The effectiveness of an intervention by specialist breast care nurses to address the perceived needs and enhance the quality of life of women with breast cancer receiving follow-up care: A randomised controlled trial.

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A thesis submitted in partial fulfillment of the requirements of Edinburgh Napier University, for the award of Doctor of Philosophy

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Declaration

I declare that this thesis is my own work, and that no material contained in it has been submitted for another academic award.

Susanne Cruickshank

Abstract

Approximately 550,000–570,000 women are alive in the UK who have had a diagnosis of breast cancer with further predictions that this will rise by 3% annually. Most of these women will be receiving follow-up care in a hospital setting and the value of this approach has been questioned for a number of years. Women transition from a very individual, personalised treatment plan to follow-up care which is not organised around individual patient need. Rather a blanket approach is used which does not consider age, risk profile, treatment or need. There is evidence that the current out-patient follow-up provision does not meet the physical, psychological and information needs of women with breast cancer, with women leaving the clinic with unmet needs. While the aim of follow-up is multifactorial, including the provision of psychosocial care, there is little evidence of how this service assesses and addresses unmet needs.

Aim

The current study sought to examine the effectiveness of providing patient reported needs and psychosocial information to the Specialist Breast Care Nurse at the breast cancer follow-up clinic in reducing cancer needs and improving quality of life compared to standard care. The primary outcome was a change in needs scored at baseline (time 1) and 12 months (time 2). The study also aimed to investigate a number of secondary outcomes namely changes in quality of life at baseline and 12 months, as well as looking at possible effects of the intervention on variables such as age, severity of treatment and time since diagnosis.

Method

This study was a prospective single blind randomised controlled trial (RCT) involving 93 women who had completed primary treatment for breast cancer and were attending follow-up in a hospital setting. Women were randomised to receive standard follow-up care (control) or a nurse-delivered intervention. The intervention was structured and guided by the self-reported needs and psychosocial information provided by the woman and coupled with a person-

centred conversation. This conversation explored the options for the intervention, desire of the woman for assistance and best way to provide it.

Results

There were high levels of need, anxiety and depression among women attending the follow-up clinic. There was a statistically significant fall in level of need, anxiety and depression in both groups after the intervention. However, no differences between groups in relation to the primary outcome; changes in needs between baseline and time 2, were seen. Quality of life scores fell in both groups; however only the overall quality of life score showed a statistically significant difference between groups in relation to the secondary outcome, changes in quality of life over time.

Conclusion

The results of this study have shown that using patient-reported needs and psychological information by the specialist breast care nurse in the follow-up clinic to inform an intervention proved to be no better than standard care, but neither is there sufficient evidence to state it was worse. This study has contributed to the methodological evidence base regarding the development and measurement of complex interventions in nursing practice.

Dedication

This thesis is dedicated to my father, Patrick James O'Sullivan. His love, advice and support were a constant source of inspiration. Sadly, he died before he could see the completion

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Table of contents

Declaration……ii

Abstract……iii

Dedication……v

Acknowledgements……vi

List of Appendices……xiii

List of figures……xiv

List of tables……xv

Abbreviations……xviii

Glossary……xx

Publications, presentation and grants……xxii

Chapter 1: Introduction to the thesis……1-8

1.1 Introduction ……1- 7

1.2 Personal position……8

Chapter 2: Breast cancer: A review of the literature……9-29

2.1 .Introduction……9

2.2 Pathophysiology, incidence and survival ……9-12

2.3 Diagnosis……12-13

2.4 Treatment……13-20

2.4.1 Surgery……15-17

2.4.2 Radiotherapy……17

2.4.3 Chemotherapy……18

2.4.3.1 Fertility, premature menopause and stopping hormone replacement therapy……18-19

2.4.4 Biological agents……19

2.4.5 Endocrine therapy……19-20

2.5 Psychosocial consequences of diagnosis and treatment……20-21

2.6 Transition between end of treatment and follow-up……21-22

.2.7 Follow-up care……22-23

2.7.1 Guidelines and recommendations……...23-25
2.7.2 Policy, follow-up and survivorship……...25-27
2.7.3 Models of delivering follow-up care…….27-28
2.8 Conclusion……..…….28-29

Chapter 3: A systematic review of unmet needs and use of patient-reported needs assessment tools in follow-up ……..30-84

3.1 Introduction……30
3.1.1 Part one……30-31
3.1.2 Part two……..…….....……31
3.2 Search strategy……..31-32
3.2.1 Inclusion and exclusion criteria…… ….....32-34
3.3 Methodological quality……..34-36
3.3.1 Patient reported outcome measure……...36-37
3.4 Results of part one……37-63
3.4.1 Outcome of search strategy…..……..37-38
3.4.2 Excluded studies……..……38-39
3.4.3 Characteristics of included studies…….……40-42
3.4.3.1 Sample strategy and recruitment……..……42-43
3.4.4 Methodological quality of included studies……..……...43-46
3.5 Outcome results……..……..……46-56
3.5.1 Age-specific needs…… ……51-53
3.5.2 Changes in needs over time…… ……..……53-54
3.5.3 Needs met and by whom…….....55-56
3.5.4 Quality of life……..56
3.6 Discussion…… ……56-63
3.7 Summary and implication for the thesis…… ..63
3.8 Results of part two…….…….63-84
3.8.1 Outcome of search strategy……..……...63-64
3.8.2 Excluded studies……..……64-66
3.8.3 Characteristics of included studies……66-67
3.8.4 Methodological quality of included studies……..…… 67-71
3.9 Outcome results ……..72-80

3.9.1 Patient-reported changes in needs……74-75
3.9.2 Patient-reported changes in quality of life……..…….75-76
3.9.3 Acceptability of the intervention……....……76
3.10 Discussion…….76-80
3.10.1 Summary……....…….80
3.11 Overall summary and implications for thesis……...80-82
3.11.1 Primary research questions…….82-83
3.11.2 Secondary research questions…….83
3.11.3 Hypothesis…….83
3.12 Conclusion……..……..84

Chapter 4: Methods……..……85-122

4.1 Introduction…….....85
4.2 Research question……..... 85- 86
4.3 Ontological and epistemological direction…….....86-87
4.4 Exploration of quantitative and qualitative approaches…….....87-89
4.5 The criteria for a randomised controlled trial(RCT)…… 89-91
4.6 Pre-clinical and modelling phases…….91-93
4.6.1 Components of the intervention and control…….....94-95
4.6.2 Undertaking a RCT in a breast cancer follow-up setting.....96
4.6.3 Patient preferences and acceptability of intervention…….…….96-97
4.6.3.1 Inclusion criteria…….……..…….97
4.6.3.2 Exclusion criteria…….....97
4.7 The trial environment……..…….97
4.7.1 Consistency in delivery of the intervention ……..98
4.7.2 Control – standard care……..…….98-99
4.7.3 Objectives and hypothesis…… …….99
4.8 Outcome measurements……...99
4.8.1 Primary outcome……..99-100
4.8.1.1 Measuring level of need……..……...…100-101
4.8.1.2 Measuring anxiety and depression…….……..102-103
4.8.2 Secondary outcome…….....103
4.8.2.1 Measuring quality of life…….…..103-105
4.8.3 Demographic and clinical information…….……105-106

4.9 Pre-study exploratory work……..……..,,,106-112
4.9.1 Introduction……..106
4.9.2 Method ……..106-107
4.9.3 Results…….…….107
4.9.3.1 Quantitative data……..……107-108
4.9.3.2 Qualitative data……....109-111
4.10 Conclusion…….……..111-112
4.10.1 Reliability and validity of using self-reported questionnaires in clinics…….…….112
4.10.2 Recurrence/mortality……..…..112
4.11 Introduction to the main study…….……..113
4.11.1 Sample size calculations…….……....113-114
4.12 Patient identification, recruitment and informed consent……....114-118
4.12.1 Identification…….…….114
4.12.2 Recruitment…….……..114
4.12.3 Informed consent……..……115
4.12.4 Randomisation and blinding……..……115-117
4.12.5 Monitoring completers and non-completers……..……..117
4.12.6 Withdrawal of patients……..……..……117
4.12.7 Managing adverse events……117
4.12.8 Follow-up of participants……..……..118
4.13 Analysis……..……118-119
4.14 Ethical approval…….……119-120
4.15 Qualitative data…….…….121
4.16 Summary……..…..……121

Chapter 5: Results…….122-172

5.1 Introduction…….……...122
5.2 Participants…….……..……...123
5.3 Completers and non-completers……123-124
5.4 Statistical analyses…….……....124-126
5.5 Participant characteristics…..……..…..……126-127
5.6 Participant Treatment Characteristics ……...……127-128
5.6.1 Deprivation levels……..……..……128-129

5.6.2 Summary of demographic and clinical findings……..129
5.7 Flow of participants through the trial…….....130
5.8 Primary outcome……131
5.8.1 Descriptive data of overall needs……..……131-134
5.8.2 Changes in needs over time……..……134-138
5.8.3 BCNQ: Dichotomous outcome ……..138-143
5.8.4 Summary of findings: Unmet needs……..143
5.8.5 Descriptive data of overall anxiety and depression……144
5.8.6 Clinical abnormal levels of anxiety and depression……144-145
5.8.7 Changes in anxiety over time……..……146-148
5.8.8 Changes in depression over time……..149-151
5.8.9 Summary of findings: Anxiety and depression…….……151
5.9 Secondary outcome……..…152
5.9.1 Descriptive data of quality of life……152-157
5.9.2 Changes in quality of life over time……158-164
5.9.3 Summary of findings: Quality of life……...165
5.10 Regression analysis…….……...166-175
5.10.1 Introduction……..……..166-167
5.10.2 Unmet needs outcomes……..…… ...167-168
5.10.3 Anxiety outcome……..……168-169
5.10.4 Depression outcome……169-170
5.10.5 Summary of findings: Unmet needs, anxiety and depression……170
5.10.6 Quality of life outcomes……..……..171-175
5.10.7 Summary of Findings: Quality of life…….……176-177
5.11 Summary of quantitative findings…….……176-177
5.12 Qualitative data……177-179

Chapter 6: Discussion and interpretation of results……180-204

6.1 Introduction……..……...180
6.2 Summary of the contextual background to the study……180-181
6.3 Summary of the results from the current study……...181-182
6.4 Hypothesis……..……182
6.5 Discussion of key results……..……..……182-190
6.6 Informing policy about needs of women with breast cancer……..190-192

6.7 Methodological limitations……192-195
6.7.1 Sample size……193
6.7.2 Blinding……..……..…...193-194
6.7.3 Intention to treat analysis……..194
6.7.4 Attrition……..…….....194-195
6.8 Comparisons with other work……..195
6.8.1 Study 1: Beaver et al. (2009)…….……195-196
6.8.2 Study 2: Vahdaninia (2010)…….....196
6.8.3 Study 3: Akechi *et al* (2011)…….....196-197
6.9 Main strengths of the present study……197-198
6.9.1 Generalisability of results……..199
6.10 Main limitations of the study……...199-204
6.10.1 The intervention……199
6.10.2 Pilot work…….……....200
6.10.3 Recruitment……..……...200-201
6.10.4 Outcome measurement…….201-202
6.10.5 Health economic…….……..……...202
6.11 The strengths and limitations of using the MRC framework…….202-203
6.12 Conclusion……..….203-204

Chapter 7 Conclusion and recommendations……..205-214

7.1 Introduction……..205
7.2 Conclusion……..206-207
7.3 New knowledge from the findings……..……207-208
7.4 Specific contribution to knowledge……..……..208-210
7.5 Recommendations……..……210-213
7.4.1 Recommendations for policy…….210-211
7.4.2 Recommendations for practice…….211
7.4.3 Recommendations for education……..212
7.4.4 Recommendations for future research…….212-213
7.5 Dissemination of findings……..213
7.6 Final Summary……..……...214

References……..215-250

List of Appendices

Appendix 1: Reflections of the researcher……...251-253

Appendix 2: Example of medline search strategy……254

Appendix 3: Breast cancer needs assessment questionnaire……...255-257

Appendix 4: Hospital and anxiety scale……258

Appendix 5: EORTC QLC C30 and BR23……259-262

Appendix 6: Mapping quality-of-life instruments……..263

Appendix 7: Data collection sheet for demographic and clinical characteristics……264

Appendix 8: Letter of invitation to take part in the study……..265

Appendix 9: Information for participants about the study……266-270

Appendix 10: Informed consent form……271

Appendix 11: Exploratory factor analysis results of BCNQ……....272-273

List of figures

Figure 2.1 Breast cancer, average numbers of new cases per year and age-specific incidence rates, Female, UK 2008-2010……...10

Figure 2.2: Pathway of care for breast cancer……...13

Figure 4.1: The MRC framework for the evaluation of complex Interventions……..91

Figure 5.1: Flow of participants through the trial……..130

Figure 5.2: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post intervention groups for BCNQ subscale scores……135

Figure 5.3: Error bar graph comparing the overall mean differences with 95% confidence intervals for baseline and post-intervention groups for BCNQ scores ……140

Figure 5.4: Error bar graph comparing mean differences with 95% confidence intervals for baseline and post-intervention group for anxiety scores……146

Figure 5.5: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post-intervention group for depression…… 149

Figure 5.6: Key areas addressed through the person-centred conversation… .178

List of tables

Table 2.1: Breast cancer age standardised 1, 5, 10 and 20 year relative survival……..11
Table 2.2: Comparison of clinical practice guidelines for breast cancer follow-up across the world……..25
Table 3.1: Scoring framework of RCTs……35
Table 3.2: Record of searches up to 2009 (part one)……....38
Table 3.3: Summary of excluded studies (part one)……...39
Table 3.4: Characteristics of included studies (part one)……...41
Table 3.5: Methodological qualities of included studies (part one)……..43
Table 3.6: Results of included studies (part one)……...47
Table 3.7: Range of unmet needs reported in the studies (part one)……48
Table 3.8: Record of searches up to 2009 (part two)……....64
Table 3.9: Summary of excluded studies (part two)……65
Table 3.10: Characteristics of included studies (part two)……66
Table 3.11: Methodological qualities of included studies (part two)……....60
Table 3.12: Summary of results from Aranda *et al*. (2006)……..72
Table 3.13: Summary of results from Boyes *et al*. (2006)……73
Table 4.1: Comparisons between research paradigms……87
Table 4.2: Illustration of the intervention and control process……95
Table 4.3: HADS scoring protocol……102
Table 4.4: Top 10 needs expressed using the BCNQ……..108
Table 4.5: Top 5 needs expressed as a moderate to high need……108
Table 4.6: Summary of comments about the questionnaire……110
Table 5.1: Comparison of demographic data between the completers and non-completers……..124
Table 5.2 Cronbach alpha levels for each subscale of the BCNQ……125
Table 5.3: Baseline demographic and disease characteristics of the study participants……127
Table 5.4: Baseline treatment characteristics of the study participants……128
Table 5.5: Descriptive baseline data for the BCNQ divided into the five subscales……132
Table 5.6: Descriptive post-intervention data for the BCNQ divided

into the five subscales……..133
Table 5.7 Top 20 needs expressed across both groups on the BCNQ……134
Table 5.8: Mean differences over time BCNQ subscale scores by
treatment group……136
Table 5.9: Linear regression: Association between BCNQ subscale scores
and treatment groups……138
Table 5.10: Summary of overall dichotomous mean BCNQ scores at
baseline and post intervention……..……139
Table 5.11: Mean differences over time for BCNQ dichotomous outcome
scores by treatment group……..……..141
Table 5.12: Linear regression: Association between BCNQ scores
and treatment groups…….……142
Table 5.13: Summary mean scores of anxiety and depression of the HADS
at baseline and post-intervention……..……..144
Table 5.14: Presence of anxiety and depression symptoms among
participants as per HADS at baseline……..……..145
Table 5.15: Presence of anxiety and depression symptoms among
participants as per HADS at post intervention……..……145
Table 5.16: Mean differences over time for HADS scores by
treatment groups…….……..……147
Table 5.17: Linear regression: Association between HAD-A scores and
treatment groups……148
Table 5.18: Linear regression: Association between HAD-D scores and
treatment groups……..151
Table 5.19: Summary mean scores for EORTC QLQ C30 at baseline……..154
Table 5.20: Summary mean scores for EORTC QLQ C30 post-intervention…155
Table 5.21: Summary mean scores for QLQ – BR23 at baseline …..……156
Table 5.22: Summary mean scores for QLQ – BR23 post-intervention ……157
Table 5.23: Mean differences over time for EORTC QLQ C30
scores by treatment group……161
Table 5.24: Linear regression: Association between EORTC QLQ-C30 subscale
scores and treatment groups……162
Table 5.25: Mean differences over time for QLQ BR23 scores by

treatment group……..……..163
Table 5.26: Linear regression: Association between BR23 subscale scores and treatment groups……..……..164
Table 5.27: Summary of regression coefficients for variables associated with BCNQ (n=55) ……168
Table 5.28: Summary of regression coefficients for variables associated with anxiety (n=57)……. ……..169
Table 5.29: Summary of regression coefficients for variables associated with depression (n=57)……... ……170
Table 5.30: Summary of regression coefficients for variables associated with BR23 (n=57)……... ……..……172
Table 5.31: Summary of regression coefficients for variables associated with emotional functioning, fatigue and sexual functioning (n=57)……..……173

Abbreviations

AI	Aromatase inhibitors
ANP	Advanced Nurse Practitioner
BASO	The association of breast surgery (UK)
BCNQ	Breast Cancer Needs Questionnaire
BR-CPNQ	Breast cancer patients' needs questionnaire
CARES	Cancer Rehabilitation Evaluation System
CBT	Cognitive behavioural therapy
CMA	Canadian Medical Association
CONSORT	Consolidated Standards of Reporting Trials
DCI	Ductal carcinoma in situ
DF	Dutch Federation (Netherlands
EBCTCG	Early Breast Cancer Trialists Collaborative Group
EORTC QLQ-C30	European Organisation for Research and Treatment of Cancer quality of life questionnaire
ER	Oestrogen receptor
ESMO	European Society for Medical Oncology
FACT-G	Functional assessment of cancer therapy – General
FLIC	Functional Living Index - Cancer
GHQ-12	General Health Questionnaire
GP	General Practitioner
HAD	Hospital Anxiety and Depression scale (Indicator of need)
HCP	Health Care Professional
HER2	Human epidermal growth factor receptor 2 (HER2)
HRT	Hormone replacement therapy
INQ	Information Needs Questionnaire
MOS	Medical Outcomes Study
MRC	Medical Research Council
NHMRC	National Health and Medical Research Council of Australia
NCCN	National Comprehensive Cancer Network (USA
NCSI	National Cancer Survivorship Initiative
NICE	National Institute of Clinical Excellence (England and Wales)

PRR	Prevalence Rate Ratio
PgR	Progesterone receptor
PICOT	Patient population, Intervention, Comparison, Outcome, Time
POMS	Profile of Mood States
PROMs	Patient Reported Outcome Measures
PSQ 111	Patient satisfaction scale (Dutch version)
RCT	Randomised Controlled Trial
SBCN	Specialist Breast Care Nurse
STAI	State –Trait Anxiety Inventory
SIGN	Scottish Intercollegiate Guidelines Network
SIMD	Scottish Index of Multiple Deprivation
SLNB	Sentinal Lymph Node Biopsy
TNM	T= tumour; N= node; M=metastasis

Glossary

Adjuvant treatment (also known as postoperative chemotherapy): This usually refers to systemic chemotherapy, hormonal treatment, or both, given to people after removal of a primary tumour (in this case, surgery for early breast cancer), with the aim of killing any remaining micrometastatic tumour cells and thus preventing recurrence.

Axillary clearance: Clearance of level I, II, and usually level III axillary lymph nodes. Level I nodes are lateral to the pectoralis minor muscle, level II nodes are under it, and level III nodes are medial to it at the apex of the axilla.

Axillary sampling: Aims to remove the four largest, most easily palpable axillary lymph nodes for histological examination.

Breast conserving surgery: Surgery consisting of lumpectomy (minimal cancer free margins), wide local excision (wider free margins)

Disease free survival: Means being alive with no local or distant recurrence or contralateral disease.

Early invasive breast cancer: (stage I or II) is M0 with T1 or T2 (tumour diameter ≤ 5 cm, no involvement of skin or chest wall) and N0 or N1 (mobile axillary nodes); or M0 with T3 (tumour diameter > 5 cm, no skin or chest wall involvement), but only N0.

Follow-up: care after primary treatment of women with breast cancer to promote physical and psychosocial rehabilitation, monitor treatment effectiveness including short and long term toxicity, and detect recurrence or new cancers

Mastectomy: Removal of the breast

Metastatic breast cancer: (stage IV) is M1 (any supraclavicular fossa node involvement or distant metastases to bone, lung, liver, etc.) with any combination of tumour and node parameters.

Needs: 'the requirement of some action or resource necessary, desirable, or useful, to attain optimal well-being' Sanson-Fisher et al (2000: p 227)

Non-invasive breast cancer (stage 0) is Tis (carcinoma *in situ*, intraductal carcinoma, lobular carcinoma *in situ*, or Paget's disease of the nipple with no associated tumour); N0 (no axillary nodal involvement); and M0 (no metastases).

Sentinel node biopsy: A procedure whereby the first nodes in the draining lymphatic basin are removed and examined by a pathologist for cancer cells.

Staging of breast cancer: A detailed description of the tumour, node status and, metastatic parameters at a particular time (TNM). These are amalgamated into broader categories called stages (0–IV). Stages can be aggregated into even broader categories (non-invasive, early invasive and advanced breast cancer).

Breast cancer survivor: Defined as women who have completed primary treatment (Surgery, chemotherapy, radiotherapy and Herceptin) and may be up to and beyond 5 years following diagnosis

Publications, presentations and grants associated with this thesis

Cruickshank, S., Alder, B., Kennedy, C., Barber, M., 2007 *Follow-up for breast cancer patients: a randomised controlled trial*. Oral Presentation: Faculty of Health, Life and Social Sciences, Edinburgh Napier University: 8th Annual Postgraduate Research Conference, 22nd March, Edinburgh.

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Cruickshank, S., Kennedy, C., Barber, M., Rowat, A,. 2010. *Using a needs assessment tool in breast cancer follow-up.* Oral Presentation: Faculty of Health, Life and Social Sciences, Edinburgh Napier University: 11th Annual Postgraduate Research Conference, 26th April, Edinburgh.

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Chapter 1: Introduction to the thesis

1.1 Introduction

Breast cancer is the most common cancer among women in the United Kingdom (UK) and relative 5 year survival is 85% (Cancer Research UK, 2012). Approximately 550,000 – 570,000 women are alive in the UK who have had a diagnosis of breast cancer with further predictions that this will rise by 3% annually (Maddams *et al*. 2009). While the biomedical definition of cancer *survival* refers to the population of cancer patients who live disease-free for at least 5 years after treatment, for an individual woman, it is the quality of the survival leading up to this, or any, milestone that impacts on their unmet needs, recovery and adaptation. After primary treatment for breast cancer, women usually attend regular follow-up examinations, irrespective of age, risk profile or treatment. In the UK frequency is no longer defined in current guidelines (Scottish Intercollegiate Guidelines Network (SIGN), 2013; National Institute of Clinical Excellence (NICE), 2009), but many units still see women in follow-up clinics up to 5 years and beyond following their diagnosis. It is this period, follow-up, and specifically the appointment within the hospital setting, which is the focus of this thesis.

The aim of follow-up is not only to detect new cancer or recurrence through examination but also to provide physical, and psychosocial rehabilitation, and monitoring of treatment effectiveness including short and long term toxicity (Rojas et al. 2009). Research and practice based literature has been critical of follow-up, questioning its cost-effectiveness in providing optimum care and its ability to achieve its many aims within a short consultation (Sakorafas, Tsiotou & Pavlakis,. 2000; Emens & Davidson, 2003; Collins, Bekker & Dodwell, 2004; Rutgers, 2004; Roche, 2006; European Society for Medical Oncology (ESMO) 2007; Tolaney & Winer, 2007; Beaver, Williamson & Chalmers, 2009; Rose & Watson, 2009; van Hezewijk *et al*. 2012).

Studies that report womens views of follow-up care suggest they are largely positive about this appointment and few women would recommend moving away

from the status quo with some expressing a wish to attend more frequently (Montgomery *et al*. 2008; Kimman *et al*. 2010). While the debate continues about the merits of providing follow-up care, a number of research studies suggest that women have multiple unmet psychological, physical and information needs post-treatment (Raupach & Hiller, 2002; de Bock *et al*. 2004a; Thewes *et al*. 2004; Beaver *et al*. 2006; McCaughan & McSorley, 2007), and that these are neither assessed nor addressed adequately through follow-up care. Unmet needs closely correlate with distress according to Carey *et al.* (2012), add to the burden of suffering and interfere with a person's ability to move on (Folkman & Greer, 2000). Therefore to aid recovery, the means to identify and intervene to improve and reduce perceived cancer needs would appear a logical goal of healthcare service.

"Human needs" does not lend itself to a clear and unambiguous definition as it has two major and competing facets namely: the motivational approach that directs human behaviour (Maslow, 1987) and that of a force which is politically driven; shaped by social and cultural influences (Marx, 1964). The idea that nursing should be dedicated to meeting patients' needs is a dominant theme that has emerged among nursing theorists (Tomey & Alligood, 2002). Within the multi professional arena of breast cancer, it could not and should not be considered solely a nursing remit.

Marx (1964) was one of the early theorists linking needs to social and political forces. He espoused that the ideal society was one which recognised the needs of the people and fulfilled them. This increased interest in human needs was closely related to the allocation of resources in society and fundamental fairness. Holmes & Warelow (1997) proposed that expressed and perceived needs are moulded by dominant political ideologies and social practices, and it is questionable whether these needs can be distinguished from desires, wants and rights. Farrell provides a tentative distinction between… "*a need which must be satisfied and a want that can be deferred*" (1991, p.1063). Similarly, Plant, Lesser & Taylor-Gooby (1980) suggest that wants are articulated and satisfied within the context of the marketplace, whereas needs ought to be met within the context of welfare services. These authors agree that the term "need" carries

persuasive connotations particularly in relation to health needs, but some ambiguity exists within healthcare whether we fulfill needs or wants.

In contrast, Maslow's scientific philosophy reflected a belief that man is a "*whole functioning, adjusting individual"*(1987, p.25) who is best understood from a holistic approach. All humans possess basic needs which must be satisfied for the sake of physical health. Maslow (1943) suggests that human needs are arranged in hierarchies of pre-potency, with the appearance of one dependent upon the satisfaction of a more pre-potent need. Maslow (1943) moves from physiological needs to those of safety, esteem and self-actualisation and suggests the influence of knowledge and understanding, motivation and behaviour on the acquisition of basic need, is fundamental to this process. If a need has been identified, action is recognised as favourable by an individual or professional as inaction can cause persistence of need and dissatisfaction (Schmid-Buchi et al. 2008). In their work with cancer patients, Sanson-Fisher et al. describes the process to address this deficit as "*the requirement of some action or resource necessary, desirable, or useful, to attain optimal well-being*". (2000, p.227).

While this is an outcome most Healthcare professionals (HCPs) would hope to achieve, the action or resource must recognise that humans have different sets of needs that have arisen out of specific contexts of life experiences before their cancer diagnosis, as a result of their diagnosis and beyond. Whether or not a woman is able to meet her own needs during a cancer experience is influenced by a variety of factors including; her psychological, physical, emotional, social, informational, spiritual and social experiences (Fitch, Porter & Page, 2009). While follow-up care may currently seek to provide psychosocial support, evidence suggests broader assessment may better identify and offer strategies to improve this. For many women, follow-up care is another important phase in their recovery.

Research into different models of delivering follow-up care have largely focused on reducing hospital-based appointments through telephone-based follow-up (Beaver, Williamson & Chalmers, 2009; Koinberg, 2004, 2009), self-referral or

point of need (Chapman et al. 2009; Sheppard et al. 2009) and delivery by a General Practitioner (GP) (Grunfeld *et al*. 2006) rather than the actual structure of the follow-up appointment in meeting the needs of the women. This distinction is important follow-up care would certainly be offered for at least some time after treatment completion and therefore making changes to the structure of the appointment may prepare women better for eventual discharge.

In UK practices, some of these models have been adopted in local settings, but not universally. There remains unease and a lack of consensus among HCP's about the best approach to use moving forward, with a paucity of evidence to convince both patients and clinicians that traditional approaches that involve a face to face consultation and clinical examination, are no longer necessary (Fallowfield & George, 2008; Molino, 2008). The picture emerging is a wide variation in follow-up practices: some units continue to offer traditional follow-up appointments for 3 - 5 years in the hospital setting, employing specialist breast cancer nurses (SBCN) and/or advanced nurse practitioners (ANP) to deliver this service in conjunction with their medical colleagues, while others have chosen to discharge women at 2, 3 or 4 years and provide some support over the telephone.

While curative intent remains the most important goal of treatment, it is of increasing importance how this goal is achieved (Ewart & Jenson, 2011). Intensive therapy is balanced with knowledge that breast cancer can keep recurring for up to and beyond 20 years following initial diagnosis (Early Breast Cancer Trialists Collaborative Group (EBCTCG), 2005). Screening for the risks associated with recurrence are evident in the current model of follow-up through mammography and clinical examination, however, screening of psychological well-being: a concept which encapsulates anxiety, depression, distress, needs and quality of life (Carlson, Waller & Mitchell, 2012) are less obvious.

Research by Zabora *et al*. (2001) reported that distress (anxiety and depression) among breast cancers survivors (n =1249) is as high as 32%, with Coyne *et al.* (2004) also reporting that distress and psychiatric morbidity continues for women over many years post-treatment. There is some evidence that an association

exists between unmet needs, anxiety, depression and quality of life among women who survive breast cancer (Karakoyun-Celik *et al*. 2010). Sanson-Fisher *et al*. (2000) reported an association between unmet needs, age, time since diagnosis and treatment modality used among cancer patients. Screening for, and offering appropriate interventions to address these unmet needs of cancer patients offer challenges to HCPs. In breast cancer, large numbers of patients are seen in follow-up clinics and there are fears that screening may increase the pressures on an already pressured service. This may be the reason that there is little evidence of HCPs using formal questionnaires to screen patients and tailor their care accordingly within many of these clinics settings (Mitchell *et al*. 2008).

Individualising supportive care interventions, particularly around diagnosis and treatment, has often been seen as the primary role of the SBCN (Cruickshank *et al.* 2008). The transfer of their skills into the follow-up setting has increased the focus on psychological well-being of women at this time. The National Cancer survivorship initiative (NCSI) has stated that, *"alternative approaches to aftercare and support for people who have reached the transition from treatment to living with and after breast cancer" (at low/moderate risk of recurrence) are required"* Davies & Batehup, 2009, p.28). While it may seem natural to stratify women according to their risk of recurrence to manage the large numbers attending follow-up care, there is to date, no evidence to suggest unmet needs differ or are associated with a woman's individual risk of recurrence.

Indeed, the wider personal influences highlighted by Fitch, Porter & Page (2009) make this area highly complex. Measures of unmet need place a greater weight on the patients, rather than the professionals', perspective and recognises that they are the best judge of their psychosocial well-being. It moves away from restricting interventions to those who meet criteria "cases" and towards those who want help. Indeed, it encourages patients to interact with services in a proactive rather than passive way, and reflects a person-centred care approach advocated widely in cancer policy across the UK (Scottish Government, 2010a; Department of Health, 2011).

Previous research undertaken in a hospital clinic setting were unable to demonstrate statistical significant changes in unmet needs between the groups studied or that the intervention was directly attributable to the actions of the clinicians who viewed the patient reported outcomes: needs assessment and psychological questionnaires (McLachlan *et al*. 2001; Aranda *et al*. 2006; Boyes *et al*. 2006). However none of the studies included women with breast cancer attending follow-up clinics where unmet needs have been reported. This approach though offered possibilities within the hospital-based setting: an area not previously researched. This, and the suggestion by Thewes (2000) regarding the possible advantage of using the breast cancer survivor specific needs questionnaire she developed as a screening tool (known throughout this thesis as BCNQ) in a clinic setting, provided the basis for the work presented in this thesis.

This led to the research aim: To determine the effectiveness of providing patient – reported needs and psychosocial information to the SBCN at the follow-up clinic in reducing cancer needs and improving quality of life over time compared to standard care.

The intention of this thesis is to describe a randomised controlled trial (RCT) that compared the effectiveness of a SBCN-delivered intervention with standard follow-up care. The trial was conceived to be an easily reproducible approach for women with breast cancer attending follow-up clinics. As one of the first reported RCT's of a specialist breast care nurse-delivered intervention to address the perceived needs and quality of life of women with breast cancer attending hospital follow-up, it is hoped that the results presented in it, constitute a significant contribution regarding the usefulness of this approach to both the understanding, and management of breast cancer patients within this setting, contributing also to new knowledge within this area.

A recent report by Eccles *et al*. (2013, p.17) titled "*the critical research gaps and translational priorities for the successful prevention and treatment of breast cancer*" has given increased weight to the work reported in this thesis. They confirm what the author believed that the current system of aftercare does not meet the needs of patients. They suggest that incorporating standardised patient-reported outcome measures (PROMs) into everyday practice is required. In

addition, they recommend studies that investigate how unmet psychosocial needs and psychological morbidity during diagnosis and treatment relate to quality of life, sexuality and physical well-being. This thesis presents research into an intervention which sought to address unmet needs and psychological morbidity among breast cancer survivors attending follow-up care.

The thesis has been divided into seven chapters. Chapter 1 has the objective of giving the reader some brief background and context to the work. Chapter 2 aims to review the field of breast cancer with particular attention to the area that bears most relevance to this thesis, follow- up care. Chapter 3 presents a systematic review of perceived unmet needs reported by women with breast cancer post-treatment, and the use, and effectiveness of using needs assessment tools in this area. It informs the rationale for the work undertaken and launches the specific aims and hypothesis that drove this thesis. Chapter 4 sets out the methodological approach taken to address the aim and hypothesis outlined in the previous chapter with details of the design, protocol, assessment, procedures and statistical analyses used in this study. Chapter 5 presents the results including descriptive and inferential statistics, and regression analyses. Chapter 6 interprets and discusses the findings and places them in the context of current practice. Chapter 7 presents a conclusion along with key findings and recommendations

1.2 Personal position

My interest in this area began many years ago when I worked as a specialist breast care nurse (SBCN) between 1996 and 2003 and my involvement in the writing group on follow-up within the Scottish Management of Breast Cancer Guideline Group (SIGN 2005). In my role as a SBCN, I met women at diagnosis and became involved in many aspects of their care. This involved the provision of a range of supportive care aspects: psychosocial, emotional, practical, information and support. I observed women attending the clinic and immediately seeking me out to talk through softer issues associated with body image, side effects and relationships, to name a few. I felt there was some duplication of effort on the part of myself and the doctor involved in the follow-up clinic, but also the appointment appeared to miss important areas of concern among women recovering from treatment. However, those who sought my support were not predictable. I had developed a strong therapeutic relationship with many women and they confidently accessed me. For others though, who did not know me as well, it seemed less easy and they were referred through community services or other agencies. It was this latter group of women who appeared to have multiple unmet needs, remaining undisclosed despite attending regular follow-up care clinics.

These experiences led me to question the effectiveness of traditional follow-up to meet the diverse needs of women after curative treatment, and identify those who required help from those who spoke loudest. Despite my observations, and indeed those voiced in the literature, hospital-based follow-up had remained largely unchanged, despite increasing numbers of SBCNs undertaking these clinics as part of their extended role. I sought to develop a study which took account of a woman's individual and unique set of needs and provided supportive care in a person-centred way, while still offering clinical examination and mammography. As I started this research I was employed as a Lecturer in Cancer Nursing at Edinburgh Napier University. Further reflections of the learning gained by the researcher are attached in Appendix 1.

Chapter 2 Breast cancer: A review of the literature

2.1 Introduction

There is a significant amount of research in the field of breast cancer, covering pre-diagnosis to end of life. So, this chapter aims to present a summary of what are the most relevant issues in breast cancer, with particular emphasis on those aspects which may impact on the present research within follow-up care. Women with breast cancer are reported by Lindop & Cannon (2001) and Minstrell *et al*. (2008) as a particular patient group who report high levels of unmet need associated with their diagnosis and treatment side effects. They are also high users of healthcare services (Carlson & Bultz, 2004).

This review will start by addressing questions about the relationship between the incidence, patho-physiology, diagnosis, treatment and survival of breast cancer. The spectrum of experiences and side effects associated with each of these areas can impact on both survival outcomes and the recovery of women over time. It was historically one of the main reasons follow-up care was offered. Breast cancer is not only a physical disease but also has a profound psychological impact on a woman and her family. A psychosocial account of breast cancer will be reviewed with particular attention to factors which may impact on mental distress and quality of life after treatment is complete.

2.2 Pathophysiology, incidence and survival

Breast cancer is a heterogeneous, highly variable disease composed of different types, each with its own specific biological characteristic and prognostic indicators (Reddy & Given-Wilson, 2006). It is these features that make it difficult to define cure, but also to assess definitively all risk factors for recurrence (Weigelt. Peterse & van't Veer, 2005), making it unclear why some women with apparently similar disease recur while others do not. The incidence of breast cancer in the UK is 48,975, with a lifetime risk of 1 in 8 among females (Cancer Research UK,

2012). The age range of women diagnosed with breast cancer in the UK is illustrated in Figure 2.1. Unlike patterns seen in most cancers whereby survival improves with age, women in their 50s and 60s at diagnosis have higher survival than younger or older women.

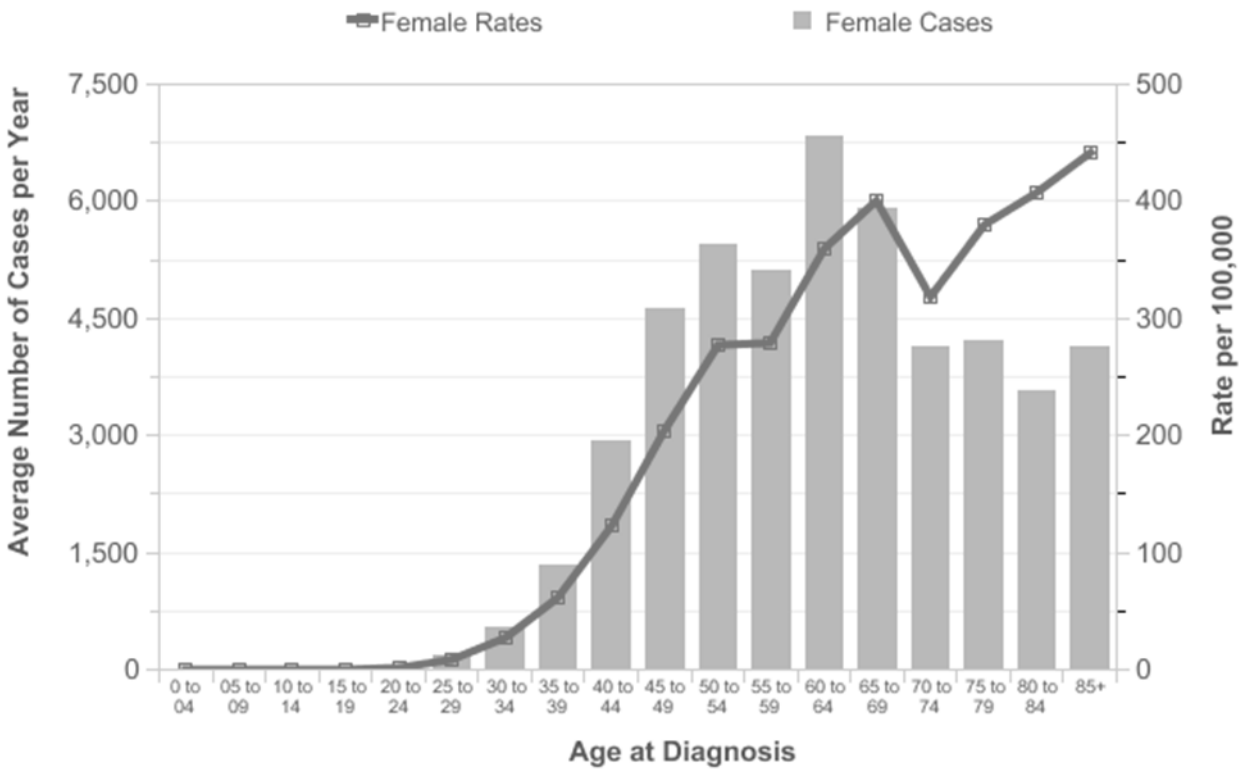


Figure 2.1: Breast cancer, average number of new cases per year and age specific incidence rates, Female, UK 2008-2010 Prepared by Cancer Research UK, 2012. Data source: Office of National Statistics, England, 2008, Welsh Cancer Intelligence Unit and Surveillance Unit, 2008, Information and Statistics Division NHS Scotland, 2010, Northern Ireland Cancer Registry, 2008.

The improvements in survival, as shown in Table 2.1, are one of the reasons there are increased pressures on follow-up services. Approximately 550,000-570,000 women are alive in the UK who have had a diagnosis of breast cancer and this group constitutes 25% of all those treated and living with cancer in the UK (Maddams *et al*. 2009).

Table 2.1: Breast cancer age standardised 1, 5, 10 and 20 year relative survival England 2005-2009, England and Wales 2007 (Maddams *et al*. 2009).

Relative survival (%)			
1 year	**5 year**	**10 year**	**20 year**
2005-2009	**2005-2009**	**2007**	**2001-2003**
95.8	85.1	77	64.5

Reducing the risk of breast cancer recurring is the main treatment goal. A combination of early diagnosis and treatment has played a significant factor in the improved survival outcomes seen today (Early Breast Cancer Trialists' Collaborative Group, (EBCTCG), 2005, 2011). However, these results are not the sole reason for success, better co-ordination of care among cancer specialists, increased specialisation among clinical staff and the introduction and extension of screening have also played an important role. Risks associated with survival outcomes are difficult to quantify and explain to women and Watson *et al*. wrote. "*a risk is something that might happen in the future"* (2012, p.1). This is so true of breast cancer with recurrences peaking in the first 2-3 years after diagnosis (10-15%) (Dixon & Montgomery, 2008), but remaining a constant risk between 3- 5 years (4.3%), and 5-9 years (4.6%) (Gligorov, Pritchard & Goss, 2007). Breast cancer, unlike other cancers, can continue to recur up to and beyond 20 years (EBCTG, 2005).

There are two types of recurrence: local or distant recurrence. The type is important as survival following discovery is considerably different: Women with local recurrence have an 80% 5-year relative survival rate, while women with distant recurrence, including bones, liver, lungs or brain, have a 25% 5-year relative survival (Isasi *et al*. 2005).

