of breast cancer (Altshuler, 2007). Therefore, understanding the experiences, motivations, perceptions, and the decision-making process of women undertaking this procedure is important.

Research highlights a number of reasons which may influence a women's decision to undergo CPM. This includes, cancer-related anxiety and distress, fear of cancer developing in the contralateral breast, perceived risk, body image issues (wanting symmetry/balance after reconstruction of both breasts), and uncertainty about cancer (Brewster & Parker, 2011). CPM may also allow women to feel a sense of control over the cancer. Although research suggests women are generally satisfied with their specific decision to undergo CPM, to decrease the risk of secondary cancer (although it is rare secondary cancer would develop in women within the low-to-medium category) and anxiety, they still report negative psychosocial outcomes (Altshuler, 2007). For example, Patenaude et al. (2008) asserts almost half of the women undergoing CPM experience ongoing disruption in intrapersonal and interpersonal areas such as sexuality and body image issues. For example, research indicates women often have unrealistic expectations regarding the reconstructive surgery after CPM and accordingly are disappointed with the results, affecting their body image, femininity, and sexuality (Patenaude et al., 2008; Altshuler, 2007). Specifically, reconstructive surgery after a CPM can leave women with reduced or no nipple sensation, an 'unnatural' look, or asymmetrical breasts. This highlights the importance of education, consideration, and reasoned decision-making when considering CPM.

Moreover, research suggests the decision to undergo risk-reducing surgery is often made based upon the consequences upon family members and the need to contain fear (Hallowell, 1998). Furthermore, the decision is often made at the time of diagnosis when

women feel under pressure or overwhelmed with the diagnosis (Patenaude et al., 2008). Accordingly, Brewster and Parker (2011) emphasise the importance of consultants and surgeons counselling and informing women to dispel women's overestimation of secondary cancer and the possible complications after reconstruction. Similarly, Patenaude et al. (2008) suggests psychological consultation prior to and after CPM is important. Some women in their study felt overwhelmed by feelings of loss and fear and felt psychological consultation would have been helpful prior to surgery to discuss these emotions, as well as, discussing the possible impact the surgery could have on their sexuality and relationships.

The decision to undergo CPM in women within the low-to-medium risk category of further cancer is complex and difficult to understand. However, psychological theories provide frameworks to understand the decision-making process. For example, the health belief model (HBM) (Becker & Rosenstock, 1988) suggests people engage in health prevention behaviour when faced with a threat to their health and accordingly evaluate the benefits of the behaviour. Therefore, in relation to CPM, the perceived benefits of reducing contralateral breast cancer (a primary motivator in women considering CPM) and the perceptions regarding balance/symmetry after reconstruction, fits well with the HBM. Moreover, affect theory in relation to cancer worry also allows understanding of the decision-making process. McCaul and Mullens (2003) state worry may accelerate the process of undertaking health-protective behaviours and can serve to keep an issue more salient. The emotional arousal of worry can also encourage proactive coping and provides a cue to action as people are naturally averse to worry. Managing the threat allows one to control worry. Therefore, a woman who is worried about developing contralateral breast cancer may choose to undertake CPM, despite the low risk of developing it in the future, and can reduce negative affect.

Although theories can elucidate some of the factors involved in the decision-making process for women, it is important to delineate the individual experiences of women undertaking CPM. Moreover, there is a lack of qualitative information within this area and limited information on how to advise women within the low to medium category when they request for CPM. Undertaking this research will allow understanding of the perceptions and motivations of women requesting this surgery and may also highlight how a psychologist can facilitate the decision making process, inform patients of the potential negative outcomes, and discuss feelings of loss and fear prior to and after surgery. Moreover, understanding the decision making process and the impact of this risk reducing surgery may lead to improved understanding and interventions on how to best approach and advise women with low to

medium risk of contralateral breast cancer. This will aid the process of devising helpful information for women within the low to medium risk category of further breast cancer.

Aims

The study aims to investigate the experiences and the decision making process of women who have undertaken CPM who have low to medium risk of contralateral breast cancer. This includes understanding the impact of the surgery on a woman's quality of life, the emotions associated with this, and its long-term impact on one's psychological and social functioning. In addition, the study aims to explore how satisfied/dissatisfied women are with the surgery and their choice to undergo CPM and the factors associated with this. Moreover, the study will also attempt to understand what information these women would have benefitted from before undergoing the surgery.

Method

Participants

Women with unilateral breast cancer and low to medium risk of contralateral breast cancer who have undergone CPM (with or without reconstruction thereafter). Recruitment of participants will take place via NHS sites and within non-NHS sites via social networking websites and online charities/forums such as facebook, twitter, and the [redacted] (internet recruitment).

Recruitment within NHS sites.

Participants will be recruited from various NHS sites within [redacted]. Participants who are within the 12-24 months post-surgery period will be initially included within the study as there can be initial complications after reconstruction and allowing 12 months to pass post-surgery can provide a more objective assessment of participants' experiences and impact on their quality of life. Suitable participants will be identified and recruitment packs will be sent out via the breast cancer nurses and surgeons.

Inclusion criteria:

- Women above the age of 18 years

- Women with unilateral breast cancer *and* within the low to medium risk category of contralateral breast cancer who have undergone CPM with or without reconstructive surgery thereafter.
- Patients who are not currently receiving any adjuvant treatment e.g. chemotherapy (as this itself can be physically and psychologically draining).
- Interview women who are within the 12-24 months post-surgery (initially as per stage 1 of the recruitment process) period.

Exclusion criteria:

- Women within the medium to high risk group for contralateral breast cancer. This includes excluding:
  - Women with high contralateral breast cancer risk factors such as mutated *BRCA1* and *BRCA2* genes.
  - Women with a significant family history of breast cancer.
- Women with a reoccurrence of cancer or any other major illness.
- Women who do not speak sufficient English to undertake the interview.

Recruitment within non-NHS sites (internet recruitment).

Potential participants will also be recruited from social networking sites such as Twitter, Facebook, and online breast cancer charities such as Breast Cancer Care. A link to the project flyer (Appendix 7) will be posted on these websites (contact will be made to the admin of the online charities/forums to facilitate this) providing an overview of the study and the aforementioned inclusion/exclusion criteria.

Anyone who does not fulfil these criteria will not be included within the study. As this is a qualitative study, a power calculation is not necessary. In contrast, a maximum sample of ten participants will be recruited. This is in line with other qualitative studies employing Interpretive Phenomenological Analysis (IPA).

Design

A qualitative approach will be used and interviews will conducted with participant's who have undergone CPM. Semi-structured interviews will be undertaken with the participant and the material will be transcribed and analysed using IPA. IPA is a useful methodology

within health research as it allows an in-depth understanding of one's lived experience and exploration of an individual's cognitive inner world (Biggerstaff & Thomson, 2008).

Materials

A semi-structured interview will be constructed to explore the experiences of women who have undergone CPM. A copy of the proposed interview schedule for the study can be found in Appendix 1. As the interview is semi-structured, questions will be adapted, removed or modified and additional ones added, depending on the participant's response. A digital recorder will also be utilised to record all the interviews carried out.

In addition the following demographic information will be collected from parents/carers:

Age

Family composition

Current or previous occupation

Time since diagnosis and surgery

Procedure

Within NHS sites, recruitment will take place within [redacted] For non-NHS sites, internet recruitment will also take place as stipulated within the participants section.

