3. Methods

3.1 Study design

This study used a qualitative research design which was most appropriate as it allows for the exploration of participants beliefs and their underlying reasoning through one to one interviews. A semi structured interview guide was developed around the phenomenon being investigated.

This interview study aimed to explore health beliefs and the reasons for these amongst BRCA carriers. The key objectives of the interviews were to explore women's perceptions of their breast cancer risk and behaviours targeted at reducing that risk. Experiences of family history of cancer as well as perceived control over personal risk and potential interest in diet prevention strategies and studies were also explored.

3.2 Sampling

The appropriate use of sampling is important in qualitative research in order to avoid problems due to generalisability (Silverman, 2005). A common approach in qualitative research is to use non-probability sampling such as theoretical sampling (sampling with the purpose of answering the research question). This is achieved by the deliberate inclusion of participants who possess characteristics relevant to the social phenomenon being investigated (May & Pope, 1995). In this study purposeful sampling was employed. The subjects selected were representative of the population being studied (BRCA carriers), they included as much variation as possible in factors which may affect attitudes and behaviours towards reducing cancer risk (education background, marital status, age, BMI)

and the number of individuals included was large enough to be theoretically meaningful (Silverman, 2005). Suitable women were identified from the EMBRACE study / North West BRCA database. The North West BRCA database is a research database and those entered have previously expressed interest in being invited to enter future research studies. The EMBRACE study is funded by Cancer Research UK, to establish the best way to manage those who have inherited a BRCA1 or BRCA2 mutations. The EMBRACE study aims to create a register of people with BRCA mutations and their relatives. To ensure that all viewpoints were represented purposeful sampling was used to recruit:

1. Known carriers of BRCA1 or BRCA2 mutations who have not previously been diagnosed with breast or ovarian cancer.
2. Known BRCA1 or BRCA2 mutation-carriers who have been treated for unilateral breast cancer (including DCIS) and who have no evidence of metastatic disease.
3. Unaffected 1st degree relatives of BRCA1 or 2 mutation carriers who have not had genetic testing who are at 50% risk of being a carrier.

The aim was to include women who were above and below the median age and weight within each of these groups, to ensure that the group studied was representative of the overall population of BRCA women. In addition we aimed to recruit BRCA2 carriers from families with different cancers in their family (breast, ovarian, pancreatic) as their experience of different cancers may influence health beliefs. This proved difficult as the database did not contain all the relevant information required to enable this.

Additional inclusion criteria were:

- At least 1 year since identified as a BRCA carrier.
- Aged > 18 years.

Specific exclusion criteria were:

- Breast cancer patients currently receiving chemotherapy / radiotherapy for breast cancer.
- Unaffected women who have had bilateral mastectomy.
- To only target recruitment to one member from each family to gain a range of views from a diverse number of families.
- BRCA1 or 2 mutation carriers identified within the past 12 months as these women may be coming to terms with their status and may be considering prophylactic surgery.

3.3 Sample size

A modified grounded theory approach was utilised and the number recruited was dependent on reaching saturation point in the data i.e. no new themes emerged in data collection and analysis (Ritchie & Lewis, 2003; Silverman, 2005). It was difficult to specify in advance the number to be recruited but it was anticipated that approximately 20 women would be interviewed. This was achieved by recruiting individuals one at a time, sampling from each of the three groups in turn. Where possible data collection and analysis took place concurrently, in order to allow for optimisation of the interview guide and increase the relevance of the data collected. This was not always possible as 2 interviews often took place on the same day. Data collection stopped when saturation point was

reached, this was achieved when no new information emerged from the interviews. 20 women were interviewed in total.

3.4 Recruitment and consent

Participants were targeted individually using a mailed recruitment letter until saturation point was achieved. Those who indicated interest returned the attached slip with their name, address and telephone number in a pre-paid envelope (Appendix 1). Those interested were contacted via telephone to discuss the study and the interview process was explained in more detail. This also gave the participants the opportunity to ask any questions. Participants who verbally consented were sent a more detailed information sheet (Appendix 1) and written consent form (Appendix 1). Arrangements were made to interview the participants in their own home or at Wythenshawe Hospital depending on participant preference. A date to interview was arranged a minimum of 72 hours later, this was intended to allow participants time to read the information sheet and to think about the study. It was emphasised that participants could withdraw from the study at any time and this would not affect the standard of care they received. Written consent was obtained prior to the interview. To ensure accuracy, interviews were audio recorded with participant consent. It was emphasised that the tape could be stopped at any time during the interview and that the participants could ask for part of the interview to be deleted from the tape. The participant's GP was informed (Appendix 1).