There is no evidence that informing women of the risks of the cancer recurring impacts on their well-being. Yet, Corter *et al*. (2013) have suggested that an association between illness perceptions, side effects and fear of recurrence does exist. In their study, women (n=153) who took endocrine therapy associated their side effects of treatment with symptoms of a possible recurrence. In particular, the women searched for a cause for their physical symptoms, and through their

perceptions of illness, feared they had a recurrence. This constant risk of recurrence creates fear, uncertainty and emotional difficulties for women and acts as a constant reminder (Oxlad *et al.* 2008). Despite these fears, statistics indicate that many women are surviving and doing well. It is therefore important that risk is balanced with optimism whereever possible. This fear is described by many women as one of the main reasons they want on-going follow-up care (Beaver & Luker, 2005; Montgomery *et al*. 2008). However, the data suggests that women attending a clinic are less likely to present with a recurrence than out with follow-up (Beaver & Luker, 2005; Rojas *et al.* 2009).

2.3 Diagnosis

In a qualitative study by Boehmke & Dickerson (2006), diagnosis is described by women as a transition period from health to illness, a pattern of healthy women transitioning to a state of illness within a short period of time following test results. Advances in diagnostic procedures mean this period can be as short as a few hours. These authors and Knobf (2001), Ganz *et al*. (2004) and Halkett (2007) indicate that how women approach their diagnosis and subsequent treatments affects how they deal with later symptoms and distress, a time when they may be receiving follow-up care. Insight into what a diagnosis may feel for a woman is described in the words of Brooks;

> *"Breast cancer is life changing, one you cannot anticipate or plan for and one in which you have no choice. How we deal with living with it differs, from one person to another" (*2006, p. 31*)*

Figure 2.2 illustrates the key points in the cancer journey as a woman enters the breast cancer service worldwide, receives a diagnosis and moves through the different stages towards follow-up and long-term monitoring, the focus of this thesis. Following diagnosis, women follow a personalised treatment plan according to the characteristics of their tumour, fitness for treatment and preference. The complexity of treatment decisions is heightened with each treatment modality added into the plan.

Depending on the plan, women can transition from diagnosis to long-term monitoring and follow-up in a matter of months, while others embark on treatment regimens which can last well over a year.

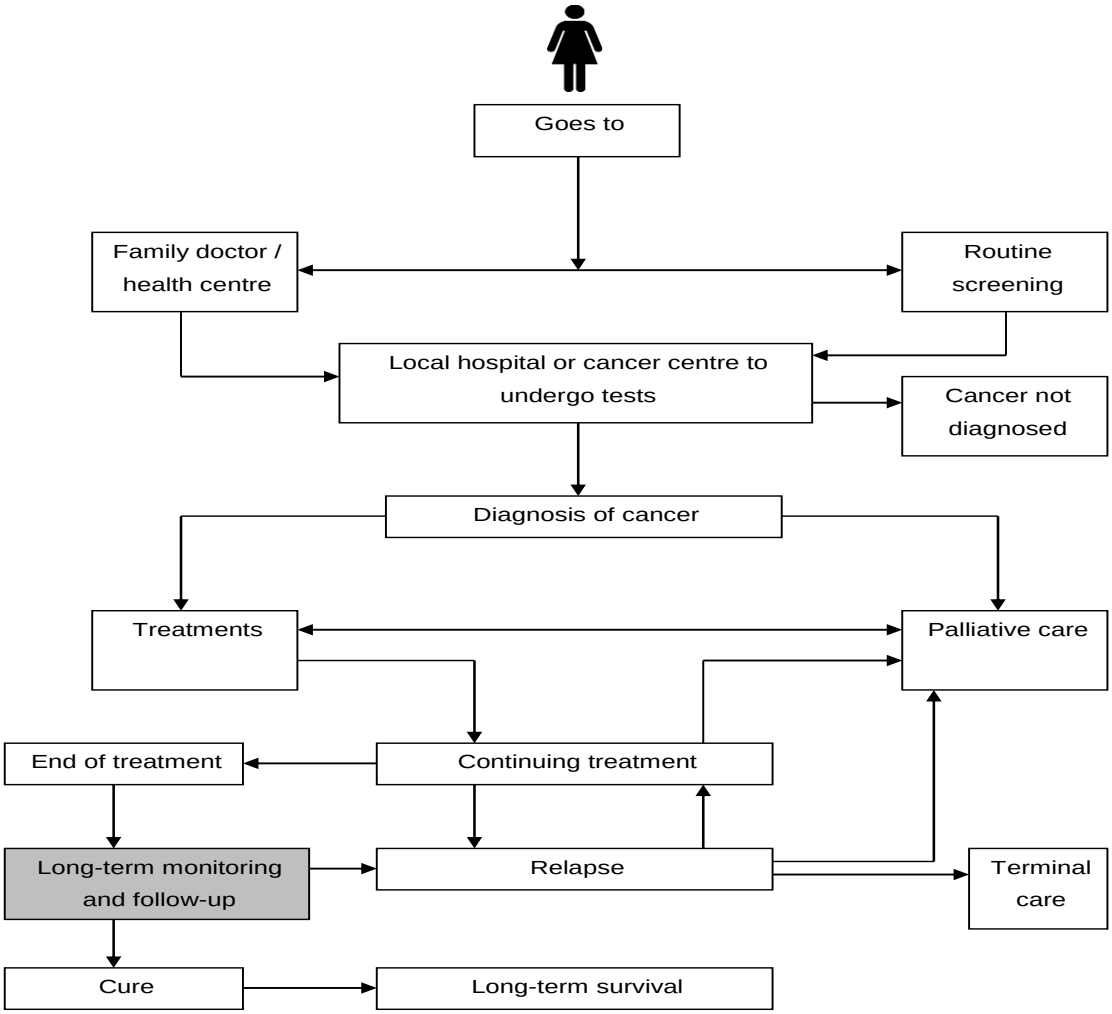


Figure 2.2: Pathway of care for breast cancer (adapted from Fitch, Porter & Page, 2002, p.15).

2.4 Treatment

Breast cancer is a cancer whereby most women present feeling well and healthy. Therefore it is the treatment, and specifically the complications of treatment, adverse effects of drugs and their impact on co-morbidities that creates unwanted symptoms which last after treatment is complete (Budin, Cartwright-Alcarase & Hoskins, 2008). This, according to Bloom *et al*. (1998) is one of the reasons

women find it difficult to understand and distinguish between what are normal and abnormal symptoms.

The goal of treatments is:

- Local control with optimum cosmesis
- Reduction of risk of developing local and distant metastases
- Minimisation of short and long-term treatment related morbidity
  (Neal & Hoskin, 2009, p.100)

Surgery remains the first treatment choice for early breast cancer (Blowers & Foy, 2009). Once the important prognostic information is obtained, additional radiotherapy and systemic therapies such as chemotherapy, endocrine therapy, and/or biological treatments are recommended (Veronesi *et al*. 2006).

Historically in the UK there has been a strong reliance on the TNM (T=tumour, N=node, M=metastases) model developed by Veronesi, Cascinelli & Bufalino, (1983) to classify the stage of breast cancer and inform treatment decisions. It has a strong focus on the pathological characterisation of lymph node status, tumour size and histological grade to understand the stage of disease. It is now known that this is no longer sufficient as it does not recognise biological features, so necessary in predicting outcomes (Aapro, 2006; Veronesi *et al*. 2006). Since 2005, the St Gallen Consensus panel (Goldhirsh *et al*. 2005) recommended that pathological assessment of oestrogen receptor (ER), progesterone receptor (PgR) and HER2/neu status of all early breast cancers should also be done, and predicted that this would substantially improve results from systemic therapies by ensuring proper targeting of therapies to the patients who need it. Future direction in gene expression profiling and tracking micro metastases offers opportunities to target treatments even more effectively (Dinh, Sotiriou & Piccart, 2007).

It is important to recognise the role of ER and /or PgR and HER2: ER positivity reflects responsiveness to tamoxifen and aromatase inhibitors and HER2 positivity, a response to trastuzumab (Baum, 2002; Dinh, Sotiriou & Piccart, 2007).

Increasing knowledge about newer biological factors such as HER2/neu receptors and proliferative index (rate of cell division in the tumour) have altered the way adjuvant treatments are prescribed and are increasingly used to predict prognosis. An over expression of the HER-2/neu protein is observed in 15%–20% of breast cancers (Slamon, Clark & Wong, 1987), and it is now accepted that high levels of expression of HER-2/neu identify those patients most likely to respond to trastuzumab in the adjuvant setting (Dinh, Sotiriou & Piccart, 2007).

Estimates of prognosis are common when managing early invasive breast cancer (Andersson *et al*. 2008). The Nottingham prognostic index is one method used to help guide treatment decisions and determine prognosis. It is calculated using the formula; 0.2 x the tumour size (cm) + grade of tumour (1, 2, or 3) + lymph node status (1= no nodes, 2 = 1 - 3 nodes, 3 = 3 or more nodes are involved). Information of this nature is regularly shared with women and their families. The combination of using prognostic and needs assessment information has been suggested by Watson *et al.* (2012) as an approach which may offer better personalised cancer follow-up care.

However, although prognostic data informs decision making it is also necessary that HCP's gain a better insight into what the consequences are of improved survival on an individual's life (M^{c}Phail, 1999; Ganz *et al*. 2000; Knobf, 2001; Harris *et al*. 2002; Thewes, 2003; Biglia *et al*. 2003; Neal & Hoskins, 2009; Shultz 2005; Walshe, Denduluri & Swain, 2006; Stricker, 2007).

2.4.1 Surgery

The majority of women undergo some form of surgery quickly after diagnosis to provide local control of the disease, although increasingly chemotherapy and endocrine therapy are being used first to shrink the tumour prior to surgery. Surgery involves breast conserving surgery, mastectomy alone, or mastectomy with immediate or delayed breast reconstruction. Despite knowledge gained in an early study about the reduced psychological morbidity associated with breast-conserving surgery (M^{c}Ardle *et al*. 1990), up to 50% of women will undergo a mastectomy (Thompson & Wells, 2006). This may be due to tumour size, position

of the tumour or a woman's preference. The removal of the entire breast will cause loss of symmetry, likely coupled with increased psychological morbidity and dissatisfaction. To improve the psychological morbidity associated with mastectomy, breast reconstruction is routinely offered to women. An audit in England of 18,216 women who had a mastectomy (NHS Information Centre for Health and Social Care, 2011) reported that 21% of these had immediate reconstruction and 10% delayed.

Survival outcomes are improved following axillary surgery compared to no treatment (Rodger, Stebbing & Thompson, 2006). Indeed the pathologic status of the axillary lymph nodes is an important prognostic indicator and determinant of adjuvant treatment. Axillary surgery involves an axillary clearance, sampling or sentinel lymph node biopsy (SLNB). Axillary surgery, particularly clearances, are associated with complications including: seroma formation (a collection of serous fluid that is evident within a surgical cavity) and lymphoedema (a condition whereby the lymphatic routes are damaged during surgical resection) (Armer *et al*. 2008) and damage to the intercostobrachial nerve or reduced arm movement (Houssami, Cuzick & Dixon, 2006).

Newer techniques favour fewer axillary clearances and more sentinal lymph node biopsies (SLNB), an accurate less invasive procedure which has lower morbidity then previous techniques (Houssami, Cuzick & Dixon, 2006). It is also used as a diagnostic procedure prior to clearance. Results report less morbidity and a high degree of histological accuracy when undertaken by an experienced multi-disciplinary team (Filippakis & Zografos, 2007). A study by Delon *et al*. (2008) found that 18.8% (n =133) of women following breast cancer surgery, reviewed over a 12 month period, had some degree of lymphoedema and another study by Franks, Williams & Moffat, (2006) found this to be as high as 20.7% (n=251) in a similar group of women following axillary node clearance. Mansell *et al*. (2006) have suggested that SLNB reduced arm morbidity and improved the quality of life of women more than standard axillary treatment. The improvements will be welcome by women because the physical impact of lymphoedema can be problematic, with fitting clothing, carrying out activities of daily living as well as, an emotional impact on self -esteem, body image and quality of life (Armer *et al*.

2008). Follow-up provides some opportunity to instigate education with women who may be unaware of the risks, and monitor for signs and symptoms.

Pain after surgery is common. In a study by Lee *et al*. (2008), the prevalence of pain in the arm and shoulder varied from between 9 and 68%, and in the breast area of between 15 and 72%. This pain can be transient but if nerve damage occurs, this problem can become more persistent and last many years.

A study by Pelusi (2006) which interviewed breast cancer survivors' adaptation to sexuality and body image concluded that baseline assessments in this area can identify those women with a poor body image, thus initiating discussion. Indeed Perreault & Fothergill Bourbonnais (2005) argue that body image is such an important area in the field of breast cancer that it should be part of a formal assessment, something which does not currently occur in most follow-up clinics.

2.4.2 Radiotherapy

The use of radiotherapy is integral to the local disease management of breast cancer. Approximately 70% of breast cancer patients in Scotland are suitable to receive radiotherapy (Scottish Executive, 2006). Radiotherapy is offered to all patients after breast conserving surgery for invasive breast cancer, and to others according to their risks of a local recurrence. Following a meta-analysis (EBCTCG, 2011), data suggested that whole irradiation following breast conserving surgery halves the annual rate of local disease recurrence (RR 0.52, 0.48 - 0.56) and reduces annual breast cancer deaths by one sixth (RR 0.82, 0.75 - 0.90), with variations occurring according to prognostic subgroups. All women receiving radiotherapy are at risk of skin damage in the short and long-term and irradiated skin can be changed permanently through loss of pigmentation, indentation or telangiectasia, with resultant poor healing (Scottish Government, 2010a). Other complications include arm and shoulder problems and pain (Ewert & Jensen, 2011).

2.4.3 Chemotherapy

Chemotherapy is associated with acute side effects; myelo-suppression, alopecia, nausea and vomiting, skin and nail growth problems, weight gain, fatigue and stomatitis (Neal & Hoskins, 2009), and late side effects: cardiac toxicity (Stegall Moss *et al.* 2009), vasomotor symptoms and premature menopause (Fenlon, Corner & Haviland, 2009), fatigue and cognitive dysfunction (Bower *et al*. 2000), risk of secondary cancers, skeletal toxicities (Shapiro & Recht, 2001), with many of these side effects evident once treatment is complete and follow-up care begins.

2.4.3.1 Fertility, premature menopause and stopping hormone replacement therapy

Cancer treatment is gonodotoxic, particularly chemotherapy drugs. The regimen, the drug dose, duration of therapy and current menopausal status appear to influence the incidence and severity of symptoms, and the experiences of women with breast cancer across different age groups (Ganz *et al*. 2000; Walshe, Denduluri & Swain, 2006; Anderson *et al*. 2011; Pinto & de Azambuja, 2011; Cardoso *et al*. 2012). These symptoms post-treatment influence a woman's recovery and quality of life (Thewes, 2003; Shultz, 2005; Stricker, 2007).

UK age-specific breast cancer incidence rates rise sharply between the ages of 35 and 39, with 48% of breast cancers occurring among women 50 - 65 years of age and around the time of the natural menopause (Cancer Research UK, 2012). Breast cancer therefore coincides with a time of natural aging, women who may be currently taking hormone replacement therapy (HRT) and those who are experiencing a premature therapy-induced menopause (Hickey *et al*. 2008; Cancer Research UK, 2012). Difficult symptoms are associated therefore with younger women, those experiencing a therapy-induced menopause, postmenopausal women and HRT users (Leining *et al*. 2006), a large number of the women diagnosed. HRT is contra-indicated in breast cancer and recommended to be stopped once a diagnosis is confirmed (SIGN, 2013) with many of these women experiencing an exacerbation of their menopausal symptoms, the reason they began taking HRT. There is some promising evidence

emerging that supports non-pharmacological approaches to reducing menopausal symptoms including homeopathic treatments, cognitive behavioural therapy (CBT) and relaxation (Hickey *et al*. 2008; Fenlon, Corner & Haviland, 2009; Hunter *et al.* 2009; NICE, 2009; Mann *et al*. 2012). However, a full assessment is necessary if these interventions can be offered appropriately.

2.4.4 Biological agents

An over expression of human epidermal growth factor receptor 2 (HER2) is a poorer prognostic indicator in women with early breast cancer (Hicks & Kularni, 2008). However, this group, which constitutes approximately 12% of all breast cancer cases in Scotland, gain significantly from targeted therapy, trastuzumab, delivered for up to one year (SIGN, 2013). This drug is associated with cardiotoxicity and contraindicated in women receiving concurrent chemotherapy, particularly anthracyline agents (NICE, 2009). Short-term data suggests the risk of cardiac dysfunction may be as high as 16% after use of trastuzumab and minimising this risk is an on-going goal (Stegall Moss *et al*. 2009).

2.4.5 Endocrine therapy

Endocrine therapy is a key treatment in the management of ER positive breast cancer (Blowers & Foy, 2009). There are four major groups of endocrine agents: i) tamoxifen and other selective ER modulators, ii) progesterone (megestral acetate), iii) aromatase inhibitors (AIs) (anastrozole, letrozole and exemestane), iv) pure anti-oestrogens (fulvestrant), Their role and function differ depending on the patients menopausal status, stage of disease and response. All endocrine therapy aims to modulate or disrupt the process of oestrogen production. Tamoxifen blocks the ER, AIs inhibit the production of oestrogen and fulvestrat degrades ER. The most commonly used first line agents are tamoxifen and aromatase inhibitors. The EBCTCG (2005) concluded that 5 years of tamoxifen is better than 1-2 years. However, in a recent review of endocrine therapies by Palmieri *et al*. (2014), they concluded that there is sufficient data to support the extension of endocrine therapies beyond 5 years, including switching between groups of drugs up to 10 years. This change is being implemented in practices across the UK but has consequences for women who may experience an increased number of side effects and for a longer period of time. Adverse events

associated with the two treatments differ quite significantly: tamoxifen is associated with hot flushes, endometrial disorders and thromboembolic events, while AIs are associated with arthralgia, muscoskeletal disorders, osteoporosis and vaginal dryness.

However, any survival benefit can only be gained if they are taken as instructed, and many women struggle to cope with the side effects. In a recent review of survival data by McCowan *et al*. (2013), those with low adherence to tamoxifen had a shorter time to recurrence, increased medical costs and worse quality of life. They propose interventions are required that encourage patients to continue taking their treatment daily and may in the long term prove highly cost-effective.

2.5 Psychosocial consequences of diagnosis and treatment

Maguire *et al.* (1978) were among the first to recognise the psychological morbidity associated with mastectomy. In their study, they compared women following mastectomy (n=75) with women with benign disease (n=50). Their findings indicated that women with breast cancer were significantly more likely to suffer from anxiety (19 - 25% compared to 5 - 10% control) and depression (16% - 33% compared to 3 - 8% control), with increased moderate to severe sexual difficulties. It drew attention to how HCP's approached the emotional well-being of women with breast cancer and was instrumental in the introduction of SBCNs into clinical practice (Fallowfield & Baum, 1989). In a later study by Maguire *et al.* (1983), simple counseling by SBCN's did not prevent depression, but they were able to recognise and refer women earlier for psychiatric support. Findings suggested this action reduced psychological morbidity.

Particular women at risk of psychological problems include: those with a previous psychiatric history; a lack of support from family and friends; an inability to accept the physical changes associated with the disease or its treatment; a lack of involvement in satisfying activities; prior adverse experiences of cancer in the family; low expectations regarding the effectiveness of treatment; pre-existing marital problems or being younger at diagnosis (Burton and Watson, 1998)

While many women psychologically adjust over time, some studies have shown that there are marked individual variations in the year following surgery and beyond, with a subgroup reporting no reduction in distress despite data suggesting average scores had reduced among the whole group (Millar *et al*. 2005). Carver et al. (2005) also reported a significant correlation between the well-being and initial adjustment of women one year after surgery and their long-term adjustment 5-13 years later, suggesting that both social and personality factors play a part in a woman's recovery. Other authors, Deshields *et al.* (2006) have also described the psychological distress associated with the end of treatment. They found elevated scores of depression were reported at this time, and a relationship between high levels of depression and poorer quality of life.

2.6 Transition between end of treatment and follow-up

Cognitive changes in breast cancer survivors as they transition from completion of primary treatment to follow-up can result, *"from the disease, the treatment, complications of treatment, co-morbid conditions, the adverse effects of drugs, other symptoms, aging, and psychological responses to the cancer diagnosis" (Nail, 2006, p.48).*

The unpredictability associated with breast cancer may contribute to the psychological and physical decline punctuated by periods of improvement and paradoxical decline that is seen among women as they complete treatment and recover. Knobf (2007) has described a woman's feelings of uncertainty, vulnerability, ambivalence and mixed emotions as she completes treatment coupled with the physical aftermath of intensive treatment regimens; arm discomfort, fatigue, menopausal symptoms and lympoedema. While de Bock *et al.* (2004b) found information about side effects, hereditary changes, fear of recurrence and identifying changes in the untreated breast areas of greatest need during the follow-up period, Schmid-Buchi *et al*. (2008) found these issues were influenced by body image perception, role limitation, and relationships, Burton & Watson (1998) by previous psychological problems and Pelusi (2006) by sexuality and body image. Follow-up has been described by Ganz *et al*. (1996) as the transitional period from the end of primary treatment to survivorship.

One woman described this period:

> *I have now finished surgery, chemotherapy, radiation, and reconstruction; I'm done, according to the medical profession. But I don't really feel done. . . . We just move from the quantifiable, treatable disease to the immeasurable uncertainty of survivorship. . . . Being in the midst of active treatment means being seen regularly by a nurse or a physician—being cared for. (*McKinley, 2000, p.479)

Embarking on their follow-up and long-term monitoring is often when the psychosocial and physical implications of treatment are either only emerging or are on-going (Vivar & Mc Queen, 2005).

A study by Ganz *et al*. (2004) investigating the quality of life of 558 breast cancer patients at the end of primary treatment found women reported increased stress, decreased energy, multiple treatment side effects and a greater need for interpersonal support. Women post-mastectomy had poorer physical functioning, and sexual functioning was worse among women who received chemotherapy ($p<0.001$). Similar findings have also been reported by Holzner *et al*. (2001). They measured quality of life differences among women who were 1 - 2 years post treatment, 2 - 5 years and more than 5 years. Results indicated that women in the early phase (1 - 2 years) following treatment had a significantly reduced quality of life in relation to social and emotional aspects, fearing relapse and adapting to the illness and its treatment, with marked problems associated with body image, menopausal symptoms, and lack of self-esteem. Although the groups that were 2 - 5 years and > 5 years reported fewer difficulties, all groups reported fatigue, sleep disturbances and pain.

2.7 Follow-up care

The pathway to long- term monitoring and follow-up is clearly individual. NICE recommends that follow-up after treatment for primary breast cancer should include:

> *clinical and radiological options for assessment of both the treated and the contralateral breast. It incorporates supervision of on-going adjuvant treatment and potential side effects, and review of patients who are in clinical trials. Follow-up should also include advice on general health, diet and exercise. (NICE, 2009, p.97)*

2.7.1 Guidelines and recommendations

While previous guidelines in the UK included substantial guidance about the provision of follow-up care (SIGN, 2005; NICE, 2004), updated versions have been less prescriptive (SIGN, 2013; NICE, 2009), and this is perhaps one of the reasons that variability is seen in follow-up care models used across the UK today. This is in contrast to the United States of America (USA) (National Comprehensive Cancer Network, NCCN 2014) and Canada (Grunfeld, Dhesy-Thing & Levine, 2005); these countries continue to recommend who, when and how follow-up should be delivered. The 13th St Gallen International Breast Cancer Conference expert panel (Goldhirsch *et al*. 2013), a highly regarded expert body in collating and disseminating up to date evidence about breast cancer globally, believes that the provision of regular follow-up at the completion of primary treatment is appropriate and should continue. They support nurse specialists undertaking this care, but recommend it continues to be done in person rather than over the telephone. Telephone follow-up is an area which has yet to be widely adopted in the UK, but early results look promising when patients are carefully selected (Beaver, Williamson & Chalmers, 2009).

Despite advances in the treatment of breast cancer, the optimum way in which patients should be followed-up remains elusive. Recommendations for the diagnosis and treatment of breast cancer are much clearer and guided by international evidence. However, follow-up differs between countries, with an

overview of some of these illustrated in Table 2.2. Only the Canadian (CMA), American (NCCN) and Australian guidelines (Cancer Australia, 2010) make any recommendation about the management of psychosocial issues, with the Canadian guideline specifically referring to the multiple needs which may arise following breast cancer treatment and the Australian one recommending an additional psycho-social assessment. While the UK guideline informs decision making, countries like the USA and Canada use them as a legal document of care which forms the basis for financial reimbursement of medical procedures (Senn, 2006).

The success or otherwise of follow-up care is usually measured against numbers of recurrences identified in a clinic, rather than number of unmet needs addressed. When compared against these criteria its success is questionable, with fewer recurrences identified in the clinic than outwith (Grunfeld *et al*. 2006; Rojas *et al*. 2009; Montgomery, Krupa & Cooke, 2007). However the more subtle benefits that women describe are less quantifiable: such as reassurance following clinical examination (Beaver & Luker, 2005; McGaughan & McSorley, 2007).

Table 2.2: Comparison between clinical practice guidelines for breast cancer follow-up across the world

Guidance	SIGN	NICE	BASO	ESMO	NCCN	CMA	DF	NHMRC
Clinical history	no	no	yes	yes	yes	yes	yes	yes
Physical exam	no	no	yes	yes	yes	yes	no	yes
Mammography	yes	yes	no	yes	yes	yes	yes	yes
Pelvic exam	no	no	no	no	yes	no	no	yes
Patient education	no	yes	no	yes	no	yes	no	no
Psychosocial support	no	no	no	no	yes	yes	no	yes
Review new signs and symptoms	no	yes	no	yes	yes	yes	yes	yes
Preferred method described	no	no	no	no	yes	yes	no	yes
Frequency stated	no	no	^ risk	no	yes	variable	yes	no
Length	no	no	5 yrs	no	not clear	no	10yr	no

Key: SIGN, Scottish Intercollegiate Guidelines Network, (2013); NICE, National Institute of Clinical Excellence (England and Wales) (2009); *BASO,* British Association of Surgical Oncology (UK) (2005); ESMO, European Society for Medical Oncology (2007); NCCN, National Comprehensive Cancer Network (USA) (2014); CMA, Canadian Medical Association (2005); DF, Dutch Breast Cancer Federation (2012); NHMRC, National Health and Medical Research Council of Australia (Cancer Australia, 2010)

Kimman *et al*. (2007) reported a general feeling among clinicians in the Netherlands that limited time during the clinic visit prevents them adequately addressing the complex psychosocial issues which arise from a diagnosis of breast cancer.

2.7.2 Policy, follow-up and survivorship

The Scottish Government healthcare policy proposes quality, flexibility, responsiveness and putting the patient at the centre of care (Scottish Government, 2010a). Follow-up care is not specifically referred to within cancer documents; rather the term used is “living with cancer” (Scottish Government, 2010b), and more recently “survivors of cancer” (Scottish Government, 2013). Unlike diagnosis and treatment, follow-up care is not governed by targets or

legislation. The sense of urgency and timely treatment following diagnosis is welcome by women (Scottish Government, 2009) and can contribute to a feeling of security and support. However, this sense of urgency stops as treatment finishes and may contribute to a sense of abandonment reported in the literature (Eccles *et al*. 2013).

The measurement of a patients' needs is increasingly seen as a means to understanding better the impact of a cancer diagnosis and treatment on an individual's well-being (Sanson-Fisher *et al*. 2000; Sanson-Fisher, Carey & Paul, 2009; Carlson, Waller & Mitchell, 2012). The term "needs" and indeed those perceived as unmet, is a conceptually complex term and by its very nature, subjective (Maslow, 1987; Tomey & Allgood, 2002). Yet the term is widely integrated into cancer healthcare policy. While it is important that the cancer workforce "*is responsive to the needs of patients…..and individuals are partners in their care*" (Scottish Government, 2008, p.3), the achievement of this goal associated with follow-up care remains unclear. A report commissioned by the NCSI suggests five 'key shifts' are required to achieve change in how HCP's meet cancer patient's needs after treatment:

> *"a cultural and attitudinal shift to focus on health and recovery; a shift towards improving information; a shift towards assessment and care planning; a shift towards providing tailored care pathways based on risk of future problems associated with the type of cancer, the type of treatment and the particular circumstances of the individual; and a shift towards improved measurement through patient reported outcome and experience measures".* (Ipsos Mori, 2011, p. 6)

Building on the work already undertaken in England, the launch of the transforming care after treatment initiative, a partnership between the Scottish Government and Macmillan Cancer Support has begun (Scottish Government, 2013). Early recommendations propose that cancer patients play an active role in their care, that services are tailored to the needs and preferences of people affected by cancer and that more support in dealing with the physical, emotional and financial consequences of cancer treatment is required. While it may not be

clear as yet how this will be achieved within the current model of follow-up care some of the principles mirror work currently undertaken by SBCNs. This includes tailoring consultations post-diagnosis with an overall aim of meeting the psychological, physical and practical needs of the women they meet.

2.7.3 Models of delivering follow-up care

Research into different models of delivering follow-up care has emerged over recent years. Primarily they have focused on reducing the number of face to face consultations within the hospital setting. The first group of studies compared providing follow-up support over the telephone without clinical examination. They found no increase in anxiety or a decrease in quality of life through this approach (Koinberg *et al.* 2004, 2009; Beaver, Williamson & Chalmers, 2009). The study by Beaver, Williamson & Chalmers (2009) indicated this approach was as effective as hospital-based follow-up care. The second group of studies compared hospital follow-up to no follow-up and encouraged women to self-refer as and when they felt they had a need. Neither study reported any decline in quality of life or increased incidence of recurrence using this approach (Brown, Payne & Royle, 2002; Chapman *et al.* 2009; Sheppard *et al.* 2009). The third group of studies compared follow- up by hospital specialists (doctors) with GP's and found no decline in quality of life or increased incidence of recurrence (Grunfeld *et al*. 2006). A consistent finding among all the studies is that alternative delivery away from the hospital does not appear to impact on psychological morbidity, quality of life or recurrences seen. However none of them sought to review the way standard follow-up care meets the needs of women in the hospital

Most follow-up in the first 2 - 3 years following completion of primary treatment is delivered in a hospital setting and increasingly by SBCNs or ANPs. The report by the National Breast Cancer Centre defines the SBCN as:

> *a registered nurse who applies advanced knowledge of the health needs, preferences and circumstances of women with breast cancer to optimise the individual's health and well-being at various phases across the continuum of care, including diagnosis, treatment, rehabilitation, follow-up and palliative care. (*National Breast Cancer Centre, NBCC, 2005, p. 4*)*

Studies to date report a high satisfaction level among patients when seeing nurses, and their clinical examination performance is equal to their medical colleagues after appropriate training (McIntosh & Fowler, 2011; Kimman *et al.* 2011). However, studies that have focused on whether the introduction of nurses has improved health needs or overall well-being of women within this clinic are less visible.

2.8 Conclusion

This chapter has provided an overview of the development of breast cancer, diagnosis, the treatment modalities used and their corresponding side effects. Each part of this pathway has influenced the experiences and symptoms women report at follow-up. While improvements in diagnosis, treatment and management have increased overall survival outcomes, the intensity of this approach has left many women experiencing cumulative physical, emotional and psychological side-effects.

There is a consensus among clinicians that follow-up care is an important part in the monitoring of women post-treatment and increasingly recognition that on-going side effects, changes to a woman's body, provision of information and educating about what may constitute a recurrence, are integral to its success. However, they also accept that there is limited evidence to support this broader objective. It is important to acknowledge that follow-up is a continuation of care rather than a separate entity for most women. Therefore they cannot easily distinguish between symptoms that are related to normal recovery and those which are abnormal and a possible recurrence. Most women have little prior knowledge or experiences of breast cancer and cannot therefore compare themselves with others with the same condition, unlike specialists working in the area daily.

If follow-up care is to be effective, it is important that an understanding of the perceived unmet needs of women attending is gained, otherwise HCP's cannot offer appropriate interventions. The next chapter systematically reviews the evidence that reports the perceived unmet needs of women post-treatment and

whether the use of patient- reported outcomes measures which assess unmet needs within a clinical setting have been used to guide care.

Chapter 3: A systematic review of unmet needs and the use of needs assessment tools in follow-up

3.1 Introduction

This chapter reviews the key literature which reports the perceived unmet needs of women with breast cancer post-treatment, the use of patient-reported needs assessment tools among this group in the follow-up setting and the effectiveness of this approach. In Chapter 2 the pathophysiology, treatment and follow-up of breast cancer was discussed from both a disease and policy perspective. It illustrated the complex nature of this heterogeneous disease, the increasing diversity of treatments a woman may receive, subsequent side effects and the role follow-up care plays in monitoring women as they recover. While follow-up care is not a new concept, there appears to be increasing evidence that the traditional hospital-based approach no longer addresses the diversity of needs women experience when primary treatment ends. The review is presented in two parts. This is to ensure the goals of the review are addressed in the broadest possible manner and aid the presentation of a wide range of literature.

3.1.1 Part one:

This part reports literature which addresses the perceived needs of women with breast cancer during follow-up and focused on the following questions:

1. What is the evidence that women with breast cancer have unmet needs in the period known as “follow-up”?
2. How and what are these reported perceived needs?
3. Do socio-demographic and clinical factors affect the perceived needs women report?
4. Do needs change for women from one follow-up consultation to another?

5. Is there any evidence of a relationship between unmet needs and quality of life?

3.1.2 Part two:

This part reports literature which reviewed the effectiveness of using needs assessment tools in a breast cancer clinic setting and focused on the following questions:

1. Have patient reported needs assessment tools been used to guide care within a breast cancer follow-up setting?
2. If so, how effective is this approach?

The presentation of this chapter is informed by the Cochrane Collaboration Systematic Approach (Higgins & Green, 2011) and is presented in a way which includes reference to: an inclusion and exclusion criteria; a search strategy; the characteristics of studies; the methodological quality of studies; the results and a discussion. This approach was chosen to manage the considerable amount of literature pertaining to breast cancer and it provided a framework to allow this review to focus on a very specific area of the care of women with breast cancer; follow-up. The search strategy and methodological approach are described first. Similar approaches are used to address all the review questions. Where these may differ, this is clearly described. A conclusion is presented at the end of each part, an overall summary is presented at the end of the chapter and an outline of how these informed the research question is presented.

3.2 Search strategy

The systematic search strategy used to search for literature pertaining to both reviews was adapted from the Scottish Intercollegiate Guideline Network (SIGN) (2005), *Management of Breast Cancer in Women* (guideline 84), section 7: follow-up. This strategy was developed to find literature that related particularly to breast cancer and follow-up, with the terms consistent with those required for this review. As an organisation, SIGN have extensive experience in systematic literature searching. Their search methods usually include methodological filters to increase specificity for RCTs and meta-analysis. However these were removed

for part one of the review as the purpose was to seek literature about perceived unmet needs and it was considered important to include both qualitative and quantitative literature.

Additional search terms included “needs” and “nursing” and “needs assessment” included as a major concept for part two to ensure it was able to answer the specific review questions (Appendix 2). The assistance of a librarian was invaluable in this process.

3.2.1 Inclusion and exclusion criteria

Both reviews sought to identify all published retrospective and prospective primary research in the English language from 1995 – 2009. The starting date was chosen to reflect the introduction of SBCNs into clinical practice and their emerging role in delivering follow-up care. The end date, 2009 was when this study commenced. Studies identified following this date are included in the discussion chapter (Chapter 6).

The Medical Subject Headings (MeSH) term “breast neoplasm” is highly sensitive within all the electronic databases and breast cancer literature is the most frequently reported. To manage this and to increase sensitivity for this particular search strategy, clear inclusion and exclusion criteria were applied. Studies could include patients of any age but was restricted to female. Breast cancer is an infrequent event in men, with approximately 0.7% of all breast cancers diagnosed occurring in men (Nordman & Dalley, 2008). Clinicians have limited experience of male breast cancer due to its rarity and therefore the treatment and management follows a similar approach to females (Nordman & Dalley, 2008; Matterella, 2010).

No studies reporting investigative medical procedures used during follow-up to identify recurrence in asymptomatic women following completion of treatment were included: mammography, PET Scans, MRI or any other.

Studies could include women up to 5 years following diagnosis, but only beyond this point if relevant to the questions asked. Studies that reported needs, unmet needs and a need for support post primary treatment, within a follow-up clinic or within primary care were included. Studies which reported the experiences of receiving follow-up care or the context of follow-up care were excluded if they did not specifically address needs.

Studies that reported a woman's needs, unmet needs and a need for support while receiving surgery, chemotherapy, radiotherapy, and trastuzumab were excluded. These treatments are known as primary treatments and are completed prior to a woman receiving follow-up care. The review presented in this chapter was solely interested in studies which reported unmet needs post-primary treatment.

Qualitative and quantitative primary research studies were included in part one, but in part two only RCTs and pilot RCTs were included. The decision to do this was guided by the nature of the question in part two; to assess the effectiveness of using needs assessment tools during breast cancer follow-up clinics. Studies could include other tools that measured quality of life, anxiety, depression or satisfaction with care, but must include a needs assessment tool. Studies could include woman at any stage of the disease trajectory other than the terminal phase.

The following search methods were used and judged as to provide the best possible coverage of the literature:

1. **Electronic searches**: Medline 1995 - 2009; CINAHL 1996 - 2009; British Nursing index and archives 1994 - 2012; Psychinfo 1996 - 2009; Cochrane Library Central 2000-2009.

2. **Hand searching**, was undertaken of Acta Oncologica (2006/2007), Psych-Oncology; and Cancer Nursing to cover the years 2008/2009 and to assess sensitivity to search strategies.

3. **Reference lists**, from relevant studies were reviewed to identify any additional studies.

3.3 Methodological quality

To establish whether a paper should be included in a review, both its closeness to the inclusion/exclusion criteria and its methodological quality are assessed. The importance of this is reported by Cochrane as a critical part of any systematic review (Higgins & Green, 2011). Qualitative and quantitative research are derived from different research views and are often seen as competing paradigms, with no consensus on the criteria for appraising mixed methods research (O'Cathain, Murphy & Nicholl, 2008). There are a number of tools to assess quality in qualitative studies (Horsburgh, 2003), and quantitative studies (Greenhalgh & Peacock, 2005; Guyatt *et al.* 2011; SIGN, 2012) with fewer papers suggesting ways of reviewing qualitative, quantitative and mixed methods research concomitantly (Pluye *et al*. 2009). Early scoring systems which grade the quality of evidence have focused almost exclusively on study design. Therefore the RCT provides stronger evidence than observational studies, and indeed qualitative studies are often not considered in the scoring systems. Dixon-Woods *et al*. (2005) acknowledge that it remains a challenge to review research with methods that vary in their strengths and abilities. Their suggestion that existing techniques are adapted rather than new approaches invented was considered the best approach for this review.

During the review process, titles and abstracts identified in the searches were read for relevance. All relevant literature was then read in full. It was apparent that the criterion by Pluye *et al.* (2009) was too restrictive for the papers in this review. Therefore a data extraction tool was adapted from SIGN (2012) with an additional scoring system used for the RCTs and described in Table 3.1.

Table 3.1: Scoring framework of RCTs (Guyatt *et al*. 2011)

<table>
<tr><th>Study design</th><th>Quality of evidence</th><th>Lower if</th><th>Higher if</th></tr>
<tr><td rowspan="2">Randomised trial→</td><td>High</td><td rowspan="3">Risk of bias
-1 serious
-2 very serious

Inconsistency
-1 serious
-2 very serious

Indirectness
-1 Serious
-2 very serious

Imprecision
-1 serious
-2 very serious

Publication bias
-1 likely
-2 very likely</td><td rowspan="3">Large effect
+1 large
+2 very large

Dose response
+1 evidence of a gradient

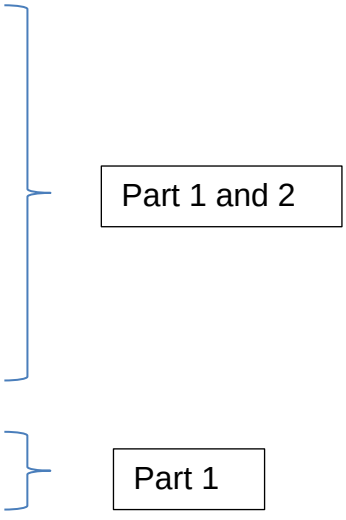
All plausible confounding
+ would reduce a demonstrated effect

+1 would suggest a spurious effect when results show no effect</td></tr>
<tr><td>Moderate</td></tr>
<tr><td rowspan="2">Observational study→</td><td>Low</td></tr>
<tr><td>Very low</td><td></td></tr>
</table>

The characteristics and methodological quality of the studies extracted informed the specific aims of both reviews. These are:

Characteristics of the studies

- Age of participants
- Time since diagnosis
- Type of follow up regimen of the participants
- Origin of study
- Stage of the breast cancer
- Breast cancer specific details
- Size of study
- Were needs defined? (yes/no)
- HCP involved



Methodological quality

- Method
- Inclusion criteria
- Exclusion criteria
- Description of intervention/interview
- Needs assessment tools or other used
- Outcome measures/aims stated

Part 1 and 2

- Randomisation process
- Sample
- Allocation concealment
- Numbers followed up
- Intention to treat analysis

Part 2

Factors that can decrease the quality of the evidence include: study limitations, inconsistency of results presented, indirectness of evidence and publication bias which may result in selective outcome reporting. Factors that may increase the quality include a large magnitude of effect and plausible outcomes. The characteristics of the studies are presented in Table 3.4 (part one) and Table 3.10 (part two), the methodological quality are presented in Table 3.5 (part one) and Table 3.11 (part two) with factors which may have decreased or increased the quality discussed in Sections 3.4.4 and Section and 3.8.4 respectively. Finally, a results table was compiled to address the specific outcomes of this review and interpreted in Section 3.5 (Table 3.6) and Section 3.9 (Tables 3.12 and 3.13).

3.3.1 Patient-reported outcome measures (PROMs)

Data on the following PROMs were sought. Data extracted for part one included (Table 3.6):

1. Patient reported levels of perceived unmet need during follow-up care to ascertain:

a) The number of unmet needs reported;
b) The type of unmet needs reported;
c) Whether changes in needs are reported over time;
d) The effect of age on perceived needs;
e) Percentage of needs met;
f) Who meets these needs?
g) Predictors of reporting a need.

2. Any patient reported data related to quality of life

Data extracted for part two (Table 3.12 and 3.13) included:

a. Patient reported changes of perceived needs.
b. Patient reported changes in quality of life.