Recruitment within NHS sites.

Although, it is intended to recruit women who are within the 12-24 month post-surgery period after CPM, this can limit the participant pool and reduce the number of people interested within the study. Therefore, a phased approach to recruitment will be employed within the study. Stage 1 of the recruitment process will involve the breast cancer nurses and surgeons identifying the women who fulfil the inclusion/exclusion criteria listed above, and accordingly, will send out a study information pack containing the information sheet (Appendix 2) and the contact sheet (Appendix 3) via post. If participants wish to meet with the researcher to learn more about the study they are invited to return the contact sheet by post, with their details so that the researcher can contact them to discuss the potential to participate further. If after this conversation the participants are happy to take part, a date

and time convenient to the participant will be arranged. On this date, participants will sign the consent form (Appendix 4) and an interview will take place on the agreed date and time.

If enough participants are not recruited within stage 1, stage 2 of the recruitment process will be employed. Stage 2 will begin four weeks after stage 1 (if enough participants are not recruited) which will involve sending the same information sheet and contact sheet (as within the Stage 1) to participants within the 24-36 month post-surgery period. If enough participants have still not been recruited within Stage 2, Stage 3 will be employed four weeks after Stage 2 which will involve sending the information sheet and contact sheet to participants who are within the 36-48 months post-surgery period.

Participants will have a choice to be interviewed either at home or interviewed in a clinic room at [redacted] depending upon which trust they have been recruited from. If participants choose to be interviewed at their home, the researcher will adhere to the Lancaster University's lone worker policy at all times. Specifically, the principal investigator will organise a 'check in' system with one of the supervisors of the study or a colleague, informing them of the time of the study and an approximate time that the researcher will 'check-in' following the completion of the interview. Should the principal investigator fail to contact the supervisor/colleague, they will attempt to contact the investigator by phone. Prior to the interview, the principal investigator will provide an envelope with the name, location, and address of the participant in a sealed envelope, that will only be opened in the event that the principal investigator fails to contact the appointed person within the agreed time frame and does not answer their phone call. This is to ensure the safety of the researcher and the participants, and confidentiality will only be broken if deemed necessary.

The interview will take place for approximately 60 minutes, and will not go beyond this without participants' agreement, and will be recorded. Once the data have been analysed and interpreted by the researcher, a summary of the final report will be sent to each participant (if requested) and will be invited to telephone the researcher if they wish to discuss the themes further.

Recruitment within non-NHS sites (internet recruitment).

A short message will be posted on social networking sites and online charity/support forums (contact will be made to the admin of the online charities/forums to facilitate this) stating 'Looking for people who have undergone contralateral prophylactic mastectomy' with a link to the project flyer (Appendix 7) thereafter. The project flyer will provide an overview of the study and the aforementioned inclusion/exclusion criteria.

Potential participants will then be given the opportunity to email me to answer some initial questions via email/telephone (I can call them from a withheld telephone number if they provide a number via email) so I can confirm they meet all the inclusion/exclusion criteria of the study. If so, the participant information sheet (Appendix 2.3) will be emailed to them thereafter. If potential participants are happy to take part in the study a date and time to meet to interview the participant will be arranged. The same 'check-in' system will be followed as mentioned previously to ensure my safety.

However, if it is difficult to arrange a suitable time/date for a face-to-face interview (due to the nationwide coverage internet recruitment entails), then a telephone interview will be offered. The loudspeaker function on a mobile/land line would be used and a digital recorded would be placed next to this in order for the interview to be recorded. The interview would take place in a lockable room within Lancaster University so I can ensure the participant's confidentiality within the interview.

Within the telephone interview, a similar process would be undertaken in relation to gaining consent as with the face-to-face interview. At the beginning of the conversation, I would read out the consent form and request that the participant verbally consent to each aspect of this. I would also offer to send them a copy of the consent form. After the interview a copy of the debrief sheet (Appendix 5) will also be sent via email. Again, the interview will take place for approximately 60 minutes, and will not go beyond this without participants' agreement. If the participant would like a summary of the final report, this can be arranged via email.

Analysis

After each interview the data will be transcribed and analysed using IPA utilising the guidelines provided by Smith, Flower, and Larkin (2009). Each participant's transcript will be analysed in isolation before analysing the next participant's transcript. This is to ensure

each participant's individual experience is preserved. All transcripts will be read and re-read numerous times to ensure the participant's 'story' becomes the focus of the analysis. The digital audio recording will also be used to aid this process. Notations of the significant aspects of the data will be made within the margins of the transcript. Possible connections between the notations across all the transcripts will be clustered together to create initial themes. These initial themes will then be checked against the data to ensure they accurately reflect the participant's account. Quotes from the transcript will also be used to support the themes and ensure the themes are grounded within the data. Initial themes will then be clustered further to identify 'super-ordinate' themes. This process will be repeated for all the transcripts.

Patterns across all the transcripts will be identified by assessing whether the super-ordinate themes are shared across all or most the transcript. These themes will then be evidenced with quotes from the individual transcripts.

Practical Issues

Costs will be met by Lancaster University Doctorate in Clinical Psychology. Moreover, all participants will be able to claim back travelling costs, up to a maximum value of £10 that may occur when participating within the study.

This project will be submitted as one of the requirements for the Principal Investigator to obtain a Doctorate in Clinical Psychology from Lancaster University.

Ethical Concerns

Interviews will be recorded and then transcribed. The audio data will then be destroyed; however, the transcripts will be anonymised and will be held securely for 5 years at Lancaster University and then destroyed. The academic supervisor will only see anonymised transcripts; however he will listen to audio data to provide feedback on the quality of the analyses. The field supervisor will only have access to final themes and anonymised quotations to ensure participant confidentiality.

As the project concerns a sensitive topic, it is possible participants may feel emotional after the interview. The information sheet advises participants to contact the researcher if they wish to discuss concerns following the interview and she will direct them to further appropriate support if necessary. Moreover, the field supervisor (a practicing clinical

psychologist), has offered to meet with participants if required to discuss the impact of the interview or any other issues that may have arisen. A debrief sheet (Appendix 5) will also be provided with relevant support numbers also. Participants may also contact the researcher's supervisor. It will be made clear that participants can withdraw from the study up until two weeks after the interview date, or terminate or postpone the interview whenever they wish to. Confidentiality will be maintained throughout, unless risk related issues arise (themselves or others); however this will be explained prior to the interview. In the instance that this does occur, advice will be sought from the field supervisor and the service risk policy will be followed.

Timescale

It is envisaged that the project will be submitted in May 2014. Participants will also have the opportunity to give the researcher contact details so as to provide them with a summary of the results if they request this. A complete version of the report will also be given to the service as well as a presentation of the overall results during a university presentation day.