3.5 Ethical issues

This study involved dealing with a vulnerable group of people, in this case women who had been treated for unilateral breast cancer, women with first degree relatives who have had breast cancer and had died of breast cancer. This is illustrated in the cancer burden table (Table 5). No increase in distress was intended however it was possible that participants may have become distressed if they recount episodes of their care or family history which may have negative connotations. Participants would have been withdrawn from the study if they asked for the interview to be terminated or if they became distressed in any way as a result of the interview. Participants with unresolved issues and concerns would be referred (with participant consent) to Dr Penny Hopwood (Consultant Psychiatrist, Christie Hospital) for further advice and support. In her absence urgent referrals would be referred back to their general practitioner. One participant became outwardly upset during her interview and the tape was stopped. The participant reported she was already under the care of Dr Penny Hopwood. At the participant's request this interview resumed and was audio recorded. No distress was reported by any of the other participants during the study.

An additional notable ethical concern was the protection of participant's identities (Babbie, 2001). To ensure confidentiality tapes were anonymised. A professional transcribing company was used to transcribe tapes and all identifying names of individuals and localities were removed. All tape recordings were destroyed at the end of the study. Identification numbers were

used on interview transcripts. Study participants were identified by a number to ensure they remained anonymous.

Ethical approval was granted from South Manchester Local Research Ethical Committee. The research and development department of University Hospital of South Manchester NHS Foundation Trust were sponsors for the study.

3.6 Data collection

The primary data collection was through audio recordings of interviews with participants. Field notes of interviews were taken after the interviews in order to capture any interruptions or discussions relevant to the study which may have taken place before or after the interview, when the tape recorder was switched off. Data on current weight, level of activity (questionnaire) (Ekelund, 2005) was also completed by participants. Participants had the opportunity to complete a 4-day food diary to be analysed by the researcher. Those who completed a 4-day food diary received written feedback post analysis. The physical activity questionnaire and 4-day food diary were not included within the scope of this study.

Interviews were conducted at a time and location convenient to the participant. All interviews except 3 took place in their homes. These 3 interviews took place in a private room at Wythenshawe Hospital. The tape recorded section of the interviews ranged from 10 to 63 minutes (mean, 30 minutes). Socio-demographic information, weights, BMIs and physical activity questionnaire were completed when the tape recorder was switched off. Concurrent data

collection and analysis allow the findings from each interview to inform the conduct of the following interviews. Due to the use of a third party transcribing service this was not always possible, as there was some delay in receiving transcriptions of the interviews. Where possible tapes were listened to before embarking on subsequent interviews. This allowed changes to be made to the interview guide. No pilot study was carried out, however some of the questions were revised after 3 interviews, as it became clear during the interviews and re-listening to the tapes that these questions needed to be clarified because it appeared the questions were too similar to each other. The original questioning guide is shown in appendix 2. The questions provided a framework but were not necessarily asked in this order, rather they were sequenced based on the responses and direction taken by the interviewees flow of conversation. To establish a rapport interviews began with some general questions about their family background then moved onto more specific questions about their experiences and beliefs about breast cancer. The interview guide is shown in table 1 and contained pertinent areas of enquiry. All interviews were conducted by CB, following advice from trained interviewers. Two interviews were reviewed by an experienced qualitative researcher and positive feedback was given on interview technique.