3.4 Results of part one

This part of the review reports literature that addresses the perceived needs of women with breast cancer during follow-up and focused on the following questions:

1. What is the evidence that women with breast cancer have unmet needs in the period known as “follow-up”?
2. How and what are these reported perceived needs?
3. Do socio-demographic and clinical factors affect the perceived needs women report?
4. Do needs change for women from one follow-up consultation to another?
5. Is there any evidence of a relationship between unmet needs and quality of life?

3.4.1 Outcome of search strategy

The combined searches across all the databases, reference lists and hand-searching identified 1,521 potential papers (Table 3.2). Once the abstracts were read it was apparent that the search strategy had identified many papers which were not relevant to this review. When the inclusion/exclusion criteria was applied only 22 (1.27%) papers were identified as potentially relevant and read in full. Of these, 16 papers were excluded and the reason for their exclusion is summarised in Table 3.3 with further discussion in Section 3.4.2.

Table 3.2 Record of searches up to 2009 (part one)

Database	Total no. of hits	Included for full text review	Included in review	Excluded from review
Medline	1066	18	5	13
CINAHL	30	1 duplicate from Medline	0	0
British Nursing Index	400	1 duplicate from Medline	0	0
PsycINFO	23	2	1	1
Cochrane Library	0	1 duplicate from Medline	0	0
Hand searching	2	2	0	2
Total	**1521**	**22**	**6**	**16**

3.4.2 Excluded studies

Sixteen papers were excluded. Thirteen were primary research studies which reported different follow-up care practices, experiences of follow-up care and nursing involvement but failed to meet the inclusion criteria relating to needs, unmet needs and need for support during follow-up care (see Section 3.2.1) (Judkins, Peterson & Singletary, 1996; Earnshaw & Stephenson, 1997; Adewuyi-Dalton *et al*. 1998; Pennery & Mallet, 2000; Sanson-Fisher *et al*. 2000; Lindop & Cannon, 2001; Brown, Payne & Royle, 2002; Koinberg *et al.* 2004; Thompson *et al.* 2006; Kimman *et al*. 2007; Minstrell *et al*. 2008; Montgomery, Krupa & Cooke, 2007; Sheppard *et al*. 2009). Three papers were excluded because they were literature reviews that considered types of follow-up care and frequency of delivery rather than the needs of the women attending (Collins, Bekker & Dodwell, 2004; Montgomery, Krupa & Cooke, 2007; Sheppard, 2007). Further details of the reasons for exclusion of all these papers is summarised in Table 3.3.

Table 3.3 Summary of excluded studies (part one)

Study	Type of study	Reason for exclusion
Adewuyi- Dalton *et al*. (1998)	Qualitative	Explored the experience of women attending follow-up
Brown, Payne & Royle, (2002)	RCT	Compared usual follow-up to no follow-up unless initiated by women
Collins, Bekker & Dodwell (2004)	Literature review	Reviewed follow-up practices and nursing involvement not needs
Earnshaw & Stephenson (1997)	Audit	Focused on nurse-led follow-up services, did not focus on needs
Judkins, Peterson & Singletary (1996)	Qualitative	Compared non-doctor to doctor provider of follow-up
Kimman *et al*. (2007)	RCT protocol	Insufficient data available, an abstract
Koinberg *et al*. (2004)	RCT	Compared doctor led follow-up to nurse led telephone based follow-up
Lindop & Cannon (2001)	Qualitative	Measured support needs across the breast cancer trajectory but data relating to follow-up period difficult to extract
Minstrell *et al*. (2008)	Longitudinal survey	Needs of women with breast cancer following diagnosis over 3 months but did not consider the follow-up period
Montgomery, Krupa & Cooke (2007)	Literature review	Reviewed follow-up practices and nursing involvement
Montgomery, Krupa & Cook (2008)	Qualitative	Explored experiences of women with breast cancer prior to receiving follow-up
Pennery & Mallet (2000)	Qualitative	Did not specifically look at the needs of women during follow-up although it did consider their views of follow-up practices
Sanson-Fisher *et al*. (2000)	Survey	Reviewed predictors and perceived needs during treatment rather than follow-up
Sheppard (2007)	Literature review	Reviewed follow-up practices and nursing involvement but not needs
Sheppard *et al.* (2009)	RCT	Compared usual follow-up to follow-up by request by women when they felt they needed to be seen but not needs
Thompson *et al*. (2006)	Qualitative	Explored the experiences of women at follow-up, particularly motivators and barriers but not needs

3.4.3 Characteristics of included studies

A summary of the characteristics of the six included studies is presented in Table 3.4. None of the six included studies defined the term “needs” or “unmet needs”, however, following a review of the full papers they met most of the inclusion criteria: one study reviewed the needs assessment literature (Girgis *et al*. 2000) while the remaining five studies explicitly used the term “needs” in their overall aim or objectives (Raupach & Hiller 2002; Thewes *et al*. 2004; de Bock *et al.* 2004b; Beaver *et al*. 2006; McCaughan & McSorley, 2007).

A total of 712 (range 21 - 229) women with a mean age of 52 (range 30 - 89 years) are included across the six studies; they are all diagnosed and treated for breast cancer, are disease free and have completed their primary treatment. The surveys constituted 645 of the participants. These data captured the range of perceived unmet needs women reported post-treatment and during follow-up care (Table 3.4).

All the studies except Beaver *et al*. (2006) gave details of the time since diagnosis of the women (range 6 months to 21 years). The study by McCaughan & McSorley (2007) included some women who were over 5 years since diagnosis. The majority of the qualitative data presented in their paper referred specifically to women who were up to 5 years and in some areas of the results, it was difficult to identify the time since diagnosis. It was expected that the papers conclusions would add to this review.

Only two studies described the follow-up regimen (de Bock *et al*. 2004b; Raupach & Hiller 2002) but all studies described the country of origin. It is important to understand the origin of the study because differences occur in the frequency, intensity of regimens and length of follow-up between countries and access to support structures may be variable (see Table 2.2). In addition, cultural beliefs may differ between countries could impact on perceived unmet needs. Two

studies were undertaken in the UK (Beaver *et al*. 2006; McCaughan & McSorley, 2007), three in Australia (Girgis *et al.* 2000; Raupach & Hiller, 2002; Thewes *et al*. 2004) and one in Holland (de Bock *et al*. 2004b).

Table 3.4: Characteristics of included studies (part one)

Study	**Needs defined Yes/no**	**Type of follow-up a. timing b. Country**	**Age a. C b. I**	**Size C or/I**	**Stage of breast cancer**	**TSD**	**HCP**
Beaver *et al.* (2006)	no	a. no b. UK	a. mean age 55: (range 32-79) b. mean age 59: range 38-84	135 patients C. 67 I. 68) 2x SBCN interviewed	n/a	n/a	SBCN Doctor
De Bock *et al.* (2004)	no	a. 6 Monthly b. Holland	Med 56: range 33-90	84	DCIS: 11 stage 1: 36 (43%) stage 2a 17 (20%) Stage 2b 17 (20%) Stage3a 14(4%)	med 3 years: range 2 - 4.1 years	n/a
Girgis *et al*. (2000)	no	a. no b. Australia	range 30-89	229 rural - 129 urban -100	n/a	6m – 5 years	n/a
McCaughan & McSorley (2007)	no	a. no b. UK	range 34-89	21	n/a	2 - 21 years	Doctor
Raupach & Hiller (2002)	no	a. 6 monthly b. Australia	mean 58	219	n/a	6 -30 m	n/a
Thewes *et al.* (2003)	no	a. no b. Australia	mean 35 (range 26-45)	24	Early stage breast cancer	12m – 5 years	n/a

Note: C = Control; I = intervention; m = months; TSD = time since diagnosis; med = medium

Two studies reported that a doctor undertook the follow-up consultation (Beaver *et al*. 2006; McCaughan & McSorley, 2007), although their level of seniority was not described. In one of these studies, the specialist breast care nurse (SBCN) undertook an additional intervention following a woman's attendance at the clinic (Beaver *et al.* 2006). In the remaining four studies this information was

unavailable (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Thewes *et al*. 2004).

Only one study (de Bock *et al*. 2004b) described the specific stage of breast cancer participants. These included women with ductal carcinoma insitu (DCI) and breast cancer, grades 1,2 and 3. Thewes *et al.* (2003) referred to participants in a generic manner as having early invasive breast cancer. This limits any comparisons between studies and is an important consideration. The stage of breast cancer at presentation is an important indicator of treatment choice, regimen used, the risk of side effects and prognosis (see Chapter 2).

3.4.3.1 Sample strategy and recruitment

Thewes *et al*. (2003) recruited 24 participants and McCaughan & McSorley (2007) 21, with a single site location used by both studies. In the study by McCaughan & McSorley (2007), women were attending a UK breast cancer follow-up clinic but no details of how women were recruited into their study were provided. However, the purpose of this study, as exploratory, reflected the sample size used.

The sample by Girgis *et al*. (2000) (n=229) was randomly selected from the New South Wales Central Cancer Registry and therefore had the highest potential to be representative. Strict ethical processes required permission from the GP prior to contacting the women by post, which according to the authors caused delays and barriers with recruitment. A significant number of women were considered ineligible to take part by the GP and this may have contributed to the non-representativeness and low response rate (51% for urban v. 55% for rural). Up to 8% (n =68) in both groups were considered emotionally or physically unstable according to the GP but the criteria by which this was arrived at is unclear. These women may have had higher needs. Additionally, 80% (n=183/229) of women in the study were at least 3 years since diagnosis, and therefore was less representative of the range of women seen in breast cancer follow-up clinics. In contrast, Raupach & Hiller (2002) and de Bock *et al*. (2004b) had good recruitment to their studies, with 82% (n=266) and 72% (n=116) taking part respectively. Both studies recruited participants from the current out- patient lists

but neither indicated how many patients overall were on these lists and so, representativeness of the sample is not clear.

3.4.4 Methodological quality of included studies

A summary of the methodological quality of the six studies is presented in Table 3.5.

Table: 3.5 Methodological qualities of included studies

Beaver *et al.* 2006	**de Bock *et al.* 20004**	**Girgis *et al.* 2000**
Method: mixed **Inclusion:** access to phone **Exclusion:** n/a **Needs assessment tool used**: yes, INQ **Other tools**: STAI, GHQ-12 **QS**: 58/100 **Description of intervention/interview:** **Place**: phone + hospital **Timeframe**: 3m and 8-12m **No**. interview x 1, questionnaires x 2 **Aim:** To examine the feasibility and acceptability of a nurse led telephone intervention to meet patient needs	**Method**: Cross-sectional survey **Inclusion**: attending follow-up **Exclusion**: n/a **Needs assessment tool used**: yes, by authors **Other tools**: HADS, PSQ111 **QS: 33/100** **Description of intervention/interview:** **Place**: home **Timeframe**: n/a **No**. questionnaire x1 **Aim**: To analyse the needs of women at routine follow-up after treatment for primary breast cancer	**Method**: Cross sectional survey **Inclusion**:6m - 6 years **Exclusion**: n/a **Needs assessment tool used**: yes, BR-CPNQ **Other tools**: n/a **QS**: 66/100 **Description of intervention/interview:** **Place:** home **Timeframe:** n/a **No.** questionnaire x 1 **Aim:** To assess prevalence of unmet needs among women diagnosed with breast cancer Identify predictors of expressing moderate – high needs
McCaughan & McSorley (2007)	**Raupach & Hiller (2002)**	**Thewes *et al*. (2004)**
Method: Non-participant observation and interviews **Inclusion:** n/a **Exclusion:** n/a **Needs assessment used**: n/r **Other tools**: n/r **QS**: 50/100 **Description of intervention/interview:** **Place**: hospital **Timeframe**: not stated **No.** Interview x 1; observation x 7 clinics **Aim:** To explore healthcare needs of women attending follow up clinics, how they are met and HCP ways to improve services	**Method**: Cross-sectional survey **Inclusion**: attending cancer centre **Exclusion**: n/a **Needs assessment used**: yes, by authors **Other tools**: not used **QS**: 66/100 **Description of intervention/interview:** **Place:** home **Timeframe**: 6 – 30m **No**. questionnaire x 1 **Aim:** needs for, use of and satisfaction with information and support of woman	**Method:** focus groups/interviews **Inclusion:** past 5 years, pre-menopausal at diagnosis **Exclusion**: n/a **Needs assessment used**: n/r **Other tools**: n/r **QS**: 83/100 **Description of intervention/interview:** **Place**: hospital **Timeframe**: not stated **No.** Interview x 1 **Aim:** To identify the fertility – and menopause – related information needs of younger women who have had early breast cancer

Note: n/a = not available; n/r = not relevant; QS = quality score

Of the six studies included, two used a qualitative approach (Thewes *et al*. 2004; McCaughan & McSorley, 2007). Of these, neither reported any evidence of using a theoretical framework or a specific qualitative research methodology; a critical component in the assessment of quality in this methodological approach (Creswell & Plano Clark, 2007). The decision to include studies with different research designs in this review enabled a more in depth overview of the literature in this field; however the methodological quality of these studies was variable. Although considered low on the hierarchical scale of study types, in that they are qualitative studies (Thewes *et al.* 2004; McCaughan & McSorley, 2007), cross sectional surveys (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b) or non-experimental studies (Beaver *et al.* 2006), Dixon-Woods *et al*. (2005) support the use of different types of evidence by practitioners and policy-makers, particularly in the absence of any RCTs.

Similarities in the overall aim or objectives across the four studies were seen (Girgis *et al.* 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; McCaughan & McSorley, 2007). De Bock *et al*. (2004b) and McCaughan & McSorley (2007) aimed to explore and assess the perceived unmet needs of women attending follow-up care, while Girgis *et al*. (2000) wanted to understand unmet needs across different populations; rural and urban. Only one study (Thewes *et al.* 2004) focused specifically on the unmet needs associated with fertility and menopausal consequences of younger women (age 25 - 45 years), and Beaver *et al*. (2006) examined the feasibility of a nurse-led intervention to meet the information needs of women. In all the studies women received follow-up care in a clinic setting, but data which described the frequency of attendance was difficult to extract. This meant there was uncertainty about the current support opportunities made available to women.

Validation of quantitative and qualitative data is important as it reflects the ability to interpret and generalise findings. Two studies used a validated needs assessment tool although differently (Girgis *et al*. 2000; Beaver *et al*. 2006). Girgis *et al*. (2000) used the Supportive Care Needs Survey (SCNS) which measures both the unmet needs associated with psychological, health

information, physical/daily living, patient care/support and interpersonal communication as well as their requirement for help. Beaver *et al*. (2006) used an Information Needs Questionnaire (INQ) covering nine information needs. The 4 point Likert scale asked questions about how much information they needed and whether they had received this information or not. It was originally developed and tested in Canada by Degner *et al*. (1998). Neither was specifically developed for use with breast cancer patients attending follow-up clinics.

The Hospital Anxiety and Depression Scale (HADS) used by de Bock *et al*. (2004b) does not specifically measure unmet need. However psychiatric morbidity associated with mastectomy (Maguire *et al*. 1987) coupled with anxiety and depression scores among breast cancer patients have shown to be consistently high (Osborne *et al*. 2004), leading a number of authors to suggest that a high score on the HADS (HAD-A and HAD-B) indicate a high psychological need (Carroll, 1993; Karakoyun-Celik *et al*. 2010; McDowell *et al*. 2010). De Bock *et al*. (2004b) combined this information with a questionnaire they specifically designed for their study. Other validated questionnaires used measured quality of life (General Health Questionnaire, GHQ-12) (Beaver *et al*. 2006), levels of distress with the State- Trait Inventory (STAI) (Beaver *et al*. 2006) and a Patient Satisfaction Scale (PSQ 111) (de Bock *et al*. 2004b).

Similar questions appeared about recurrence, side effects of treatment, spread of disease and impact on self and family in the questionnaires designed by Raupach & Hiller (2002) and de Bock *et al.* (2004b) and those used by Girgis *et al*. (2000) and Beaver *et al*. (2006). The distribution of all questionnaires following recruitment was clear. All participants were completed them at home (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Beaver *et al*. 2006). In addition, Beaver *et al.* (2006) offered an interview to women at the hospital when attending their clinic appointment and two others interviewed women at the hospital (Thewes *et al*. 2004; McCaughan & McSorley, 2007).

One limitation noted is the selective outcome reporting associated with a number of the publications. Two studies aimed to investigate and explore the perceived needs of women attending follow-up care (Raupach & Hiller, 2002; de Bock *et al*.

2004b), one aimed to understand perceived needs from different populations; rural and urban, post treatment (Girgis *et al*. 2000) or younger women (Thewes *et al*. 2004) or to understand the perceived needs through observation of the nature and context of the follow-up clinic (McCaughan & McSorley, 2007). One study aimed to examine the feasibility of a nurse-led intervention to meet the information needs of women (Beaver *et al*. 2006). While presenting aims rather than outcomes is consistent with non-experimental and qualitative designs, some inconsistencies in how the results were presented by Beaver *et al*. (2006), Girgis *et al*. (2000) and McCaughan & McSorley (2007) impacted on the interpretation of their studies.

Thewes *et al.* (2003) did not provide detail of the qualitative approach used but did provide a clear explanation of the patients in their study, the interview, and the analytical approach that led to its findings. This strengthened the quality of data reported.

3.5 Outcome results

The six studies indicated that some level of unmet need persists for women post treatment and during a time they would receive follow-up care (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Beaver *et al*. 2006; McCaughan & McSorley, 2007). A summary of the results is presented in Table 3.6.

Table 3.6: Results of included studies in part one

Study	Unmet needs reported	Change in needs over time	Predictors of reporting a need	Relationship between age and need	% needs being met
Beaver *et al.*(2006)	**Control**: no data **Intervention** 17-36% (time 1); 3 - 40% (time 2)	Cure, p <0.01 Family impact, p 0.05 Genetic risk, p <0.01 (p=>0.05)	n/a	n/a	Time 2 **Control** 27% - 57% **Intervention** 60% - 91%
De Bock et *al*.(2004)	19 - 86%	n/a	Higher HADS scores Hormonal therapy Fear of recurrence	General needs -0.35** Specific needs -0.32**	n/a
Girgis *et al.* (2000)	rural 28- 55% urban 28 - 41%	n/a	Age Family income Chemo and radio in past month Younger women	30 - 59 years 70 - 89 years	n/a
McCaughan & McSorley (2007)	n/a	n/a	n/a	n/a	n/a
Raupach & Hiller (2002)	36 - 90%	n/a	n/a	Over 69 > needs compared to 50-69 Under 50 some <needs	2 - 26%; (mean 16%)
Thewes *et al.*(2003)	n/a	n/a		26 - 45 years	Yes – narrative only

The type and number of unmet needs reported across the studies varied depending on the specific aims of the study, its design and questions asked. It was clear though that irrespective of method used, common themes were emerging about the type of unmet needs reported by women at this time. These were categorised as: psychological, information and physical needs. Some of these categories were already pre-determined due to the nature of the questionnaires used (Girgis *et al*. 2000; Rauper & Hillier, 2002; de Bock *et al.* 2004; Beaver *et al*. 2006). In other studies this was not as clear and a pragmatic decision was made according to the results described. A summary of the categories and particular needs is presented in Table 3.7

Table 3.7: Range of unmet needs reported in the studies (part one)

Study	Psychological needs	Information needs	Physical and daily living
Beaver *et al*. (2006)		Genetics, Spread, Side effects, Cure, Social Life, Sexual attractiveness, Treatment options, Self-care, Family impact	
Girgis *et al*. (2000)	Fear of spread/ recurrence Anxiety/stress Feeling down/depressed	Test results, knowledge of side effects, self-care, remission, treatment success, written information, support groups side effects	Lack of energy and tiredness
De bock *et al*. (2004)	Fear of cancer returning	Long term effects of treatment, prognosis, diagnosis information, side effects, hereditary factors, changes in untreated breast, reconstruction, family/friends, adaptation, additional investigations, prevention	Fatigue, pain nutrition
Rauper & Hiller, (2002)		Recurrence, cure, risk to family, Tamoxifen, effect on family, arm problems/Lymphoedema, appearance after surgery, menopause/HRT, prostheses sexuality and relationships, breast reconstruction, additional support	
Thewes *et al*. (2003)		Fertility, menopause, treatment, sexuality (narrative)	
McCaughan & McSorley (2007)	Fear of recurrence Psychosocial needs (general) (narrative)		

All the studies are report unmet needs as a percentages except Thewes *et al*. (2003) and McCaughan & McSorley (2007) who described unmet needs through narrative. The most frequently reported unmet needs related to a fear of recurrence; managing side effects; and coping with the impact on self. Beaver *et al*. (2006) reported results relating to the 9 questions on the INQ, Raupach & Hiller (2002) only 13 and de Bock *et al*. (2004b), 15; Girgis *et al*. (2000) presented

data on the top 15 high to moderate needs expressed out of the 61 questions asked.

The five highest unmet needs reported by de Bock *et al*. (2004b) was for information about long term side effects (84%, n=69/84), hereditary implications (68%, n=57), prognosis (85%, n= 69), identifying changes in the untreated breast (65%, n=55) and prevention of breast cancer (72%, n=60). These were similar to those reported by Rauper & Hiller (2002): recognising a recurrence (90% n=191/217), chances of cure (82%, n=167), risk to family (81%, n=167), side effects of endocrine therapy (72%, n=148) and effects on family (68%, n=142).

Girgis *et al* (2000) reported similar results but these needs were lower among their sample; fears about cancer spreading (rural 55%, n=70 v. urban 41%, n= 40), being fully informed of test results (45%, n=58v. 44%, n=43), benefits and side effects of treatment (44%, n=57 v. 42%, n-41), self-care (44%, n=56 v. 40%, n=39) and being informed about cancer remission (45%, n=58 v. 37%, n=36). Women continue to be fearful of a recurrence and anxious about their chances of cure and treatment success, despite regular engagement with HCPs during follow-up. Women described attending follow-up allayed their fears (McCaughan & McSorley, 2007) but in observations by the researcher, no evidence of specific conversations addressing this area of need was seen, rather a sense that if women left with no recurrence found, everything was alright. In contrast, women reported that needs associated with the side effects of treatment, body image, and sexuality were not addressed. This suggests that once fears are allayed, women wish to focus on issues that affect their day to day lives. These areas though may require more active enquiry.

Some authors suggest that any form of reassurance within a clinic will improve a woman's ability to cope with the wider effects of treatment (de Bock *et al*. 2004b; Beaver *et al*. 2006), understanding the risk posed by breast cancer for their family members (Rauper & Hiller, 2002; Beaver *et al*. 2006;) and their general anxieties about the whole cancer experience (de Bock *et al*. 2004b; Beaver *et al*. 2006). Despite these conclusions, only one study (Beaver *et al.* 2006) gathered data from more than one time point to demonstrate changes over time.

The wish to receive information related to the consequences of breast cancer was more frequently reported than any other category (Table 3.7). Apart from information about the risk of recurrence, the other frequently reported information needs included: menopausal or fertility issues through narrative (Thewes *et al*. 2003), genetics, 41% (n=27/67) and side effects of treatment, 35% (n=23) (Beaver *et al.* 2006) prevention, 72% (n=84/116) and hereditary factors, 68% (n=79) (de Bock *et al*. 2004), benefits and side effects of surgery prior to treatment, 44% (n=57) v 42% (n=41) (Girgis *et al*. 2000), and information about their prescribed hormone treatments (McCaughan & McSorley, 2007).

Raupach & Hiller (2002) found that 205 out of 217 women reported the importance of receiving information. This included information about reconstruction (36%, n=74), sexuality and relationships (39%, n=81) and prostheses (41%, n=82). De Bock *et al.* (2004b) also found 26% (n=22) of women wanted information about reconstruction. In their study specific questions related to sexuality and prostheses were not included. Considering mastectomy and/or reconstruction is a common treatment questions of this nature are important to include. Girgis *et al*. (2000) did not ask women about any of these areas. Lower needs were associated with lack of energy and tiredness (28% v. 28%) and feeling down or depressed (33% v. 29%).

The wide range of information needs which are reported reflect the different types of breast cancer, the different treatments used and the individual reaction a woman may experience (Chapter 2). The participants in the study by Girgis *et al*. (2000) scored information about support groups and self- care approaches higher than participants in the study by Beaver *et al*. (2006). Why this may be the case is unclear from the results.

None of the studies measured the unmet needs of women before and/or after the follow-up consultation, therefore it is difficult to know if some of these information needs were met during the follow-up consultation. Beaver *et al*. (2006) did offer their intervention following the follow-up consultation. They reported high levels of unmet needs in their sample following the consultation, measured using the INQ.

Five studies reported psychological needs or referred to it as psychological distress (Girgis *et al*. 2000; Thewes *et al*. 2003; de Bock *et al*. 2004; Beaver *et al*. 2006; McCaughan & McSorley, 2007). Beaver *et al*. (2006) reported a significant difference between the mean STAI scores between the intervention (mean 31.1) and control (mean 34.9) post-intervention (t = - 2.02, p=0.05). The STAI scores between a range from 0 - 80.

In contrast, de Bock *et al*. (2004b) reported that 18% (n=15) of their participants warranted further psychiatric evaluation after completion of the HADS. They applied a cut-off score of 8; a score considered the optimal balance between sensitivity and specificity (0.80) when the HADS is used as a screening tool (Bjelland *et al*. 2002). Satisfaction with care was measured using Ware's tool (Hagedorrn *et al*. 2003). Multivariate analyses of the satisfaction with care results, in particular the interpersonal aspects, indicated that the score on the HADS was an independent predictor of needs and preferences (p<0001=0.52, anxiety; p<0.001=0.29, depression). These results suggest the HADS is a useful tool to measure psychological needs.

3.5.1 Age-specific needs

The age of women diagnosed with breast cancer includes those at a childbearing age, pre-, peri- and post-menopausal stage in their life cycle. This was apparent among the participants in the studies whose ages ranged from 26 – 90. Four studies considered how the age of a woman may predict her level of need (Girgis *et al.* 2000; Rauper & Hiller, 2002; Thewes *et al*. 2003; de Bock *et al*. 2004b).

Rauper & Hiller (2002) (sample of 219) reported women over 69 (6%) were significantly less likely than women of 50-69 (27%) to receive information about physical appearance post-surgery (prevalence rate ratio (PRR) 0.24, 95% CI 0.06-0.94) and where to go for information (6% v. 28%, PRR 0.23, 95% CI 0.06 – 0.92). Women over 69 expressed lower needs with respect to information about sexuality and relationships (3% v. 41%, (PRR) 0.07, 95% CI 0.01-0.52), breast reconstruction (3% v.38%, PRR 0.08. 95% CI 0.01-0.56), menopause and HRT (10% v.50%, PRR 0.20, 95% CI 0.07-0.60), and physical appearance (20% v.

63%, PRR 0.32, 95% CI 16-0.63). Women under 50 reported higher needs for information compared to women 50-69 about: complementary and alternative therapies (71% v. 53%, PRR 1.34, 95% CI 1.12-1.83), menopause and HRT (72% v. 50%, PRR 1.43, 95% CI 1.12-1.83), sexuality and relationships (59% vs. 41%, PRR 1.45, 95% CI 1.06-1.98), and breast reconstruction (54% v. 38%, PRR 1.43, 95% CI 1.02-2.02).

Two studies undertook multivariate analyses. They reported an association between different variables and reporting "some" need (Girgis *et al*. 2000; de Bock *et al*. 2004b). In the study by de Bock *et al*. (2004b) age (-0.35** -0.32**) having adjuvant hormonal treatment (0.24*), having chemotherapy (0.25*, 0.23*), anxiety (0.52***) and depression (0.29*) were predictors of reporting 'some' need.[1]

Girgis *et al*. (2000) reported age as being associated with a psychological need (ages 30 - 49, p = 0.005), having radiotherapy or chemotherapy in the last month was associated with a patient care and physical need (p=0.023; p=0.033) and rural inhabitants were associated with having a physical and daily living need (p=0.014).

The study by Thewes *et al*. (2003) particularly focused on the perceived unmet needs of younger women (age range 25 – 45) and who were attending follow-up (2 - 5 years since diagnosis). Through a series of focus groups facilitated by a psychologist, fertility-related, menopause related, treatment specific and sexuality issues were explored. Women described complex side effects associated with an iatrogenic menopause, loss of fertility and concerns about having further children. They felt their follow-up consultations had afforded them few opportunities to express a need for support in these areas.

They described a process of "grieving" when faced with fertility issues and a premature menopause, placing increasing importance on it the further they were

[1] *p<0.05, **p<0.001, ***p<0.0001 First result relates to general topics associated with need, the second score relates to specific topics of need.

from treatment (Thewes *et al*. 2003). The menopause is diagnosed after 12 months of amenorrhoea resulting from the permanent cessation of ovarian function regardless of whether the menopause was natural or induced (Greendale, Lee & Ariola,1999). Symptoms would therefore become more apparent during follow-up. The interviewed participants ranged in age, numbers of births, and status (single or married). Each participant expressed a highly individual situation associated with fertility and menopausal needs. Although some women sought formal support from HCPs there is no details reported about the nature of this. The authors recommend that fertility and menopause related issues should be revisited during follow-up.

Menopausal issues are not exclusive to women under 50. The median age that menopause occurs in Europe ranges from 50.1 to 52.8 years (Palacios *et al*. 2010). Rauper & Hiller (2002) also reported that menopausal issues were an unmet need. In their study, women aged 50-69 had high information needs relating to menopausal and HRT, rather than fertility needs. Many of these women would be receiving endocrine therapy, which can cause menopausal symptoms: therefore the result is perhaps not surprising. Distinguishing between these needs is difficult and currently rests with the clinician who has the responsibility to provide opportunities for women to raise issues of a personal nature. Although the study by McCaughan & McSorley (2007) included women as young as 34, the data presented did not make reference to the age and need for support of individual participants.

Girgis *et al*. (2000), using the Breast Cancer Patient Needs Questionnaire (BR-CPNQ) reported that younger age was a predictor of psychological need (Odds Ratio 6.43, age 30-49 compared to 1.04, 60-69). The generalisability of these results is limited though as the study reports an under-representation of women aged 30 - 39 years.

3.5.2 Changes in needs over time

Beaver *et al*. (2006) was the only study included in this review which reported changes in needs over time, baseline (1 - 2 months) and time 2 (8-12 months) on a population of 135 (control, 67; intervention, 68). This study evaluated a

telephone intervention which aimed to meet the information needs of women with breast cancer. Although methodologically a RCT would have provided the most powerful rigor in establishing cause and effect, this pilot study aimed to test the feasibility and acceptability of this approach. The shortness of the questionnaire was appropriate when undertaking a telephone intervention. In addition, the STAI and the GHQ-12 were used.

Beaver *et al*. (2006) reported needs associated with seroma formation, altered arm sensation and Lymphoedema, plus nine additional needs reported on the INQ. Changes were reported in both control and intervention groups between baseline and time 2. These included: seroma formation >16.7% (control) v. 59.3% (intervention); altered arm sensation > 11.1% v. 51.9%; Lymphoedema no change v. > 11.8%, however it is unclear from the data reported whether this was significantly different between the two groups. The participants were all post-surgery (mean time since surgery 3-4 months). However, it is unclear from the data reported whether some of the participants were also receiving additional treatments such as chemotherapy or radiotherapy.

The STAI scores indicated a significant difference at time 2 between the intervention (M=31.1) and control (M=34.9, t= - 2.02, p=0.05). The ability of the nurse to meet the information needs through the intervention was high (73% - 90%), though only 3 items were statistically different (information about cure: p=<0.01; family impact, p=0.05; genetic risk, p=<0.01). The intensity of the intervention by Beaver *et al*. (2006) may have contributed to these positive results. However, the SBCN involved in the study found the intervention to be quite time consuming and the discussion of sensitive issues over the telephone, difficult at times. Despite this, the study indicated that using a structured approach to the assessment of need, nurses are able to respond to these in an effective way. Effectiveness was measured by noting a significant reduction in anxiety and an increase in the perception of women that the nurses were able to meet their information needs over time.

3.5.3 Needs met and by whom

Different HCPs are involved in the follow-up care of women. Both nurses and doctors were integral to the care of the women in the studies. Two studies specifically reported the input of the nurse or doctor (McCaughan & McSorley, 2007; Beaver *et al*. 2006). In McCaughan & McSorley (2007) study, women described limited opportunities to have their information needs about hereditary implications, family issues or tiredness met by a HCP within the clinic setting. Despite the SBCN being viewed as an important source of support, women did not seek these nurses' support when attending the clinic. A surprising finding was that women did not view the clinic nurses as someone who could meet their needs. It is concerning that women did not feel confident to access the SBCN when in the hospital. Rauper & Hiller (2002) and de Bock *et al*. (2004b) acknowledged that there is a decline in the level of information and support women are offered the further they are from diagnosis, including access to a SBCN.

Patients reported that they saw the nurses and doctors as integral to having their needs met (Rauper & Hiller, 2002; Beaver *et al*. 2006). Beaver *et al*. (2006) asked participants to indicate if they had received the information they needed. At time 2 (8 - 12 months post-treatment) more participants in the intervention group than the control group had had their needs met across all nine questions on the INQ. These changes were statistically significant in relation to information about cure ($p=<0.01$), family impact ($p=0.05$) and genetic risk ($p=<0.01$).

Raupach & Hiller (2002) asked women in their survey which HCP met their needs. The results were difficult to interpret and appeared conflicting. Women reported high levels of satisfaction with the cancer specialists (no detail given of who they are) (98%) and SBCNs (85%) they met but dissatisfaction about information to meet their needs. Information needs met in the previous 6 months ranged from 2% about sexuality and 32% about the chances of cure. There may have been some misunderstanding about the way questions were worded as they aimed to explore a need for help rather than how satisfied the women were with their care. This incidental finding is interesting and suggests that while

satisfaction with overall services may be good, there remain gaps in services at an individual patient level. Women also reported a decline in the level of information and support the further they were from diagnosis. Few women (<7%) used formal support services or the Internet to meet their needs and may reflect the timing of data collection in 2002.

3.5.4 Quality of life

Only two studies (de Bock *et al*. 2004b; Beaver *et al*. 2006) measured the impact of unmet needs on quality of life. One study (Beaver *et al.* 2006) reported the relationship between needs being met and changes in quality of life. No significant differences in the quality of life between control and intervention are reported at baseline and first measurement respectively but there is limited data to validate these findings. De Bock *et al*. (2004b) measured quality of life using a simple 3-item scale to ascertain fear of recurrence. It was unclear how the three items were chosen and therefore their validity or reliability.

3.6 Discussion

Six studies specifically focused on the unmet needs of women post treatment and around the period of follow-up. This review showed that breast cancer survivors reported between 19 - 90% of unmet needs related to physical, psychological and information domains during the period when they would be receiving follow-up care. The studies were varied in design, with no RCTs identified. Therefore there are some limitations in this review due to the quality of evidence. Although all the participants had a diagnosis of breast cancer, inconsistencies in the way data were collected, selective outcome reporting, and results made it difficult to compare and contrast the studies. This led to an inability to determine the overall prevalence of unmet needs among this group.

The three studies that were cross-sectional in design precluded any conclusions being made with regard to causality between women's needs and psychological distress and /or quality of life (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b). However, there was evidence that higher scores on the HADS were predictors of "some" level of need (de Bock *et al*. 2004b). Based on this limited

data, further exploration of the relationship between perceived needs and psychological distress/quality of life would be warranted.

It was not clear how studies viewed the concept of need; with only one study reviewing any literature about needs (Girgis *et al*. 2000), leading to differences in how studies interpreted and categorised need. Furthermore, the lack of longitudinal data in the majority of the studies meant unmet needs were identified but no action or input was initiated to reduce this need for support (Girgis *et al*. 2000; Raupach & Hiller 2002; Thewes *et al*. 2003; de Bock *et al*. 2004b; McCaughan & McSorley, 2007). Therefore, the studies primarily informed this review about the type and nature of perceived unmet needs identified with women with breast cancer following treatment, and in some case the usefulness of using a tool to allow women to identify their priority needs, and what might be the potential predictors of reporting 'some' level of need (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b).

The literature indicated that through a series of focused interviews and questionnaires, many needs of women can be understood. These included: fears about recurrence and a possible cure; managing side effects of treatment, understanding hereditary factors; menopausal and fertility issues; self - care strategies; adaptation to physical and psychological changes; and fatigue (Girgis *et al*. 2000; Raupach & Hiller, 2002; Thewes *et al.* 2003; de Bock *et al*. 2004; Beaver *et al*. 2006; McCaughan & McSorley, 2007). Although similarities were seen across the studies (Table 3.6), differences were acknowledged depending on the overall aims and design of the study.

No conclusion could be reached about why some studies categorised the fear of recurrence/anxiety as an information need, while others viewed it as a psychological need. On-going psychological distress of women with breast cancer after their primary treatment finishes is estimated to be between 20 and 30 % (Carroll *et al*. 1993), a level which has remained consistent (McDowell *et al*. 2010). Knowledge of this is important in the future design of studies. If not, this may affect how HCPs provide psychological support for these women.

The fear associated with the cancer returning, spreading or being cured is identified as important to women in all the studies. There is good reason for this concern, with the risk reaching a peak in the first two years after surgery of up to 10-15%. While there is a decline in the incidence of recurrences after this point, risk continues between 3 - 5 years (4.3%), and 5 - 9 years (4.6%) (Gliogorov, Pritchard & Goss, 2007). Furthermore this risk continues throughout the second decade (EBCTCG, 2005). In the two qualitative studies (Thewes *et al.* 2003; McCaughan & McSorley, 2007), both reported that this fear is partially being met through attendance at a follow-up clinic and the act of the clinical examination. This reassurance, which is difficult to quantify has also been reported in other studies out- with this review (Pennery & Mallet, 2000; Beaver *et al*. 2005). The relatively small numbers involved in the studies and the subjective nature of fear makes conclusions difficult. However, it is clearly important that studies which seek to assess need in this population include questions about this area of concern.

Studies using questionnaires allowed women to self-report their fears directly (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Beaver *et al*. 2006). Only the study by Beaver *et al.* (2006) was able to report a reduction in needs following the introduction in an intervention over time. While this was not statistically significant, it could be argued this was clinically meaningful; representing an important shift in how SBCNs use self-reported tools to engage effectively with their patients. Although this intervention was undertaken following the clinic appointment with the doctor, it may be as beneficial if provided directly at the clinic, otherwise it may not be cost effective.

Measuring data longitudinally may have been helpful in the studies by Girgis *et al*. (2000), Rauper & Hiller, (2002), and de Bock *et al.* (2004b). Their combined sample included 587 women reporting unmet needs during their follow-up period. The next stage is research into interventions to address these needs.

In the study by Thewes *et al*. (2003) women described a range of needs including fatigue, breast and arm pain, late effects, and specific issues associated with early menopause; however they spoke about a need for support to understand

whether the multiple symptoms they experienced were normal or a sign of recurrence. This suggests that just focusing on recurrence is unhelpful for women, particularly when the symptomatology of breast cancer is primarily treatment related (Bloom *et al.* 1998). While follow-up clinics try to give women the opportunity to discuss their needs, education about distinguish effectively between what is normal or abnormal post-treatment requires a more focused approach.

Most of the women in the study by Thewes *et al.* (2003) spoke about the importance of their treatment team at follow-up in providing emotional support and reassurance. Unfortunately, some of the younger patients felt physical aspects of care were viewed as more important than emotional needs. Similar issues were also reported by McCaughan & McSorley (2007). This affirms some of the criticism of the traditional model of follow-up care that little time is afforded to explore psychosocial needs (Chapter 2; Pennery & Mallet, 2000; Rojas *et al*. 2008).

While the risk associated with recurrence is important, menopausal changes, pain, side effects of treatment and adapting to the changes a diagnosis brings were also reported as important (Girgis *et al.* 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Beaver *et al*. 2006). The importance of women verbalising the wide range of unmet needs is clear in all the studies but this takes time. In the study by Thewes *et al.* (2003) women took part in a focus group lasting one and a half hours, a timeframe which would be difficult to match in the follow-up clinics, where appointments last approximately 10 - 15 minutes. The BR-CPNQ used in the study by Girgis *et al.* (2000) took approximately 20 minutes to complete at home. There may be merit in women completing questionnaires at home and bringing them to the clinic to share with their clinicians. This could save time, provide clinicians with an overview of a woman's specific need for help and provide an opportunity to directly access and respond to patient-important outcomes. It would also address one of the limitations in the study by Girgis *et al.* (2000) not specifying the need for help to a specific time period. This makes interpretation more difficult.

Timing was also important in the qualitative studies. The retrospective design by Thewes *et al.* (2003) was a limitation and could have caused recollection bias. The women were recalling information that occurred 12 months (n=6), 12months to 2 years (n=11) and up to 5 years (n=8) since diagnosis. When interviewed, the women recalled receiving insufficient, inappropriate information. The nature in which this information was delivered at the time may have been a contributing factor, as many reported that it was “verbal”.

Some studies used a breast cancer specific tool to assess need for support, while others did not. The tools used by de Bock *et al*. (2004b), Rauper & Hiller (2002) and Beaver *et al.* (2006) did appear to ask questions which were of importance to women with breast cancer, but further research is required to establish their validity and reliability in the follow-up setting. In contrast, the tool used by Girgis *et al.* (2000) was validated and specifically asked questions associated with breast cancer. However the results appear to underestimate levels of need compared to other studies and no explanation is given. The wording of questions and their relevance to women at different stages is important. This has implications for future studies. The solution is perhaps more studies which are prospective in design and explicitly indicate to participants the specific time period of interest in the study. In the case of studies associated with follow-up, this may be prior to a clinic appointment when women are preparing to attend the clinic and are reflecting on their current needs.

The women did not report any difficulty completing the questionnaires. While the intention of the studies was not to incorporate into a clinic consultation, use of the INQ by Beaver *et al.* (2006) showed the SBCN can be effective in assessing and responding to women’s needs. Unfortunately, the practicality of providing patients with two consultations: a follow-up consultation with a doctor face to face plus a telephone consultation may not be cost effective. In fact, a later publication from this study suggested it was indeed more costly. Further involvement of nurses during follow-up consultations is important according to Rauper & Hillier (2002) and de Bock *et al.* (2004b) and practice has responded accordingly, specifically identifying SBCNs to provide services into the future. There is currently no

research evidence that these changes to follow-up practice have seen improvements in psychosocial needs reported or addressed.

Women receive different treatment regimens depending on their disease, their age and their preference. This was reflected across the studies. The age of the women (range 26 - 89) appeared to determine where their emphasis lay in relation to needs. Needs associated with hereditary factors, side effects of treatment, sexuality, impact on self and reconstruction. Acknowledging these differences is very important to an individual's recovery and for the HCP, and encourages a more personalised approach to the follow-up consultation. Only 5-10% of breast cancer cases (Clark & Domchek, 2011; Van der Groep, Van der Wall & Van Diest, 2011) are linked to hereditary factors and this area appeared as a disproportionately high area of need for information in relation to actual occurrence. None of the studies suggested why this may be the case. It is clearly an important area of dialogue to have with women as it may impact on how they discuss this aspect with their own daughters and friends.