References

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Appendix 4-G: REC Ethics Application

NHS REC Form Reference: IRAS Version 3.5

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)
Experiences of women undergoing contralateral prophylactic mastectomy

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?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] 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

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

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):
This study will form one part of the requirements for the researcher/principal investigator to obtain a doctorate in clinical psychology (DClinPsy)

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

NHS
Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. 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 familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Experiences of women undergoing contralateral prophylactic mastectomy

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

REC Name:

REC Reference Number: **Submission date:**

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Fehmida	Patel
Address	Lancaster University, C16 Furness College, Lancaster		
Post Code	LA1 4YG		
E-mail	f.patel@lancaster.ac.uk		
Telephone	01524593378		
Fax			

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

Name and level of course/ degree:
Doctorate in Clinical Psychology (DClinPsy)

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title Forename/Initials Surname
	[redacted]
Address	Doctorate in clinical psychology Furness College, Division of Health Research Faculty of Health and Medicine LA1 4YG
Post Code	
E-mail	[redacted]
[redacted]	[redacted]
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)
Student 1 Miss Fehmida Patel	☑ [redacted]

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
	Miss Fehmida Patel
Post	
Qualifications	MSc Forensic Psychology (Merit) BSc Psychology with Independent studies (with Honours)
Employer	Lancaster University
Work Address	Lancaster University, C16 Furness College Lancaster
Post Code	LA1 4YG
Work E-mail	f.patel@lancaster.ac.uk

* Personal E-mail	fahmidanatha@hotmail.co.uk
Work Telephone	
* Personal Telephone/Mobile	07581164959
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
	Ms	Debbie	Knight
Address	RSO, B Floor, Bowland Main Lancaster University, Lancaster		
Post Code	LA1 4YT		
E-mail	ethics@lancaster.ac.uk		
Telephone	01524592605		
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):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	Version 1
Protocol Date:	20/11/2013
Funder's reference number:	N/A

Project website: N/A

Additional reference number(s):

Ref.Number Description	Reference Number

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.*

Women with unilateral breast cancer are increasingly requesting a double mastectomy (of the cancerous and non-cancerous breast) - referred to as contralateral prophylactic mastectomy (CPM) - so that they may not have to undergo the 'cancer process again' (Khan, 2011). Although there is evidence to suggest this procedure is beneficial for women within the high-risk group of secondary cancer (i.e. significant family history of breast cancer or have mutated BRCA1 or BRCA2 genes), women without these risk factors are increasingly requesting this surgery who fall into the low-to-medium risk group. Moreover, there is a lack of evidence to suggest an increased risk of death from secondary breast cancer, and there is limited patient information regarding the risks and benefits of CPM for women with low-to-medium risk of developing secondary breast cancer in the non-cancerous breast.

Most research into psychosocial outcomes after CPM is based on women within the high risk category for secondary cancer. One study examining these outcomes in the high risk group found surgery impacted upon self-esteem, femininity, body image (after reconstruction), and reduced level of stress in their life (Frost, 2003). Therefore, more research is required regarding the outcomes for women within the low-to-medium risk group.

Moreover, there appears to be a lack of patient information regarding the procedure for women within the low-to-medium risk category; with decisions being made upon information for the high risk group.

The aim of the study is to understand the decision-making process and the impact of CPM. Semi-structured interviews will be undertaken with women who have undergone CPM within the low-to-medium risk group and the qualitative data will be analysed using Interpretative Phenomenological Analysis (IPA). The information obtained may lead to improved interventions on how to best advise women with low-to-medium risk of secondary breast cancer.

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.

Recruitment:

Participants will be individuals who have underg one Contralateral Prophylactic Mastectomy (CPM) who are within the low-to-medium risk group of secondary breast cancer. Participants meeting the inclusion criteria will be identified by the breast surgeons and breast care nurses and will be sent a participant information pack by post comprising of a participant information sheet (Appendix 2.1) and contact sheet (appendix 3). Participants will then have an opportunity to contact the researcher by returning the participant contact sheet by post with a prepaid envelope provided. Participants will also be sent a reminder sheet (Appendix 2.2)with a covering letter (Appendix 2.3) two weeks after the initial participant information sheet has been sent together with the original participant information and contact sheet. It is thought this process can enhance recruitment.

At this stage, participants may either decline to take part, or, can provide the researcher with a date and time suitable to them to undertake the interview. This will either be within a clinical room at [redacted] or, at the participant's home. If the participant chooses the latter the Lancaster University lone working policy will be adhered to.

Participants may ask further questions regarding the purpose of the project. Engaging with participants in this way may maximise recruitment and highlights the service's support for the research, but at the same time preserves anonymity and ensures no one is under pressure to take part.

Phased approach to recruitment: Stage 1 of the recruitment process involves recruiting women within the 12-24 month post-surgery period, and it is hoped enough participants will be recruited within this time bracket. The reason for this is to ensure homogeneity within the sample and to reduce the broad range of experiences that women could be encountering. Within the analysis chosen for this study (Interpretative Phenomenological Analysis - IPA) this is an important consideration. It is also important to allow a minimum of 12 months to pass post-surgery as there can by initial complications after the surgery or incomplete surgery and allowing 12 months to pass can provide a more objective assessment of women's experiences once the complications/pain has subsided.

However, if enough participants are not recruited within stage 1, stage 2 of the recruitment process will be implemented. This will be employed four weeks after stage 1 (if enough participants are not recruited) and will involve increasing the post-surgery time bracket to 24-36 months and will be recruited in the same manner as stage 1 noted above. Thereafter, if enough participants are not recruited in stage 2, stage 3 will be employed four weeks after this and will involve increasing the post-surgery time bracket to 36-48 months.

Confidentiality:
Participant confidentiality and anonymity will be respected at all times, and participants will be fully informed of the limitations of confidentiality (BPS Code of Conduct, 2006). That is, should information be disclosed during the interview regarding the risk of harm to self or others, appropriate action would be taken and the information would be passed on to the field [redacted] and research [redacted] supervisors. If this were the case, the principal investigator would try to discuss this with the participants prior to passing the information on.

Interviews will be conducted either within a clinic room within [redacted] away from the main offices or within the participants home to ensure the breast care nurses or breast surgeons are not able to identify which participants have taken part in the study.

The interview data will be anonymised (names exchanged for pseudonyms known only to the researcher) and personal identifiers removed from transcripts. Full Anonymised transcripts will be restricted to being viewed by the researcher (Fehmida Patel), and research supervisor [redacted]

The service based field supervisor [redacted] will only have access to selected extracts where there is no possibility for her to identify clients. The research supervisor will have access to transcripts to monitor and provide feedback on the quality of the analyses. The researcher will receive ongoing academic and clinical supervision throughout the study, for development purposes and to ensure that the ethics research protocol is adhered to.

Transcript data will be stored on the University electronic network within an encrypted password protected document for 10 years, after which they will be destroyed.

Participant wellbeing:
It is possible due the nature of the interview schedule that participants may become upset when talking about their experiences of undergoing CPM and the impact on their quality of life. Should a participant become upset, the researcher will use their therapeutic skills, as a trainee clinical psychologist, to contain and manage that distress. Moreover, being a trainee clinical psychologist trained in risk assessment will allow identification of whether there is significant risk to the participant. The researcher will offer to break or stop the interview if necessary. Moreover, the field supervisor [redacted] is also a clinical psychologist and participants will be offered to speak with her, if required, to discuss the impact of the interview. [redacted] has agreed to offer a telephone discussion soon after the interview to discuss the issues raised for the participant. Thereafter, a formal appointment will be offered by [redacted] within 2-3 weeks of the interview to discuss the impact of the interview in person, and the participant can meet with [redacted] for as many sessions as required. [redacted] will also signpost the participant to other appropriate services if required.

After the interview, all participants will be provided with a debrief sheet (Appendix 5) which includes a list of relevant agencies to contact independently for any further support.