Table 1. **Semi-structured interview guide**

Interview Guide
1. Could you tell me a little bit about your background, for example marital status, if you have any children? o Do you go to work? o When did you leave school (Did you leave school at 16 or did you stay on)?
2. Can you tell me something about the people who have had breast cancer in your family?
3. What do you think are the main causes of breast cancer?
4. Do you think you are at risk of breast cancer?
5. Do you think you have any control over your own risk?
6. Do you think there is anything you could do to reduce your own risk? (potential prompts: modification of risk through diet, exercise, medications, breast screening, surgery, hormone tablets, stress management, smoking cessation, complementary therapies, i.e. nutritional supplements) (Beliefs).
7. Have you changed your behaviour at all to try to reduce your breast cancer risk? (Actions)
8. Other than the changes you have already made, are there any other changes that you have considered or are considering making? (Possible actions).
9. Putting aside considerations of breast cancer. Are there any other illnesses that concern you?
10. Are there any changes you think you could make that would help prevent these illnesses?
11. Would you be interested in entering future breast cancer prevention trials?
12. Would you be interested in entering a diet and exercise based trial?
13. Would you be interested in entering a drug based trial?

3.7 Analysis

Due to the time consuming nature of transcribing a professional transcribing company was used to transcribe the tapes verbatim. The transcription of the tapes was funded by The Genesis Appeal. All transcripts were completed in a word processing package (MS_WORD 2002) and analysed using the Framework Approach (Ritchie & Lewis, 2003). Completing the analysis manually rather than using any of the available software packages, helped me to become fully emerged in the data, which enabled me to become familiar with all aspects of the data. There are computer software packages such as nVIVO available which can help to facilitate analysis. These may be beneficial as they allow data to be stored, retrieved and coded easily (Ritchie & Lewis, 2003). Access and support for this software was not available for this project.

The main approach used was Framework Analysis and elements of Discourse Analysis were also applied. The principles of Discourse Analysis were used to assess the language used when participants discussed their beliefs about their breast cancer risk and behaviours targeted at reducing that risk. It is common in qualitative research to use a combination of approaches to analyse the data (Ritchie & Lewis, 2003; Silverman, 2005). Because the analysis of qualitative data is more iterative and flexible than for quantitative data with which I'm more familiar, I chose to use the well established methodology of Framework Analysis (Ritchie & Lewis, 2003). This provides an initial set of structured procedures which are often recommended to help guide inexperienced qualitative researchers through the initial stages of the analysis process (Rabiee, 2004).

Framework Analysis was developed at the National Centre for Social Research in the 1980s. It develops a hierarchical thematic framework and organises data into a series of matrices according to main themes (Ritchie & Lewis, 2003). These main themes are sub divided by related categories and sub categories to enable thematic analysis. The five key stages of analysis are outlined in detail in appendix 3 along with the initial theme tables.

Quantitative data such as response rate and socio-demographic information were entered into an excel spreadsheet and descriptive statistics were used to identify numerical aspects of the data.

3.8 Validity and reliability

In this study thorough records of interviews and field notes were maintained and the analysis method was described in detail (Appendix 3). This approach is recommended by May and Pope (1995) as the key to ensuring reliability in qualitative research.

Care has been taken to avoid using specific quantification of the distribution of themes or concepts from the qualitative analysis, as this may suggest levels of relative occurrence which could be erroneous if applied to the wider population outside the study group (Ritchie & Lewis, 2003).

To ensure rigor a systematic approach to study design, data analysis and interpretation of the data was employed to minimise any concerns surrounding potential bias, non reproducibility and to maximise generalisability (Mays &

Pope, 1995). This enables an independent researcher to analyse the same data in the same way and arrive at the same conclusions adding to the validity of the study.

The problem of anecdotalism was addressed by using a variety of quotes from different transcripts, rather than using a few examples of beliefs from those who articulated well. In some instances several quotes were included to show the strength of belief (Silverman, 2005). In addition 'negative' or 'deviant' cases that refute theory were included in the data analysis, a further validation strategy (Mays & Pope, 2000). Triangulation through a mixed methods approach and respondent validation would have enhanced the reliability and validity of this study as well as reducing anecdotalism. Due to restricted resources triangulation was not possible during this project. This is discussed further in the limitations of study.

As further validation strategies this study utilised aspects of grounded theory and theoretical sampling. The constant comparison method was incorporated into data analysis to comprehensively check and compare fragments within a single interview and between interviews (Silverman, 2005).