Only one study included data on the stage of the breast cancer participants (de Bock *et al.* 2004). Although breast cancer is a heterogeneous, highly variable disease (Reddy & Given-Wilson, 2006), there is a distinct correlation between the stage of disease, the treatment regimen used, the risk of complications and long-term effects. Without knowledge of the stage, it was impossible to make comparisons between different groups. Although Girgis *et al.* (2000) and de Bock *et al.* (2004) reported that those receiving chemotherapy expressed a greater number of unmet needs than those who had not received this treatment, the data presented was difficult to interpret.

The literature indicated that younger women (under 50) have different and often more needs to older women. This age group represents approximately 10,000 cases annually in the UK (Cancer Research UK, 2012). They are a group who often receive multiple modalities of treatment and are more likely to be pre-menopausal at diagnosis. Although the method used in the study by Thewes *et al.* (2003) was appropriate and a relatively new area of enquiry when data was collected in 1995, the timeframe could be considered a limitation to generalising

results to current practice in 2013. Since 1995, written information for younger women and menopausal issues has been produced in the UK by organisations such as Breast Cancer Care (2012), which have sought to address the deficit in information and may have some impact on these needs. However, in a qualitative study by Cruickshank & Hume (2014), there still appeared no clarity about how HCP's assessed and managed women who reported significant distress associated with menopausal issues.

Two studies reported their samples were under-representative of certain age groups, particularly younger women (Girgis *et al*. 2000; de Bock *et al*. 2004). As discussed above, these particular groups often report different unmet needs. The use of a needs assessment questionnaire may allow specific questions to encompass the range of needs across age groups.

On the whole recruitment was very good in the studies, with no indication that women had any difficulty completing the questionnaires. Despite its name, the BR-CPNQ only asked 8 of the 61 questions specifically about breast cancer. This may have led to an under-estimation of the prevalence of unmet needs in the breast cancer population studied. Eighty per cent of the women were at least 3 years since diagnosis and many of the questions were related to active treatment and irrelevant to this particular population. Asking the right questions at the right time is clearly important, and careful consideration needs to be given to the questionnaires used in any new study. One must also consider the value of each question asked, the length of the questionnaire and how clinicians can use the results effectively in practice.

None of the studies had been undertaken in the past five years, prior to the introduction of new standardised treatments such as biological agents and aromatase inhibitors. An increased toxicity profile is associated with these newer agents (Moss *et al*. 2009) and may or may not alter the need for support of women currently; however, in the absence of any literature these remain anecdotal. It is important to include women who have received these treatments.

In conclusion, this review did find evidence that women with breast cancer report unmet needs post-treatment and during a period when they are receiving follow-up care, but no studies were directly linked with women reporting these needs prior to their actual clinic appointment.

3.7 Summary and implications for the thesis

The findings from part one provide evidence that women with breast cancer have unmet needs post-treatment, a period when they would be receiving follow-up care. The literature describes a need for support which may be of a psychological, physical or informational nature. Despite using different methods of data collection a picture emerged that needs are very individual and different influences play a part, including the trajectory of care, response to treatment, age, menopausal, and psychological distress. Although women reported confidence in their treatment team, there is evidence that the way follow-up care meets their needs or improves their quality of life, could improve. Only one study considered changes in needs over time but the intervention was not delivered during the follow-up consultation, rather in addition. Indeed, none of the studies specifically focused on the follow-up consultation and interventions to address deficits in needs at this time. Before developing a new study, it was important to identify any research which reported the effectiveness of using patient reported needs assessment questionnaires to guide care within a follow-up setting. A further search was undertaken to explore this and discussed in part two.

3.8 Results of part two

This part of the review addressed two specific questions;

1. Have patient reported needs assessment questionnaires been used to guide care within a breast cancer follow-up setting?
2. If so, how effective is this approach?

3.8.1 Outcome of search strategy

The combined searches across all the databases including hand-searching identified 1,378 papers (Table 3.8). Once the abstracts were reviewed it was apparent that the search strategy had identified many papers which were not

relevant to this review and already reviewed in part one. Initially a total of 11 were identified and thought to be relevant and read in full. However, none of the papers met the inclusion criteria. It was decided to broaden the inclusion/exclusion criteria and include all RCTs which included breast cancer patients irrespective of the stage of care. When the changes were applied, nine of these papers were excluded and a rationale for their exclusion is summarised in Table 3.9.

Table 3.8 Record of searches up to 2009 (part two)

Database	**Total no. of hits**	**Included for full text review**	**Included in review**	**Excluded from review**
Medline	334	7	1	6
CINAHL	979	3	1	2
British Nursing Index	52			
PsycINFO	0			
Cochrane Library	0			
EMBASE	12			
Reference Lists	1	1		1
Total	**1378**	**22**	**2**	**9**

3.8.2. Excluded studies

Nine papers were excluded according to the exclusion criteria and presented in Table 3.9. Seven studies reported the development, reliability and validation of a generic needs assessment tools (Cull, Stewart & Altman, 1995; Bonevski *et al*. 2000; Sanson-Fisher *et al*. 2000; Fortner *et al*. 2003; National Comprehensive Cancer Network (NCCN), 2003; Zebrack *et al*. 2006). Two of these studies reported data from the same work (Sanson-Fisher *et al*. 2000; Bonevski *et al*. 2000). Using a tool known as the Supportive Care needs Survey (SCNS), both Bonevski et al. (2000) and Sanson-Fisher *et al*. (2000) sought to identify the prevalence and predictors of need across a cancer population, including breast cancer. Although it signified the ability of a tool to identify specific areas where patients required the most help when undergoing treatment, it did not use this to inform care delivery and subsequent interventions and was therefore excluded.

Table 3.9: Summary of excluded studies

Study	Type of study	Reason for exclusion
Bonevski *et al*. (2000)	Survey	Reported on the development of the supportive needs assessment tool
Cull, Stewart & Altman, (1995)	Audit	Reported on the development of a needs assessment tool
Fortner *et al.* (2003)	Quantitative	Reported on the development of a needs assessment tool
NCCN (2003)	Qualitative	Reported on the development of a tool to measure distress not needs
Sanson-Fisher *et al.* (2000)	Survey	Reviewed predictors and perceived needs during treatment rather than follow-up. Used same data as Bonevski et al. 2000
Zebrack *et al.* (2006)	Qualitative	Reported on the development of a needs assessment tool
McLachlan *et al.* (2001)	RCT	Did not include participants with breast cancer diagnosis at any stage of the disease trajectory
Velikova *et al*. (2004)	RCT	Use a QOL tool rather than a needs assessment tool
Thewes *et al.* (2004)	Qualitative	Reported on the development and validation of a breast cancer needs assessment tool (BCNQ)

One study (McLachlan *et al*. 2001) used a needs assessment tool to guide care within a cancer clinic setting and measured the effectiveness of this approach to reduce cancer needs and improve quality of life over time. Despite this study excluding those with a breast cancer diagnosis and ineligible for inclusion in this review, it does warrant some further discussion. This trial did not record any meaningful difference in changes from baseline in cancer needs or quality of life between the intervention and control groups. A number of limitations in the study design was highlighted but overall this approach warrants further testing in everyday clinical practice among other disease specific groups. Another study (Velikova *et al.* 2004) was excluded as it used a quality of life questionnaire to guide care rather than a needs assessment tool. It is the only study which reported that using patient reported quality of life measurements, with feedback from the HCP, led to clinically meaningful improvements in overall quality of life and emotional well-being. Another excluded is the study by Thewes *et al*. (2004) which described the validity and reliability of a breast cancer questionnaire,

designed specifically for women who have completed treatment and are survivors.

3.8.3 Characteristics of included studies

A summary of the two included studies is presented in Table 3.10.

Both studies were undertaken in Australia (Aranda *et al*. 2006; Boyes *et al.* 2006). Although neither of the studies defined needs, both referred to the literature which describes unmet needs of cancer patients (Boyes *et al*. 2006; Aranda *et al*. 2006).

Both studies aimed to examine the effectiveness of patient self- reported needs questionnaires being made available to HCPs at the clinic to inform care delivery, although they differed in their design. Aranda *et al*. (2006) specifically examined the effectiveness of a nurse delivering interventions following presentation of the data to a doctor at the clinic, whereas Boyes *et al.* (2006) explored the use of a team approach to managing needs following presentation of the data to the oncologist within the clinic.

Table 3.10: Characteristics of included studies (part two)

Study	**Aranda *et al.* (2006**	**Boyes *et al.* (2006)**
Needs defined yes/no	no	no
Types of follow-up **a. described** **b. country of origin**	a. no b. Australia	a. no b. Australia
Age **a. Control** **b. Intervention**	a. 55 (range 36-82) b. 57 (range 34-85)	a. 38 b. 42
Size of sample	105	80
Breast cancer specific details	All advanced breast cancer	Breast cancer specific a. 34% b. 38%
Stage of breast cancer	Stage 4	Not stated
Time since diagnosis (TSD) **Time to metastases (TTM)**	TSD: 0-27 years (med 5 yrs.) TTM a. 0-14 yrs. (med 1) b. 0-7yrs (med 1)	TSD: overall data presented Within last month: 21% v 29% 1-6m: 68% v. 36% 7-12m: 3% v. 10% >1 year: 8% v. 26%
HCP involved	Doctor , SBCN	Doctor

In total 185 (range 80 - 105) cancer patients were involved in the studies: they were primarily patients on treatment and were all being reviewed within a clinic setting. A total of 127 (range 22 - 105) had breast cancer and of these 105 had confirmed metastases, 16 had primary disease, and the stage of the other four is unclear.

Aranda *et al*. (2006) only included participants with advanced breast cancer (stage 4), while Boyes *et al*. (2006) included primary breast cancer patients among their sample. These included 34% (n =13) in the control group and 21% (n =9) in the intervention group, with the majority still receiving treatment. Aranda et al. (2006) reported no significant differences across most demographic, disease and treatment characteristics apart from the proportion receiving radiotherapy (intervention 93% v. control 73%, p = 0.001). The time since diagnosis differed between the studies. In Aranda *et al*. (2006) both control and intervention were similar 0-26 years (median 5 years). Boyes *et al*. (2006) included participants: within last month, (control 21% v. intervention 29%); 1-6 months (control 68% v intervention 36%); 7-12 months (control 3% v intervention 10%); >1year (control 8% v. intervention 26%).

Both studies reported participants meeting a doctor at the clinic but nurses were involved in the development of the strategies to meet the unmet needs (Aranda *et al.* 2006: Boyes *et al*. 2006). In the study by Aranda *et al*. (2006) the SBCN led and managed the intervention, which formed part of an additional 1 hour face to face session and follow-up telephone call. In contrast, strategies to meet the unmet needs were developed in consultation with the treatment team at the clinic with nurse's part of this team alongside occupational therapists, nutritionists, social workers and medical staff, with no additional intervention out-with the clinic consultation reported (Boyes *et al*. 2006).

3.8.4 Methodological quality of included studies

A summary of the methodological quality is provided in Table 3.11. One study was a RCT (Aranda *et al.* 2006) and one a pilot RCT (Boyes *et al.* 2006). The randomisation process was described in both the studies however neither included details of a sample size calculation. In both studies the inclusion criteria

was clear. Boyes *et al.* (2006) included participants with cancer of the breast, colon, rectum, lung, lymphoma, and melanoma, attending the medical oncology clinic and receiving active treatment, whereas Aranda *et al*. (2006) included women with advanced breast cancer. In deciding to include studies which did not include women attending follow-up care and with a primary diagnosis, the quality of the studies to answer the initial objective of this review is recognised as being limited. Only Aranda *et al.* (2006) reported their primary outcome: quality of life. In Boyes *et al*. (2006) this is not explicit and they expressed an interest in improving a patient's well-being.

Table 3.11: Methodological qualities of included studies (part two)

Study	Aranda *et al.* (2006)	Boyes *et al.* (2005)
Method	**Inclusion:** Newly diagnosed advanced stage breast cancer, recurred or progressed in preceding 12 months; 18 or older; access to a telephone **Exclusion**: Not stated **Randomisation**: Sealed envelopes consecutively numbered **Sample**: No calculation reported **Allocation concealment**: Yes **Follow-up**: Overall response rates 71 And 63% for the 1 and 3 month follow-ups respectively **Intention to treat analysis**: Yes	**Inclusion**: Deemed eligible by clinic staff, 18 or older, first attendance at medical oncologists clinic, to receive treatment **Exclusion**: Not stated **Randomisation**: Computer **Sample**: No calculation reported; pilot study **Allocation concealment**: No **Follow-up** : Over response rates 60% (both groups) at third follow-up **Intention to treat analysis**: Not stated
Intervention/ Control groups	**Intervention** (1 and 3 months) Two components: **1.** 1 hour face to face session within 10 days covering: orientation, tailored responses, coaching and practising self-care, concluding the session **2.** Telephone follow-up 1 week after first session **Control** Standard care (no specific details) referral to a SBCN or cancer support nurse out with study if appropriate	**Intervention** (1,2,3 times at follow-up) Completed SCNS prior to clinic appointment, score generated and feedback sheet given to oncologist **Control** Usual consultation with oncologist, survey results not made available
Needs assessment tool used	SCNS (59 questions)	SCNS (short form, 34 questions)
Other data tools used	Demographics EORTC QLQ-C30	Demographic and cancer characteristics Physical symptoms HADS
Outcome	Quality of life	Not clear

Aranda *et al*. (2006) used the Supportive Care Needs Survey full version (SCNS) and Boyes *et al*. (2006) used the Supportive Care Needs Survey truncated version (SCNS-SF34). Both have high-level consistency and demonstrated construct and content validity (Bonevski *et al.* 2000). The full version contains 59 questions: designed to measure patients perceived needs in five core domains:

psychological, health information, physical and daily living, patient care and support, and sexuality. The truncated version has 31 items across four domains: psychological (8 questions), health information (13 questions), physical and daily living (3 questions), and patient care and support (7 questions). There are five response options: 1 [no need: not applicable – This was not a problem for me as a result of having cancer]: 2 [no need: satisfied – I did need help with this, but my need for help was satisfied at this time], 3 [low need: This item caused me little concern or discomfort. I had little help for additional help], 4 [moderate need: This item caused me some concern or discomfort. I had some need for additional help], 5 [high need; this item caused me a lot of concern or discomfort. I had a strong need for additional help]. A higher score indicates a higher perceived need. Additional tools were also used. These included: the European Organisation for the research and treatment of cancer (EORTC) QLQ-C30 (Aranda *et al.* 2006) and HADS (Boyes *et al.* 2006).

Aranda *et al*.'s (2006) intervention was facilitated by a breast cancer research nurse. The nurse focused responses and plan of care for the patient (intervention) on items which scored a 5 on the scale (a high need for help). The intervention was in addition to the consultation with the doctor. It lasted one hour for session 1 and included a telephone follow-up call. A written summary was inserted in the medical notes. Despite the uptake of the intervention being very high (100%), patients were more likely to accept physical symptom recommendations rather than counseling for emotional needs. The consistency in the number of interventions offered and accepted was variable. Overall 67% (n= 40) of participants were offered care to address unmet needs but only 38% (n = 15) accepted. This may have affected the statistical differences in the groups as the uptake of the self-care strategies was essential to the success of enhancing quality of life and reducing needs. Following the intervention, 56% (n = 20) of women reported their needs remained unmet and increased intensity may have allowed a greater number of needs to be addressed.

Aranda *et al*. (2006) reported adequate allocation concealment despite the doctors seeing both control and intervention participants prior to randomisation. Boyes *et al*. (2006) reported difficulties in achieving an optimum experimental

design within a clinic where there were continuous complex interactions, and the doctors saw both the control and intervention patients over the study period. Patients lost to follow-up were reported in both studies. Attrition was 29% and 37% respectively between 1 and 3 months (Aranda *et al*. 2006). This compared to 40% (57/107) attrition at the third follow-up in the study by Boyes *et al*. (2006).

Participants in the study by Boyes *et al.* (2006) were mainly one year since diagnosis. This included approximately 16/80 with a primary breast cancer. Because the results are not stratified to cancer groups, interpretation of the data is difficult. There were no significant statistical differences in changes over time for anxiety and depression *(*p =0.20) or between the groups in changes of moderate or high psychological needs over time (p = 0.83). This had been affected by three main reasons: sample size, eligibility criteria, and inability to blind sample effectively. This pilot RCT did not report and sample calculations. By not establishing an effect size at the beginning, ability to identify a change was more difficult. This was particularly important as participants reported high levels of psychological functioning and low levels of need for support at baseline. When considering the overall quality of these studies and applying the scoring by Guyatt *et al*. (2011), both studies were of low quality.

3.9 Outcome results

A summary of the results for the study by Aranda *et al*. (2006) and Boyes *et al.* (2006) is provided in Table 3.12 and 3.13 respectively.

Table 3.12: Summary of results from Aranda et al. (2006)

	Difference in EORTC and SCNS domain scores post intervention baseline -1 month) mean (SD)		**Difference in EORTC and SCNS domain scores post intervention (1-3 months) mean (SD)**	
EORTC	**Usual care**	**Intervention**	**Usual care**	**Intervention**
Physical functioning (PF)	19.6 (23.6)	21.7 (19.5)	17.9 (23.1)	21.6 (20.3)
Role functioning (RF)	-2.8 (34.8)	-2.0 (29.9)	1.5 (33.9)	0.0 (32.9)
Emotional functioning (EF)	2.2 (24.3)	1.7 (18.3)	5.4 (25.6)	3.7 (20.6)
Cognitive functioning (CF)	1.9 (17.3)	-2.9 (21.3)	2.0 (19.1)	0.8 (22.4)
Social Functioning (SF)	1.4 (29.4)	7.8 (26.7)	10.8 (29.3)	2.4 32,2)
General quality of life	-26.2 (42.7)	-28.1(36.1)	-33.6 (36.6)	-22.6 (39.1)
SCNS	**Usual care**	**Intervention**	**Usual care**	**Intervention**
Psychological needs	2.3 (21.4)	-6.1 (17.7)	-6.5 (21.7)	-2.8 (18.5)
Health information	-3.4 (21.9)	-7.5 (27.6)	-11.7(25.7)	-9.4 (23.4)
Physical and daily living	2.2 (19.2)	-1.7 (14.6)	-3.6 (22.6)	-3.6 (16.4)
Patient care and support	2.2 (11.3)	0.3 (16.7)	-4.0 (9.4)	-2.0 (16.2)
Sexuality	1.3 (32.6)	-6.5 (28.2)	-6.8 (25.1)	-9.8(28.5)
When the sample is stratified to higher (score over 50) psychological needs, there was a significant difference (p=0.026) between intervention and usual care groups. No other *p* values reported				

Notes**: SCNS:** Higher scores mean higher level of need (out of 100 and averaged),
EORTC QLQ – C30: Higher scores mean better function (out of 100)
HAD: Higher scores mean more distress (out of 20)

The type of unmet needs reported offered parallels with those reported in part one, although categories were broadened to include psychological, health and information needs, physical and daily living, patient care and support needs and sexuality needs. Unfortunately despite similar questionnaires used by Girgis *et al.* (2000), Aranda *et al*. (2006) reported only three of the highest perceived unmet

needs among participants. These were concerns about family (31%, n=18), treatment related issues (31%, n=18) and fatigue and sleeping difficulties (29%, n=17). This varied to those reported in part one, reflecting the specific stage of these participants with advanced breast cancer, with fear and concerns about recurrence no longer an issue.

Table 3.13 Summary of results from Boyes et al. (2006)

Study: Boyes et al. 2005				
(HADS) Mean (SE) anxiety and depression scores at each visit				
	Visit	Control	Intervention	*p* value
Anxiety	1	6.1 (0.8)	6.8 (0.7)	Baseline to 4th visit 0.90
	2	5.5 (0.8)	5.7 (0.8)	
	3	5.8 (0.8)	5.1 (1.0)	
	4	5.2 (0.7)	4.8 (1.1)	
Depression	1	3.8 (0.6)	5.0 (0.7)	Baseline to 4th visit 0.20
	2	3.9 (0.7)	5.0 (0.8)	
	3	4.4 (0.7)	3.7 (0.8)	
	4	3.9 (0.7)	4.2 (0.9)	
SCNS mean % (Standard Error) numbers of items within each domain reported as moderate or high need				
Psychological	1	0.24 (0.06)	0.26 (0.05)	Baseline to 4th visit 0.82
	2	0.16 (0.05	0.22 (0.06)	
	3	0.17 (0.05)	0.13 (0.05)	
	4	0.15 (0.05)	0.11 (0.05)	
Health system and information	1	0.20 (0.05)	0.14 (0.04)	Baseline to 4th visit 0.44
	2	0.10 (0.04)	0.18 (0.06)	
	3	0.11 (0.04)	0.08 (0.03)	
	4	0.11 (0.04)	0.06 (0.03)	
Patient care and support	1	0.10 (0.04)	0.07 (0.02)	Baseline to 4th visit 0.83
	2	0.07 (0.03)	0.11 (0.04)	
	3	0.07 (0.03)	0.06 (0.02)	
	4	0.06 (0.03)	0.01 (0.01)	
Physical and daily living	1	0.20 (0.05)	0.19 (0.05)	Baseline to 4th visit 0.38
	2	0.18 (0.04)	0.23 (0.06)	
	3	0.11 (0.06)	0.11 (0.05)	
	4	0.17 (0.06)	0.08 (0.05)	

Notes: **SCNS:** Higher scores mean higher level of need (out of 100 and averaged)
HAD: Higher scores mean more distress (out of 20)

3.9.1 Patient reported changes in needs over time

The presentation of the data precluded a meta-analysis of the results despite similar questionnaires being used. This was partly because of differences in how results were presented. Aranda *et al*. (2006) presented the difference between domain scores post intervention as a mean score adjusted for baseline whereas Boyes *et al.* (2006) presented the mean scores for each domain at each time point as a percentage and standard error. Neither study reported any significant statistical differences in changes in needs between baseline and end of the trial following the intervention.

When data were stratified according to higher psychological needs (a score over 50) or lower needs (a score 50 or below), Aranda *et al.* (2006) reported that those with higher baseline needs reported a 19point decrease in the intervention group compared to a 14point decrease in the control group. Although this difference was statistically significant (p=0.026), it is unclear whether this was also clinically meaningful.

In Table 3.13, the average proportion of items in each domain that were reported as a moderate or high need is presented by Boyes *et al*. (2006). Both the control and intervention groups saw a decrease in average number of moderate or high needs reported over time; time 1 - 4. However there was no significant difference across any of the domains (psychological domain, p=0.82).

It is difficult to draw any definitive conclusions about the fall in level of needs in both studies due to lack of statistical significance and limited explanation of how they have interpreted these in a clinically meaningful way. A further reason for a lack of significant differences in the studies may have been the expertise of the HCP to respond to the needs identified by the patients. In part one, Beaver *et al.* (2006) suggested this was extremely important in achieving a reduction in unmet needs for information between baseline and post-treatment in their study. While neither commented on this, Aranda *et al*. (2006) offered a very short 2-day training for the SBCN while Boyes *et al*. (2006), offered no specific training. Of

concern is the doctor's reluctance to use the information provided to inform their decision. This led Boyes *et al*. (2006) to advocate that training in the use and significance of questionnaires should be included when introduced into clinical practice to optimise the effectiveness of them. They recommend that future studies provide the feedback reports to other members of the healthcare team including nurses.

The intervention approaches used were not clearly represented in the data presented, limiting reproducibility of the study in other populations. Although management strategies were developed in response to different needs, Boyes *et al.* (2006) did not record this information and therefore it was unclear how the actions of the medical staff influenced any changes. Despite fears that repeated collection of questionnaire data could train patients and influence their scores, Aranda *et al*. (2006) and Boyes *et al.* (2006) found no evidence of this. This may have been the first opportunity for patients to express a need for support and reflect on how they viewed their health.

3.9.2 Patient-reported changes in quality of life

Aranda *et al.* (2006) was the only study which measured quality of life as their primary outcome, measured using the EORTC QLQ-C30. This scale has been widely used in the field of breast cancer (Fayer *et al.*1999). They reported no significant differences over time**.** However, they did report that physical functioning increased from baseline to 3 months (20 - 22 points on the scale). The reason for this is unclear, but the nurse recorded that patients accepted physical interventions more readily than emotional ones. Caution is required in interpretation of these results in relation to women attending follow-up care

Psychological needs were measured using the HADS in the study by Boyes *et al.* (2006). Their interpretation is similar to the results reported by de Bock *et al*. (2004): with a score over 11 considered clinically significant for anxiety and depression. Boyes *et al*. (2006) reported mean anxiety scores decreased between baseline (control M=6.1; intervention M= 6.8) and time 4 (control M=5.2; intervention M =4.8). This change was not significantly different (p=0.09). A

decrease in depression across both groups was also not statistically significant. An examination of the change scores between those classified as clinically depressed was also not significantly different.

3.9.3 Acceptability of the intervention

The acceptability of the intervention is described by both studies. Aranda *et al*. (2006) reported a high uptake of the intervention (100%), and perhaps these patients felt their needs were not being addressed currently in healthcare services. They did not though; specifically assess the views of the SBCN or doctors. However, the nurse did report that only allowing one week between the intervention and follow-up phone call was too short. It did not allow enough time for the strategies which involved referral to other HCP's to be put in place. Boyes *et al.* (2006) posted an acceptability survey to both patients and medical oncologists at the end of the study. Of these, 48 out of 80 patients completed the survey. Most (n=34) reported the questionnaires were easy to complete and a good way of informing their doctors about their overall well-being and were happy to complete at each visit. Conversely, only 3 reported that their oncologist discussed feedback with them and all of them would have liked a summary to take home. The medical oncologists (n=4) completed the survey. The majority (n=3) read the report prior to the consultation and found it helpful. However, it is unclear how many implemented the recommendations suggested as this was not recorded.

3.10 Discussion

Two studies were included in this part of the review. The initial objective of this review was to evaluate the effectiveness of using needs assessment questionnaires within a follow-up clinic among women with primary breast cancer. However no evidence was found in the literature that needs assessment questionnaires have been used in this particular setting and among this group of women. The studies in this review did include women with breast cancer, and illustrated that this approach is both feasible and practical within clinical practice. This review therefore concluded that there was further research required to fully explore the use of needs questionnaires in a breast cancer follow-up setting.

The quality of these studies was low. The reasons for this included: low sample sizes, limited generalisability due to inclusion of different cancer groups and blinding of participants. The quality reporting of RCTs-is sub-optimal according to Consolidated Standards of Reporting Trials (CONSORT), (2010) and the absence of details in the reporting of these studies contributed to some of the quality issues. These will now be discussed in more detail**.**

Neither study was able to demonstrate any significant differences with any of the questionnaires used over time, in part due to a lack of power. Boyes *et al.* (2006) acknowledged that their study was not a large-scale RCT, rather a pilot study. They sought evidence that a feedback strategy which responds to a cancer patient's self-reported needs could be an effective approach to improve cancer patients' psychosocial outcomes. While the effects of this strategy on perceived needs was less evident, patients who had information about their well-being fed back to the medical oncologist reported fewer debilitating symptoms than patients for whom feedback was not provided. This suggests that research would be useful to explore this approach further.

Aranda *et al.* (2006) recognised that their sample size may have been insufficient but question whether an increase in sample size and modest differences would represent a clinically significant change. A retrospective power calculation suggests that using the sample obtained, a standardised difference of 0.5 could be detected assuming $p<0.05$ and power of 70%. Projections using the new calculation suggest that there would continue to be no differences in quality of life between the two groups.

Where possible a meta-analysis may have allowed pooling of data to quantify the benefits (or harms) of the interventions. Unfortunately this was not possible as significant differences in the participants, interventions and setting precluded this option. In addition the outcomes measured differed in each study, with neither paper containing the necessary information required to be extracted. Two of the studies that were excluded in this review also used the SCNS (Bonevski *et al.*

2000; Sanson-Fisher *et al*. 2000) and thought the possibility of pooling data would be worth exploring in the future.

In addition to sample size, Boyes *et al*. (2006) reported difficulties in attrition. This may in part be due to the longitudinal nature of the study, measuring data at four time-points. However, the benefits of providing clinicians with information about specific issues that were important to individual patients at each visit outweighed the concerns of attrition. Attrition in the study by Aranda *et al*. (2006) reached 35% (n = 37) of participants and impacted on overall results and indeed generalisability. Recruiting participants with advanced disease or experiencing acute treatment side effects can be difficult. It is unclear whether similar difficulties would occur with women during follow-up.

One of the challenges with these two RCTs was blinding of participants to the intervention. In the study by Boyes *et al*. (2006), medical staff saw patients in both the intervention and control groups, presenting difficulties in achieving the optimal experimental design. A solution may have been to randomise medical staff, if sufficient doctors were available. The integration of the feedback into the consultation rather than patients having additional appointments was an interesting aspect of this study. It may offer a more cost effective approach, although economic costing was not undertaken. In contrast, while the doctors saw both intervention and control, in the study by Aranda *et al*. (2006), the SBCN only saw the intervention group and out-with the clinic appointment. This is an important distinction and caution is required when interpreting results. Any new study should consider these issues carefully in their design: real time clinic environment or post clinic.

The review indicated that patients could easily self-report their needs. The lack of breast cancer specific questions was a limitation for this review; type of treatment and outcomes differ widely between cancer groups. Part one indicated that women have very specific needs associated with menopause (iatrogenic or natural) and issues around self-image (prosthesis, reconstruction, fertility and sexuality), which would not be a focus for other cancers. The fear of recurrence which was a strong area of need for support in the studies reported in part one

would no longer be as relevant in an advanced breast cancer population. It remains unclear, then, how best to measure needs among breast cancer patients who are free of disease. One conclusion that can be made from these studies is that a needs assessment questionnaire should capture needs which are relevant to the population being studied.

Although the study by Thewes *et al.* (2004) was excluded from this review as it did not meet the inclusion criteria, it did describe the development of a breast cancer specific questionnaire. As the use of a tool in breast cancer follow-up is an under researched area, this tool may offer an important contribution to this area. Choice of tool was an important consideration in this review. Quality of life instruments do differ in their purpose compared to needs assessment tools with Gustafson indicating that:

> *"Satisfaction with care documents how well an organization satisfies patient and family needs, HRQOL captures how well the patient or family member is doing and the needs assessment provides the raw material for both these measures but primarily guides patient planning". (*Gustafson, 2005, p. 306)

Thus, needs assessment tools can measure patients' own perceptions of their need for help on given issues but also directly measures the magnitude of the desire for help in dealing with unmet needs for themselves and their family. The importance of choosing the right tool to answer the research question is critical. Boyes *et al.* (2006) indicated they were interested in an individual's psychosocial well-being, and it is clear from other literature in this field that this is broader than anxiety and depression.

The studies did indicate that women with breast cancer (both primary and metastatic) can self-report their needs (Aranda *et al.* 2006; Boyes *et al.* 2006), and further research would confirm whether this approach is transferable to other groups. Although there were no significant changes, some improvements were seen in psychological needs which may have been clinically meaningful. This design would suit a follow-up setting as, there are many months between

appointments and women are seen over long periods of time. Offering HCP the opportunity to refer back to PROMs may be helpful to them and their patients when continuity of staff is difficult.

When designing studies researchers must be mindful of the practicality of an intervention for a particular population. The intervention lasted a minimum of 90 minutes in the study by Aranda *et al*. (2006). While cost-benefit analysis was not considered, the numbers of women who attend follow-up services would preclude its routine use in this population, other than perhaps those with complex needs. The integration of patient-reported questionnaires in a clinical setting as was done by Boyes *et al*. (2006) offers more promise. Offering all women attending follow-up a separate intervention as well as a follow-up consultation would not be practical or financially viable. However, integrating patient -reported questionnaires at the clinic to guide care provides HCP's the opportunity to identify patients who require additional support.

3.10.1 Summary

There is no evidence from the literature that the effectiveness of using a needs assessment tool or indeed another tool, to guide care within a breast cancer follow-up clinic, has been measured. However, there is some evidence that needs assessment tools have been successfully used to identify an individual's need for help in clinical practice. Neither study was able to demonstrate any clinically significant change in quality of life and perceived needs over time. Without the use of a tool it is unclear how the HCP would have identified the wide range of needs identified within these studies.

3.11 Overall summary and implications for thesis

The diagnosis, treatment and management of breast cancer causes significant impact on a woman's adaptation and recovery following primary treatment. As they recover they continue to experience unpleasant side effects, altered body image and a future perspective which has been changed. The literature in part one focused primarily on the many unmet needs women experienced months and indeed years following completion of primary treatment. The range of unmet needs identified include: fears or recurrence; fertility or menopausal issues;

treatment side effects; the impact of hereditary factors; sexuality and relationships; Lymphoedema and the impact on self. While it is very important for HCP's to know about these to inform their practice, no single study adequately addressed how these could be met by HCP's when primary treatment is complete. Indeed most of them suggested patient needs and individual preferences should be incorporated into current or new follow-up care, with strategies devised to address them. Currently, recovery post treatment includes regular visits to see a HCP at a follow-up clinic. The research in this part tended to focus on women's unmet needs at different time points of recovery and it is unclear if these would persist if the follow-up consultation identified and addressed the unmet needs earlier in this period.

The review presented in part two illustrated that measuring unmet needs in a consistent and systematic manner in a clinic setting is an infrequent event in the field of breast cancer, with few studies having used this approach. However, both studies were able to show that PROMs such as needs assessment tools can be integrated within a clinic setting; patients are comfortable completing these questionnaires, clinicians can use the information to guide care and the approach is equitable across patient groups. The question that arises, however, is whether this approach is feasible and practical to be used in breast cancer follow-up clinics. However, with large numbers of women attending follow-up clinics across the UK and numbers likely to rise further, it is clearly important for HCP's to distinguish between women with low, moderate or high levels of need if they want to target support effectively. The research to date has mainly used generic needs assessment tools, although while this has provided useful evidence, it fails to take into account the very specific needs of women with breast cancer who are free of disease but may be experiencing a broad range of side effects due to their treatment.

Breast cancer is not a single disease and the research to date has clearly illustrated the huge variability reported among women in relation to their unmet needs. The use of PROMs in many of the studies was useful in gauging the extent of unmet needs within the breast cancer population and most of them

concluded that patient needs and individual preferences should be incorporated into current or new follow-up care approaches. Using the existing literature explored in this chapter, the PICOT format was used to formulate the research question on the effectiveness of an intervention in a follow-up clinic. PICOT refers to P = Patient population; I = Intervention; C = Comparison; O = Outcome; T = Time. The success or otherwise of follow-up care is ultimately based on how effectively it meets the needs of the women who attend. Irrespective of whether a doctor or a SBCN delivers the care, an understanding of what these needs are is critical. There are no adequately tested interventions which respond directly to patient-reported psychosocial needs attending follow-up clinics. Research in this area would move away from restricting interventions to those who meet criteria "cases" associated with risk of recurrence due to their breast cancer and towards those who want help. To address this gap, the following question is used:

> What is the effectiveness of providing patient reported needs, quality of life and psychosocial information to the SBCN at the follow-up clinic in reducing cancer needs and improving quality of life compared to standard care?

3.11.1 Primary research question

This primary research question above is answered using the PICOT format.

(P) – Patient population: Women with primary breast cancer attending follow-up clinics

(I) – Intervention:
Definition: The patient completed self-reported questionnaires and this information was available to the SBCN at the clinic. In conjunction with the patient the nurse targets her consultation to address perceived needs which are identified as requiring support. Pre-specified guidance was developed for the needs assessment tool from an expert group in the field of breast cancer. These were not prescriptive, rather a guide, and not a substitute for clinical assessment and judgment. The local practice guidelines were used to inform management of anxiety/depression levels.

(C) – Comparison: Standard follow-up
Definition: a conventional clinical encounter
The self-reported information was not available to the HCP in the clinic

(O) – Outcome:

- Change in identified needs over time;
- Change in numbers of needs over time;
- Change in anxiety and depression over time;
- Change in quality of life over time.

(T) – Time: one year

3.11.2 Secondary research questions

What are the perceived needs of breast cancer patients attending follow-up clinics?

Is there a relationship between the measures of perceived need and quality of life?

3.11.3 Hypothesis

Null hypothesis: Using interventions for women with breast cancer during follow-up clinics will result in no differences in perceived need, or improvements in quality of life between the intervention and control groups.

Alternative hypothesis: Using interventions for women with breast cancer during follow-up clinics will result in a decrease in need and a greater improvement in quality of life between the intervention and control groups.

3.12 Conclusion

In conclusion, from the findings of the literature review and what is known about follow-up care and breast cancer (Chapter 2), it is apparent that women with breast cancer post -treatment, have unmet needs and psychosocial distress which remains for many month or years. There is no consistent method to suggest the best way of identifying these unmet needs during this time. To date, no studies have used patient reported questionnaires in the hospital follow-up setting to identify and address need. Although some studies have indicated that this is both feasible and acceptable in other breast cancer settings or cancer groups, further research is required to meet the needs of women attending follow-up clinics. This led the researcher to use the PICOT format to formulate the research questions, which seek to measure the effectiveness of an intervention which would respond to the patient reported needs and psychosocial information within a follow-up setting. In the next chapter the methodological approach taken to address the research question and hypothesis will be described.

Chapter 4: Methods

4.1 Introduction

This study was a single-centre randomised controlled trial (RCT) of an intervention by Specialist Breast Care nurses (SBCN) to address the perceived needs and quality of life of women with a diagnosis of breast cancer while attending their follow-up clinic in the hospital. To understand what a woman's needs are, the Breast Cancer Needs Questionnaire (BCNQ) and the Hospital Anxiety and Depression Scale (HADS) was used, coupled with a person-centred conversation. The trial compared a study group (known throughout this thesis as the intervention group) and a control group. The SBCN intervention was delivered at a single follow-up clinic appointment and outcome measurements were taken at baseline and twelve months. The trial followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines on the conduct and reporting of RCTs of non-pharmacologic treatments (Boutron *et al*. 2008).

In this chapter the overall design of the study and the epistemological and ontological underpinnings of the thesis will be discussed. In addition, the justification of tools used, the implementation of the methods and the analysis are described.

4.2 Research question

As described in Chapter 2, the number of women surviving breast cancer is increasing year on year. Studies revealed in Chapter 3 that there is a physical, psychological and social cost to this survival for a woman, with unmet needs continuing for many years despite regular monitoring at a follow-up clinic (Girgis *et al*. 2000; Raupach & Hiller, 2002; de Bock *et al*. 2004b; Beaver *et al.* 2006; McCaughan & McSorley, 2007). Although there are differences in the frequency that follow-up is delivered across the UK, it remains an important part of care, with many more nurses involved in this area of care. The researcher, informed by Chapter 2, the literature review in Chapter 3, and a personal interest in the

particular topic area, sought to measure the effectiveness of a new approach to delivering care to women at the follow-up clinic in the hospital. The method used was determined by the research question and discussed throughout this chapter;

> What is the effectiveness of making patient reported needs, quality of life and psychosocial information available to the SBCN at the follow-up clinic, in reducing cancer needs and improving quality of life compared to standard care?

The null hypothesis for this study is:

> H_0 Women with breast cancer attending follow-up receiving the intervention show no significant difference in level of need and quality of life than those receiving standard follow-up care

The study's primary outcome measure was change in needs scored at baseline and 12 months using the BCNQ and HADS. The study also aimed to investigate a number of secondary outcomes namely changes in quality of life at baseline and 12 months using the EORTC QLQ C30 and BR23, as well as looking at possible effects of the intervention on variables such as age, treatment severity and time since diagnosis.

4.3 Ontological and epistemological direction

Research paradigms are sets of beliefs and practices characterised by ontological, epistemological and methodological differences in their approaches to conducting research and contributing to knowledge (Weaver & Olson, 2006; Welford, Murphy & Casey, 2011). Parahoo (1997) suggests these are sometimes referred to as schools of thought; whereby different scientific communities share very clear but different beliefs, values and methods for determining how a question is answered. Paradigms are therefore mechanisms to bridge a disciplines requirement for knowledge, its systems and producing that knowledge (Weaver & Olsen, 2006). Furthermore, making explicit the conceptual framework in which the researcher is working determines the overall research approach.

This paradigmatic position or approach taken to data collection and analysis relates to the real world and what is known about it (ontological position), the relationship between the inquirer and that being studied (epistemological position), and the best way of finding out what can be known (methodology). These differences between what constitute knowledge and reality has been driven by opposing paradigms: positivism or interpretivism (see Table 4.1).

Table 4.1: Comparisons between research paradigms (adapted from Polit & Beck (2004, p.14) and Welford, Murphy & Casey (2011, p.4)

Assumption	**Positivism**	**Interpretivism**
Ontology	Reality exists in a ordered and regular world	Reality is multiple and subjective
Epistemology	The inquirer is independent from those being researched and findings not influenced by them	Interaction between inquirer and those being researched
Methodology	Deductive processes Emphasis on discrete, specific concepts Fixed design Emphasis on measured. quantitative information; Statistical analysis Seek generalisation	Inductive processes Emphasis on entirety of some phenomenon, holistic Emerging interpretations grounded in participants experiences Flexible design Seeks patterns

The evolution of these paradigms has created debate about which is best for nursing research. Polit & Beck (2004) contend that this is irrelevant when the ultimate goal of any discipline is to gain understanding of phenomena. Therefore irrespective of differences in philosophy and methodological approach, selection is determined principally by the nature of the research question and the researchers own position in respect to the question.

4.4 Exploration of quantitative and qualitative approaches

Healthcare purports to be based on evidence and has led to a hierarchy of research methods, with quantitative, namely the randomised controlled trial (RCT), placed at the top of the list (Shuldham & Hiley,1997). This view of the RCT as a “gold standard” approach reflects its robustness in design that can minimise certain systemic biases in the research. Polit & Beck (2004) describe a hierarchy of evidence whereby meta -analysis of RCTs are the pinnacle and other studies

such as expert opinion are at the base. Welford, Murphy & Casey (2011) dismiss the notion that there is a single paradigm superior to another, with Mantzoukas (2008) suggesting that the linearity and orderliness attributed to a hierarchy does not exist in the daily practice of HCPs, rather it is complex and uncertain. The RCT has been described by Cochrane "*as a very beautiful technique, of wide applicability, but as with everything there are snags, in particular when humans have to make observations there is always the possibility of bias* "(1972, p.2).