Participants feeling obliged to take part:
As the breast surgeon and breast care nurses will be assisting the recruitment process, it is important to ensure the potential participants do not feel obliged to take part or feel it will affect their care. This has been addressed by making clear on the participant information sheet (Appendix 2.1) that this will not be the case. Although the breast surgeons and breast care nurses may have the details of potential participants interested in hearing about the study, they will not have any information on which participants have agreed to finally take part. All participants will remain anonymous.

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.*

To explore the experience and decision-making process of women undergoing contralateral prophylactic mastectomy who are within the low-to-medium risk group of secondary (contralateral) cancer. The purpose of this information is to to provide more comprehensive information to clinicians and women contemplating this procedure.

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

Secondary research questions include:

What reasons do women describe for having contra-lateral mastectomy?

Women's hopes/fears before surgery

What are the psychological and social outcomes of undergoing contra-lateral mastectomy in women with low to medium risk of secondary breast cancer?

How does the surgery affect women's long-term psychological and social functioning?

How satisfied/dissatisfied are women with the contra-lateral mastectomy? What factors are associated with this satisfaction/dissatisfaction?

What impact has the procedure had on women's body image/self-esteem/sexuality/mental health etc?

What impact has the procedure had on relationships and interactions with others?

What information would these patients benefited from before undergoing the surgery.

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

Breast cancer is the most common form of cancer within England and Wales, affecting more than 40,000 women each year (NICE, 2009). As such, women who have been diagnosed with unilateral breast cancer (cancer in one breast) may request a contralateral prophylactic mastectomy (CPM), or a double mastectomy, of the non-cancerous breast. This is referred to as a risk-reducing procedure and is considered beneficial for women within the high risk group of developing contralateral breast cancer (cancer within the other breast). Women falling in the high risk group are those who have a significant family history of cancer or have mutative BRCA1 and BRCA2 genes.

However, there are an increasing number of women who do not have the presence of these risk factors, falling into the low-to-medium risk group who are increasingly requesting this surgery. Research suggests women with unilateral cancer are at increased risk of developing cancer within the same breast again, as opposed to developing contralateral breast cancer (Brewster & Parker, 2011). Moreover, it is thought women over-estimate the risk of contralateral breast cancer, and therefore surgeons view CPM in women within the low-to-medium risk group as an unnecessary, mutilating procedure (Spear, Carter, & Schwarz, 2004).

There is limited information regarding the clinical value, risks, and benefits of women undergoing CPM who are within the low-to-medium risk group. Therefore, surgeons are uncertain on how to advise women who are contemplating this procedure, with decisions being made upon the information based upon the high-risk group.

Research suggests a number of factors that may influence a woman's decision to undergo CPM. This includes, cancer-related anxiety and distress, fear of cancer developing in the contralateral breast, perceived risk, body image issues (wanting symmetry/balance after reconstruction of both breasts), and uncertainty about cancer (Brewster & Parker, 2011).

However, although research on women who are within the high-risk group suggests women are generally satisfied with their decision to undergo CPM, as it reduces future cancer worry in the contralateral breast, many women report negative outcomes in relation to the procedure. Specifically, the reconstructive aspect of the surgery can cause negative impact on a woman's sexuality, relationships, and body image (Patenaude, et al., 2008). Moreover, research conducted on women within the high risk group suggests women often have unrealistic expectations of the reconstruction after CPM and accordingly become disappointed with the results. Reconstruction is not always successful, leaving some women with an unnatural look or reduced nipple sensation (Altshuler, 2007). This can leave women experiencing feelings of loss (Patenaude et al., 2008).

Furthermore, the decision to undergo CPM is often made at the time of diagnosis when a woman feels overwhelmed with the diagnosis. However, given the aforementioned issues, it seems important for women to make a more informed decision with the support of psychological services.

Undertaking this research will allow understanding of the motivations, perceptions, and resulting experiences of women who have undergone CPM within the low-to-medium risk group. This understanding will inform clinicians on how to best advise other women contemplating this procedure and aid the process of devising patient-information for women contemplating this procedure. Additionally, this research can highlight how a psychology services can better facilitate the decision-making process and understand the psycho-social impact of CPM in women within the low-to-medium risk group of contralateral breast cancer.

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.*

Once ethical clearance has been granted from the ethics and R and D department, the breast surgeons and breast care nurses will access the medical records at [redacted] (this has been discussed and agreed by the breast surgeons and nurses)and identify which women fulfill the the following inclusion/exclusion criteria:

Inclusion criteria:
Women between the ages of 18-65 years
Women with unilateral breast cancer and within the low to medium risk category of contralateral breast cancer who have undergone CPM and reconstructive surgery.
Patients who are not currently receiving any adjuvant treatment e.g. chemotherapy (as this itself can be physically and psychologically draining).
Interview women who are within the 12-24 months post-surgery (initially as per stage 1 of the recruitment process) period.

Exclusion criteria:
Women within the medium to high risk group for contralateral breast cancer. This includes excluding:
- Women with high contralateral breast cancer risk factors such as mutated BRCA1 and BRCA2 genes.
-Women with a significant family history of breast cancer.
Women with a re-occurrence of cancer or any other major illness.
Women who do not speak sufficient English to undertake the interview.

Potential participants who fulfill the above criteria will be sent a participant information pack which includes a participant information sheet (Appendix 2) and a contact sheet (Appendix 3) via post to their home address. If potential participants wish to participate or would like further clarity on the study they will be requested to complete the contact

form (Appendix 3)and return it via the pre-paid envelope provided within the information pack. The potential participants will be requested to to take a minimum of 24 hours to consider their participation.

Once contact sheets have been returned the researcher will contact the potential participant to discuss any further questions the participant may have. If they decide to take part in the study after this, the researcher will arrange a suitable time and data for the interview at a location convenient to the participant. This will be either at their home or within a clinic room at [redacted] On the date of the interview, participants will read and sign a consent form (Appendix 4) before commencing the interview.

The recruitment process will employ a phased approach. That is, it is intended to initially recruit women within the 12-24 month post-surgery time bracket (stage 1) to limit the variation of experiences and allow enough time to pass post-surgery for recovery and completion of reconstruction. However, it is acknowledged that this can limit the participant pool and if enough participants are not recruited within Stage 1, Stage 2 will be employed. Stage 2 will be implemented four weeks after stage 1 if enough participants have not been recruited and will involve sending out the same information packs to women within the 24-36 month post-surgery time bracket. If after this, enough participants are not recruited, Stage 3 will be implemented for weeks after Stage 2. This will involve the same process as stage 1 and 2, however, will involve sending information packs to women within the 36-48 month post-surgery time bracket. At each phase of the recruitment, all potential participants will be sent a reminder letter/information sheet (Appendix 2.2 and 2.3) of the study two weeks after the initial participant information packs have been sent out.

All the interviews will use a semi-structured interview schedule (Appendix 1) to explore the experiences of women with low-to-medium risk of contralateral breast cancer who have chosen to undergo a contralateral prophylactic mastectomy (CPM). Each interview will last approximately one hour, and participants will be interviewed once. However, in the exception that the participant wants to stop the interview mid-way and would like to continue on another date and time, then another time will be scheduled. After the interview, participants will be given a debrief sheet (Appendix 5)which includes a list of contact details for support agencies that they may contact if required.

A digital recorder will also be used to record all interviews carried out. The interviews will then be transcribed by the researcher. Interpretative Phenomenological Analysis (IPA) will be used to analyse the qualitative data collected as it will allow the researcher to identify themes that would give meaning and help to understand participants' experiences after undergoing CPM.

A summary of the final report will be sent to participants if requested.

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?

- [x] 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.
Service users were present during the peer review process before deciding on the final project. This process formed part of the University procedure when designing a project. A letter confirming this peer review process can be found in Appendix 6.
Service users provided feedback and suggestions for the propo sed project.

All participants that took part in the study will receive a summary of the final report if requested.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

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

Women between the ages of 18-65 years

Women with unilateral breast cancer and within the low to medium risk category of contralateral breast cancer who have undergone CPM and reconstructive surgery.

Patients who are not currently receiving any adjuvant treatment e.g. chemotherapy (as this itself can be physically and psychologically draining).

Interview women who are within the 12-24 months post-surgery (initially as per Stage 1 of the recruitment process) period

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

Women within the medium to high risk group for contralateral breast cancer. This includes excluding:
- Women with high contralateral breast cancer risk factors such as mutated BRCA1 and BRCA2 genes.
- Women with a significant family history of breast cancer.

Women with a reoccurrence of cancer or any other major illness.

Women who do not speak sufficient English to undertake the interview.

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
Information giving/opportunity for interested participants to ask questions about research study	1	0	30 minutes	Principal Investigator, telephone or email
Reading participant information sheet	1	0	up to 30 minutes	Participant would read information regarding the study in their own time at their home
Informed consent and research interview	1	0	1 hour & 15 minutes	Principal Investigator, either within clinic room at Burnley General Hospital or participant's home

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

Each participant will only be involved during the semi-structured interview part of the study, which is expected to last for approximately one hour and fifteen minutes. However, in addition to this the participant would need to set aside time to read the information sheet, complete the contact form (sent through the post), and discussing and arranging a time for interview. The latter would take an additional fifteen minutes.

Participants who request to receive a copy of a summary of the report will receive this via post.

No other involvement is required of 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.

The issues that have needed to be addressed before conducting this study have been separated into two categories, ethical and practical.

Ethical:

Right to withdraw: All service users who participate in this study will be allowed to withdraw their data for up to two weeks after the interview. A request to withdraw after this point may not be possible as the data collected may have been already analysed and themes elicited. It would therefore be difficult to separate individual data and themes from the pool collected.

Psychological support: If during the interview the participant feels upset/distressed the investigator will stop the interview and allow the participant time to settle and utilise her skills as a trainee clinical psychologist to contain the participant's emotions. If the participant is comfortable to continue the investigator will resume the interview or rearrange another appointment. If they feel they cannot continue, the interview will stop and the participant's data will be removed from the study. In addition to this, if during or after taking part in this study the participant's feel they need emotional support, they will be able to contact the researcher's field supervisor, [redacted] (clinical psychologist) for support. The participant will also be provided with contact details for other support agencies such as Breast Cancer Care and Macmillan Cancer Support.

Data protection: All the data with participant identifiers will be stored separately from the data (to ensure the data and identifiers cannot be matched) on the Lancaster University computer systems and on the researchers desktop computer. All data will be password protected and encrypted to ensure confidentiality.

Practical

Burdens regarding the logistics of the interview is minimised by allowing participants to choose to be interviewed either at home or at Burnley General hospital at a time most convenient to them. Moreover, all participants will be able to claim back travelling costs, up to a maximum value of £10 that they may occur to participate in this study.

Questions during interview: The researcher will cover the same topics with all participants, however, will follow the participants' lead on a discussion if it is relevant to the study.

The researcher will endeavor to maintain confidentiality. Whilst direct quotes will be used in the final report, no personal identifying information will be included that would compromise participant anonymity.

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:

Participants will be informed within the information sheet that if they do not want to answer any specific questions, they can refuse to answer without giving a reason why.

As the study entails the use of a semi-structured interview schedule, it leaves the discussion open to the participant in terms of what they want to disclose within the interview. The interview schedule provides a guide to the researcher, and therefore questions can be added or modified depending on the responses of the participant.

The boundaries of confidentiality (British Psychological Society, 2006) will be explained clearly to all participants prior to the interview. There may be circumstances in which the researcher has concerns about the participant's risk of harm to themselves or others, which will need to be passed on. If a breach of confidentiality is required under these circumstances, the researcher will inform the participant of these intentions where possible, and the relevant supervisors (field and research supervisors) will be notified.

Moreover, the points raised in question A22 will be implemented if it appears the participant is upset or distressed by the interview.

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

It is not anticipated that the participants in this study will receive any direct benefit from taking part in this study, although some people do find it helpful and therapeutic to share their experiences. Moreover, their experiences can

benefit other women contemplating this procedure.

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

The only potential risk for the researcher could be if the participants are interviewed within their own home. To reduce this risk the researcher will adhere to the Lancaster University lone working policy. Specifically, the researcher will organise a 'check in' system with a colleague, informing them of the time of the study and an approximate time that the researcher will 'check-in' following the completion of the interview. Should the researcher fail to contact the colleague, they will attempt to contact the researcher by phone. Prior to the interview, the researcher will provide an envelope with the name, location, and address of the participant in a sealed envelope, that will only be opened in the event that the researcher fails to contact the appointed person within the agreed time frame and does not answer their phone call. This is to ensure the safety of the researcher and the participants, and confidentiality will only be broken if deemed necessary. If the researcher does not return the colleagues phone call within fifteen minutes of the agreed time frame, the colleague will open the envelope and call the police.

After the interview, the researcher will obtain the sealed envelope from the supervisor/colleague and dispose of this securely by utilising an electronic shredder.

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).*

After gaining permission from the relevant ethics and R&D department, the breast surgeons and breast care nurses who already have access to medical records within [redacted] will check and identify patients (potential participants) who fulfill the inclusion/exclusion criteria.

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:
The breast care nurses and surgeons involved in the patients' care

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

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

All potential participants will initially be approached or receive initial information regarding the study via the participant information sheet (written by the researcher) that will introduce them to the researcher and the nature of the study. However, this information will be sent out by the breast surgeons and breast care nurses.

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.

When participants have read the information sheet, completed the contact form and have been contacted by the researcher, a convenient time and location for interview will be arranged. Prior to the interview commencing the participant will be asked to read a consent form (Appendix 4) which both the participant and the researcher will be required to sign.

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?

All participants will be asked to take a minimum of 24 hours to consider their participation as noted within the participant information sheet. Participants will also have time to decline between the time they post out the contact sheet and the phonecall they receive from the researcher.

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)*

As this is a student project, translators/interpreters cannot be utilised due to a lack of funding. Therefore, participants who can speak fluent English will be approached as per the research protocol.

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:

Consent will be taken immediately before the interview takes place, and will be taken from participants that are considered to have capacity to consent. This means whilst the interview is being conducted all participants will be considered to have capacity. if participants lose capacity after the interview date, this will not be known by the researcher, therefore continued capacity will be assumed.

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:
See details below.

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.*

Confidentiality and anonymity will be discussed with each partici pant prior to the interview. Personal identifying information will be removed from written transcripts and pseudonyms assigned. Only the researcher will have access to this password protected and encrypted document in which participant names are recorded alongside pseudonyms.