Historically, the use of an experiment has contributed to the universal knowledge now acquired in healthcare, especially in the field of medicine (Maynard, 1999). Although this view point has been embraced worldwide, there remains a dearth of nursing studies which have used this approach (Watson, 2003; Cecil, Thompson & Parahoo, 2006). Certainly this conclusion was reached following the systematic review in Chapter 3 in relation to the topic area of this study. Qualitative approaches are invaluable for subjective experiences and can provide *"rich insight into human behavior"* (Guba & Lincoln, 1998, p.198). However, their value to nurses in practice has been questioned by Watson (2003) and Lipscomb (2012).

The focus in nursing is to provide holistic care to our patients, and few would disagree that the interpersonal relationship between a nurse and a patient in the provision of care in health and illness, is a holistic art, recognising the multiplicity of factors that influence the psychosocial and physical environment (Hicks & Hennessy, 1997). This has sometimes been the reason that the quantitative approach and in particular the RCT, has been rejected in favor of a qualitative approach as a means of enquiry (Poole & Jones, 1996; Black, 1998).

This study aimed to measure the effectiveness of making patient - reported needs and psychosocial information available to the SBCN at the follow-up clinic on its ability to reduce a woman's needs over time and improve quality of life. The quantitative approach, and in particular the RCT was considered the best way of measuring the efficacy of an intervention, due to its ability to minimise bias and avoid wrong conclusions (Stephenson & Imrie, 1998). If interventions by SBCN's hope to reduce needs and improve quality of life, measuring their effectiveness

through the use of a RCT would seem an appropriate approach. In designing the study it was recognised that interviews would have yielded a rich source of data about the needs of women during follow-up. However, the use of a needs assessment tool would also provide data about the needs of this population in a systematic way. While one disadvantage of questionnaires is the inability to probe deeper and to allow the respondents to express in detail what matters to them and by using the information in conjunction with a consultation with the SBCN, opportunities for participants to engage in a meaningful way is provided.

4.5 The criteria for a randomised controlled trial (RCT)

A successful RCT is according to Sibbald & Martin (1998, p.201) and Altman (2001) dependent on a number of important features including:

- Random assignment to intervention or control groups;
- Patients and researchers remain unaware of which treatment is assigned which facilitates blinding and reduces bias;
- All groups are treated identically except for the intervention given to the experimental group;
- Patients are analysed within the group to which they are allocated; irrespective of whether they experienced the intended treatment (intention to treat analysis).

The inherent challenges of evaluating the effectiveness of a nurse-initiated intervention with a RCT design was acknowledged by the researcher, indeed Thompson suggests the very nature of RCT's ignore individual differences and as "*nurses don't treat, a RCT is inappropriate" (2004,* p.11). However Jadad (1998) found that it is too easy to conceptualise interventions as only "treatment" when active treatment is a small element of the healthcare experience of the patient. Historically, women attending follow-up clinics only met a doctor but since the late 1990s this has changed, with nurses across the UK involved with this part of care (Baildam *et al.* 2001). SBCN's have many opportunities to influence the outcomes of women with breast cancer through their provision of information, support and advice within their day to day practice. It is reasonable to

hypothesise that their influence could extend further if they were able to identify and address more effectively the unmet needs of the women they see.

As alluded to earlier, interventions in healthcare are frequently complex and this one, along with the majority of nursing interventions (Mohler *et al*. 2010), was of a complex nature. The UK Medical Research Council (MRC) (2000) has suggested a framework for the development and evaluation of complex interventions which has been updated by Craig *et al*. (2008).

The MRC (2000, p.2) describes complex interventions as;

> *"built up from a number of components, which may act both independently and inter-dependently. The components usually include behaviour, parameters of behaviour (e.g. frequency, timing), and methods of organising and delivering those behaviour (e.g. type(s) of practitioner, setting and location). It is therefore not easy precisely to define the active ingredients of a complex intervention".*
> (MRC, 2000, p.2)

Although the original framework (MRC, 2000) was presented as a discussion document, and clearly suggested that interventions can be influenced by theory, qualitative and quantitative evidence, proposing a stepwise approach along a continuum of increasing evidence (Figure 4.1), it became an authoritative guidance. Critics of the framework suggest the definition of the complexity of interventions is perhaps a little narrow and the phases are more aligned to describing a commercial drug evaluation rather than a complex intervention between a patient and health professional (Hawe, Shiell & Riley, 2006; Corry *et al*. 2012) but there is wide evidence that the framework has provided a useful platform when undertaking evaluations of complex interventions. Although the newer version by Craig *et al*. (2008) addressed the stages and simplified both the language and process, its impact, according to the authors is harder to gauge (Craig & Petticrew, 2013). However, with more emphasis given to the value of careful development work and the need to be mindful of the implementation

process throughout, more consideration about the context in which the complex intervention is delivered, has emerged as a key change.

The flexibility of the model provided a useful process to guide the researcher's decision making. The authors of the original framework (MRC, 2000) acknowledge that in many areas of intervention development preliminary evidence already exists and this was the case in the present study.

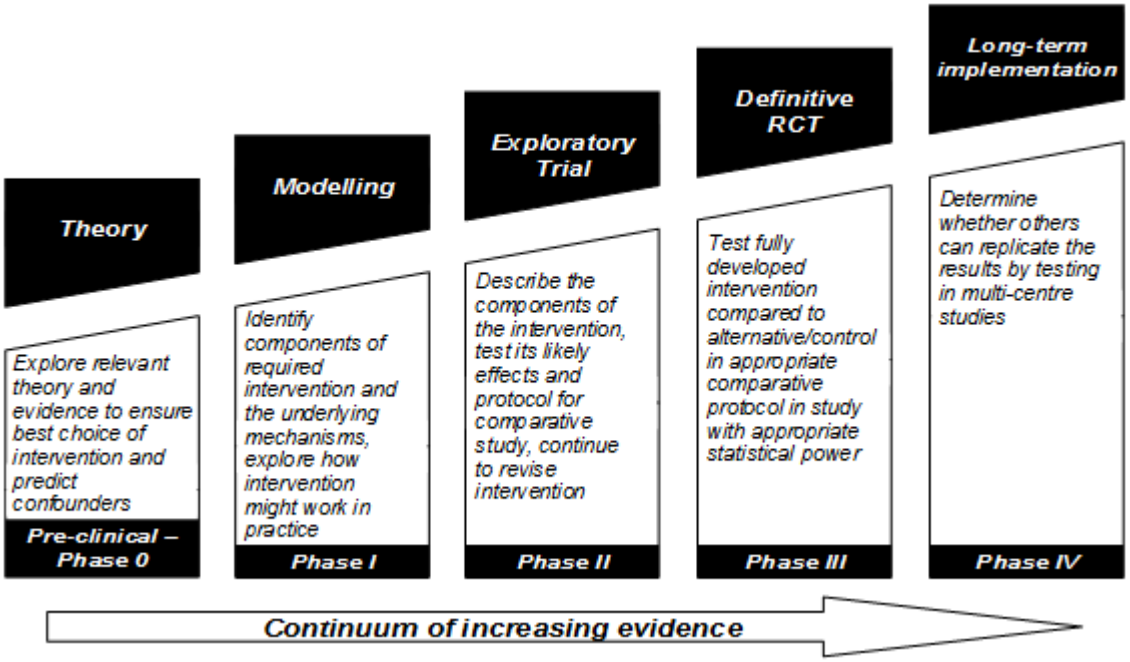


Figure 4.1: The MRC framework for the evaluation of complex interventions (MRC, 2000, p.695)

4.6 Pre-clinical and modelling phases

Using the original framework as guidance, the pre-clinical and modelling phase established the theoretical basis for the intervention and allowed the development and understanding of its component parts and how they inter-relate.

The intervention was delivered in response to the perceived need for support reported by the individual woman. The core principles of the intervention were to target support to women in response to their self-reported needs, psychosocial and quality of life information. The overall aim of the intervention was to provide

supportive care through a person-centred approach by allowing the woman to engage in a meaningful way with the nurse in the follow-up clinic.

As discussed in Chapter 3, the literature revealed that there was no precedence of using this approach in response to patient- reported needs and psychosocial information within a breast cancer follow-up setting. Boyes *et al*. (2006) and Aranda *et al*. (2006) had used "targeted interventions" in other settings (women during treatment and with advanced breast cancer) however; there was no reproducible intervention guide to use in this study. From a theoretical level, the principles and aim of the intervention were influenced by the Supportive Care Framework for Cancer Care developed by Fitch. She defines supportive care as

> *"The provision of the necessary services for those living with or affected by cancer to meet their physical, emotional, social, psychological, informational, spiritual and practical needs during the diagnostic, treatment, and follow-up phases, encompassing issues of survivorship, palliative care and bereavement' (*Fitch, 1994, p.22).

This framework draws upon the constructs of human needs, cognitive assessment, coping and adaptation as a basis for conceptualising how individuals experience the effects of cancer and deal with them. Maslow (1987, p.25) believed that a human being is a *"whole functioning, adjusting individual"* who is best understood from a holistic approach. These needs are arranged in hierarchies of pre-potency, with the appearance of one dependent upon the satisfaction of a more pre-potent need, with an individual moving from physiological needs to those of safety, esteem and self-actualisation. Maslow suggests the influence of knowledge and understanding, motivation and behaviour on the acquisition of basic needs, is fundamental to this process.

The changing situation that women face creates new demands and anxieties in addition to their daily needs, therefore their usual way of meeting their daily needs may no longer be effective. They seek new information and support. As discussed in Chapter 2, an individual woman's pathway as she enters the healthcare system (Figure 2.1) can vary considerably, with no two individuals responding in the same way to a particular event. Fitch *et al*. (2009) suggests this

variation is attributed to an individual's cognitive appraisal of the situation whereby they think about the circumstances they find themselves in and its effect on their own well-being. They are influenced by their individual experience or perceptions of breast cancer throughout the period from diagnosis, through treatment and beyond (Stanton, 2006), past experiences, self-concept, culture and socioeconomic status. If the woman can remove, minimise or counteract the perceived threat, emotional distress reduces. However, if unable to do this, emotional distress escalates.

Coping therefore becomes everything an individual does in order to deal with and manage a situation and its inherent distress. Predicting the specific combination of coping strategies a particular woman will use is difficult. Fitch *et al*. (2009) contends that the key to understanding a specific person's behaviour and emotional response is to understand the person's interpretation and meaning of the situation. Hence, given the changing nature of needs, variation in human responses and the complexity of coping strategies, it can be challenging for HCPs to find a pathway to assist or intervene to help a person cope, adapt and recover. Although Fitch *et al.* (2009) acknowledge that outcomes may be defined or labelled in a common manner such as needs, quality of life and well-being; interventions should be matched or tailored according to the individual's frame of reference. Based therefore on this approach, the intervention used careful assessment of an individual's perceived needs across a range of domains coupled with a person-centred conversation. This conversation, often associated with the therapeutic relationship observed between the HCP and service user (Manley & McCormack, 2008), explored the options for the intervention, desire of the woman for assistance and best way to provide it.

Supportive care supports the notion that a range of expertise is required to provide all the dimensions of care and is not the prerogative of a single profession. The researcher felt the SBCNs were the single most obvious group of HCPs to deliver the intervention. Hence, this study was developed to be delivered by an experienced SBCN who would refer women to other professionals as required.

4.6.1 Components of the intervention and control

Table 4.2 illustrates the structure of the intervention and how it compares to standard care (control group). The timeline of the trial runs from top to bottom on the left hand side, with the times of randomisation and outcome measurement marked clearly. Each component of the intervention is represented separately. The components delivered concurrently are shown side by side, while those delivered sequentially are shown in a linear way. Components are either objects or activities. Objects are indicated by a square (to represent a fixed nature) and activities by circles (to reflect their flexibility). Different components are labelled with different letters and the second section of Table 4.2 provides a brief description of each component including its content, function and details of who delivers it.

Table 4.2: Illustration of the intervention and control process (adapted from Perera, Heneghan & Yudkin, 2007).

Time Line	Specialist Breast Care Nursing (Intervention)	Standard Care (Control)
	a	
Randomisation		
Baseline (time 1) Pre-follow up clinic	b c	b c
Follow-up clinic	d e	d
1 - 4 weeks post clinic	g	f
Time 2 (12 months)	Measurement of outcomes b	

a	Training the nurse about meeting the needs of women with breast cancer and providing clinical examination to women post breast cancer diagnosis (see protocol)
b	Questionnaires completed by patients prior to clinic at home to elicit whether they have a need for support on areas associated with breast cancer, their anxiety and depression level, and their quality of life
c	Demographic data collected
d	A clinical examination of the chest wall, ipsilateral nodes and axilla undertaken by the SBCN and the doctor plus an annual mammogram
e	The nurse scores the HADS and uses this and the information on the needs assessment questionnaire (score 3, 4 or 5) to structure and guide the consultation. The nurse tailors the intervention to the woman's individual needs and wishes. The nurse has extensive experience of advising and supporting women with breast cancer. Possible responses to the 40 items relating to a specific need for support was developed as a guide, based on best available evidence. This guide is used in conjunction with the clinical judgement of the nurse and the patient's wishes. The immediate concerns are discussed with the woman in the clinic environment. Additional actions may be required out with the clinic and the nurse co-ordinates this
f	Researcher scores the HADS in the control group according to protocol and refers any patient with a score of 11 or above to the nurse not involved in the study
g	Phone call from nurse to any patient (5-10 minutes) who required additional information/therapeutic consultation organised alone or with family member

4.6.2 Undertaking a RCT in a breast cancer follow-up setting

The participating hospital formed part of a larger hospital group providing breast cancer services to over 700 patients a year. The participating hospital covered a geographical area 20 miles West of Edinburgh with approximately 100 new breast cancers diagnosed annually. Deprivation levels are recorded as higher in the participating hospital than the larger hospital site. There is an established breast cancer service. The study was co-ordinated by the researcher (SC). The follow-up clinic was run by a Consultant Surgeon, an Associate Specialist and at the commencement of this study, a SBCN. The SBCN undertook a training programme to gain experience of clinical examination and meeting the needs of women with breast cancer post-treatment within the clinic setting. However she had extensive expertise in managing psycho-social areas of need. She provided care to all participants in the intervention group.

4.6.3 Patient preferences and acceptability of intervention

Changes in the delivery of follow-up care had not been initiated by patients with breast cancer in this participating hospital, moreover driven by service level requirements (Scottish Cancer Advisory Network, 2009). There was a strong possibility that some of the women attending the follow-up clinic would be attending for their first appointment following chemotherapy, radiotherapy or/and biological agents, and may wish to discuss the option of reconstructive surgery with the Consultant Surgeon. This raised the possibility that women would not want to be randomised into the group with the SBCN. Torgeson & Roland (1998) indicate that strong preferences could lead to compliance or the way a participant reports outcomes. Recognising patient preference in a RCT is favored by Coates (2010) in relation to complex interventions. She argues that taking no account of preference in complex trials which involve interventions that depend on patient involvement and co-operation, may be unwise. While this may or may not have influenced the decision of the participants to respond, the researcher considered this approach would have compromised the robustness of the randomised process.

The purpose of this study was not to compare the doctor to the nurse; rather, participants in this study were being randomised to a different model of receiving

support within the hospital follow-up clinic. There was no reason, if the SBCN felt there was a clinical need or if the patient wished, for participants not to see the doctor.

4.6.3.1 Inclusion criteria

Breast cancer is an infrequent event in men, with approximately 0.7% of all breast cancers diagnosed occurring in men (Nordman & Dalley, 2008), therefore this group were not considered for this trial.

The study enrolled women attending follow-up clinics at one single participating centre. This centre discharged women from follow-up at 5 years or until a woman reached 50. Women were considered eligible if they *had a primary breast cancer; were of any age; had no evidence of secondary spread; had completed their primary treatment; surgery, radiotherapy and chemotherapy; could be on continuous endocrine treatment; were not due to be discharged at 5 years; were able give informed consent.*

4.6.3.2 Exclusion criteria

Women were considered ineligible if they *were either participating in another trial requiring specialist follow-up care; had known mental health difficulties; had a medical condition that required the expertise of the medical staff.*

4.7 The trial environment

The context in which the trial was conducted was crucial. Some of the resistance to RCTs is that researchers make them so controlled however, Wilkinson (2011) suggests that in a post-positivist world the notion of practical effectiveness, rather than the ideal conditions of a RCT, should become a greater focus. While the context of the healthcare environment may be complex, this is in fact the ordinary circumstances of a practice environment (Gotay, 2006), one in which RCT findings are implemented and used. It was important that the trial mirrored the realities of the follow-up clinic setting that women attended. While it was hoped the findings would reflect this it was more difficult to control all the confounding factors.

4.7.1 Consistency in delivery of the intervention

On-going support was provided to the SBCN through regular meetings to discuss any problems which had arisen: the safety of the participants was paramount in this study. The usual practice of a SBCN is guided by standard 9 (follow-up) of the Clinical Standards for working in a breast speciality (Royal College of Nursing, (RCN), 2007). In addition, individual experiences of the nurse informs decision making. As indicated in Chapter 3, the training of HCPs to undertake an intervention is extremely important to its success. Guidance is already available from a number of avenues which set out standards, knowledge and skills for SBCN working in follow-up care. Skills for Health (2006) have developed workforce generic competencies to monitor and assess individuals following treatment for breast cancer. Specifically, the Clinical Standards for working in Breast speciality (RCN, 2007) provides a guide to the essential knowledge and skills required to undertake follow-up care. This is supported by a European position paper by Cataliotti *et al.* on behalf of EUSOMA (2007).

Despite these guidelines, the training of SBCNs to undertake follow-up is not uniform across the UK. This was addressed within this study by ensuring that the SBCN was fully trained before she began the clinic. The intervention required the SBCN to assess the BCNQ and HADS prior to seeing the participants so they could be used to guide the consultation. In addition she was undertaking clinical examination. Initially the intervention took longer than standard care (approximately 10 minutes), but very quickly the timing improved. Using only one individual to undertake the intervention ensured consistency.

4.7.2 Control - standard care

In order to understand the impact of the intervention it was necessary to collect the same data from a control group. Altman *et al*. (2001) criticises the literature when reporting RCTs for not providing sufficient information about “standard care”. Standard care in this study describes what is currently practiced in this breast cancer unit. It involved an outpatient clinic appointment annually, whereby the woman was seen by a doctor. In other parts of the hospital group and indeed other hospitals nationally it is delivered by a SBCN or ANP.

This appointment is known as a “clinical consultation”. The patient is examined and undergoes a mammogram. History taking/problem seeking is unstructured and led by very broad open questions. There is little or no specific inquiry about any symptoms as it depends on the patient raising concerns themselves. It is not usual practice to systematically assess unmet needs, anxiety, depression or quality of life at this clinic and have this information available to the doctor.

4.7.3 Objectives and hypotheses

H_0 Women with breast cancer attending follow-up receiving the intervention show no significant difference in level of need and quality of life than those receiving standard follow-up care

H_1 Women with breast cancer attending follow-up receiving the intervention show significant reduction in the level of need and improvement in quality of life than those receiving standard follow-up care.

4.8 Outcome measurements

The choice of measurement tools was a vital component of this study. Self-rated scales were chosen. All participants in the trial were asked to complete questionnaires prior to a follow-up clinic on two occasions, 12 months apart. It was difficult to ascertain the best time-point from reviewing the literature, leading to a pragmatic decision, aligning time point with clinic appointments.

4.8.1 Primary outcome

As described in Section 4.2, the primary outcome was a change in unmet needs at baseline and 12 months, between treatment groups.

The 40-item breast cancer survivor-specific needs questionnaire was chosen (Thewes *et al.* 2004) to measure the primary outcome (Appendix 3). It is referred to in abbreviated form throughout this thesis as the BCNQ. This decision was guided by the literature, consideration of a number of needs assessment tools and the findings from the exploratory work and is discussed below (Section 4.9). Analysis suggested this was a valid instrument and internal consistency was high

with Cronbach alpha values ranging from 0.76 - 0.82 (mean=0.78). When compared to the generic Supportive Care Needs Survey (SCNS) - Short Form, this tool reported a greater proportion of high to moderate unmet needs expressed by women, suggesting that it assessed issues of greater relevance to women with breast cancer post-treatment (Thewes, 2000). It is a self-report measure asking the patient their level of need for help in a range of different areas using a 5-point Likert scale (where 1 = no needs: not applicable; 2 = no needs: satisfied; 3 = low need for help; 4 = moderate need for help; 5 = high need for help). The score is gained by calculating a Likert summated scale by summing the individual items with a domain. There are five domains with possible values ranging from 0 to 5.

4.8.1.1 Measuring level of need

The assessment of patients' needs is considered a vital step in achieving good patient centred care (Richardson, Medina & Brown, 2007). This recognition of need is a significant indicator to the HCP that the individual perceives a deficit or deficiency in their care or life situation (Davison *et al.* 2004). However any form of patient-centred care is unachievable without a good understanding of what patient needs are and the influences that contribute to this state (Girgis *et al.* 2006; Richardson, Medina & Brown 2007). Despite Davidson *et al.* (2004) intimating that similarities arise between different conditions, particularly chronic ones; Gustafson (2005) maintains that an effective needs assessment instrument pursues detail and captures information that enables the clinician to understand what it is like for the person in the particular context. Indeed although Fitch, Porter & Page (2009) identified types of unmet needs which may arise as a result of cancer, she recognised the benefits of a questionnaire which could identify those patients who might need help.

As described in Chapter 2, an individual woman's pathway of treatment can vary considerably. In addition the variety of needs in relation to physical, psychological or social issues also had the potential to differ considerably. By contextualising the situation for an individual the decision was made to only consider instruments that reflected a cancer experience. While Richardson, Medina & Brown (2007) are strong advocates of the benefits of considering individual needs, the

measurement of these constructs has not been widely explored in a practice setting within the field of breast cancer.

In Chapter 3, the literature indicated that women post-treatment expressed many unmet needs relating to emotional, physical, social and psychological areas. This aligns with the beliefs espoused by Maslow (1987, p.25) that a human being is a *"whole functioning, adjusting individual" and their needs are* best understood through a holistic approach. Therefore the needs assessment tools considered for use in this study required to reflect this. Few studies to date had used validated tools to gather data in a holistic manner. Of the studies which did, Beaver *et al.* (2006) used the INQ. Although it was relatively short (11 items) and easy to use, with validity and reliability confirmed by Degner *et al.* (1998), it was not suitable for this study as it only enquired about information needs rather than view a woman holistically and include aspects related to physical, emotional, psychological and practical needs. Although Girgis *et al.* (2000) used the BR-CPNQ which was breast-cancer specific, it was not available for this study. Aranda *et al*. (2006) and Boyes *et al.* (2006) described using the SCNS questionnaire developed by Bonevski *et al*. (2000) in Australia. Although the validity and reliability is established (Bonevski *et al*. 2000), and the tool was specifically designed to be used in a cancer setting, it was a generic instrument rather than specific for breast cancer.

In 2004, Thewes *et al*. reported a pilot study following the development and validation of a breast cancer survivor-specific needs assessment instrument. Ninety-five participants were recruited through radiation and oncology clinics and completed the questionnaire at two time points (14 days apart). Results suggested good reliability and validity. Initially it had been designed to be used in conjunction with the 59-item SCNS instrument described above (Bonevski *et al.* (2000), although the authors did report it had the potential to be used alone. Following a small pilot of this instrument and recognition that it could capture information to enable the clinician to understand what it is like for a woman in the post-treatment, in a holistic way, it was considered the most suitable tool to use in this study. Alternative tools did not offer this specificity.

4.8.1.2 Measuring anxiety and depression

The HADS was chosen (Appendix 4). It is a 14-item self-administered questionnaire used to measure the anxiety and depression of medically ill patients (Carroll *et al.*1993). There are 14 questions to answer: seven associated with depression (HAD-D), seven with anxiety (HAD-A). Scores with a cut off of 8 for both HAD-A and HAD-D has been established as providing the optimum indication of anxiety/depression in cancer patients (Bjelland *et al.* 2002) and these parameters are used in the clinical area where the study was undertaken (see Table 4.3). The literature also suggests that this instrument it is a good predictor of need and is used regularly within clinical practice, in particular breast cancer (Watson, Greer & Rowden, 1991; Hall, A'Hern & Fallowfield, 1999). Recognising the relationship between needs, anxiety and depression, this instruments sensitivity and specificity has been established (Osborne *et al*. 2004). The HADS is routinely used within the breast services where the study is undertaken as a screening tool at diagnosis. Both the women and the SBCN were familiar with it. The HADS scores were collected at baseline (time1) and 12 months (time 2) to measure changes over time. This tool has been tested for validity and reliability (Zigmond & Snaith, 1983). Each item on the questionnaire is scored from 0 - 3. A person can score 0 - 21 for either anxiety or depression.

Table 4.3: HADS scoring protocol

Abnormal scoring **The anxiety and depression subscale scores were categorised as:**	
0 – 7	normal
8 – 10	borderline anxious/depressed
> 11	probably case of anxiety/depression

Participants were asked to complete the HADS at baseline (time 1) and 12 months (time 2) to measure how these had changed over time. The patients in the SBCN group were scored and assessed by the SBCN who would initiate care as appropriate.

The participants in the control group were scored by the researcher. If they scored 11 or over, the researcher referred to a SBCN not involved in the study for further assessment. All the participants were informed of this possibility in the information sheet and again when the researcher discussed the study.

4.8.2 Secondary outcome

As described in Section 4.2, the secondary outcome was a change in quality of life between baseline and 12 months, between the groups

The quality of life domains were measured using the European Organisation for Research and Treatment of cancer (EORTC) QLQ-C30 and a breast cancer specific domain EORTC BR23 (Appendix 5). The justification of this choice is discussed below. The EORTC QLQ-C30 is a reliable and validated self -report measure of quality of life domains including physical, personal, cognitive, emotional and social domains with the EORTC QLQ-BR23 breast cancer-specific (Aaronson *et al.* 1993; Nagel *et al.* 2001). These are 30 and 23 - item questionnaires which combine self -reported generic and breast-cancer specific questions.

In this study the EORTC QLQ C30 and the QLQ BR23 was not used as a screening tool, as recommended by the authors. The individual patient scale score has large standard deviations and therefore the confidence intervals are wide, making the scores unreliable for decision making.

4.8.2.1 Measuring quality of life

Health-related quality of life is considered a multidimensional construct which at a minimum encompasses physical, mental and social domains (Ferrans, 2005) and in a broader sense evolves to refer to well-being, quality of survival, human values and the satisfaction of needs (Ferrell *et al.* 1996; World Health Organisation, 1995).

The literature reported a relationship between a diagnosis of breast cancer, subsequent treatments and a change in a woman's quality of life (Ferrell *et al.* 1997; Ferrell *et al.* 1998; Holzner *et al.* 2001; Ganz *et al.* 2004; Schultz *et al.* 2005). Research has suggested that assessing the effectiveness of an

intervention on a woman's quality of life is a valuable indicator of care (Montazeria, Gillies & McEwen, 1996). The concept of assessing quality of life in routine practice has not been uniformly embraced (Schwartz, Mirjam & Spranger, 2002), the length and complexity of many tools making them difficult to use in a clinical environment. The secondary outcome of this study was overall quality of life and changes over time of quality of life. The challenge and focus was identifying a suitable instrument for the population of interest under study; women with breast cancer, free of disease and attending follow-up care. Despite the multidimensional nature of quality of life experienced by women with breast cancer, caution was needed to ensure the dimensions measured were ones that could reasonably be expected to be affected by this disease, its treatment regimens and toxicity profile. To guide this process the quality of life instruments were mapped to gain a clearer overview of the constructs they measured and how they aligned with the multidimensional constructs broadly covered in the breast cancer literature (Appendix 6).

A questionnaire which measured overall quality of life rather than single constructs of quality of life was favoured. Sloan *et al.* (2002) recommend that the choice of a quality of life assessment should include a combination of generic, supplemented with disease specific questionnaires. A number of generic instruments were identified which have been validated in a breast cancer population and included; the functional living index- cancer (FLIC) (Schipper *et al*. 1984), the European Organisation for Research and Treatment of Cancer quality of life (EORTC QOL C30) (Aaronson *et al.* 1993), the Cancer Rehabilitation Evaluation System – (CARES) (Ganz *et al.* 1992), the Medical Outcomes Study – short form health status survey (MOS SF-36), the Profile of Mood States (POMS) (Curran, Andrykowski & Studts, 1995), and the Short Form health survey (SF-36) (Grov *et al.* 2005).

Some instruments were immediately excluded for practical purposes: this included POMS because a charge was required to use this questionnaire; CARES because it was considered too onerous for women to complete with 139 items assessed including many that were deemed irrelevant to the study population. Others such as the SF-36, and FLIC were excluded because they did

not include items of importance to primary breast cancer patients such as menopausal symptoms, body image and sexual function, distress/adjustment.

The EORTC QOL-C30 version 3.0 alongside the supplementary module for breast cancer QLQ-BR23, were chosen. These are 30 - and 25 - item respectively, self-reported generic and breast cancer specific questionnaires. The EORTC C30 instrument assesses the functional, cognitive, emotional and social aspects of life and has been widely used in clinical trials globally (Aaronson *et al*. 1993), but like so many quality of life instruments, has not been used much in day-to day clinical practice. The different domains including functional, psychological and physical were consistent with those identified within the quality of life breast cancer literature (Ferrell *et al.* 1997; Ferrell *et al.* 1998; Holzner *et al.* 2001; Ganz *et al.* 2004; Schultz *et al.* 2005). It has been shown to be sensitive to change and can distinguish between performance status levels, with internal consistency 0.65-0.92 (Aaronson *et al.* 1993).

The breast cancer module (BR23) is also sensitive to different stages of disease and treatment modalities. It addresses body image, sexual functioning, systemic therapy side effects, arm symptoms and future perspective. Its validity and reliability with this group has been established (Spranger *et al*.1996).

Permission was granted for its use from the European Organisation for Research and Treatment of Cancer Quality of Life Study Group. This permission includes a caveat that the EORTC QLC-C30 and QLQ BR 23 data are made available to the group for validation purposes. Information is provided on the consent form for the participants and also disclosed to the Ethics Committee.

4.8.3 Demographic and clinical information

Data were collected from medical notes by the researcher on the following: age, type of surgery, type of axillary surgery, time since diagnosis, side of primary, pathological tumour size, tumour grade, histological type, node status, HER2 status, ER status, and adjuvant treatment (Appendix 7). Socioeconomic status is defined by The Scottish Index of Multiple Deprivation (SIMD) (Scottish Government, 2012) whereby an individual's postcode serves as a proxy for their

socioeconomic status. The SIMD defines relative deprivation by combining information from across seven domains: employment; income; health; education, skills and training; geographic access to services; crime; housing.

4.9 Pre-study exploratory work

4.9.1 Introduction

The aim of the exploratory work was to:

- test the recruitment process;
- test the questionnaires to be used and
- Assess the intervention procedures.

This is an important stage and recommended as good practice by Lancaster, Dodd & Williamson (2004) and Craig *et al.* (2008) when using the MRC framework as guidance. Although this process allowed assessment of the validity and reliability of the instruments within the clinical setting, Gerrish & Lacey (2006) acknowledge that this is not as necessary when instruments used are already validated. All three instruments: BCNQ, the EORTC C30 and QLQ BR23 were validated. Permission to undertake the exploratory work was included in the original ethics application.

4.9.2 Method

Women with a diagnosis of breast cancer were approached during an end of treatment meeting, facilitated by the SBCN at the Cancer Centre which formed part of the overall group of hospitals within the NHS Trust in April 2008. Women attended this “end of treatment meeting” voluntarily following an invitation from the SBCN. As the title suggests, all women had completed their primary treatment.

The literature clearly indicates that a woman’s needs while receiving follow-up care are shaped by life experiences and their treatment pathway. The women were asked to complete the 40-item BCNQ and the EORTC C30 and BR23 and return these to the researcher to ensure the efficiency of the process. In addition,

they were sent the short-form (SCNS-SF34: 34 items), the long-form (SCNS-SF59: 59 items) (Bonevski *et al*. 2000) and the 8-item BCNQ instrument to review and return in a stamped addressed envelope. The HADS questionnaire was not included. This instrument is currently used within the breast cancer service and as a screening tool at diagnosis. It was decided this would not be further reviewed.

4.8.3 Results

Eight women attended the "end of treatment meeting'" and were invited to participate: 65% (n=5) agreed to be contacted and this occurred within a week of the clinic. Following contact, four gave verbal consent. The questionnaires, a consent form and the information sheet about the main study were sent to the participants. All four women returned their questionnaires, the BCNQ, the EORTC QLQ C30 and QLQ BR23.

4.9.3.1 Quantitative data

The women were aged 52 – 67 (mean age 58.5 years). Two had undergone a mastectomy, one a bilateral mastectomy and one a wide local excision. Two had received chemotherapy, three had received radiotherapy, and all were receiving on-going endocrine therapy.

Within this small sample, women reported some need for help across 24 out of the 40 items. This was not particularly surprising. Numerous studies have reported that the impact of a diagnosis of breast cancer and side effects associated with treatment continue for many years after curative treatment is completed (McPhail, 1999; Ganz *et al*. 2000; Knobf, 2001; Harris *et al*. 2002; Biglia, 2003; Thewes *et al*. 2003; Shultz, 2005; Walsh, Denduluri & Swain, 2006; Stricker, 2007; Neal & Hoskins, 2009). This questionnaire had clearly provided women the opportunity to voice their needs as well as have them subsequently met.

The 10 most frequently expressed low to high unmet needs (3 or more women identified need for support) on the BCNQ are reported in Table 4.4

Table 4.4 Top 10 needs expressed using the BCNQ.

	Type of need for support
1	Pain or discomfort in the area of your affected breast
2	Dealing with fears of the cancer returning
3	Trying to find meaning in this experience
4	Coping with changes with others attitudes and behaviour toward you
5	Finding a support group which addresses their particular needs
6	Meeting other breast cancer survivors who are your age
7	Being informed about the possible effects of the cancer on the length of your life
8	Being informed about the causes, preventions and treatment of Lymphoedema
9	Being informed about the causes and possible triggers of breast cancer
10	Receiving information which is specific to women of your age

Of the 10 highest needs expressed, seven items related to information and medical communication, one to the impact of pain and two to coping. Table 4.5.reports the top five expressed moderate to high unmet needs on the BCNQ reported by the four women. Again, information and medical communication were the most prevalent items identified among this group.

Table 4.5: Top 5 needs expressed as a moderate to high need.

Type of need for support	**% sample reporting of a moderate (score 4) or high (score 5) need (n=4)**
Dealing with fears of the cancer returning	75
Being informed about the causes, preventions and treatment of Lymphoedema	50
Being informed about the causes and possible triggers of breast cancer	50
Having one doctor who knows all about your condition, treatment and follow-up	50
Being able to negotiate with your specialists about the frequency or length of follow-up appointments	50

The quality of life data indicated that the overall quality of life of the participants ranged from 4 - 6 (0=poor to 7=excellent). However, the sample was too small to do any inferential statistics.

4.8.3.2 Qualitative data

Each of the women who returned questionnaires were contacted individually and the following questions were explored over the telephone and unmet needs identified were explored further:

- How long each questionnaire took to complete?
- How clear were the instructions?
- Did they have a preferred option?
- Did they have further comments about the information sheet, consent, study?

The time spent on the phone ranged from 30 - 90 minutes. The interview was not recorded and in hindsight this may have been useful to aid my recall at a later date. However, notes were taken. As well as determining the reliability and content validity of the questionnaires, the researcher explored with the women some of the needs they had identified as requiring help with, within the questionnaire. As mentioned earlier, the researcher was previously a SBCN and had worked in the area of breast cancer for many years. This experience allowed the researcher to understand the needs identified by the women and, if able to, the necessary support was provided. One question relating to “finding a support group” registered as a low need for support (score=3) and was simply managed by sending out information and contact details of the local support group. However, two women scored more than five areas of need (score =4 or 5). They were offered a referral to a SBCN to further discuss these issues, and both accepted.

An overview of the feedback is presented in Table 4.6. Some women included written comments on their questionnaires and these are presented among the more generic comments made on the telephone.

Table 4.6: Summary of comments about the questionnaire

Instrument	Time to complete	Additional written comments from participants (4)
The supportive care needs Survey SCNS (SF-59)	20 - 30 minutes	No.1: “Some questions were very broad” commented on Q37 specifically as she felt there was a lack of continuity experienced
		No.2: “It was at times puzzling and I found myself changing my answers again and again, seeing the questions from a different angle. I think it all stems from the clarity of the instructions on the front page”
		No.3: “Instructions unclear”
		No.4: no comment
The short form SCNS (SF-34)	20 minutes	Similar comments to above
Breast cancer survivor-specific needs assessment (40 items) (BCNQ)	10 minutes	All the women commented on the telephone that the questions captured many of their current needs
		No. 2 Found the questionnaire an opportunity to reflect with her daughters about how well she was coping/recovering
Breast Cancer Module (8 items)	3 minutes	All the women commented on the telephone that this questionnaire was too short to capture all their needs
EORTC QLQ-C30	10 - 15 minutes	No.1: no comment
		No.2: “I did not feel comfortable about questions 44-46 related to sexual activity. If questions were framed differently they may be more acceptable”.
		No.3: no comment
		No.4: no comment

All the women expressed a preference for the BCNQ. They felt it closely reflected the context of their stage at this time and was quick and easy to complete. The women raised concerns that any further questions (adding in the SCNS –SF59) would make it too cumbersome to be reviewed in a clinic environment. They viewed the use of questionnaires as of personal benefit to them, especially as some questions were quite sensitive to raise within the clinic.

Two SBCNs from a different hospital reviewed the questionnaires. They could identify similarities between the individual items on the questionnaire and the clinical consultations they had with women at the end of treatment. They provided

additional expertise and validation about the type and range of approaches they currently use to address areas of need highlighted in the questionnaire. This was collated and used as part of the training for the SBCN undertaking the intervention.

4.10 Conclusion

This pre-study exploratory work was able to gather data from 50% (n=4) of the sample approached. Dellson *et al*. (2011) suggests that worldwide only 5 - 10% of cancer patients are treated in clinical trials. Although this data refers primarily to pharmacological trials, 50% recruitment in this trial seemed a reasonable target. Although the numbers were small, the researcher concluded that the self-rated 40-item BCNQ met content and face validity within a follow-up setting. It picked up needs which were common to this group of women such as “fear of the cancer returning” but was specific to capture needs associated with different age groups. Further areas that were informed through this pilot work included:

- The information about the study and consent form was reported as easy to understand. No further amendments were made.

- The recruitment process seemed overly cumbersome, in particular identifying patients who were receiving follow-up care and accessing their information in a timely manner. This was refined for the main study and a clinical protocol developed (available as a separate document).

The feedback from the women confirmed my decision to use the BCNQ alone. From a practical perspective asking women to identify more than 40 items would be excessive. Equally, from a practical perspective, having more than 40 items on the BCNQ and 14 items on the HADS were felt to be too difficult for the SBCN to review in a short clinical consultation.

The BCNQ identified areas of need that were important to the four women on a personal level. Through the telephone interview, the researcher was able to offer specific support in response to some, but not all, of these needs. It indicated that

the intervention was feasible, acceptable to the women and manageable within the context of a follow-up clinic.

4.10.1 Reliability and validity of using self-reported questionnaires in clinics

The lack of research to support the use of self-reported needs assessment questionnaires within a breast cancer follow-up setting raised potential reliability and validity issues:

- There was a risk that women would express unmet needs which did not appear on the BCNQ. If this happened, the SBCN would document accordingly, respecting the wishes of the patient and use her clinical judgment to initiate care as required;
- There was a concern that the use of patient-reported questionnaires would impact on the time patients spent in the clinic, prolonging the consultation. This was monitored and when it occurred, discussed by the researcher with the SBCN about the reasons;
- There was a risk that women would tick multiple unmet needs. This could reflect the complexity of a diagnosis of breast cancer or the first time these women had been given the opportunity to identify some of their need for help. In this situation, the SBCN in consultation with the patient identified the three most important needs. The SBCN used their clinical expertise and determined if a longer consultation out-with the follow-up clinic was required and this intervention was recorded.

4.10.2 Recurrence/mortality

Any patients presenting with a recurrence/mortality during the study will be documented as per policy. A recurrence changes the status of an individual participant.

4.11 Introduction to the main study

The results from the previous phases informed the central aspects of the complex intervention and the main randomised controlled trial. The importance of the power, randomisation, blinding, outcome measures and informed consent and other features are considered to ensure a well-designed trial.

4.11.1 Sample size calculation

An important aspect of this study and indeed quantitative studies in general, is the number of participants required to test the research hypotheses. An approach to sample size estimation is known as "power analysis" (Ingram, 1998) and was calculated for the purpose of this study. The researcher acknowledged the complex nature of undertaking power analysis and took advice from the statistician involved with the study. Altman *et al*. (2001, p.670) suggest the sample size should be large enough

> *"to have a high probability (power) of detecting as statistically significant a clinically important difference of a given size if such a size exists." (*Altman *et al.* 2001, p.670*).*

A power analysis is based on four factors:

- sample size (N): determined by the study population and purpose of the study;
- significance level (α): criterion used in hypothesis testing such as rejecting the null hypothesis;
- effect size (ES): a measure of the strength of the relationship between variables;
- the statistical power expressed as a probability.

(Polit & Sherman, 1990)

There were no studies found that examined the effectiveness of the intervention described in the present study, therefore an initial calculation was performed based on the original primary outcome, quality of life, and the instrument to be used, EORTC QLQ-C30. Ingram (1998) suggests there are three ways of determining the effect size; using data from pilot studies, to consider previous

research where similar instruments have been used or to make a personal assessment. The researcher chose to use previous research by Cheung *et al*. (2005), who had considered the variability and sample size requirements of the quality of life instruments; EORTC C-30, FACT-G and FLIC. They found the effect size in relation to the Eastern Cooperative Oncology Group was 0.5 although other studies had placed 0.07 to 0.73. The figure of 0.5 was used and considered an arbitrary level (medium effect size) which could be adopted if using indices set out by Cohen (1992) when no specific data is available. The two most frequently used significance levels are 0.05 and 0.01. Polit & Beck (2004) maintain that with a significance level of 0.5 we are accepting the risk that a true null hypothesis will be rejected 5 times in every 100. If we had taken the significance level to 0.1 this would have lowered the risk of a type 1 error but in turn potentially increased the risk of type ll errors.

It was therefore concluded that based on a power of 80% to detect a significance level (p=0.05) between the groups, the study required a sample size of 64 in each arm. To allow for attrition of 15%, 74 patients would need to be randomised in each arm. The researcher recognised that as this is a new area of enquiry and the effect size may have been set too high. Black *et al.* (1998) suggest that in new areas of enquiry estimates of sample size should not be considered as precise because of uncertainty about the underlying assumptions.