Audio files will be transferred to a secure comput er to an encrypted password protected document as soon as the researcher returns home and will be deleted from the portable recording device immediately after this.

This information and all data will be saved on the university network within an encrypted file (password protected) and will be accessed securely through the university secure netowrk which is considerable as a more secure method when storing personal data.

Where direct quotes are used in written reports, these will be anonymised and any other personal identifiers removed.

The limits of confidentiality (British Psychological Society, 2006) will also be explained clearly to each participant prior to interviewing. There may be circumstances in which the researcher has concerns abour risk of harm, which will need to be passed on. If a breach of confidentiality is required under these circumstances, the researcher will inform the participant of these intentions where possible, and the relevant supervisors will be notified.

Personal data such as the participants home address and telephone number will be stored within a password protected encrypted file on a home computer which only the researcher has access to. After completion of the interview, this information will be destroyed/deleted.

Participant names will be exchanged for ps eudonyms in an encrypted password protected document known only to the researcher. The allocated pseudonym will be used throughout the transcript, and any other personal identifying information will be removed.

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 will have access to the contact details of participants whom volunteers their participation. These will be kept on a secure password protected and encrypted document until completion of the interview, after which they will be destroyed.

Anonymised transcripts will restricted by being vi ewed by the researcher (Fehmida Patel) and the research supervisor [redacted]. The research supervisor will have access to the audio transcripts to monitor and provide feedback on the quality of analyses. The field supervisor [redacted] will only see anonymised excerpts of the transcripts so there is no possibility that she could identify participants from the transcripts.

The researcher will receive ongoing academic and clinical supervision throughout the study, for development purposes and to ensure that the ethics research protocol is adhered to.

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.
The participants will not be paid for their participation in the study. However they will be able to claim back travelling costs, up to a maximum value of £10 that may occur to participate within the study.

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)

Findings of the study will be presented by the researcher during a research presentation day at Lancaster University. A copy of the final report will be made available to the service in which the participants were recruited.

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.
If participants would like to be informed of the findings of the study (they can request this at interview), they will be provided, by post or email a summary report of the findings once the main report has been submitted.

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 of the study has been subjected to a peer review at Lancaster University and has also been discussed with the clinical team at [redacted] where the study is being conducted.

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:	10
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
It is estimated that 10 participants will be recruited for the study within the UK at Burnley General Hospital Oncology department.

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.*

A maximum sample of ten participants will be recruited, which is comparable with other qualitative studies using Interpretative Phenomenological Analysis (IPA).

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.

Once the audio recording of the interviews have been transcribed, IPA will be used to analyse the data collected. IPA will be used as it will allow the researcher to identify themes that would give meaning and help understand the participants' experience.

The aim is to identify a comprehensive account of participants' experiences through a process of reflection and re-examination of the transcripts which have significance within the original transcripts.

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
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Mobile

Work Email [redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Lancaster University, RSO, B Floor, Bowland Main
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

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

[redacted]

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: 20/11/2013
Planned end date: 31/05/2014
Total duration:
Years: 0 Months: 6 Days: 12

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 1

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	1
☐ NHS organisations in Wales	
☐ 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)

Lancaster University legal liability cover 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)

Lancaster University legal liability cover 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)

Normal NHS indemnity will apply as the researcher is an NHS employee employed by Lancashire Care NHS trust.

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 [redacted]	Title [redacted]

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: Fehmida Patel

Date: *(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. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. 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.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. 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:

Post:

Organisation:

Date: *(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: [redacted]

[redacted] [redacted]

[redacted] [redacted]

Date: *(dd/mm/yyyy)*

Appendix 4-H: REC Approval Letter

National Research Ethics Service

07 March 2014

Miss Fehmida Patel
Lancaster University, C16 Furness College,
Lancaster
LA1 4YG

Dear Miss Patel

Study title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).
REC reference: [redacted]
IRAS project ID: 143457

The Research Ethics Committee reviewed the above application at the meeting held on 28 February 2014. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter.
Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager [redacted]

Ethical opinion

The Chair welcomed you to the REC and thanked you for attending to discuss the study. The Committee told you that this is a really good study addressing a very important question.

The Committee noted that 10 participants are required and asked you how you will recruit up to the sample size and what you would do if too many volunteer. You told the Committee that you are looking for 6-10 participants but if you get up to 15 this will be better. You will invite 30 women initially and will stop sending out packs if you get more than 15 volunteers. At that stage you will contact them to say that the study has reached saturation point and decline their participation. The Committee asked that a sentence be added to the Participant Information Sheet to this effect.

The Committee asked for the pool size and you said that there are 10—15 people who meet the initial inclusion criteria.

The Committee commented that the phasing is very good and told you they could see a lot of thought has gone into it.

The Committee pointed out that the application states an hour for the interview in one part and an hour and a quarter in another. They asked you to ensure the Participant Information Sheet is correct and asked that if it is potentially an hour and a quarter, this longer time be stated.

The Committee asked you whether the participants would be familiar with the term contralateral prophylactic mastectomy and you stated that according to breast surgeons they will be familiar with this term and it is the best term to use.

The Committee asked whether cancer dept is the most used terminology for the department, and you said that it is on the letters and is used interchangeably with oncology. It is used frequently at the [redacted] site.

The Committee asked that the Consent Form be revised to provide for consent to the use of anonymised direct quotes and to include the standard regulatory clause.

The Committee requested changes to the Participant Information Sheet as detailed below.

The Committee commended you on the very clear explanation of the process in the Participant Information Sheet.

The Committee asked that the debrief sheet be amended as below.

You confirmed for the Committee that the service users consulted in the design of the study are the review panel.

The Committee asked how results of the study will be disseminated, and you explained that you will inform participants at the interview that they can have the results if they wish and will take their details and store them on a secure password protected device until they are needed. The Committee suggested you might wish to add a tear off to the Consent Form as another option.

The Committee asked that the debrief sheet include the telephone number for the Haven. You said that you have not been able to find one but will look again.

You asked the Committee whether you should change the REC form and was advised that this is not necessary.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

a. The Committee would like to see the Participant Information Sheet revised to

i) Change the paragraph title “How long will the interview last?” to “What will I have to do if I agree to take part?” and start the paragraph with “You will have to be interviewed by the researcher about your experience”

ii) Include the correct timing for the interview

iii) Under “What will happen after the interview ends?” include a sentence after the report on the third line. “However, I may use anonymised direct quotes, with your permission, in writing up the findings.”

iv) Include a sentence at the end of “Do I have to take part?” “If too many people volunteer I will contact you to thank you for your interest and advise that I will not be asking to for an interview on this occasion”

v) Include a contact point and telephone for complaints for someone independent of the study

vi) Include a telephone number for the Haven or advise no telephone contact

vii) Give the correct name of the reviewing committee – [redacted]

b. The Committee would like to see the Consent Form revised to

i) Include a further clause “I understand that data from the study may be looked at by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this study. I consent to these individuals having access to this information”

ii) **Optional –** include a tear off clause to request study results and leave contact details

c. The Committee would like to see the debrief sheet revised to

i) Change “will allow services to develop…” to “may allow services to develop..”

ii) Include the telephone number for the Haven if found or state no telephone

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact [redacted], the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		08 January 2014
Evidence of insurance or indemnity		08 January 2014
Interview Schedules/Topic Guides	1	08 January 2014
Investigator CV	Patel	
Investigator CV	Murray	
Letter from Sponsor		06 February 2014
Other: PIS Reminder	1	08 January 2014
Other: Reminder cover letter	1	08 January 2014
Other: Participant Contact Sheet	1	08 January 2014
Other: Participant Debrief Sheet	1	08 January 2014
Other: Peer Review Letter		08 January 2014
Participant Consent Form	1	08 January 2014
Participant Information Sheet	1	08 January 2014
Protocol	1	08 January 2014
REC application	3.5	13 February 2014

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website After Review

14/NW/0114 Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments "After ethical review – guidance for researchers"

NRES Committee North West - Preston

Attendance at Committee meeting on 28 February 2014

Committee Members:

Name	*Profession*	*Present*
[redacted]	Lay member	Yes
	Lay Member	Yes
	Consultant Cardiologist	No
	Acute Care Manager	Yes
	Lay Member	No
	Service Improvement Manager	Yes
	Lay Member	Yes
	Radiographer	Yes
	Consultant Orthopaedic Surgeon	Yes

Appendix 4-I: Confirmation of REC conditions met

NHS
Health Research Authority
National Research Ethics Service

Dear Miss Patel

Study title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).
REC reference: [redacted]
Protocol number: N/A
IRAS project ID: 143457

Thank you for your email of 12 March. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 07 March 2014

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other: Debrief Sheet	2	11 March 2014
Other: covering email		12 March 2014
Participant Consent Form	2	11 March 2014
Participant Information Sheet: Reminder sheet	2	11 March 2014
Participant Information Sheet	2	11 March 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering Letter		08 January 2014
Evidence of insurance or indemnity		08 January 2014
Interview Schedules/Topic Guides	1	08 January 2014
Investigator CV	Patel	
Investigator CV	[redacted]	
Letter from Sponsor		06 February 2014
Other: Reminder cover letter	1	08 January 2014
Other: Participant Contact Sheet	1	08 January 2014
Other: Peer Review Letter		08 January 2014
Other: Debrief Sheet	2	11 March 2014
Other: covering email	1	2 March 2014
Participant Consent Form	2	11 March 2014
Participant Information Sheet: Reminder sheet	2	11 March 2014
Participant Information Sheet	2	11 March 2014
Protocol	1	08 January 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

[redacted]
Please quote this number on all correspondence

Yours sincerely
REC Manager

Appendix 4-J: REC Amendment Approval Letter

NHS
Health Research Authority
National Research Ethics Service

Miss Fehmida Patel
Lancaster University, C16 Furness College,
Lancaster
LA1 4YG

Dear Miss Patel

Study title: The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM).
REC reference: [redacted]
Protocol number: N/A
Amendment number: 1
Amendment date: 23 May 2014
IRAS project ID: 143457

Change to inclusion criteria, extend to non NHS sites specifically Internet

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Sub-Committee had no ethical issues with this amendment.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	23 May 2014
Other [Project Flyer]	1	23 May 2014
Participant information sheet [Internet Recruitment]	1	23 May 2014
Research protocol or project proposal	2	23 May 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

[redacted] **Please quote this number on all correspondence**

Yours sincerely
Chair

Appendix 4-H: R&D Approval Letter and Letter of Access

Research and Development
2014/006 Our Ref:
Your Ref:

10 March 2015

Fehmida Natha (nee Patel)
Trainee Clinical Psychologist
Lancaster University
C16 Furness College
Lancaster
LA1 4YG

Dear Fehmida

Letter of access for research

This letter should be presented to each participating organisation before you commence your research at that site.

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on 12 March 2015 and ends on 31 August 2015 unless terminated earlier in accordance with the clauses below.

As an existing NHS employee you do not require an additional honorary research contract with the participating organisation. The organisation is satisfied that the research activities that you will undertake in this organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this organisation that the necessary pre-engagement checks are in place in accordance with the role you plan to carry out in this organisation. Evidence of checks should be available on request to your employer.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving this organisation's permission to conduct the project.

You are considered to be a legal visitor to NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and NHS Trust, in particular that of an employee.

While undertaking research through NHS Trust, you will remain accountable to your employer, , but you are required to follow the reasonable instructions of your nominated manager in each organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Trust in discharging its duties under the Health and Safety at Work etc Act 197 4 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Trust premises.

Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each participating [Insert organisation] prior to commencing your research role at each site.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The organisation will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this organisation accept no responsibility for damage to or loss of personal property.

This letter may be revoked and your right to attend this organisation terminated at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the organisation that employs you through its normal procedures. You must also inform the nominated manager in each participating organisation .

Yours sincerely

Associate Medical Director for Research and Development

Appendix 4-I: Site Specific Approval

[redacted] [redacted] NHS

[redacted] [redacted]

7 April 2015

Miss Fehmida Patel
Trainee Clinical Psychologist
Lancashire University
C16 Furness College
Lancaster
LA1 4YG

Dear Miss Patel

Study Title: **The Experience and Decision-Making Process of Women with Low to Medium Risk of Contralateral Breast Cancer who Have Chosen to Undergo a Contralateral Prophylactic Mastectomy (CPM)**
R&D Ref: **2015BR002**
REC Ref: **14/NW/0114**
CSP Ref: **n/a**

Thank you for providing all of the documentation for the above study.

I am pleased to inform you that the above referenced study has been given Trust R&D approval and you may begin your study at [redacted]

The approval has been granted for the duration of the REC approval for the study.

The list of documents reviewed and approved for use are as follows:

Document	Version	Date
Protocol	2.0	23.05.14
Participant Information Sheet	2.0	11.03.14
Participant Information Sheet: Internet recruitment	1.0	23.05.14
Consent Form	2.0	11.03.14
Project Flyer	1.0	23.05.14
Interview Schedule	1.0	08.01.14
Participant Reminder Sheet	2.0	11.03.14
Reminder Covering Letter	1.0	08.01.14
Contact Sheet	1.0	08.01.14
Debrief Sheet	2.0	11.03.14
For your information I confirm we have the corresponding regulatory approval letters for each of the current approved documents listed above.		

Appendix 4-J: Author Guidelines

Manuscript Submission Guidelines: *Qualitative Health Research* (QHR)

Qualitative Health Research (*QHR*) is an international, interdisciplinary, refereed journal for the enhancement of health care and furthering the development and understanding of qualitative research methods in health care settings. We welcome manuscripts in the following areas: the description and analysis of the illness experience, health and health-seeking behaviors, the experiences of caregivers, the sociocultural organization of health care, health care policy, and related topics. We also consider critical reviews; articles addressing qualitative methods; and commentaries on conceptual, theoretical, methodological, and ethical issues pertaining to qualitative inquiry.

1. Article types
Each issue of QHR provides readers with a wealth of information - book reviews, commentaries on conceptual, theoretical, methodological and ethical issues pertaining to qualitative inquiry as well as articles covering research, theory and methods in the following areas:
Description and analysis of the illness experience
Experiences of caregivers
Health and health-seeking behaviors
Health care policy
Sociocultural organization of health care

A Variety of Perspectives
QHR addresses qualitative research from variety of perspectives including: cross-cultural health, family medicine, health psychology, health social work, medical anthropology, medical sociology, nursing, pediatric health, physical education, public health, and rehabilitation.