4.12 Patient identification, recruitment and informed consent

4.12.1 Identification

Patients were identified by the SBCN from the follow-up clinic lists available through a computerised system. Unfortunately, this system was cumbersome to use and a patients stage of follow-up difficult to extract, therefore the researcher decided to invite all patients on the follow-up clinics. A patient known to have underlying mental health problems, complications/special circumstances which required monitoring by the doctor or were known to have dementia was excluded at this stage.

4.12.2 Recruitment

Following ethical approval, all patients who were eligible for inclusion were sent a letter of invitation to take part in the study (Appendix 8) and an information sheet about the study (Appendix 9) from the SBCN. An administrator helped with this process. Those women interested in participating sent a reply slip back to the researcher or emailed. The researcher contacted the women by phone to confirm trial eligibility and offer an opportunity to ask further questions. The reason for a women being ineligible at this stage was documented. The women gave verbal consent to be randomised during the phone call and provided the researcher with their full name and address to send out questionnaires and consent forms. Once randomisation was done (detailed below), the study questionnaires and consent form were posted to the women. Those allocated to the intervention were provided with new appointment details which were organised through the outpatient clinic by the researcher. This was a challenging process as this frequently occurred within a day or two of the clinic and required the researcher to telephone the participant to indicate which arm of the trial they had been allocated to.

4.12.3 Informed consent

The women received information about the study through the post. Women could contact the researcher by post, email or phone. The researcher telephoned all the participants to answer any questions they may have and sent the forms at least 48 hours prior to the women attending the clinic. It was the responsibility of the researcher to obtain written informed consent from the participants prior to entering the study (Appendix 10). The SBCN checked that a consent form was completed prior to the first consultation (baseline), while the control group returned their forms to the researcher.

4.12.4 Randomisation and blinding

An individually-randomised parallel group design was used for randomisation and considered a robust approach (Craig *et al*. 2008), and conducted independently by a statistician. Participants were assigned a unique number and this number remained with them throughout the study. A computer-generated block design randomisation was used to keep the numbers of subjects in the different groups

closely balanced at all times. Subjects were allocated on a consecutive basis to the next group within the block.

The researcher recognised that the trial was small and that baseline characteristics risked being imbalanced. It would have been useful to have achieved certain baseline characteristics between the groups at the end of recruitment. The literature has suggested that characteristics such as psychological status, age and type of treatment were associated with a moderate to high expressed need for help. However, randomisation by minimisation was not possible in this study. Access to the notes by the researcher was only possible once randomisation had occurred and was part of the requirement set out by the ethics committee. Coupled with the short timeframe to consent, randomise and ensure the questionnaires were completed prior to the clinical consultation (minimum 1 week, maximum 3 weeks) further prevented this occurring.

Blinding is the ability to keep the study participants, those providing the healthcare and those collecting and analysing the data unaware of the assigned groups (Noseworthy *et al*.1994). All opportunities to blind aspects of the study and minimise these effects was maximised. The SBCN sent out the initial information but replies were returned to the researcher. This guaranteed that the SBCN was unaware of who had agreed to participate and could not influence the randomisation process. The randomisation process was discussed with a statistician prior to commencing the study and undertaken externally and off site: the researcher was unaware of any medical details of the patients until after randomisation, when documentation could be sent and the consent form was received.

The researcher was responsible for contacting and informing the participant about which study arm they were in. Participants were allocated to either the intervention or control groups: however, blinding of specific group allocation was impossible as both the SBCN and the doctor undertook the clinic in the same clinic area. Care was taken to maintain blinding of patients seen by the doctor

and if they required a referral to a nurse, they were seen by one of the other nurses in the department not involved in the study.

4.12.5 Monitoring of completers and non-completers

If a woman failed to attend her second follow-up appointment or complete the questionnaires the reason was ascertained and further questionnaires were sent. If they failed to respond they were considered a non-completer. All participants were intended to be analysed within the groups to which they were randomly allocated on, an “intention to treat “basis.

4.12.6 Withdrawal of patients

Participants could decide to withdraw from the study at any time. The researcher could also withdraw a patient from the study if it was felt to be in the best interest of the participant, for example a recurrence. If a patient withdrew, this was documented as a loss to follow-up. All analyses were to be done on an intention to treat basis.

4.12.7 Managing adverse events

Breast cancer is an unpredictable disease (Gligorov, Pritchard & Goss, 2007). Although this study was a non-drug intervention, the patients were attending routine follow-up care and had primary breast cancer. This meant that any incidence of recurrence and a change in management altered their primary status and care requirements. They were treated as lost to follow-up and the reason given.

The following was reported and documented in the patients’ notes to ensure that clinical characteristics were updated and interventions undertaken were reported:

- Any confirmed local recurrence;
- Any confirmed metastatic recurrence;
- Any change to their psychological status;
- Death due to breast cancer;
- Death due to other causes.

4.12.8 Follow-up of participants

Patients were seen in the clinic by either a doctor (Control group) or the SBCN (Nurse group) at two time points, 12 months apart. The intervention group returned the questionnaires to the SBCN and therefore she was aware immediately if a patient had not received the questionnaires through the post. This happened on a number of occasions and the nurse was able to allow the participant time prior to the clinic to complete the questionnaires. Because the control group posted their questionnaires back to the researcher in a stamped addressed envelope provided, there was a time lag to knowing if the patients had received them. The researcher had intended to phone the patients if no questionnaires were returned but this proved difficult since many of the women were working and it was not always easy to contact them. As a solution, a different SBCN in the department, not associated with the study, was contacted who knew the patients to ensure that the participant's attended when planned, was still eligible and to check their current survival status. Further questionnaires were then sent as soon as the researcher could confirm this. Prior to the second questionnaires being sent out, all the participants' survival status were checked before any forms were sent. For non-responders, a reason was obtained if possible and recorded.

4.13 Analysis

The data were analysed using SPSS version 20 software (IBM, 2011). All analyses were to be based on intention to treat, meaning that all study participants are retained in their groups to which they were originally allocated and no participants are removed from the analysis by the researcher. It was agreed that participants, who chose to withdraw following randomisation, were removed from the analyses. Descriptive statistics were to be used to summarise the demographic and clinical characteristics of the data, including subgroups based on age, stage of disease and treatment received.

A score was calculated to compute severity of treatment (women who had multiple treatments). This may or may not be an important variable when

predicting unmet needs. The types of perceived needs will be presented as: domain, number of items, minimum, maximum and mean (standard deviation).

Differences between completers and non-completers on demographic characteristics will be assessed through t-test and chi-square tests. Comparison of baseline characteristics between the control and intervention group uses inferential statistics such as t-tests for means and x^2 for proportions. A p-value of p=<0.05 would be considered statistically significant.

Initial review of the BCNQ using factor analysis includes examining the adequacy of sample size and the factorability of the correlation matrix. The Kaiser Meyer-Olkin measure of sampling adequacy (0.64) indicates satisfactory factorability of the correlation matrix (values above 0.5 are acceptable; between 0.8 and 1 are viewed as very good) (Field, 2012). In conjunction with the high significance (p = < .001) of Bartlett's test of sphericity, the data were considered suitable for factor analysis. Exploratory factor analysis using an extraction method is undertaken to examine the factor structure of the items of the BCNQ.

Linear and multiple regression analysis is used to investigate the relationship between measures of perceived needs, anxiety, depression and quality of life.

4.14 Ethical approval

Ethical approval was gained from Napier University Ethics Committee, Lothian Research Ethics Committee (LREC) on 30th August 2007 and the Lothian NHS management approval was granted on 15th September 2007. In accordance with research governance principles which decree that honorary contracts should be issued to researchers to ensure access to NHS data and premises. One was issued to the researcher on the 24th July 2007 for the duration of the study period.

There were a number of points raised from the ethics submission. These primarily related to the indemnity and indeed competence of the SBCN to undertake the clinical examination as part of standard care. Confirmation was provided by the senior management that SBCN currently delivered follow-up care in the Trust, indemnity concerns were covered within the Trust and guidance is

provided to nurses to ensure that any risk to patients and clients are minimised through the Nursing and Midwifery Council (NMC).

> *' if an aspect of practice is beyond your level of competence or outside your area of registration, you must obtain help and supervision from a competent practitioner until you and your employer consider that you have acquired the required knowledge and skill'* (NMC,2008, p.9).

However, despite precedence in the service of nurses undertaking clinical examination and indeed a willingness from both the clinician and the SBCN to ensure competent practice prior to delivery, no formal protocol for training was in place. In discussion with the SBCN, a training package was developed by the researcher and the SBCN and included guidance on managing unmet needs identified (see protocol). The competencies required were aligned to a number of key documents including the NHS Knowledge and Skills Framework which "*defines and describes the knowledge and skills which NHS staff need to apply in their work in order to deliver quality services"* (Scottish Executive, 2004, p.3).

The Royal College of Nursing Clinical Standards for working in a Breast specialty states that nurses should:

> *"Articulate dimensions of breast care nursing to promote uniform and high quality care. They provide guidance for nursing performance, and define what it means to provide skilled nursing care within a breast specialty".*(RCN, 2007, p.2).

And as mentioned earlier, the guidance provided by NMC, the nursing professional body includes: Code of Professional Conduct: Standards for Conduct, Performance and Ethics, Record Keeping (2007), Confidentiality (2006a) and Consent (NMC, 2006b).

4.15 Qualitative data

As part of the intervention, the SBCN kept a narrative of the person-centred conversation she had, and the actions she undertook to address unmet needs. These are presented in Chapter 5 and discussed in Chapter 6.

4.16 Summary

If time, manpower and resources had been available, it may have been useful to have combined a qualitative and quantitative approach. However throughout the development of this study, it was evident that much of the research to date has focused on describing the unmet needs of women post-treatment rather than measuring the effectiveness of interventions to address them. Drawing on these data, the intervention and subsequent methodology has been derived. Changes in follow-up care are evolving and there is no clear approach, particularly when addressing unmet needs.

The researcher recognised the methodological challenges posed when evaluating a complex intervention in a clinical setting, but to answer the research question, the RCT was the appropriate approach. From a clinical perspective, knowing the effectiveness of two follow-up care practices and how they differ in meeting the unmet needs of women with breast cancer will provide information that is valuable to those working in the field of breast cancer.

On a theoretical level, this study integrated factors within the complex intervention which recognised the individual nature of cancer recovery, morbidity associated with treatment, fear of recurrence, and adaptation to survival. The next chapter reports the results of the study.

Chapter 5: Results

5.1 Introduction

In this chapter the descriptive and inferential results are presented. As discussed in Section 4.2, the primary outcome for the study was a change in needs scored at baseline (time 1) and at the end of the trial (12 months, time 2). The study also aimed to investigate a number of secondary outcomes namely changes in quality of life at baseline and 12 months, as well as looking at possible effects of the intervention on variables such as age, treatment severity of treatment and time since diagnosis. The following hypothesis was tested:

H_0 Women with breast cancer attending follow-up receiving the intervention show no significant difference in level of need and quality of life than those receiving standard follow-up care

H_1 Women with breast cancer attending follow-up receiving the intervention show significant reduction in the level of need and improvement in quality of life than those receiving standard follow-up care.

Data were analysed using SPSS version 20 software (IBM, 2011). Statistical significance was accepted at the 5% level ($p<=0.05$). This chapter presents details of the numbers of participants, non-completers and completers, and statistical analyses used. This is followed by the descriptive demographic, clinical and deprivation characteristics of the participants. Descriptive statistics relating to the primary outcome are presented first followed by the inferential statistics. This includes data related to the BCNQ, HADS-A and HADS-D. This is followed by the secondary outcome; descriptive statistics are presented first followed by inferential statistics. This includes data related to the EORTC QLQ C30 and BR23. The regression analyses will then be presented. Following each section a short synopsis of the results is given and the chapter concludes with an overall summary of the whole chapter.

5.2 Participants

The participants were identified from the clinic lists available from the online patient record system. According to these records, 360 women were due to attend clinics over a 1 year period. It was impossible at this stage to apply the exclusion criteria (see Section 4.6.3.2) due to limited access to individual cases. A pragmatic decision was therefore made to invite all 360 women to participate in the present study, knowing that the number may not fully reflect all eligible participants. In total 47 were excluded, 22 did not meet the inclusion criteria, 18 were not contactable prior to the clinic to screen for eligibility, and there was no reason documented for 7. Ninety-three were randomised to the present study but 11 of these withdrew following randomisation. Therefore 37 participants were randomised to the standard care group (CG) and 45 to the nurse group (NG). Of the 82 entered at baseline, at 12 months there were 24 participants in the CG and 37 participants in the NG. The expected attrition drop in the original power calculation was 15% at 12 months; excluding deaths, the actual drop-out was 20% overall; 22% in the CG and 16% in the NG. Figure 5.1 in Section 5.7 presents a flow diagram of the participants through the study.

5.3 Completers and non-completers

There were 82 participants randomised into the study of which 61 completed. In both arms of the study if a woman failed to attend her appointment or complete the questionnaires, the reason was ascertained. Further questionnaires were sent and if they failed to respond they were considered a non-completer. All participants were analysed within the groups to which they were randomly allocated. The numbers completing were proportionally higher in the NG: 82.2% compared to the CG: 64.9%, however this was not found to be a significant statistical difference (Pearson's chi-square, p=0.073). The proportion of completers having a mastectomy was 75% or a wide local excision 73.8%, with no significant statistical difference between the two groups (Pearson's chi-square, p=0.902).

Comparisons between the completers and non-completers using t-tests was undertaken to determine if there was a difference in demographic variables such

as age, time since diagnosis and socio economic status between the groups. The results, as shown in Table 5.1 indicate no significant differences were found for age (two sample t-test, t=0.28, df=80, p=0.978), time since diagnosis (two sample t-test, t=-0.365, df=80, p=0.716) or SIMD (two sample t-test, t=-0.555, df=77, p=0.580). Therefore, demographic variables did not seem to influence whether or not a participant completed the study.

Table 5.1: Comparison of demographic data between the completers and non-completers

	Completers (61) Mean (SD)	**Non-completers (21)** Mean (SD)	**p-value**
Age	53.26 (10.41)	53.33 (9.01)	0.978
Time since diagnosis	33.74 (18.63)	32.00 (19.33)	0.716
SIMD	3592.31 (1841.41)	3335.95 (1803.26)	0.580

5.4 Statistical analyses

Univariate analyses were used to describe the demographic characteristics of the sample and the HADS, BCNQ, EORTC QLQ C30 and QLQ-BR23 measures.

In preparation to measure the primary outcome, change in need scores, an initial review of the BCNQ was undertaken that included the examination of item frequency distributions to identify items with skewed response distribution or low variability. Sample size and factorability of the correlation matrix were examined using the Kaiser Meyer-Olkin sampling adequacy measure and Bartlett's test of sphericity. Exploratory factor analysis using Maximum Likelihood extraction was conducted to examine the underlying factor structure of the items of the BCNQ (Appendix 11). The scales internal consistency were analysed through Cronbach alpha and item-scale correlations were assessed to decide if any item should be removed.

The alpha level for all the scales is presented in Table 5.2. Alpha levels above 0.7 are considered good and levels above 0.8 are very good (Field, 2005). The alpha

levels for all except sexuality indicated good to very good reliability. Although the sexuality scale was low in meeting adequate levels of internal consistency, it was retained because there was no significant improvement overall if this factor was deleted. The result may also reflect that the measures are not specific enough to measure sexuality, particularly in an older population, as many of the population in this study were.

Table 5.2: Cronbach alpha levels for each subscale of the BCNQ

Scale	**Cronbach alpha levels**	
	Baseline	**Post intervention**
Psychological	0.910	0.906
Health system and information	0.882	0.919
Physical and daily living	0.831	0.754
Patient care and support	0.746	0.774
Sexuality	0.534	0.482

Pearson's chi-square was used to compare frequencies between the groups and *t*-tests were used to compare continuous variables between the groups. These included the independent t-test to compare the means of the NG and CG for the BCNQ, HADS, EORTC QLQ C30 and QLQ-BR23 and the paired t-test to analyse data before and after the intervention.

A series of models were constructed using multiple regression analysis to assess the contribution of patient and clinical characteristics to reporting "some need", anxiety or depression. The following were examined: age, severity of treatment (severity), time since diagnosis (TSD): treatment group (TG) and postcode on developing a need for support, anxiety and depression levels at baseline and time 2. Initially, a series of tests were carried out to examine the suitability of the present data for regression analysis – a stepwise method was used and retained based on statistic criteria (probability of F to enter<.05, and to remove >.10. No multicollinearity was suggested, as tolerance values were all above 0.4 (0.1 is the minimum; Field 2005, p.175)

The whole EORTC QLQ C30 and QLQ BR23 have been fully analysed; however, only selected scales were used in the linear regression models. This decision was informed by previous research. The scales used as dependent variables from the EORTC QLQ C30 included: physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning, fatigue and pain. All scales were used as dependent variables in the QLQ-BR23.

5.5 Participant characteristics

The baseline demographic and disease characteristics of the two groups were similar and these are presented in Table 5.3. The baseline treatment characteristics are presented in Table 5.4. Statistical comparison tests were carried out in two ways depending on whether the demographic variables were considered: categorical or continuous. The results, as shown in Table 5.3 indicate no significant differences between the age of the NG: *M* = 53.48, *SD* 9.25 compared to the CG: *M* = 53.11, SD 10.70 (two sample t-test, *t* (168) = 80, p=0.867. They also indicate that there are no significant differences between the time since diagnosis of the NG: *M* = 34.48 months, *SD* 20.79 compared to the CG: *M* = 32.31, *SD* = 16.97 (two sample t-test, *t* (522) = 80, p=0.865).

Table 5.3: Baseline demographic and disease characteristics of the study participants

Variable		Nurse group (44)		Control group (37)		p-value
Age in years mean(range)		52 (range 38 - 72)		53 (range 21 - 76)		0.86[a]
Months since diagnosis mean(range)		25 (range 6 - 84)		26 (range 5 - 64)		0.86[a]
		N	**%**	**N**	**%**	
Tumour grade	1	8	22	7	16	0.10[a]
	2	8	22	20	44	
	3	18	48	15	33	
	unknown	0	0	2	4	
	DCIS	3	6	1	2	
Histological type	ductal	33	75	38	78	0.61
	lobular	4	11	6	13	
	not reported	0	0	1	2	
Node status	positive	15	41	16	36	0.65[b]
	negative	22	59	29	64	
HER2 status	positive	5	13	6	13	0.74[b]
	negative	22	60	30	67	
	unknown	10	27	9	20	
Pathological tumour size	0-0.9	1	2	0	0	0.49[a]
	1.0-1.9	16	36	11	28	
	2.0-2.9	16	36	11	30	
	>3.0	12	26	15	41	

Notes: SD=standard deviation [a] t-test [b] x^2 test

5.6 Participant treatment characteristics

In Chapter 2 the type of treatments a woman would be offered were outlined. Many of these treatments cause short-term but also long-term side effects. Although all treatments have their unique set of side effects there is a cumulative effect seen the more treatments received. Breast cancer is unique because most women receive more than one treatment and for some, up to five. The researcher made an assumption that the more treatments a woman receives, the greater the likelihood of a cumulative risk of side-effects. To adjust the analyses for this occurring, an additional variable was calculated based on the number of, and anticipated impact of a different treatment for each individual participant; scoring range 0 (surgery alone) → 8 (surgery plus endocrine, herceptin,

chemotherapy and radiotherapy, with more toxic treatments like chemotherapy scoring higher). This variable is referred to throughout this thesis as “severity of treatment”. There are no significant statistical differences observed between the mean values of the severity of treatment of the NG (M = 4.27, SD = 2.10) compared to the CG (M = 4.37, SD = 2.05), (two-sample t-test, *t* (183) = 80, p=0.855). All other variables are found not to be significantly different.

Table 5.4: Baseline treatment characteristics of the study participants

Variable		**Nurse group**		**Control group**		**p-value**
		N	%	N	%	
Mastectomy		20	54	20	44	0.50[b]
Wide local excision		17	46	25	56	
Reconstruction	yes	12	32	10	22	0.33[b]
	no	25	68	35	78	
Axillary surgery	sample	18	49	18	40	0.56[a]
	clearance	17	46	22	49	
	SLNB	2	5	5	5	
Endocrine	yes	26	70	34	76	0.63[b]
	no	11	30	11	24	
Chemotherapy	yes	25	67	28	62	0.65[b]
	no	12	32	17	38	
Herceptin	yes	4	11	4	9	1.00[b]
	no	41	89	33	91	
Radiotherapy	yes	11	30	12	27	0.81[b]
	no	26	70	33	73	

Notes: [a] t-test [b] x^2 test

5.6.1 Deprivation levels

The Scottish index of Multiple Depression (SIMD) (Scottish Government, 2012) was used to determine the overall deprivation of the population being studied. The SIMD is based on seven domains: employment; income; health; education, skills and training; geographic access to services; crime and housing. The scores categorise deprivation levels according to an individual’s location using the postcode (1 = most deprived to 6,505 = least deprived). The mean SIMD score for the sample was 3524.16 (range 599 to 6474); with 25% of participants falling within the most deprived ranked 30% of the Scottish population (1-1952). There

was no significant difference between the groups (Pearson x^2 0.574, df 69). The scores indicated there were more participants classified as living in a deprived as non-deprived area in both groups compared to the Scottish breast cancer average (Information Services Division, 2013). However, these results are similar to the UK overall average of 23% (National Cancer Intelligence Network, 2011). This was anticipated as the location of the study is in an area categorised, according to SIMD, as being an area of higher deprivation.

5.6.2 Summary of demographic and clinical findings

- Demographic, disease and treatment characteristics were similar between the two groups at the onset of the trial
- Completers and non-completers did not differ on demographic variables and therefore did not appear to influence whether a participant completed the study or not.

5.7 Flow of patients through the trial

The progress of patient through the trial is shown in Figure 5.1, which is based on that recommended in the CONSORT statement on the reporting of trials (2010)

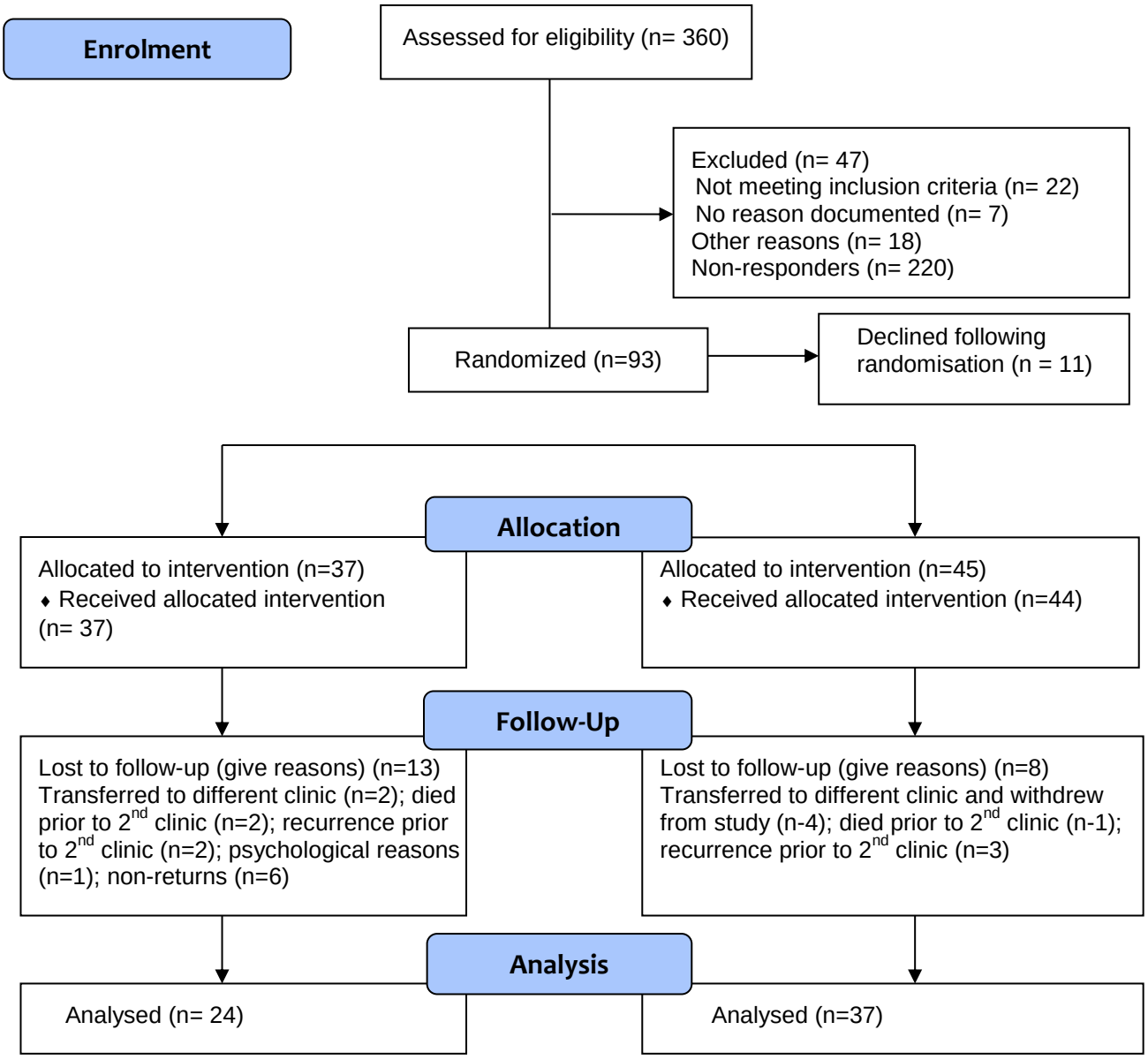


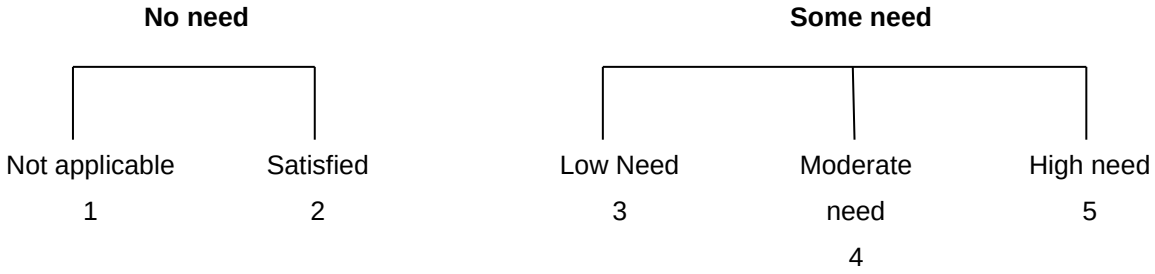
Figure 5.1: Flow of participants through the trial

5.8 Primary outcome

The descriptive statistics associated with the primary outcome are reported first. This includes the means, standard deviation (SD), minimum and maximum scores for all the measures used. All testing was two-tailed and statistical significance was accepted at the 5% level (p=<0.05). Participants completed measures for level of need using the BCNQ and levels of depression and anxiety using the HADS. Although depression and anxiety scores are collected together on one questionnaire they are analysed separately; HAD-A, anxiety and HAD-D, depression and is consistent with the reporting of this in the literature.

5.8.1 Descriptive data of overall needs

Participants completed a 40 item BCNQ questionnaire. For each item, participants are asked to indicate their level of need for help over the last month as a result of having breast cancer, using the following responses:



Scored 1-5, a higher domain score represents a higher level of need for help. The distribution of the summated scales, which form part of the BCNQ, at baseline for the nurse group (NG) and control group (CG) are presented in Table 5.5.

Table 5.5: Descriptive baseline data for the BCNQ divided into the five subscales

		Baseline – nurse				Baseline – control			
Scale	**No. of items**	**M**	**SD**	**Min**	**Max**	**M**	**SD**	**Min**	**Max**
Psychological	14	1.92	0.70	1	3.57	1.84	0.80	1	3.93
Health system and information	16	1.92	0.76	1	4.90	1.94	0.76	1	3.5
Physical and daily living	4	2.35	1.09	1	4.67	2.23	1.04	1	5
Patient care and support	3	1.97	0.97	1	5	2.09	0.95	1	4
Sexuality	3	2.02	0.94	1	4.50	1.7	1.09	1	5
M= mean, SD = standard deviation									

Scores were normally distributed. The responses of both groups to individual items were compared. There was a significant difference between mean values for item 7 “Coping with lymphoedema” on the psychological scale between the NG (M=1.92, SD=0.70) compared to the CG (M=1.84, SD=0.80), (two-sample t-test, *t* (2.126) = 76, p=0.037).

Some questions would be more relevant to women of a certain age, particularly item 30 “Being informed about the impact of cancer treatment on your fertility” on the health system sub-scale. In the analysis of this question all women over 45 were excluded, leaving nine participants. The results indicate there are no significant statistical differences between the NG (M=1.22, SD=0.44) and the CG (M=1.40, SD=0.55), (two sample t-test, t (-0.665) =12, p=0.519).

No other responses for items on the scales are statistically significant.

The distribution of the summated scales at the end of the trial for the NG and CG are presented in Table 5.6. An independent t-test indicated there are no significant differences in unmet needs expressed across all the subscales between the two groups at the end of the trial.

Table 5.6: Descriptive post-intervention data for the BCNQ divided into the five subscales

		Post intervention – nurse				Post intervention – control			
Scale	**No. of items**	**M**	**SD**	**Min**	**Max**	**M**	**SD**	**Min**	**Max**
Psychological	14	1.54	0.49	1	2.5	1.68	0.59	1	2.93
Health system and information	16	1.58	0.50	1	2.81	1.71	0.61	1	3.25
Physical and daily living	4	1.86	0.8	1	3.73	1.9	0.72	1	3.75
Patient care and support	3	1.72	0.66	1	3.33	1.76	0.74	1	3.67
Sexuality	3	1.55	0.59	1	3	1.52	0.76	0.5	3.5
Notes: M= mean SD = standard deviation									

The individual questions informed the direction the intervention took. The 20 most frequently reported unmet needs expressed on the BCNQ are presented in Table 5.7.

Table 5.7: Top 20 needs expressed across both groups on the BCNQ

Ranked	Item no.	Needs
1	15	Dealing with fears about the cancer spreading or returning
2	10	Dealing with a lack of energy or tiredness
3	31	Being informed about the causes and possible triggers of breast cancer
4	28	Being informed about the latest developments in treatment and prevention of breast cancer
5	12	Pain or discomfort in the area of the affected breast
6	11	Pain of discomfort in the arm near your surgery
7	26	Being informed about the possible effects of the cancer on the length of your life
8	37	Having one doctor who knows all about your condition, treatment and follow-up
9	19	Accepting changes in your appearance
10	27	Being informed about the causes, preventions and treatment of lymphoedema
11	40	Having access to HCP (eg. GPs,dieticians, physiotherapists) who specialise in dealing with people who are cancer survivors (or people who are recovering from cancer)
12	17	Coping with changes to your usual routine and lifestyle
13	20	Coping with changes in your sexuality or to your sexual relationships
14	8	Coping with what having breast cancer might mean for your daughters and sisters
15	9	Being informed about your daughters and/or sister's risk of developing breast cancer
16	25	Meeting other breast cancer survivors who are your age
17	35	Receiving information which is specific to your age
18	22	Coping with the impact your cancer is having on your relationship (both to you and/or your partner)
19	29	Being informed about insurance issues
20	36	Feeling able to ask your cancer specialist specialists for information about a range of issues not just medical issues

5.8.2 Changes in needs over time

The primary outcome of interest was testing the effect of the intervention between baseline (time 1) and the single post-intervention (time 2). The sub-scores that make up the total BCNQ scores were analysed separately first. Presented in Figure 5.2 is a graphical representation of results across all the five subscales: psychological, health system and information, physical and daily living, support and sexuality at baseline (time 1) and post intervention (time 2). The error bars for each mean are the 95% confidence intervals for that mean based on each means standard error.

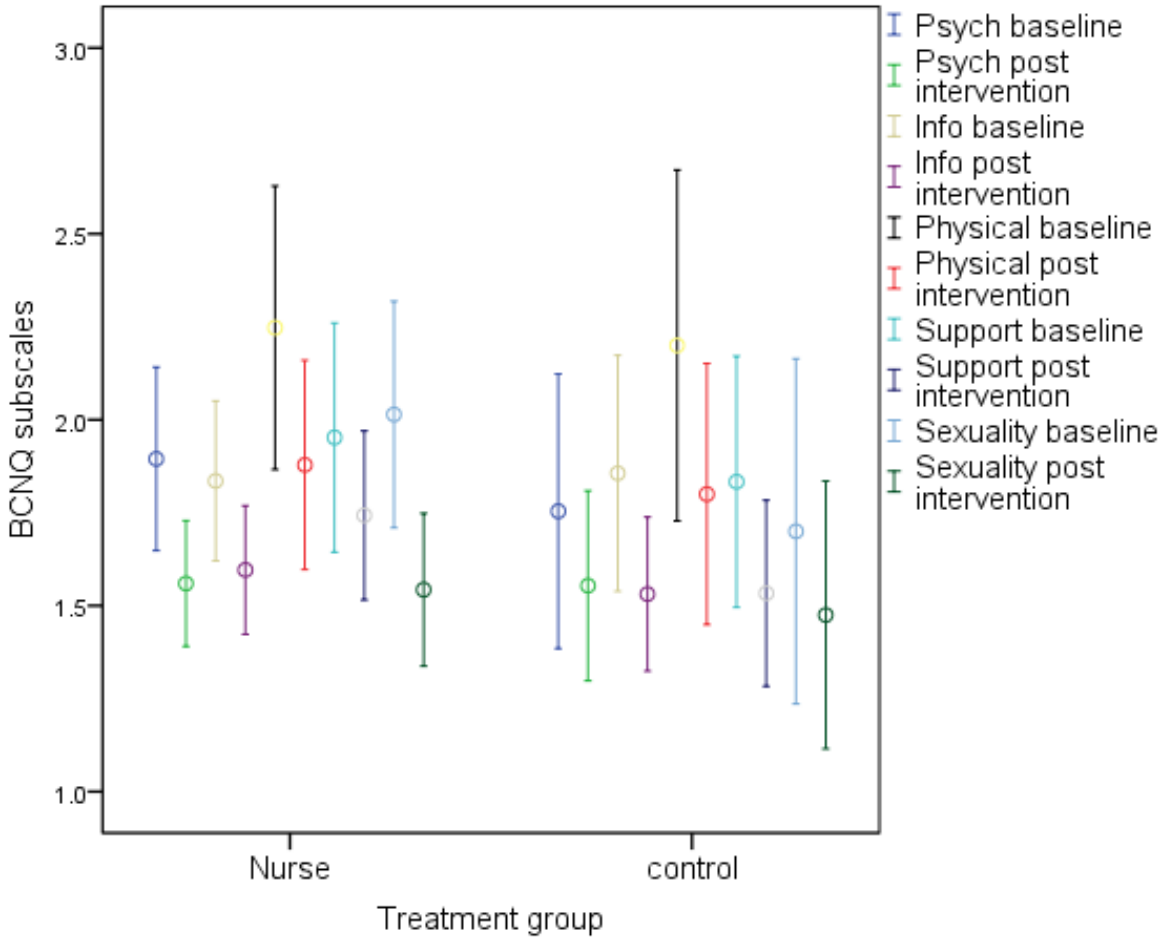


Figure 5.2: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post intervention groups for BCNQ subscale scores

The first analysis undertaken compared the mean response scores before and after the intervention on the five subscales of the BCNQ in each group to understand the changes that occurred in each of the groups. This was conducted on 55 participants to test the following hypothesis:

$H_{0:}$ There is no significant difference in mean values of unmet needs (subscales) between beginning and end of the trial for control group
v
$H_{1:}$ There is a significant difference in mean values of unmet needs (subscales) between beginning and end of the trial for control group

$H_{0:}$ There is no significant difference in mean values of unmet needs (subscales) between beginning and end of the trial for intervention group
v
$H_{1:}$ There is a significant difference in mean values of unmet needs (subscales) between beginning and end of the trial for intervention group

Using a paired t-test, the results, as shown in Table 5.8 indicate that four subscales (psychological, health system and information, physical and daily living and sexuality) showed a significant difference in mean value responses before and after treatment compared to one subscale in the control group (health system and information).

Table 5.8: Mean differences over time for BCNQ subscale scores by treatment group

			Paired Differences							
Group	*Pair*		*M*	*SD*	*SE Mean*	*95% Confidence Interval of the Difference*		*t*	*df*	*Sig. (2-tailed)*
						Lower	*Upper*			
Nurse	P1	Psychological	.34	.66	.11	.11	.56	3.025	34	.005*
	P2	Information	.24	.60	.10	.03	.44	2.370	34	.024*
	P3	Physical	.37	.92	.16	.05	.69	2.368	34	.024*
	P4	Support	.21	.90	.15	-.10	.52	1.376	34	.178
	P5	Sexuality	.47	.82	.14	.19	.75	3.393	34	.002*
Control	P1	Psychological	.20	.52	.12	-.04	.45	1.711	19	.103
	P2	Information	.32	.60	.13	.04	.61	2.428	19	.025*
	P3	Physical	.40	.99	.22	-.06	.86	1.804	19	.087
	P4	Support	.30	.92	.21	-.13	.73	1.453	19	.163
	P5	Sexuality	.22	.75	.17	-.13	.58	1.339	19	.197

* Denotes significance

Nurse Group: Results indicate that there is a significant difference between the mean value psychological responses before (M=1.89, SD=0.72) and after (M=1.56, SD= 0.83) (paired t-test, t = 3.025, df = 34. p=0.005).

Nurse group: There is a significant difference between the mean value health system and information responses before (M=1.84, SD=0.63) and after (M=1.60, SD=0.50) (paired t-test, t = 2.370, df = 34, p=0.024)

Nurse Group: There is a significant difference between the mean value physical responses before (M=2.25, SD=1.11) and after (M=1.88, SD=0.82). (paired t-test, t = 2.368, df = 34, p=0.025 (CG).

Nurse Group: There is a significant difference between the mean value sexuality responses before (M=2.01, SD=0.90) and after (M=1.54, SD=0.60). (paired t-test, t = 3.393, df = 34, p=0.02)

Control Group: There is a significant difference between the mean value health system and information responses before (M=1.86, SD=0.68) and after (M=1.53, SD=0.44) (paired t-test, t = 2.428, df =19, p=0.025)

These results reject the hypothesis in four out of five subscales for the nurse group and one subscale for the control group. It appears that participants exposed to the nurse group saw more improvements compared to the control group.

To understand the extent of this improvement and whether there was a significant difference between the control and intervention groups, a regression approach was used. This approach adjusted for any chance imbalance between the groups in any of the outcome variables at baseline.

This approach tested the following hypothesis:

> *H_0: There is no significant difference in mean values in unmet needs (subscales) between the control and treatment groups at end of the trial*
> *v*
> *H_1: There is a significant difference in mean values in unmet needs (subscales) between the control and treatment groups at end of the trial*

The results, as shown in Table 5.9 indicate there is no significant difference between any of the subscales between the two groups at the end of the trial. The results fail to reject the null hypothesis.

Table 5.9: Linear regression: The association between BCNQ subscale scores and the treatment groups

	Score at time 1		Co-efficient of group indicator	
BCNQ Subscales	β	p value	β	p value
Psychological	0.377	<0.001	0.124	0.311
Information	0.353	<0.001	0.009	0.94
Physical	0.373	<0.001	0.007	0.971
Support	0.245	<0.016	0.054	0.739
Sexuality	0.387	<0.001	0.054	0.739

*Group indicator=0 if control group; 1 if nurse group

5.8.3 BCNQ: Dichotomous outcome

To test the effect of the intervention and determine if it was successful or not in achieving changes in unmet needs over time, a dichotomous outcome measure was established. The criteria to classify the outcome was having a need for any one of the items in a subscale and therefore an item was scored 3, 4 or 5 compared to those who had no need and therefore scored an item 1 or 2. The analysis indicated that the proportion of participants expressing a need across the whole BCNQ score at baseline was 77.8% (n=34) (NG) and 78.9% (CG). Following the intervention, this level decreased to 58.3% and 66.7% respectively. The overall dichotomised score was added together (range 0–34) and this gave a continuous score whose summary mean at baseline and post-intervention are presented in Table 5.10.

Table 5.10: Summary mean BCNQ scores at baseline and post intervention

BCNQ		**Nurse**		**Control**		**p value**
Participants		44		37		
Time 1: Baseline						
Need for support	40 items	11.11 M	8.99 SD	9.23 M	8.64 SD	p 0.35
Time 2: Post Intervention						
Participants		36		24		
Need for support	40 items	4.19 M	6.09 SD	7.75 M	6.63 SD	p 0.35
Notes: M=mean, SD = standard deviation						

In Figure 5.3, the error bars for each mean are the 95% confidence intervals for that mean based on each mean's standard error.

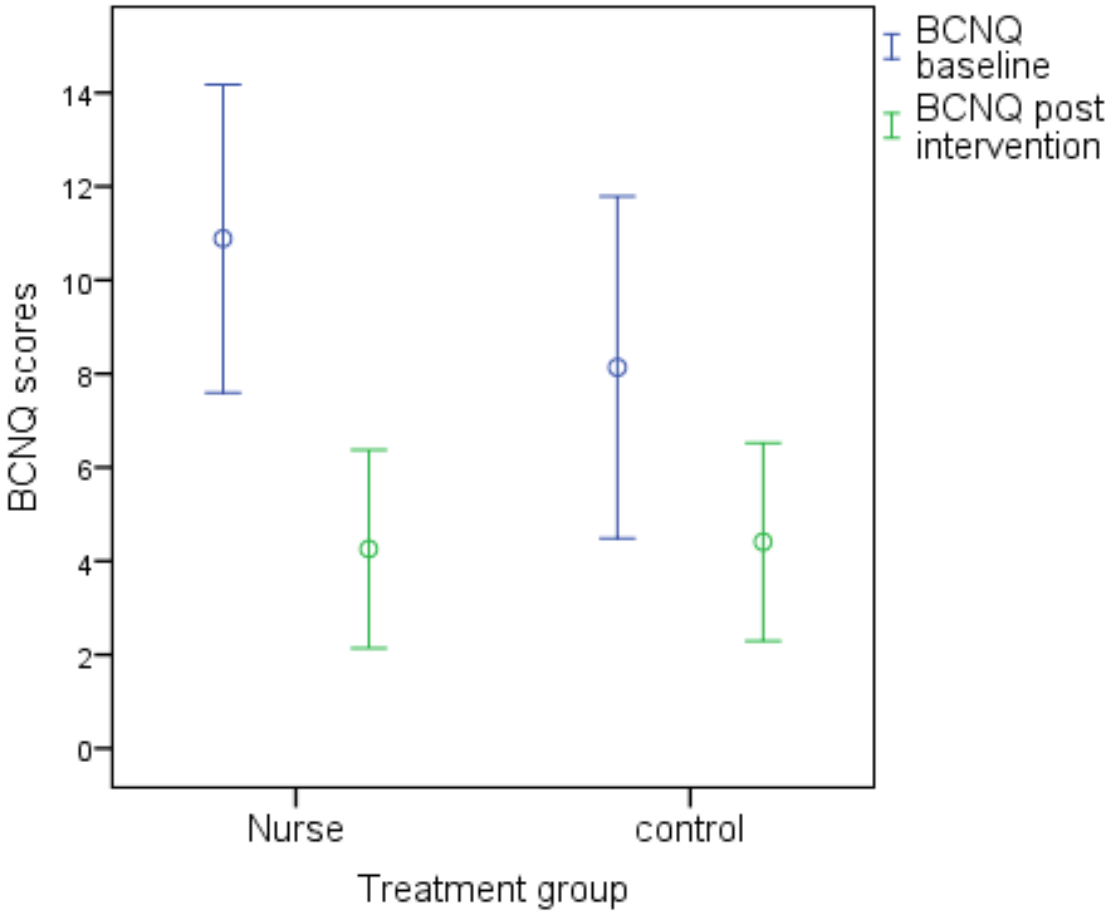


Figure 5.3: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post intervention group for BCNQ scores

The graph shows the differences between the groups at baseline and post intervention in regard to overall needs. There was an improvement in both groups. The first analysis compared the mean response scores before and after the intervention using the dichotomous outcome variable.