In-Depth Timely Coverage
Articles in QHR provide an array of timely topics such as: experiencing illness, giving care, institutionalization, substance abuse, food, feeding and nutrition, living with disabilities, milestones and maturation, monitoring health, and children's perspectives on health and illness.

2. Editorial policies

2.1 Peer review policy

QHR strongly endorses the value and importance of peer review in scholarly journals publishing. All papers submitted to the journal will be subject to comment and external review. All manuscripts are reviewed initially by the Editors and only those papers that meet the scientific and editorial standards of the journal, and fit within the aims and scope of the journal, will be sent for outside review.
QHR adheres to a rigorous double-blind reviewing policy in which the identity of both the reviewer and author are always concealed from both parties. Please refer to the editorial on blinding found in the Nov 2014 issue: http://qhr.sagepub.com/content/24/11/1467.full.

2.2 Authorship

Papers should only be submitted for consideration once consent is given by all contributing authors. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.
The list of authors should include all those who can legitimately claim authorship. This is all those who:
(i) Made a substantial contribution to the concept and design, acquisition of data or analysis and interpretation of data,
(ii) Drafted the article or revised it critically for important intellectual content,
(iii) Approved the version to be published.

Authors should meet the conditions of all of the points above. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.
Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section.
Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.

2.3 Acknowledgements

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

2.3.1 Writing assistance

Individuals who provided writing assistance, e.g. from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgements section.
Authors must disclose any writing assistance – including the individual's name, company and level of input – and identify the entity that paid for this assistance").
It is not necessary to disclose use of language polishing services.
Please supply any personal acknowledgements separately to the main text to facilitate anonymous peer review.

2.4 Funding
QHR requires all authors to acknowledge their funding in a consistent fashion under a separate heading. Please visit the Funding Acknowledgements page on the SAGE Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

2.5 Declaration of conflicting interests
It is the policy of QHR to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.
Please ensure that a 'Declaration of Conflicting Interests' statement is included at the end of your manuscript, after any acknowledgements and prior to the references. If no conflict exists, please state that 'The Author(s) declare(s) that there is no conflict of interest'.
For guidance on conflict of interest statements, please see the ICMJE recommendations here

2.6 Research ethics and patient consent
Medical research involving human subjects must be conducted according to the World Medical Association Declaration of Helsinki.
Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, and all papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you have provided the full name and institution of the review committee, in addition to the approval number.
For research articles, authors are also required to state in the methods section whether participants provided informed consent and whether the consent was written or verbal.
In terms of patient privacy, authors are required to follow the ICMJE Recommendations for the Protection of Research Participants. Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published. Participant descriptors should not be listed individually. Because qualitative research is descriptive, it is recommended that participant quotations not be linked to identifiers in the manuscript.

2.7 Clinical trials
QHR conforms to the ICMJE requirement that clinical trials are registered in a WHO-approved public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. The trial registry name and URL, and registration number must be included at the end of the abstract.

2.8 Reporting guidelines
The relevant EQUATOR Network reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed Consolidated Standards of Reporting Trials (CONSORT) flow chart as a cited figure, and a completed CONSORT checklist as a supplementary file.
Other resources can be found at NLM's Research Reporting Guidelines and Initiatives.

2.9 Data
SAGE acknowledges the importance of research data availability as an integral part of the research and verification process for academic journal articles.
QHR requests all authors submitting any primary data used in their research articles alongside their article submissions to be published in the online version of the journal, or provide detailed information in their articles on how the data can be obtained. This information should include links to third-party data repositories or detailed contact information for third-party data sources. Data available only on an author-maintained website will need to be loaded onto either the journal's platform or a third-party platform to ensure continuing accessibility. Examples of data types include but are not limited to statistical data files, replication code, text files, audio files, images, videos, appendices, and additional charts and graphs necessary to understand the original research. [The editor(s) may consider limited embargoes on proprietary data.] The editor(s) [can/will] also grant exceptions for data that cannot legally or ethically be released. All data submitted should comply with Institutional or Ethical Review Board requirements and applicable government regulations. For further information, please contact the editorial office at vshannonqhr@gmail.com.

3. Publishing Policies
3.1 Publication ethics
SAGE is committed to upholding the integrity of the academic record. We encourage authors to refer to the Committee on Publication Ethics' International Standards for Authors and view the Publication Ethics page on the SAGE Author Gateway

3.1.1 Plagiarism
QHR and SAGE take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. We seek to protect the rights of our authors and we always investigate claims of plagiarism or misuse of articles published in the journal. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked using duplication-checking software. Where an article is found to have plagiarised other work or included third-party copyright material without permission or with insufficient acknowledgement, or where authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting the article (removing it from the journal); taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; banning the author from publication in the journal or all SAGE journals, or appropriate legal action.
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4. Preparing your manuscript

4.1 Word processing formats
Preferred formats for the text and tables of your manuscript are Word DOC, RTF, XLS. LaTeX files are also accepted. The text should be double-spaced throughout and with a minimum of 3cm for left and right hand margins and 5cm at head and foot. Text should be standard 10 or 12 point. Word and LaTex templates are available on the Manuscript Submission Guidelines page of our Author Gateway.

4.2 Artwork, figures and other graphics
For guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit SAGE's Manuscript Submission Guidelines. Please refer to clause 4.5 for information on SAGE Language Services.
Figures supplied in color will appear in color online regardless of whether or not these illustrations are reproduced in colour in the printed version. For specifically requested color reproduction in print, you will receive information regarding the costs from SAGE after receipt of your accepted article.

4.3 Supplementary material
This journal is able to host additional materials online (e.g. datasets, podcasts, videos, images etc) alongside the full-text of the article. These will be subjected to peer-review alongside the article. For more information please refer to our guidelines on submitting supplementary files, which can be found within our Manuscript Submission Guidelines page.

4.4 Journal layout
In general, QHR adheres to the guidelines contained in the Publication Manual of the American Psychological Association ["APA"], 6th edition (ISBN 10:1-4338-0561-8, softcover; ISBN 10:1-4338-0559-6, hardcover; 10:1-4338-0562, spiral bound), withregard to manuscript preparation and formatting. These guidelines are referred to as the APA Publication Manual, or just APA. Additional help may be found online at http://www.apa.org/, or search the Internet for "APA format."

4.5 Reference style
QHR adheres to the APA reference style. Click here to review the guidelines on APA to ensure your manuscript conforms to this reference style.

4.6 English language editing services
Authors seeking assistance with English language editing, translation, or figure and manuscript formatting to fit the journal's specifications should consider using SAGE Language Services. Visit SAGE Language Services on our Journal Author Gateway for further information.

5. Submitting your manuscript

5.1 How to submit your manuscript

QHR is hosted on SAGE Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts. Visit http://mc.manuscriptcentral.com/qhr to login and submit your article online.

5.2 Title, keywords and abstracts

Please supply a title, short title, an abstract and keywords to accompany your article. The title, keywords and abstract are key to ensuring readers find your article online through online search engines such as Google. Please refer to the information and guidance on how best to title your article, write your abstract and select your keywords by visiting the SAGE Journal Author Gateway for guidelines on How to Help Readers Find Your Article Online

5.3 Corresponding author contact details

Provide full contact details for the corresponding author including email, mailing address and telephone numbers. Academic affiliations are required for all co-authors. These details should be presented separately to the main text of the article to facilitate anonymous peer review.