This was conducted on 57 participants to test the following hypotheses:

$H_{0:}$ There is no significant difference in unmet needs between beginning and end of trial for the control group (paired).
v
H_1 There is a significant difference in unmet needs between beginning and end of trial for the control group (paired).

$H_{0:}$ There is no significant difference in unmet needs between beginning and end of trial for the intervention group (paired).
v
H_1 There is a significant difference in unmet needs between beginning and end of trial for the intervention group (paired).

It can be seen from the data that the mean response scores for the BCNQ at time 1 was 10.9 (NG) compared to 8.1 (CG), whilst the mean response scores at time 2 was 4.26 (NG) compared to 4.41 (CG) (95% confidence interval for the difference 3.5–9.8, NG, compared to 0.7–6.8, CG). The results, as shown in Table 5.11 indicate that there is a significant difference between the mean response scores for the BCNQ before and after the intervention (paired t-test, NG: t = 4.282, df = 34, p =< 0.001; CG: t = 2.627, p=0.016. This result rejects the null hypothesis for control and intervention.

Table 5.11: Mean differences over time for BCNQ dichotomous outcome scores by treatment group

			Paired Differences					t	df	Sig. (2-tailed)
			M	SD	SE Mean	95% Confidence Interval of the Difference				
Group	Pair					Lower	Upper			
Nurse	P1	BCNQ	6.63	9.16	1.55	3.48	9.77	4.282	34	.000*
Control	P1	BCNQ	3.73	6.66	1.42	.78	6.68	2.627	21	.016*

* Denotes significance

To understand the extent of this improvement and whether there was a significant difference between the control and intervention groups, a regression approach was used which adjusted for any chance imbalance between groups in any of the outcome variables at baseline.

The regression analysis tested the following hypothesis:

H_0: There is no significant difference in unmet needs between control and intervention groups at the end of the trial
v
H_1: There is a significant difference in unmet needs between the control and treatment group at the end of the trial

The results, as shown in Table 5.12 indicate that although the intervention improved unmet needs in the expected direction, this change is not statistically significant between the groups (p=0.518). This result rejects the alternative hypothesis.

Table 5.12: Linear regression: The association between BCNQ scores and the treatment groups

	Score at time 1		coefficient of group indicator	
	β	p value	β	p value
BCNQ dichotomous	0.279	<0.001	0.918	0.518

* Group indicator=0 if control group; 1 if nurse group

5.8.3 Summary of findings: Unmet needs

- Levels of unmet needs as measured by the BCNQ are not significantly different across both groups.
- The overall proportion of participants expressing an unmet need was high in both groups.
- Both groups saw a reduction in overall unmet needs between the beginning and end of the trial.
- Changes before and after the intervention are significantly different in four out of five subscales in the NG compared to one in the CG. However, this is not a statistically significant difference between the groups.
- The intervention improved unmet needs in the right direction but this change is not statistically significantly and no differences between the groups.

5.8.4 Descriptive data of overall anxiety and depression

Participants completed a 14 item HADS questionnaire: 7 items associated with levels of anxiety, 7 items associated with levels of depression. The distribution of the summated scales that form the HADS are presented in Table 5.13. Although the baseline mean scores are higher for anxiety among the CG (M=8.24) compared to the NG (M=7.07) and depression among the CG (M=4.88) compared to the NG (M=3.36), there is no statistical difference between the groups' mean anxiety scores t (- 1.002) = 75, p= 0.319 or mean depression scores (two-tailed, t (- 1.682) = 75, p= 0.97).

Table 5.13: Summary mean scores of anxiety and depression of the HADS at baseline and post-intervention

HAD		**Nurse**				**Control**			
		Baseline (44)				**Baseline (37)**			
Scale	No. of items	M	SD	Min	Max	M	SD	Min	Max
Anxiety	7	7.07	4.75	0	18	8.24	5.51	0	20
Depression	7	3.36	3.59	0	17	4.88	4.31	0	17
		Post intervention (37)				**Post intervention (23)**			
Anxiety	7	5.81	4.86	0	21	6.04	4.01	0	13
Depression	7	3.14	3.65	0	17	3.08	2.57	0	9
Notes: M = Mean, SD = standard deviation									

5.8.5 Clinical abnormal levels of anxiety and depression

Each scale for anxiety and depression is scored from 0 – 21. Clinical indicators of psychological distress are determined by the overall score: a score of 0 -7 is considered normal; a score of 8-10 is borderline anxious/depressed; a score >11 is probably a case of anxiety/depression (Zigmond & Snaith, 1983; Bjelland *et al.* 2002). To distinguish between the mean scores and the presence of anxiety and depression scores of the individual participants, the results, shown in Table 5.14 (baseline) and Table 5.15 (post-intervention) are categorised according to the abnormal scoring protocol (see Table 4.3). The single most striking observation is the high number of women in both groups who appear to have clinically significant levels of anxiety at baseline (NG=43%; CG=60%) and which appear to decline but not resolve at the end of the trial (NG=35%; CG = 48%). Pearson's x^2

chi-square was performed on the data at the onset of the trial and the end to determine if there was a significant difference in the frequency of these scores reported between the two groups. Results, as shown in Table 5.14 and 5.15 indicate there is no statistical difference between the start and end of the trial.

Table 5.14: Presence of anxiety and depression symptoms among participants as per HADS at baseline

HADS Score	**Baseline anxiety**				**Baseline depression**			
	Nurse (44)		Control (33)		Nurse (44)		Control (33)	
	n	%	n	%	n	%	n	%
0 - 7	24	54.55	13	39.39	40	90.91	27	81.82
8 - 10	11	25.00	12	36.36	1	2.27	4	12.12
>11	8	18.19	8	24.24	3	6.82	2	6.07
	x^2.369				x^2.458			

Table 5.15: Presence of anxiety and depression symptoms among participants as per HAD scale at post intervention

HADS Score	**Post-intervention anxiety**				**Post-intervention depression**			
	Nurse (37)		Control (23)		Nurse (37)		Control (23)	
	n	%	n	%	n	%	n	%
0 - 7	24	64.86	13	56.52	34	91.89	22	95.65
8 - 10	6	16.22	7	30.43	2	5.41	1	4.54
>11	7	18.92	4	17.39	1	2.70	0	0
	x^2.326				x^2.563			

5.8.5 Changes in anxiety over time

The following section presents data associated with changes in anxiety over time.

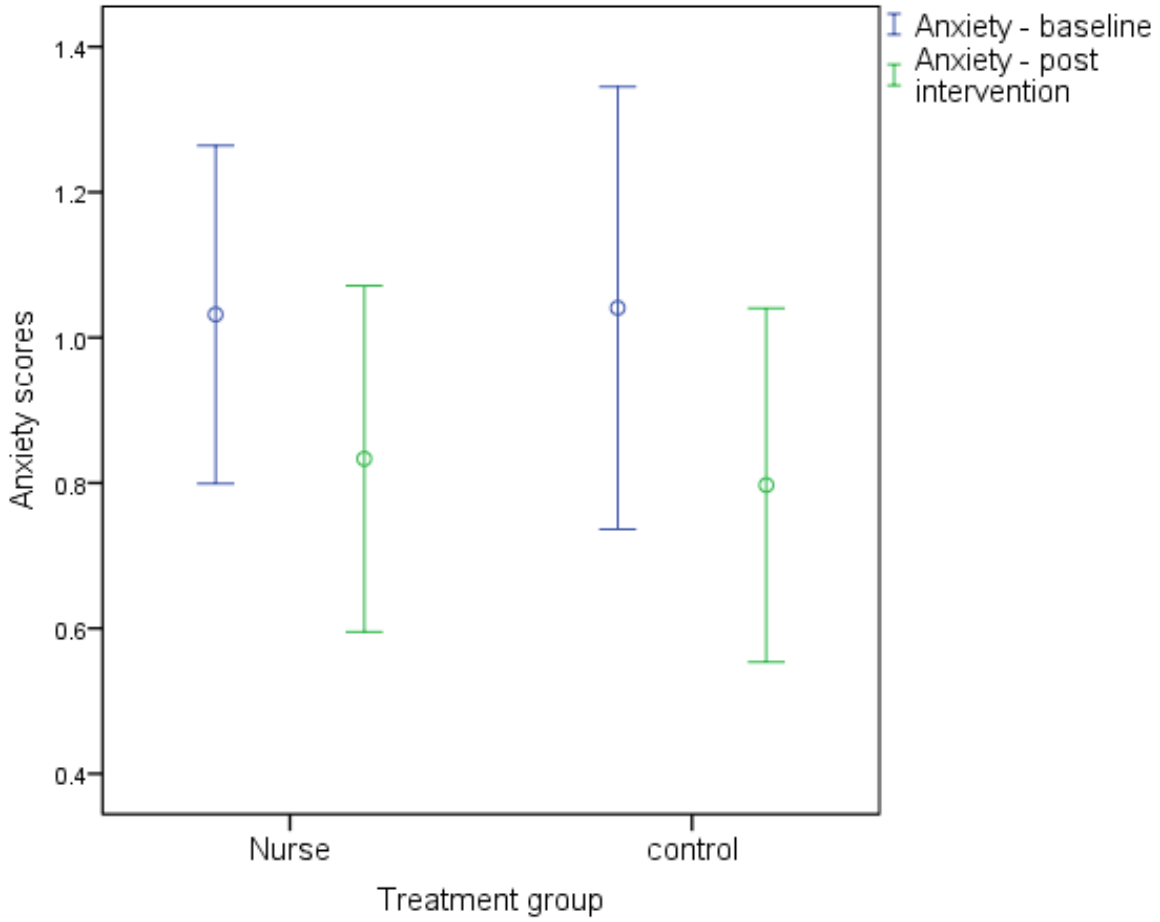


Figure 5.4: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post intervention group for anxiety scores

In Figure 5.4, the error bar for each mean are the 95% confidence intervals for that mean based on each mean's standard error. From the graph above a fall in anxiety occurs in both the nurse and the control group. The first analysis compared the mean value of the anxiety response scores on the HADS before and after the intervention. This was conducted on 57 participants to test the following hypothesis:

H_0 There is no significant difference in anxiety between beginning and end of trial for the intervention group
v
H_1 There is a significant difference in anxiety between beginning and end of trial for the intervention group

H_0 There is no significant difference in anxiety between beginning and end of trial for the control group

v

H_1 There is a significant difference in anxiety between beginning and end of trial for the control group

The mean anxiety score at time 1 was 1.03 (NG) compared to 1.04 (CG), whilst the mean anxiety score at time 2 was 0.83 (NG) compared to 0.80 (CG) (95% confidence interval for the difference 0.07–0.33, NG, compared to 0.04 – 0.45, CG). It can be seen from the data in Table 5.16 that there is a significant difference between the mean value responses before and after the intervention in both groups (paired t-test, NG: t = 3.043, df =35, p = 0.004; CG: t = 2.457, df = 20, p = 0.023). This result means that a significant difference in anxiety in both groups has been shown and supports the alternative hypothesis.

Table 5.16: Mean differences over time for HADS scores by treatment group

Group	Pairs		Paired Differences					t	df	Sig. (2-tailed)
			M	SD	SE mean	95% Confidence Interval of the Difference				
						Lower	Upper			
Nurse	P1	Dep	.05	.39	.07	-.08	.18	.785	35	.437
	P2	Anx	.20	.39	.07	.07	.33	3.043	35	.004
control	P1	Dep	.19	.19	.04	.10	.28	4.513	20	.000
	P2	Anx	.24	.45	.10	.04	.45	2.457	20	.023

To understand the extent of this improvement and whether there was a significant difference between the control and intervention groups, a regression approach was used. This adjusted for any chance imbalance between groups in any of the outcome variables at baseline.

This approach tested the following hypothesis:

H_0: There is no significant difference in anxiety between control and treatment groups at end of the trial;
v
H_1: There is a significant difference in anxiety between control and treatment groups at end of the trial.

Table 5.17: Linear regression: Association between HAD-A scores and treatment groups

	Score at time 1		coefficient of group indicator	
HAD A	β	p value	β	p value
anxiety	0.764	<0.001	0.366	0.632

* Group indicator=0 if control group; 1 if nurse group

The results, as shown in Table 5.17 indicate that although the intervention improved anxiety levels in the expected direction, this change is not statistically significant between the groups (p=0.632). The results fail to reject the null hypothesis.

5.8.6 Changes in depression over time

There is a higher proportion of participants with depression in the control group compared to the nurse group at baseline (CG: 68%) compared to NG: 48%).

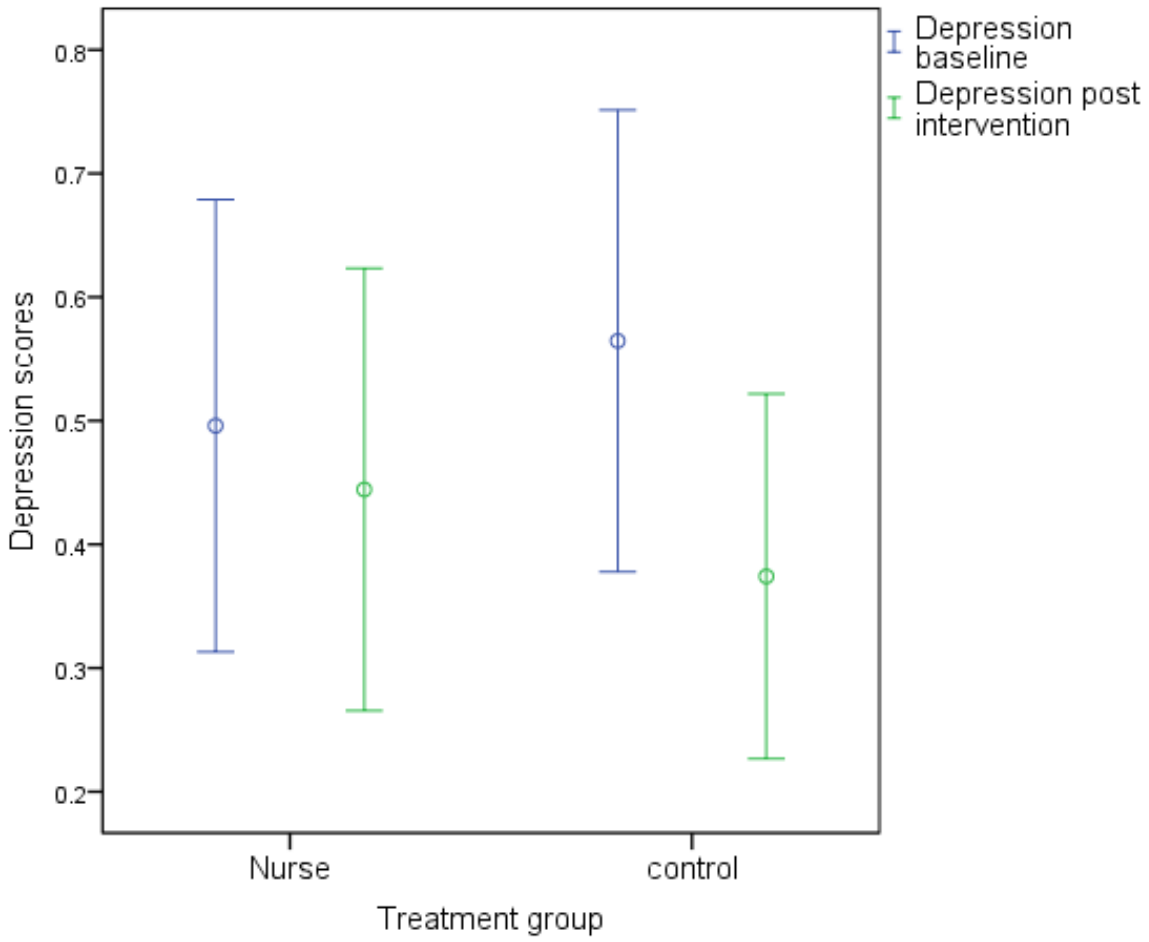


Figure 5.5: Error bar graph comparing the mean differences with 95% confidence intervals for baseline and post intervention group for depression

In Figure 5.5, the error bars for each mean are the 95% confidence intervals for that mean based on each mean's standard error. A fall occurs in the control group between baseline and the end of the trial. The first analysis compared the mean value of the depression response scores on the HADS before and after the intervention.

This was conducted on 57 participants to test the following hypothesis:

H_0 There is no significant difference in depression between beginning and end of trial for the intervention group
v
H_1 There is a significant difference in depression between beginning and end of trial for the intervention group

H_0 There is no significant difference in depression between beginning and end of trial for the control group
v
H_1 There is a significant difference in depression between beginning and end of trial for the control group.

The mean response scores for the depression values at time 1 is 0.50 (NG) compared to 0.56 (CG), whilst the mean response values at time 2 was 0.44 (NG) compared to 0.37 (CG) (95% confidence interval for the difference 0.10– 0.28, NG, compared to -0.82 – 0.18, CG). It can be seen from the data in Table 5.16 that there is a significant difference between the mean response scores for depression before and after the intervention in the control group (paired t-test, t = 4.513, df=20, p=< 0.001) but not the nurse group (t=0.785, df=35, p=0.437.

To understand the extent of this improvement and whether there was a significant difference between the control and intervention groups, a regression approach was used. This adjusted for any chance imbalance between groups in any of the outcome variables at baseline. This approach tested the following hypothesis:

H_0: There is no significant mean difference in depression values between the nurse and control group at the end of the trial;
v
H_1: There is a significant mean difference in depression values between the nurse and control group at the end of the trial.

Table 5.18: Linear regression: Association between HAD-D scores and treatment groups

	Score at time 1		coefficient of group indicator	
HAD-D	β	p value	β	p value
depression	0.71	<0.001	-0.833	0.163

* Group indicator=0 if control group; 1 if nurse group

The results, as shown in Table 5.18 indicate that although the intervention improved depression levels in the expected direction, this change is not statistically significant between the groups (p=0.163). The results fail to reject the null hypothesis

5.8.8 Summary of findings: Anxiety and depression

- Anxiety levels are high in both groups at the onset of the trial.
- Anxiety and depression levels are not significantly different between the groups at the onset and end of the trial.
- Anxiety and depression responses fell in both groups between baseline and the end of the trial.
- There is a significant statistical difference in anxiety and depression between the beginning and end of the trial in both groups.
- There are no significant differences between the control and treatment groups at the end of the trial.

5.9 Secondary outcome

5.9.1 Descriptive data of quality of life

The whole quality of life questionnaires: the QLQ C30 and the QLQ BR23 were administered to participants at baseline and 12 months. The QLQ C30ver3.0 was a 30-item generic cancer questionnaire. For items 1 - 28, participants are asked to answer questions relating to their health, using the following responses: not at all (1); a little (2); quite a bit (3); very much (4). Item 29 and 30 ask participants to rate their health and quality of life on a scale of 1 (very poor) to 7 (excellent). The questionnaire is divided into functional scales (5), symptom scales/item (8) and global health status/quality of life (1). All the measures range in score from 0 - 100. Interpretation of high scores is as below:

> *A high score for a functional scale represents a high/healthy level of functioning*
> *A high score for the global health status/quality of life represents a high quality of life*
> *A high score for a symptom scale/item represents a high level of symptomatology/problems*
> *(*Fayers *et al*.1999, p.7)

The distribution of all the summated scales, which form part of the EORTC QLQ C30, at baseline for the nurse group (NG) and control group (CG), are shown in Table 5.19. The summated scales for post intervention scales are shown in Table 5.20. The cognitive functioning scale (CF) at baseline is the only scale in which one could not assume equality of variances.

Independent t-tests are used to determine if there is a significant difference in quality of life scores (EORTC QLQ C30) between the two groups at baseline. The results, as shown in Table 5.19 indicate that in the CG four symptom scales are higher compared to the NG. These scores are for appetite loss (CG, M=14.20) compared to the NG (M=5.30), constipation, (CG, M=22.78) compared to NG (M = 12.12), diarrhoea (CG, M=25.49) compared to the NG (M=11.63), and financial

difficulties (CG, M=28.44) compared to the NG (M=13.18). However, none of these are statistically different between the groups', appetite loss scores (two-sample t-test, t (- 0.236) = 77, p= 0.48, constipation scores t (0.130) = 77, p = 0.90, diarrhoea t (0.663) = 76, p=0.97, financial difficulties scores t (0.069) = 75, p = 0.95).

Independent t-tests are used to determine if there is a significant difference in quality of life between the two groups at the end of the trial, measured using the EORTC QLQ C30. The results, as shown in Table 5.20 indicate that there are no significant differences in quality of life between the NG and CG at the end of the trial. The results however do indicate that there have been some changes in the scores either upwards (functional scales) or downwards (symptom scales).

The distribution of the summated scales, which form part of the QLQ BR23, at baseline and post intervention for the nurse group (NG) and control group (CG), are shown in Table 5.21 and Table 5.22 respectively. BRB1 (body image) was the only scale on the QLQ BR23 one could not assume equality of variance at baseline. The results, as shown in Table 5.21 indicate that body image scores in the CG (M=69.76) are lower compared to the NG (M=81.35). However, this is not a statistically significant difference between the groups at the end of the trial (two-tailed t-test, t (- 1.755)=58.7, p=0.08).

The results also indicate that breast symptom scores in the NG (breast symptoms, M=18.94) are higher compared to the CG (M = 14.05), as are arm symptom scores in the NG (arm symptoms, M= 23.48) compared to the CG (M=16.19). However, this is not a statistical difference between the groups (two-tailed t-test, t (1.394.) = 77, p=0.17, and arm symptoms scores t (1.471) = 77, p=0.15.

Post intervention, independent t-tests were carried out across all the scales and presented in Table 5.22. There is no significant difference in quality of life (BR 23) between the CG and NG at the end of the trial.

Table 5.19: Summary means scores for the EORTC QLQ C30 at baseline

	Scale	No. of items	Baseline – Nurse				Baseline – Control				p-value
Global health status/QoL			**M**	**SD**	**Min**	**Max**	**M**	**SD**	**Min**	**Max**	
Global health status/QoL	Ql2	2	70.70	19.87	16.67	100	69.3	25.06	0	100	0.78
Functional scales											
Physical functioning	PF2	5	79.55	16.79	33.33	100	81.71	19.02	6.67	100	0.59
Role functioning	RF2	2	82.95	26.53	0	100	80.00	26.13	0	100	0.62
Emotional functioning	EF	4	76.16	25.24	8.33	100	69.52	28.44	8.33	100	0.28
Cognitive functioning	CF	2	79.46	19.87	16.67	100	68.57	34.00	0	100	0.10
Social functioning	SF	2	84.11	21.81	33.33	100	80.88	25.99	0	100	0.57
Symptom scales											
Fatigue	FA	3	32.30	25.75	0	88.89	33.33	24.40	0	100	0.86
Nausea and vomiting	NV	2	3.79	8.70	0	33.33	11.83	11.83	0	50.00	0.68
Pain	PA	2	31.40	28.69	0	100	24.03	24.03	0	83.33	0.09
Dyspnoea	DY	1	18.94	25.31	0	66.67	21.91	21.91	0	66.67	0.50
Insomnia	SL	1	32.58	34.09	0	100	36.28	36.28	0	100	0.49
Appetite loss	AP	1	5.30	14.28	0	66.67	14.20	14.20	0	33.33	0.48
Constipation	CO	1	12.12	23.94	0	100	22.78	22.78	0	66.67	0.90
Diarrhoea	DI	1	11.63	19.08	0	66.67	25.49	25.49	0	100	0.97
Financial difficulties	FI	1	13.18	26.37	0	100	28.44	26.44	0	100	0.95

* Denotes significance

Table 5.20: Summary mean scores for EORTC QLQ C30 post-intervention

	Scale	No. of items		Post-intervention – Nurse				Post-intervention – Control					p-value
Global health status/QoL			**M**	**Change scores**	**SD**	**Min**	**Max**	**M**	**Change scores**	**SD**	**Min**	**Max**	
Global health status/QoL	Ql2	2	73.20	2.5	22.06	8.33	100	79.17	9.37	19.50	33.33	100	0.29
Functional scales													
Physical functioning	PF2	5	85.77	6.22	16.57	33.33	100	84.44	2.73	13.28	46.67	100	0.74
Role functioning	RF2	2	87.39	4.44	27.33	0	100	90.97	10.97	13.88	66.67	100	0.56
Emotional functioning	EF	4	77.03	0.87	22.77	0	100	80.43	10.91	19.88	16.67	100	0.56
Cognitive functioning	CF	2	83.33	3.87	20.41	0	100	80.56	11.99	20.67	33.33	100	0.61
Social functioning	SF	2	89.64	5.53	20.54	16.67	100	87.50	6.62	25.18	0	100	0.72
Symptom scales													
Fatigue	FA	3	21.32	-10.98	26.50	0	88.89	20.83	-12.50	17.43	0	55.56	0.94
Nausea and vomiting	NV	2	4.05	0.26	9.94	0	50	3.47	-8.36	8.48	0	33.33	0.81
Pain	PA	2	18.10	-13.3	21.53	0	83.33	24.60	+0.57	26.68	0	100	0.32
Dyspnoea	DY	1	9.91	-9.03	15.45	0	33.33	16.67	-5.24	26.00	0	100	0.21
Insomnia	SL	1	30.63	-1.95	29.79	0	100	27.78	-8.50	34.98	0	100	0.73
Appetite loss	AP	1	8.10	+2.8	19.88	0	100	8.33	-5.87	17.72	0	66.67	0.96
Constipation	CO	1	12.61	0.49	26.47	0	100	8.33	-14.45	17.72	0	66.67	0.49
Diarrhoea	DI	1	8.33	-3.3	18.47	0	66.67	5.56	-19.93	21.23	0	100	0.69
Financial difficulties	FI	1	9.00	-4.18	20.26	0	100	11.11	-17.33	25.38	0	100	0.72

* Denotes significance

Table 5.21: Summary mean scores for the QLQ – BR23 at baseline

	Scale	No. of items	Baseline – Nurse				Baseline – Control				p-value
			M	SD	Min	Max	M	SD	Min	Max	
Functional scales											
Body image	BRBI	4	81.35	22.83	16.67	100	69.76	33.03	0	100	0.84
Sexual functioning	BRSEF	2	19.76	20.97	0	83.33	18.57	24.18	0	100	0.82
Sexual enjoyment	BRSEE	1	53.03	24.47	0	100	57.78	32.04	0	100	0.61
Future perspective	BRFU	1	56.81	30.14	0	100	55.24	34.25	0	100	0.83
Symptom scales											
Systemic therapy side effects	BRST	7	16.56	11.22	0	38.10	19.73	16.26	0	80.95	0.31
Breast symptoms	BRBS	4	18.94	15.08	0	66.67	14.05	16.01	0	75	0.17
Arm symptoms	BRAS	3	23.48	21.99	0	88.89	16.19	21.78	0	77.78	0.15
Upset by hair loss	BRHL	1	35.71	38.04	0	100	27.78	34.33	0	100	0.58

Notes: * Denotes significance

Table 5.22: Summary mean scores for QLQ – BR23 post-intervention

	Scale	No. of items	Post intervention – Nurse						Post intervention – Control						p-value
			n	M	Change in score	SD	Min	Max	n	M	Change in score	SD	Min	Max	
Functional scales															
Body image	BRBI	4	37	87.16	5.81	20.66	25.00	100	24	82.84	13.05	24.44	16.67	100	0.44
Sexual functioning	BRSEF	2	37	77.48	**57.24**	22.64	33.33	100	24	79.55	60.98	30.83	0	100	0.77
Sexual enjoyment	BRSEE	1	23	44.93	-8.1	29.49	0	100	10	53.78	-4.00	35.83	0	100	0.49
Future perspective	BRFU	1	37	63.06	1.7	29.17	0	100	24	55.56	0.32	30.56	0	100	0.34
Symptom scales															
Systemic therapy side effects	BRST	7	37	14.80	-1.76	12.74	0	47.62	24	13.10	-6.99	12.74	0	42.86	0.61
Breast symptoms	BRBS	4	37	11.81	-7.13	16.23	0	66.67	24	10.76	-3.29	13.57	0	50.00	0.80
Arm symptoms	BRAS	3	37	14.81	-8.67	18.01	0	88.89	24	17.13	-0.15	16.04	0	55.56	0.61
Upset by hair loss	BRHL	1	11	24.24	-11.47	39.70	0	100	8	41.67	+13.89	49.60	0	100	0.41

Note: *Denotes significance

Change scores for functional scales: a negative result indicates a lower level of functioning over time and a positive result an improvement
Change scores for symptom scales: a negative result indicates a lower level of problems and a positive result a worsening of symptoms/problems

5.9.2 Changes in quality of life over time

To aid the interpretation of quality of life scores, Fayers *et al*. (1999) recommend that comparisons are made with reference data. Although this was made available to the researcher, this data excluded participants who were “off treatment”: those who had completed chemotherapy and radiotherapy. As the present study specifically recruited women with breast cancer who had completed primary treatment, datasets were not comparable.

Analyses were undertaken to determine if there was a significant difference between the mean value responses to the EORTC QLQ C30 and QLQ BR23 before and after treatment (paired sample t-test) and then the differences between the groups compared. In addition, an alternative to interpreting whether the change in mean scores were clinically meaningful across any of the scales, a method described by Osaba *et al*. (2005), was used. They suggest that on a scale of 1-100 the mean changes required to constitute a clinically meaningful difference are: 5-10 equals little change; 10-20 moderate change; >20 a large change. The score at time 2 was subtracted from those at time 1 to give the mean change score.

Using the scoring process above, the results, as shown in Table 5.20, indicate that all scores changed in the desired direction apart from appetite in the NG and pain in the CG. Although most recorded little change, fatigue registered a moderate change in both the NG (-10.98) and the CG (-12.50), as did constipation (CG, -14.45), diarrhoea (CG, -19.93), financial difficulties (CG, -17.33), and pain (NG, -13.3).

The results, as shown in Table 5.20 indicate that there are some mixed results. There was a moderate improvement in body image in the CG (13.05) and a large improvement in sexual functioning across both groups. While a moderate improvement in symptoms associated with hair loss was noted in the NG (-11.47), a moderate worsening of symptoms was seen in the CG (+13.89). Further statistical tests were undertaken.

To assess if there is a statistically different change in the mean value responses across the EORTC QLQ C30 and QLQ BR23, analysis was conducted on 57 participants to test the following hypothesis:

H_0 There is no significant difference in quality of life between beginning and end of trial for the control group.
v
H_1 There is a significant difference in quality of life between beginning and end of trial for the intervention group.

H_0 There is a significant difference in quality of life between beginning and end of trial for the control group.
v
H_1 There is a significant difference in quality of life between beginning and end of trial for the intervention group.

The results, as shown in Tables 5.23 and Table 5.25 indicate that a number of sub scales on both the EORTC QLQ C30 and BR23 showed a significant difference in mean value responses over treatment period. Results indicate that there was a significant difference between the mean value fatigue responses in both groups before (NG: M=31.43, SD=27.15; CG: M=32.32, SD=21.11) and after (NG: M=22.54, SD= 26.74, CG: M=20.71, SD=17.91) (paired t-test, NG, t = 2.198, df = 34. p=0.035; CG, t = 3.352, df = 21. p=0.003). This was the only scale where both groups saw a significant change.

The results, as shown in Table 5.23 indicate that a further three subscales (physical functioning, pain and social functioning) showed a significant difference in mean value responses before and after treatment in the NG compared to two subscales in the CG (role functioning and insomnia). An improvement in functional scales is an increase towards 100; an improvement in symptom scales is a decrease towards 0.

Nurse Group: Results indicate that there is a significant difference between the mean value physical functioning responses before (M=80.19, SD=17.49) and after (M=85.37, SD=16.62) (paired t-test, t = -2.129, df = 34. p=0.040).

Nurse Group: Results indicate that there is a significant difference between the mean value pain (symptom) responses before (M=28.79, SD=27.72) and after (M=18.18, SD=21.80) (paired t-test, t = 2.514, df = 34. p=0.017).

Nurse Group: Results indicate that there is a significant difference between the mean value social functioning responses before (M=81.90, SD = 22.28) and after (M= 89.05, SD=20.98) (paired t-test, t = -2.001, df = 34. p=0.053).

Control Group: Results indicate that there is a significant difference between the mean value role functioning responses before (M = 81.06, SD = 23.73) and after (M= 91.67, SD = 13.36) (paired t-test, t = -2.388, df = 21. p=0.027).

Control Group: Results indicate that there is a significant difference between the mean value insomnia (symptom) responses before (M = 37.88, SD = 38.89) and after (M= 25.76, SD = 32.42) (paired t-test, t = 2.347, df = 21, p=0.029).

These results both support and reject the null hypothesis.

For the QLQ BR23, the results, as shown in Table 5.25 indicate that there is a significant difference between the mean value sexual functioning responses in both groups before (NG: M =17.59, SD = 19.08; CG: M = 17.50, SD = 25.06) and after (NG: 77.78, SD= 22.89, CG: 78.33, SD = 32.04) (paired t-test, NG, t = -9.992, df = 35. *p* = <0.001; CG, t = -5.075, df = 19. p = <0.001). This is the only scale where both groups saw a significant change.

They also indicate that there is a significant difference between the mean value breast symptom (symptom) responses in both groups before (NG: M = 18.10, SD = 14.07; CG: M = 16.67, SD = 17.06) and after (NG: 11.67, SD= 16.44, CG: 9.47, SD = 11.00) (paired t-test, NG, t = 1.961, df = 34. p = <0.058; CG, t = 2.610, df = 21. p = <0.016).

Table 5.23: Mean differences over time for QLQ C30 scores by treatment group

Paired Samples Test

Group	Pairs		Paired Differences					t	df	Sig. (2-tail)
					Std. Error	95% Confidence Interval of the Difference				
			M	SD	Mean	Lower	Upper			
Nurse	P1	FI	5.71	28.57	4.83	-4.10	15.53	1.183	34	.245
	P2	PF	-5.19	14.62	2.44	-10.13	-.24	-2.129	35	.040*
	P3	RF	-4.17	29.65	4.94	-14.20	5.86	-.843	35	.405
	P 4	FA	8.89	23.92	4.04	.67	17.11	2.198	34	.035*
	P 5	NV	-1.39	11.53	1.92	-5.29	2.51	-.723	35	.475
	P 6	PA	10.61	24.23	4.22	2.01	19.20	2.514	32	.017*
	P7	DY	6.48	23.66	3.94	-1.53	14.49	1.643	35	.109
	P 8	SL	2.78	31.24	5.21	-7.79	13.35	.533	35	.597
	P 9	AP	-4.63	19.76	3.29	-11.32	2.06	-1.405	35	.169
	P10	CO	-.93	25.80	4.30	-9.66	7.80	-.215	35	.831
	P 11	DI	1.96	21.62	3.71	-5.58	9.50	.529	33	.600
	P12	EF	-.95	13.52	2.29	-5.60	3.69	-.417	34	.680
	P13	CF	-4.76	17.42	2.94	-10.75	1.22	-1.617	34	.115
	P 14	SF	-7.14	21.11	3.57	-14.40	.11	-2.001	34	.053*
Control	P1	FI	3.17	25.61	5.59	-8.48	14.83	.568	20	.576
	P 2	PF	-2.73	9.12	1.94	-6.77	1.32	-1.402	21	.175
	P 3	RF	-10.61	20.92	4.46	-19.88	-1.33	-2.378	21	.027*
	P 4	FA	11.62	16.26	3.47	4.41	18.82	3.352	21	.003*
	P 5	NV	.76	14.06	3.00	-5.48	6.99	.253	21	.803
	P 6	PA	-2.63	36.54	8.38	-20.24	14.98	-.314	18	.757
	P 7	DY	-3.03	9.81	2.09	-7.38	1.32	-1.449	21	.162
	P 8	SL	12.12	24.22	5.16	1.38	22.86	2.347	21	.029*
	P 9	AP	-1.52	7.11	1.52	-4.67	1.64	-1.000	21	.329
	P 10	CO	3.03	14.21	3.03	-3.27	9.33	1.000	21	.329
	P 11	DI	-3.03	14.21	3.03	-9.33	3.27	-1.000	21	.329
	P12	EF	-8.33	23.27	5.08	-18.93	2.26	-1.641	20	.116
	P13	CF	-6.82	26.05	5.55	-18.37	4.73	-1.227	21	.233
	P14	SF	-6.35	17.85	3.90	-14.48	1.78	-1.630	20	.119

To understand the extent of this improvement and whether there was a significant difference between the control and intervention groups, a regression approach was used. This adjusted for any chance imbalance between groups in any of the outcome variables at baseline. This approach tested the following hypothesis:

H_0: There is no significant mean difference in EORTC subscale values between the nurse and control group at the end of the trial;
v
H_1: There is a significant mean difference in EORTC subscale values between the nurse and control group at the end of the trial.

Table 5.24: Linear regression: Association between EORTC QLQ-C30 subscale scores and treatment groups

		Score at time 1		coefficient of group indicator	
EORTC	Scale	β	p value	β	p value
Global health status/QoL	Ql2	0.723	<0.001	8.366	0.048*
Functional scales					
Physical functioning	PF2	0.647	<0.001	-1.774	0.574
Role functioning	RF2	0.374	<0.001	5.307	0.364
Emotional functioning	EF	0.615	<0.001	6.494	0.109
Cognitive functioning	CF	0.503	<0.001	-0.470	0.922
Social functioning	SF	0.498	<0.001	0.721	0.88
Symptom scales					
Fatigue	FA	0.588	<0.001	-2.359	0.647
Nausea and vomiting	NV	0.094	0.500	-1.232	0.634
Pain	PA	0.280	0.035	7.033	0.302
Dyspnoea	DY	0.530	<0.001	8.087	0.073
Insomnia	SL	0.551	<0.001	-7.302	0.266
Appetite loss	AP	0.892	<0.001	-2.86	0.522
Constipation	CO	0.570	<0.001	-3.920	0.467
Diarrhoea	DI	0.563	0.006	1.368	0.797
Financial difficulties	FI	0.261	0.006	-0.509	0.921

*significant p=0.05
** Group indicator=0 if control group; 1 if nurse group

The results, as shown in Table 5.24 indicate that although the intervention improved EORTC subscale levels in the expected direction; this change is only statistically significant between the groups for global health status/QoL at the end of the trial. This result indicates that there was an improvement in global health status for those participants in the nurse group (p=0.048)..

The results in Table 5.25 also indicate two further significant differences in the nurse group.

Table 5.25: Mean differences over time for QLQ BR23 scores by treatment group

Paired Samples Test

			Paired Differences					t	df	Sig. 2-tailed
			M	SD	SE Mean	95% Confidence Interval of the Difference				
						Lower	Upper			
Nurse	P1	BRBI	-8.33	15.39	2.60	-13.62	-3.05	-3.203	34	.003*
	P2	BRSEF	-60.19	36.14	6.02	-72.41	-47.96	-9.992	35	.000*
	P3	BRSEE	-2.78	17.16	4.95	-13.68	8.13	-.561	11	.586
	P4	BRFU	-7.41	32.96	5.49	-18.56	3.74	-1.348	35	.186
	P5	BRST	.66	13.57	2.26	-3.93	5.25	.292	35	.772
	P6	BRBS	6.43	19.40	3.28	-.23	13.09	1.961	34	.058*
	P7	BRAS	7.62	25.10	4.24	-1.00	16.24	1.796	34	.081*
	P8	BRHL	26.67	64.12	28.67	-52.95	106.28	.930	4	.405
Control	P1	BRBI	-8.71	24.05	5.13	-19.38	1.95	-1.699	21	.104
	P2	BRSEF	-60.83	53.61	11.99	-85.92	-35.75	-5.075	19	.000*
	P3	BRSEE	13.33	18.26	8.16	-9.34	36.00	1.633	4	.178
	P4	BRFU	-7.58	20.40	4.35	-16.62	1.47	-1.742	21	.096
	P5	BRST	.87	8.77	1.87	-3.02	4.76	.463	21	.648
	P6	BRBS	7.20	12.93	2.76	1.46	12.93	2.610	21	.016*
	P7	BRAS	5.56	17.73	3.78	-2.31	13.42	1.469	21	.157
	P8	BRHL	-11.11	17.21	7.03	-29.18	6.95	-1.581	5	.175

*Denotes significance

Results indicate that there is a significant difference between the mean value body image (function) responses before (M = 79.29, SD = 23.60) and after (M= 87.62, SD=21.14) (paired t-test, t = -3.203, df = 34. p=0.003). Results also indicate that the difference between the mean value arm symptoms responses before (M = 22.85, SD = 19.42) and after (M= 15.24, SD=18.09) (paired t-test, t = 1.796, df = 34. p=0.081) failed to meet significance. These support the alternative hypothesis.

To understand the extent of this improvement and whether there was a significant different between the control and intervention groups, a regression approach was used. This adjusted for any chance imbalance between groups in any of the outcome variables at baseline. This approach tested the following hypothesis

H_0: There is no significant mean difference in quality of life values between the nurse and control group at the end of the trial;
v
H_1: There is a significant mean difference in quality of values between the nurse and control group at the end of the trial.

Table 5.26: Linear regression: Association between BR23 subscale scores and treatment groups

		Score at time 1		coefficient of group indicator group	
EORTC BR23	Scale	β	p value	β	p value
Functional scales					
Body image	BRBI	0.583	<0.001	-0.780	0.858
Sexual functioning	BRSEF	0.766	<0.001	0.485	0.934
Sexual enjoyment	BRSEF	1.266	<0.001	23.649	0.051
Future perspective	BRFU	0.487	<0.001	-1.126	0.864
Symptom scales					
Systemic therapy side effects	BRST	0.608	<0.001	-0.893	0.772
Breast symptoms	BRBS	0.322	0.011	-1.737	0.648
Arm symptoms	BRAS	0.258	0.017	0.843	0.851
Upset by hair loss	BRHL	0.630	0.092	32.432	0.265

* Group indicator=0 if control group; 1 if nurse group

The results, as shown in Table 5.26 indicate that although the intervention improved BR23 subscale levels in the expected direction; this change is not statistically significant between the groups at the end of the trial.

5.9.3 Summary of findings: Quality of life

- The overall quality of life of the women was good at baseline
- There is no significant differences in quality of life subscales between the groups at the onset or at the end of the trial
- Clinically meaningful changes in quality of life, using Osaba's approach, are seen for fatigue (NG and CG), pain (NG), constipation, diarrhoea and financial difficulties (CG).
- A number of quality-of-life scales significantly improved when measured at the beginning and end of the trial for both group: fatigue, sexual functioning and breast symptoms; the nurse group alone, physical functioning, pain, social functioning, body image and arm symptoms; control group alone, role functioning and insomnia.
- There is a statistically significant difference between the groups for global health status/QoL at the end of the trial.

5.10 Regression analysis

5.10.1 Introduction

Previous research has indicated that anxiety and depression may predict some level of unmet need among cancer patients (McDowell *et al*. 2010), fatigue and pain post treatment predicts anxiety and depression (Vahdaninia, Omidvan & Montazeria, 2009), and quality of life variables such as body appearance, emotional status and fatigue predict anxiety and depression (Karakoyun-Celik *et al*. 2010). In studies reporting all cancers together, demographic variables such as age, treatment received and time since diagnosis have also been suggested as predictors of unmet need (Sanson-Fisher *et al*. 2000). However although these findings informed a series of regression analyses, these analyses were to determine if an association between the independent and dependent variables was evident.

The following section reports of the procedure of which, if any, of the independent variables: age, treatment group, anxiety at time 1, severity of treatment, time since diagnosis, postcode, depression at time 1, needs at time 1 are associated with the dependent variable of needs, anxiety, depression, QLQ BR 23 (overall score and individual scales) and a number of EORTC QLQ C30 scales. The procedure sought to test the following hypothesis:

> *H_0 There is no relationship between unmet needs and treatment group, or anxiety at time 1, or severity of treatment, or time since diagnosis, or postcode, or depression at time 1, or quality of life variables;*
> *v*
> *H_1There is a relationship between unmet needs and treatment group, or anxiety at time 1, and severity of treatment, or time since diagnosis, or postcode, or depression at time 1 or quality of life variables.*

Prior to beginning the regression analysis, the SIMD (postcode) variable, was recoded into a dichotomised outcome: either, a participant fell within the most deprived ranked 30% of the Scottish population (score=1) or not (score=0). The rationale for doing this is based on previous research which has suggested breast cancer patients in the most deprived group have poorer survival outcomes than those less deprived. Understanding if there is an association between unmet

need, anxiety, depression, quality of life and being in the deprived ranked 30% is useful to clinicians in providing appropriate support to this group of women.

A backward stepwise approach was used for all regression models. It was chosen because unlike forward selection, it was less likely to exclude variables involved in suppressor effects and thus reduce the risk of making a type 11 error (missing a variable that is associated with the outcome).

5.10.2 Unmet needs outcomes

Standard multiple ordinary least squares regression was conducted to determine the accuracy of the independent variables (treatment group, age, SIMD, time since diagnosis, anxiety at time 1, severity of treatment, , depression at time 1 and needs at time 1 in their association with the dependent variable, needs at time 2. In the first model, the independent variables were entered simultaneously as a block and a summary of regression coefficients is presented in Table 5.27. The overall model (model 1) accounts for 39% of overall variance in needs scores, (adjusted $R^2 = 0.386$; $F_{5,48} = p < 0.001$). Once all the variables are excluded only depression at time 1 significantly contributed to the model ($p=0.005$) and anxiety at time 1 just failed to meet significance ($p=0.074$). This result indicates that having depression at time 1 is associated with having unmet needs among women attending breast cancer follow-up.

Table 5.27: Summary of regression coefficients for variables associated with BCNQ (n=55)

	Model 1:BCNQ				Model 2:BCNQ			
Independent variable	B	SE B	β	p value	B	SE B	β	p value
Constant	2.900	4.104		0.483	-0.852	1.043		0.418
Age	0.047	0.059	.087	0.433				
Severity	-0.64	0.288	.024	0.825				
SIMD	0.998	1.454	.077	0.496				
Anxiety t1	0.298	0.209	.25	0.16	0.328	0.180	.276	0.074
Depression t1	0.724	0.277	.464	0.009	0.728	0.246	.448	0.005
TSD	0.012	0.035	.039	0.732				
Treatment group	0.379	1.278	.033	0.768				
Need t1	0.033	0.087	.054	0.702				
R^2	0.474				0.461			

Notes: * p < 0.05, ** p< 0.01, *** p<0.001

5.10.3 Anxiety outcome

Following the outcome in Section 5.10.2, a further model was developed. It was conducted to assess the association of the independent variables: age, severity, SIMD, anxiety (time 1), depression (time1), time since diagnosis, treatment group, needs (time 1) and their association with anxiety at time 2 (dependent variable). In the first model, the independent variables were entered simultaneously as a block and a summary of regression co-efficient is presented in Table 5.28. The overall model (model 1) accounts for 61% of overall variance in anxiety scores, adjusted $R^2 = 0.614$; $F_{8,47} = p < 0.001$. When severity was removed, $R^2 = 0.396$; $F_{7,48,} =$ p 0.825, when treatment group was removed, $R^2 = 0.409$; $F_{6,49} =$ p 0.757, when time since diagnosis was removed, adjusted $R^2 = 0.420$; $F_{5,50,} =$ p 0.745, when needs t1 was removed, $R^2 = 0.429$; $F_{4,51,} =$ p 0.688), and when SIMD was removed, $R^2 = 0.435$; $F_{3,52} =$ p 0. 471) and when age was removed, $R^2 = 0.441$; $F_{2,53} =$ p 0.506. A summary of regression coefficients is presented in Table 5.28. Once all the variables are excluded only anxiety at time 1 significantly contributed to the model (p=<0.001). The results indicate that higher anxiety at time 1 is associated with higher anxiety at later date.

Table 5.28: Summary of regression coefficients for variables associated with anxiety (n=57)

	Model 1: Anxiety t2				Model 2: Anxiety t2			
Independent variable	**B**	**SE B**	**β**	**p value**	**B**	**SE B**	**β**	**p value**
Constant	-0.344	2.702		0.899	0.184	0.662		0.782
Age	0.020	0.039	.045	0.61				
Severity	-0.007	0.182	-.003	0.971				
SIMD	-0.360	0.934	-.035	0.701				
Anxiety t1	0.62	0.133	.652	<0.001*	0.764	0.077	.804	<0.001*
Depression t1	0.192	0.179	.147	0.289				
TSD	-0.005	0.023	-.021	0.819				
Treatment group	-0.288	0.815	-.029	0.744				
Need t1	0.047	0.054	.095	0.395				
R^2	0.671				0.647			

Notes: * p < 0.05, ** p< 0.01, *** p<0.001

5.10.4 Depression outcome

Based on results in Section 5.10.2 whereby depression was significant in the model, the depression score at time 2 became the dependent variable

This regression model was constructed to assess the association of the independent variables anxiety at time 1, treatment group, and severity of treatment, age, and time since diagnosis, SIMD and needs at time 1 and their association with having depression at time 2. All variables were entered into the model and removed one at a time based upon a level of significance for removal (p>0.10). When all variables were entered, the R^2 value account for a variance of 57% (adjusted $R^2 = 0.569$; $F_{8,48}$ = p <0.001). When SIMD was removed, R^2 = 0.578; $F_{7, 49,}$ = p 0.948, when severity was removed, $R^2 = 0.587$; $F_{6,50}$ = p 0.941, when needs t1 was removed, adjusted $R^2 = 0.593$; $F_{5,51}$, = p 0.688, when age was removed, $R^2 = 0.596$; $F_{4,52}$, = p 0.434), and when time since diagnosis was removed, $R^2 = 0.592$; $F_{3,53}$ = p 0. 212) and when treatment group was removed, $R^2 = 0.586$; $F_{2,54}$ = p 0.194. A summary of regression coefficients is presented in

Table 5.29. The results indicate that depression and anxiety at time 1 are associated with changes in depression scores at time 2. However, having depression is twice as likely as anxiety to affect depression scores.

Table 5.29: Summary of regression coefficients for variables associated with depression (n=57)

	Model 1 Depression t2				**Model 2 Depression t2**			
Independent variable	**B**	**SE B**	**β**	**p value**	**B**	**SE B**	**β**	**p value**
Constant	0.668	1.972		0.729	0.341	0.509		0.506
Age	0.021	0.028	.067	0.471				
Severity	0.010	0.137	.006	0.943				
Dichotomous SIMD	0.046	0.697	.006	0.948				
Anxiety t1	0.177	0.100	.258	0.084	0.202	0.089	.283	0.027
Depression t1	0.568	0.133	.607	<0.001	0.496	0.121	.530	<0.001
TSD	0.019	0.017	.105	0.269				
Treatment group	0.984	0.612	-.148	0.114				
Need t1	0.016	0.041	-.046	0.692				
R^2	0.631				0.601			

Notes: * p < 0.05, ** p< 0.01, *** p<0.001

5.10.5 Summary of findings: Unmet needs, anxiety and depression

- Being in the intervention group was not associated with unmet need, anxiety or depression.
- A higher level of depression at baseline was found to be associated with being anxious at baseline; the more depressed a woman was, the more anxiety they had at baseline.
- Age, time since diagnosis, SIMD, and severity of treatment are not associated with changes in unmet needs, anxiety or depression.

5.10.6 Quality of life outcomes

The secondary outcome was changes in quality of life. Based on data in the previous sections and studies suggesting fatigue and pain may be associated strongly with quality of life variables, a regression model was constructed using a backward stepwise approach to assess the association of the independent variables anxiety at time 1, depression at time 1, fatigue, and pain and treatment group, age, needs at time 1, time since diagnosis, SIMD, severity of treatment and BR23 total scores at time 2 (dependent variable). The regression analysis sought to test the following hypothesis:

> *H_0There is no relationship between quality of life variables and level of unmet needs, or treatment group, or anxiety at time 1, or severity of treatment, or time since diagnosis, or postcode, or depression at time 1;*
> *v*
> *H_1There is a relationship between level of unmet needs and treatment group, or anxiety at time 1, and severity of treatment, or time since diagnosis, or postcode, or depression at time 1.*

Regression results indicated that the overall model was found to be associated with changes in BR23 total scores. When all variables were entered, the R^2 value accounted for a variance of 41%, adjusted $R^2 = 0.424$; $F_{9,47}$ = p<0.001, when anxiety at time 1 was removed, $R^2 = 0.436$; $F_{8,48}$ = p 0.997, when SIMD was removed, $R^2 = 0.447$; $F_{7,49}$ = p 0.849, when time since diagnosis was removed, $R^2 = 0.458$; $F_{6,50} = 0.834$, when needs at time 1 was removed, $R^2 = 0.465$; $F_{5,51}$ = p 0.603, when severity was removed, R^2= 0.470; $F_{4,52}$ = p 0.450, when treatment group was removed R^2= 0.466; $F_{3,53}$ = p0.253. A summary of regression coefficients is presented in Table 5.30 and indicates that only depression (p=<0.001) and age (p=0.012) significantly contributed to the model. The result suggests that having depression at time 1 and being younger is associated with changes in overall BR23 scores.

Table 5.30: Summary of regression coefficients for variables associated with BR23 (n=57)

	Model 1: BR23				Model 2: BR23			
Independent variable	B	SE B	β	p value	B	SE B	β	p value
Constant	2.903	1.668		0.88	2.768	1.274		0.034
SIMD	-0.111	0.594	-.02	0.853				
Severity	0.085	0.116	.737	0.465				
Treatment group	-0.634	0.519	-.131	0.227				
Age	-0.041	0.024	-.182	0.092	-0.046	0.022	.206	0.040
TSD	0.003	0.015	.022	0.849				
Anxiety t1	0.000	0.086	-.001	0.997				
depression t1	0.357	0.112	.524	0.002	0.329	0.073	.483	<0.001
needs t1	-0.017	0.037	-.067	0.646				
BR23 t1	0.257	0.111	.307	0.026	0.234	0.090	.280	0.012
R^2	0.517				0.495			

Notes: * p < 0.05, ** p< 0.01, *** p<0.001

Further multiple separate regression models were constructed to assess the association of the independent variables anxiety at time 1, treatment group, severity of treatment, age, time since diagnosis, SIMD and needs at time 1, and their association with changes in the scores on the QLQ BR23 (total scores) and individual subscales (body image, sexual functioning, sexual enjoyment, future perspectives, systemic therapy side effects, breast symptoms, arm symptoms and hair loss), and some of the EORTC QLQ C30 subscales (physical, role, emotional, cognitive and social functioning; fatigue and pain). A summary of regression coefficients that were significant is presented in Table 5.31.

Table 5.31: Summary of regression coefficients for variables associated with emotional functioning, fatigue and sexual functioning (n=57)

	Model 1 Emotional Functioning (n=55)				Model 2 Fatigue (n=56)				Model 3 Sexual Functioning (n=55)			
Predictor	**B**	**SE B**	**β**	**p value**	**B**	**SE B**	**β**	**p value**	**B**	**SE B**	**β**	***p* value**
Constant	52.768	11.471		<0.001	-25.093	12.252		0.039	89.119	6.048		<0.001
SIMD												
Age					0.475	0.210	.215	0.028				
Needs t1									-0.889	0.363	-.312	0.018
Treatment group	8.996	3.626	.213	0.016								
Depression t1	-2.519	0.830	-.419	0.004	2.983	0.819	.442	0.001				
Anxiety t1									1.551	0.715	.275	0.035
TSD												
Severity												
EF t1	0.309	0.108	.394	0.006								
Fatigue t1					0.346	0.114	.371	0.004				
BRSEF t1									-0.767	0.131	-.622	<0.001
R^2	0.628				0.543				0.451			

Notes: * p < 0.05, ** p< 0.01, *** p<0.001

Model 1: Emotional Functioning

The first model examined the association of the independent variables EF at time 1, anxiety at time 1, treatment group, severity of treatment, age, time since diagnosis, SIMD, needs at time 1 and EF at time 2. Regression results, indicate that the overall model is able to explain emotional functioning scores, $R^2 = 0.628$; $F_{3,51} = 28.653$, $p < 0.001$. This model accounts for 56% of variance in emotional functioning scores. A summary of regression coefficients is presented in Table 5.31 and indicates that the most important independent variable contributing to the model is depression (p=0.004), followed by emotional functioning scores at baseline (p=0.006) and then treatment group (p=0.016). The results indicate all three are associated with changes in emotional functioning scores. In addition being in the nurse group is positively associated with changes in emotional functioning scores.

Model 2: Fatigue

The second model examined the association of the independent variables anxiety at time 1, treatment group, severity of treatment, age, and time since diagnosis, SIMD, fatigue at time 1, needs at time 1 and fatigue scores at time 2. Regression results indicate that the overall model is able to explain changes in fatigue scores, $R^2 = 0.543$ $F_{3,52} = 20.572$, $p < 0.001$. This model accounts for 54% of the variance in fatigue scores. A summary of regression coefficients is presented in table 5.31 and indicates two of the seven variables significantly contributed to the model (depression p=0.001, age p= <0.001, time since diagnosis p=0.027). Depression, age and time since diagnosis are associated with change in fatigue scores.

Model 3: Sexual Functioning

The third model examined the association of the independent variables anxiety at time 1, treatment group, severity of treatment, age, time since diagnosis; postcode, sexual functioning at time 1 and needs at time 1 and sexual functioning at time 2. Regression results indicate that the overall model predicts sexual functioning, $R^2 = 0.451$. $F_{3,51} = 13.967$; p= <0.001. This model accounts for 45% of the variance in sexual functioning. A summary of regression coefficients is presented in Table 5.31 and indicates that the most important independent

variable contributing to the model is sexual functioning score at baseline (p=<0.001), needs at baseline (p=0.018 and anxiety (p=0.035). The results indicate that having a higher score of sexual functioning was associated with higher baseline scores.

5.10.7 Summary of findings: Quality of life

- A depression score at baseline is associated with changes in QLQ BR23 scores
- The age of a woman, depression scores at baseline and the time since diagnosis are associated with changes in fatigue scores.
- Emotional functioning scores at baseline, depression and treatment group are associated with changes in emotional functioning.
- Sexual functioning scores at baseline, needs and anxiety are associated with changes in sexual functioning.
- The intervention was associated with changes in emotional functioning.

5.11 Summary of quantitative findings

This chapter has presented the findings of both descriptive and inferential statistics to investigate the primary outcome, changes in unmet need between baseline and the end of the trial, the secondary outcome, changes in quality of life baseline and the end of the trial, and the relationship of a number of variables in predicting changes in unmet need, anxiety, depression and quality of life domains.

The demographic and clinical characteristics of the breast cancer participants in the present study were similar at baseline, with no significant differences between the two groups. The diversity of participants' age, breast cancer characteristics and treatment are reflective of the spectrum of breast cancers seen and managed within breast cancer services, and illustrated in Chapter 2. Although the groups did not differ, there were higher deprivation scores among the overall sample compared to the Scottish average. This can partly be explained by the geographical area the study was in, but this will be discussed further in the following chapter.

The participants reported unmet needs, anxiety and depression which were high in both groups at baseline. Although there are no significant differences between the groups for changes in any of the measurements over time, there is a statistically significant decrease in the mean needs, anxiety and depression scores *within* both groups, between baseline and the end of the trial. These significant decreases *within* groups could be seen as a positive outcome, although caution with this interpretation is required.

The quality of life of participants is high at baseline and therefore any changes that occurred at the end of the trial are small. There are significant differences when measured at the beginning and end of the trial for both groups in relation to: fatigue, sexual functioning and breast symptoms; the nurse group alone for, physical functioning, pain, social functioning, body image and arm symptoms; and the control group alone for role functioning and insomnia. These differed to the clinically meaningful changes in quality of life, using Osaba's approach: fatigue

(NG and CG), pain (NG), constipation, diarrhoea and financial difficulties (CG). The overall quality of life score showed a statistically significant difference at the end of the trial but no other scores on the EORTC QLQ BR23 and QLQ BR23 showed a significant different between groups at the end of the trial.

Finally, a series of regression analyses sought to determine which, if any, of the independent variables anxiety at time 1, treatment group, severity of treatment, age, time since diagnosis, postcode and needs at time 1 could explain unmet need, anxiety or depression, QLQ BR23 (subscales: body image, sexual functioning, sexual enjoyment, future perspectives, systemic therapy side effects, breast symptoms, arm symptoms and hair loss), and some of the EORTC QLQ C30 subscales (physical, role, emotional, cognitive and social functioning, fatigue and pain).

Regression results indicate that depression and anxiety are significantly associated with unmet needs; having depression at baseline was strongly associated with anxiety, depression at baseline was significantly associated with poorer levels on the QLQ BR23, younger age. Time since diagnosis was significantly associated with higher levels of fatigue, unmet needs at baseline are associated with poorer emotional functioning, and lower socioeconomic status and younger age are significantly associated with poorer sexual functioning.

In summary, these findings suggest that the intervention was as effective as standard follow-up care in reducing cancer needs, anxiety and depression, and improving quality of life between baseline and post intervention. Regression analysis revealed that having anxiety and depression are independently associated with unmet needs, and a number of quality of life independent variables.

5.12 Qualitative data

The primary outcome of this study was a change in needs from baseline to time 2. The key components of the intervention required the SBCN to interpret the needs; anxiety and depression scores self-reported by the women and use these and the wishes of the women to guide the consultation. The initial guide

developed following the pilot work about responding to the BCNQ was used as part of the training plus the protocol for scoring and managing the HADS. However, the flexibility of the intervention was a key factor, placing a greater emphasis on the woman's perspective of their well-being rather than the professional perspective. It also required the SBCN to use her clinical judgement and the patient to follow through recommendations.

The SBCN kept a record of the needs she discussed with the participants in the intervention group. Although the provision of this data is perhaps not usual, in this thesis it is entirely appropriate as this conversation provided the context in which actions were agreed and the complex intervention delivered. Many of these needs were raised by multiple participants and from the nurse's records, some areas associated with mood, self-esteem, body image and menopausal symptoms continued to require support at time 2. The Wordle™ below illustrates the issues discussed between the patients and the SCBN at the clinic. The size of the Wordle denotes the frequency that the word was used with the SBCN's notes.

Figure 5.6: Key areas addressed through the person-centred conversation

It was unclear from the nurses notes if there was a relationship between the symptoms discussed and her actions in response to the needs identified. Corter *et al*. (2013) have suggested that an association exists between illness perceptions, side effects and fear of recurrence. It may explain why symptoms appeared so prominently in the Wordle when fear of recurrence was expressed as a high need among the participants.

In conclusion, the results of this present study have shown that using patient reported needs and psychological information by the SBCN in the follow-up clinic to inform an intervention proved to be no better, rather equally effective as standard follow-up care. The next chapter will explain and interpret these findings further, how they inform clinical practice in this area, and situate and compare these results with other work in this field.

Chapter 6: Discussion and interpretation of results

6.1 Introduction

The present study was designed to determine the effectiveness of a different way of delivering follow up care by the SBCN, which sought to target support to women in response to their self-reported needs and psychosocial information compared to follow-up care delivered by medical staff in the NHS. This chapter will begin with a brief summary of the research and the main findings. The design and sample characteristics will then be reviewed and the hypotheses considered in more detail. The ethical and clinical implications of the study will be discussed and finally, the main strengths and weaknesses of the present study will be discussed and recommendations for future work.

6.2 Summary of contextual background to the study

Results from an extensive review of the literature demonstrated that there had been few RCTs which had used PROMs such as needs assessment and psychological information to guide care. Follow-up is an integral part of the pathway of care for women diagnosed with breast cancer. While the literature indicated that unmet needs post-treatment were expressed in relation to fears of recurrence, fertility or menopausal issues, treatment side effects, the impact of hereditary factors, sexuality and relationships, lymphoedema and the impact on self, the assessment of these, and interventions to address them within a follow-up setting is underpinned by limited evidence. Evidence from studies in the field of breast cancer illustrated that measuring unmet needs in a consistent and systematic manner in a clinic setting is an infrequent event, with few studies having used this approach.

Whilst no studies to date have examined the effectiveness of this approach specifically in a breast cancer follow-up clinic in the hospital, some have reported findings among other breast cancer populations that indicate the feasibility of this approach (Boyes *et al*. 2006; Aranda *et al.* 2006). Indeed, patients appeared at

ease completing these questionnaires and the results provided the HCP an opportunity to use the information to guide care. If, by using PROMs by SBCNs in the follow-up setting reduces cancer needs and improves quality of life, it may be considered an effective intervention in the management of these women in this setting. In order to investigate the effectiveness of introducing this new model, a RCT was chosen as the most appropriate method.

6.3 Summary of the results from the current study

The study results showed that the effectiveness of using patient-reported data to inform the SBCN's provision of supportive care at follow-up to reduce needs, anxiety and depression was not proved to be better than standard care, nor was there sufficient evidence to suggest it was any worse. Global health status/QoL showed significant differences between groups. However, all the other outcome measurements, showed no significant differences between the groups in the present study. Although there were no significant differences between the groups, there were statistically significant changes over time *within* groups for needs, anxiety, depression and quality of life, and some clinically meaningful changes observed. Regression analysis revealed that having higher levels of depression at baseline was found to be associated with anxiety at baseline; the more depressed a woman was, the more anxiety she had at baseline.

In addition, depression at baseline is associated with poorer scores on the QLQ BR23: the age of a woman and the time since diagnosis is associated with changes in levels of fatigue; unmet needs at baseline are associated with changes in sexual functioning and the intervention was associated with changes in emotional functioning.

The present study confirms previous findings that women breast cancer treatment experience unmet needs months and indeed years following their diagnosis. It contributes additional evidence about how unmet needs can be assessed within a follow-up clinic and the information used to guide the consultation. Although the current study is based on a small sample of participants, the findings suggest that PROMs can be integrated successfully into a follow-up clinic and the evidence emerging of associations between needs, anxiety and depression will serve as the basis for future studies in this area. The study will also inform the National

Survivorship Initiative (2014) and go some way to addressing the gaps in breast cancer research identified by Eccles *et al*. (2013).

6.4 Hypothesis

Returning to the hypothesis posed at the beginning of this study:

> H_0 Women with breast cancer attending follow-up receiving the intervention show no significant difference unmet needs and quality of life than those receiving standard follow-up care
>
> H_1 Women with breast cancer attending follow-up receiving the intervention show significant difference in unmet needs and improvement in quality of life than those receiving standard follow-up care.

It is now possible to state that the intervention improved global health status but it was as effective, and certainly no worse than standard follow-up care, in reducing unmet needs, anxiety and depression, and improving quality of life. The results do not support the null hypothesis. Anthony (1999) suggests that in all areas of scientific enquiry equivalent results are as important as positive ones. The interpretation therefore of the results will consider possible explanations for the results presented in Chapter 5 incorporating its main strengths and limitations.

6.5 Discussion of key results

One of the first aspects in the design of this study concerned the measurement of unmet need and psychological status in this particular population. As discussed in Section 4.6.1, this provided the basis from which the person-centred conversation occurred and the intervention delivered.

The BCNQ was used as it specifically asked questions of relevance to women with breast cancer (Chapters 2 and 3) and initial factor analysis indicated good validity and reliability (Thewes, 2000). Due to the limited use of the BCNQ in previous research, exploratory factor analysis was undertaken again in the preliminary analysis stage. The results indicated very good reliability across all scales except sexuality, which was good. Overall the data suggested the BCNQ

can be used as a reliable and valid measure to assess unmet needs in woman post-treatment attending follow-up clinics. In addition, the tool was able to distinguish between women with unmet needs and those with no need for support. This is crucial in the applicability to everyday practice as the detection of problems is the first step towards a positive outcome and the benefits of introducing them routinely.

The present study included participants across a wide range of ages (21-76), disease and treatment characteristics (Tables 5.3 and 5.4). This reflects the age range seen among breast cancer generally. The non- completers were not statistically different to those who completed, and therefore the researcher concluded that age, deprivation level or time since diagnosis did not appear to adversely affect attrition although may have affected recruitment. Overall deprivation scores were higher than the Scottish average in breast cancer, but only slightly above the UK average. Women with lower socio-economic factors are known to be under-represented in cancer trials (Dellson *et al*. 2011), however there is no evidence this affected attrition or indeed recruitment in this trial.

Initial analyses of the mean needs scores of participants in both groups included all scores (1 - 5), and all subscales. Differences between groups in mean scores of needs were not significant at the start or end of the trial, and scores were normally distributed across each subscale and between each group. The mean scores ranged from 1.7 - 2.35 (range 1-5) and suggested that needs were not particularly high in both groups, which did not concur with previous studies that had measured unmet need among this population (Beaver *et al*. 2006; de Bock *et al*. 2004; Raupach & Hiller, 2002; Girgis *et al*. 2000). However, when overall scores were analysed further; either having a need or having no need, the data revealed a different picture. The results indicated that the proportion of women expressing a need for support was 77.8% (n=34) (NG) and 78.9 (n=29) (CG) at baseline and at the end of the trial 58.3% (n=21) (NG) and 66.7% (n=15) (CG).

Although participants were at different time points since diagnosis, the results indicate that many women still require support across many areas as they attend follow-up care. The fall in the proportion of needs reported in both groups

represented a significant improvement and suggested the BCNQ was sufficiently sensitive to capture changes over time. However, in the absence of published clinical guidelines regarding the clinical significance of the improvements seen, or indeed the magnitude of change required to be clinically meaningful, one can only speculate on the causes of these improvements based on statistical significance.

The same pattern of improvements in both groups was observed for anxiety and depression using the HADS. However, again there was no statistical difference between the groups at the end of the trial. A number of studies have suggested that a high score on the HADS indicates high psychological need among breast cancer survivors (Carroll *et al*. 1993; Karakoyun-Celik *et al*. 2010; McDowell *et al*. 2010). The results showed that using this scale, psychological needs, and specifically anxiety levels was more prevalent than depression among the sample and clinically high at baseline. These are in line with other studies that have used the HADS among breast cancer survivors (Osborne *et al*. 2004; Boyes *et al*. 2006), although levels in the study by de Bock *et al*. (2004b) were lower. One possible explanation for the high levels of anxiety at baseline may be due to the timing of the questionnaires, close to the clinic appointment and a time, known to be when women feel anxious in anticipation of the outcomes of the clinic. (Montgomery *et al.* 2007).

The improvements over time in both groups were clinically significant and this pattern of improvement does not reflect other RCTs which have measured psychological morbidity in this population over time. Sheppard *et al*. (2009) reported no benefit following clinical review for women two years or more post diagnosis and Beaver *et al.* (2009) reported mean scores in their groups did not improve over time in either the hospital or telephone based follow-up groups. One explanation for the results is that the HADS is more sensitive to change in this population than the tools used in the other studies: general health questionnaire and the STAI. It may also suggest the skills of the practitioner may be critical in their ability to influence psychological morbidity.

Overall, the findings did not support the primary hypotheses that there would be a significant difference between the groups in unmet needs from baseline. There

are a number of possible explanations for this. First, the sample size was not sufficiently large to detect differences between the two groups and discussion related to this will be explored in more depth within methodological limitations. Second, it may be that the intervention was not sufficiently different or intense compared to standard care to achieve a greater change.

The results indicated that needs were similar and changed over time in both groups. Systematically assessing needs revealed the most important ones expressed in both groups using the BCNQ as being: fears about the cancer spreading or returning; lack of energy; pain in the breast and surrounding area; receiving information on causes; triggers and latest developments in breast cancer; sexuality and sexual relationships; appearance; hereditary risks and the requirement to receive age specific information. These findings extend knowledge gained from previous studies. Interestingly, the top 10 needs expressed in this study were the same apart from one question to those reported by Thewes (2000) during the development of the questionnaire, some 14 years earlier. The question, dealing with menopausal symptoms, was not ranked highly as an expressed need in this study in either group. This is perhaps a little surprising considering previous research in this area which suggests women are experiencing menopausal symptoms which impact on their quality of life (Fenlon, Corner & Haviland, 2009; Cruickshank & Hume, 2014).

One explanation may be that in recent years there is an increased awareness among HCPs of the high possibility of symptoms occurring post chemotherapy or while taking endocrine therapies, and this has led to better information and support. Another explanation is that there is more detailed guidance available about interventions to reduce symptoms, the overall management has improved. Alternatively, when faced with 40 different questions, women ranked other areas as more important than dealing with menopausal symptoms at this time, reflecting the broader context of supportive care described by Fitch, Porter & Page (2009). From a clinical perspective, these results are important as they help services understand about where future intervention strategies may be required. These results suggest an increased focus may be required on strategies to manage fear, anxiety, fatigue; pain and sexuality post-treatment.

Using the information of participant's specific needs, the SBCN tailored the intervention, providing a person-centred approach to care. However, the results imply that the intervention was as effective as, and certainly no worse than standard follow-up care. Although previous research about hospital-based follow-up has suggested that its primary focus is detecting recurrence rather than the psycho-social needs of women (Raupach & Hiller, 2002; de Bock *et al.* 2004a; Beaver *et al*. 2006), the results do not support this conclusion when using the current measures in this study. It is possible that the current standard care, in this study delivered by senior doctors, shares common goals in achieving a person-centred approach to care and already adequately addresses patients' needs and psychological distress. Person-centred care is care which is responsive to individual preferences, needs and values and assures that patient values guide all clinical decisions (NHS Education for Scotland, 2014). It is unlikely that the doctors undertaking standard care did not address some, if not all, of the needs expressed by women in their clinic, minimising the effect of the intervention. It is important to recognise that not all follow-up care in the hospital is delivered by senior doctors; indeed junior doctors frequently undertake this care. Therefore changes between the groups may have differed if the doctors were less experienced in the field.

However it is also possible that the completion of the questionnaires by women in the control group immediately prior to the clinic acted as a reminder for women to raise concerns with the doctor. One cannot also preclude that women spontaneously volunteered information about their unmet needs and psychological state because they felt comfortable seeing the senior doctor.

Although average anxiety and depression scores improved over time, the analysis revealed that a subgroup of patients maintained high levels of anxiety at the end of the trial. This finding corroborates with other studies that have measured anxiety and depression levels using the HADS among breast cancer survivors (Millar *et al*. 2005; Vahdaninia, Omidvari & Montazeria, 2010). On the BCNQ women expressed high needs associated with the fear of recurrence which may cause an element of anxiety Without previous knowledge of an

individual's psychological state it is difficult to draw any definitive conclusions. However, one explanation may be that the uncertainty and fear that is associated with a breast cancer diagnosis is expressed as an unmet need through the BCNQ or HADS, and it is possible that no intervention would be able to adequately address this fear. Reassurance may be effective at the time of the clinic but may not be sustained over time for some women. It is also possible that high levels of anxiety are an obstacle to women responding to the information and interventions offered, requiring perhaps a different approach to providing support or a further consultation to clarify the nature of this need. The results together support a role for the use of screening tools which measure psychological needs in follow-up services in conjunction with clinical judgement.

While data were recorded by the SBCN in relation to the interventions she initiated, any additional referrals in the control group were not recorded. Of particular interest would have been the number of times women attending the clinic in the control arm also met a SBCN from the team during the same visit to address psychosocial areas of care. The SBCN delivering the intervention referred to other professionals but not to other SBCNs in the team during the consultation. This additional support which may have been sought by the doctors in the control group may or may not have impacted on the overall result.

The secondary outcome, changes in quality of life, was measured using the EORTC QLQ C30 and QLQ BR23. The results show that for most women, their overall quality of life was high at the beginning of the trial and improved in a positive direction at the end of the trial. Comparisons with reference data to aid interpretation were not possible as they differed to the sample in this study.

Improvements were seen within both groups across symptom and functional subscales, although these differed between the groups, at the end of the trial changes between groups were not statistically significant. There are similar topics covered in both the BCNQ, EORTC CLC C30 and BR23 and include among them: pain, fatigue, body image, sexual functioning but the quality of life data was not used by the SBCN to guide care within the clinic. In this study the BCNQ encouraged women to express the needs they wished help with while the quality

of life measures captured how well they felt they were doing in relation to their overall well-being.

Some interesting findings emerged from the data that saw statistically different and clinically meaningful changes in both groups over time. In the nurse group more improvements were seen across symptom and functional domains than in the control group, but none were statistically significant between the groups at the end of the trial. In the nurse group improvements over time occurred in relation to physical functioning, social functioning, pain, body image and arm symptoms. In the control group, these improvements occurred in relation to role functioning and insomnia. In both groups' improvements over time occurred in relation to fatigue, sexual functioning and breast symptoms. The areas identified by the women concur with previous research studies reporting the short and long-term effects of treatment on a woman's quality of life (Bower *et al*. 2000; Holzner *et al*. 2001; Ganz *et al*. 2004; Lee *et al*. 2008) and those reported as requiring help when using the BCNQ.

Taken together, these results suggest that the SBCN using PROMs has not been proven to be any better than standard care in improving a woman's overall quality of life as she recovers from a diagnosis and treatment. The improvements seen in the nurse group and not in the control group may be explained by the very nature of the SBCN's role, which provides information and support daily to address pain, body image, and breast symptoms, social and physical functioning aspects of a woman's recovery. Some symptoms may also have improved over time due to the healing process, but for some of these women it had taken 3 - 5 years since diagnosis to achieve improvements.

Much of the research in breast cancer focuses on prognostic characteristics of breast cancer and their ability to predict survival outcomes (Goldhirsh *et al*. 2013; Dinh, Sotiriou & Piccart, 2007). The findings from this study undertook a series of regression analysis and provide a new understanding about the association between levels of anxiety, depression, unmet needs, quality of life, demographic and treatment characteristics. The results of this study could not corroborate the findings by Sanson-Fisher *et al*. (2000) that age, time since diagnosis or the

combinations of treatment are predictors of unmet needs. However, the present study did suggest that age is associated with higher levels of fatigue, poorer sexual functioning and poorer emotional functioning.

Of particular importance is the association of depression in explaining changes to the BR23 overall scores and unmet needs. Although the number of participants who were depressed at baseline was small, identification of these women earlier may allow more timely interventions to be offered. The present study suggests that both depression and indeed anxiety, when identified in this post-treatment population can be improved by HCPs.

Early studies supporting the wide introduction of SBCNs focused on their role supporting women post-mastectomy (Maguire *et al.* 1983), the first line treatment at that time, rather than on survivorship, a term used today. With more and more SBCN and ANP involved in the delivery of follow-up services in the hospital setting, there is now evidence that their actions in conjunction with assessment tools can reduce women's needs and intervene early to manage anxiety and depression. It is not simply that a nurse can provide follow-up but rather how the SBCN interprets the information provided to her by the patient which will be effective.

The overarching purpose of any research study is that there is no harm to the participant (Watson, 2012). Although the present study did not show any significant differences between the nurse and control group in terms of changes in need, the study adhered to the ethical recommendations set out by the NHS Research Ethics Committee and showed no evidence of causing any harm.

The enquiry of participants about their psychological needs raised ethical issues about the management of the control group. In the planning stage it was accepted that screening the participants for anxiety and depression was outside the normal or usual practice for the participant; a recognition that this may impact on the individual guided the decision-making to score the control group and initiate referral to a SBCN not involved in the study based on their scores on the HADS (<11). There were ten participants referred for further assessment. This may have

contributed to the statistically significant changes over time *within* both groups for anxiety and depression at the end of the trial.

6.6 Informing policy about needs of women with breast cancer

The momentum to improve and change the way cancer patients receive care once their primary treatment is completed has seen the National Cancer Survivorship Initiative (England), and the Transforming Care after Treatment programme (Scottish Government, 2013) gain prominence. Their common goal is to consider how best aftercare could be tailored to meet individual cancer patient's needs by providing an assessment of the full range of cancer survivors needs, encouraging professionals to work in partnership, and develop post treatment strategies to encourage patients to self-manage their recovery. The language is inclusive and ambitious with the suggestion that assessment of need is already an integral part of cancer care. However, the literature reviewed at the outset and end of this study clearly indicated that measuring needs in a systematic manner which then informs evidence-based interventions is very limited, certainly in the field of breast cancer. There is no 'gold standard' needs assessment tool identified to date. This study goes some way to extending the knowledge in this area by indicating how current systems can be adapted to deliver on these goals.

Using tools to screen for unmet needs, psychological information and quality of life is insufficient to facilitate any change in patient outcomes alone. The clinical skills of the practitioner are vital to interpret findings. The results of this study provide evidence that the BCNQ and HADS can be used successfully within a planned follow-up clinic setting. However when faced with these questionnaires, the SBCN took time adapting to their use in the beginning. This was especially so among those women who expressed a high number of unmet needs. The SBCN adopted a triage approach: dealing with those needs requiring urgent management and then putting a plan in place with the woman to address other less urgent areas. However some needs such as making sure the woman always saw the same HCP were not easy to achieve within the current system. Therefore the suggestion that HCPs can meet all needs must be tempered with caution. The

SBCN was very experienced, as were the doctors in the control group so it is unclear if the same results would be seen in other groups. However, despite the experience of the SBCN, some form of training in how to interpret the information provided by patients using needs assessment tools or HADS was required. In essence, the introduction of an assessment instrument needs guidance for HCPs, otherwise the information is collected and the HCPs don't know what to do with it.

This study did not stratify patients to their individual risk of recurrence at baseline; rather all women were invited to participate. The BCNQ and the HADS successfully identified those with unmet needs and those without. This is an important result, especially if services wish to use resources efficiently and effectively. Breast cancer affects many thousands of women and identifying those women with the highest needs, and therefore requiring help, from those who may have no needs and are recovering well, is very important. It links to the quality ambitions that aim to be person-centred, safe, effective, efficient, equitable and timely (Scottish Government, 2010; NHS Quality Improvement, England, 2014), recognising that resources are finite and HCPs must consider how best to use them in practice. In addition, not all women have the confidence to raise concerns verbally within clinics or directly to HCPs. The questionnaires gave the opportunity to women who may be less confident in articulating their needs to identify areas of importance to them. Following the study, the SBCN stated she found issues about sexuality, relationships, body image and other sensitive issues difficult to raise spontaneously in a clinic environment. When identified by the woman on the questionnaire, the subsequent conversation was easier.

The potential use of the tool for those who might benefit from specific interventions to address these areas, and others, offers real potential. If those who require no need for support are discharged from follow-up with clear mechanisms to re-establish relationships, there is scope to focus on those requiring help. This would change the landscape of follow-up care from a service which offers all women the same follow-up care, to one that is needs driven. This may require additional training of the SBCN's to address more and perhaps different complex needs than they currently address. Considering fear of recurrence is identified as the most important expressed need in this study, a

stronger focus on teaching women to recognise signs and symptoms of recurrence, and adjusting to changes after cancer would appear timely.

Stratifying follow-up care according to a woman's risk of recurrence, individual needs or both is currently being debated (Watson *et al*. 2012). The NCSI (2014) is soon to report on models of aftercare which have evaluated risk stratifying cancer patients according to their needs, disease and co-morbidities. The results in this study indicated that disease and treatment characteristics were not associated with changes in unmet needs or improvements in quality of life. Rather, specific treatment side effects and emotions appear to influence this change. Being younger is associated with higher levels of fatigue, poorer sexual functioning and body image; higher levels of depression at baseline was found to be associated with being more anxious at baseline; expressing a need at baseline is associated with changes in emotional functioning over time and lower deprivation scores and a younger age are associated with changes in sexual functioning over time. If treatments are delivered to minimise the risk of recurrence but the uncertainty of predicting recurrence remains, this outcome may not be a good indicator of whether follow-up care effectively meets the psychosocial needs of a woman and therefore may not be a good determinant of who is offered support and who is not. Conversely, the results indicate that the nurse group that used PROMs to inform care did not do better than standard care; assessment of needs alone may not be a good indicator in isolation of other information.

6.7 Methodological limitations

It is important to review the internal and external validity of the study to understand the limitations associated with the interpretation of the conclusions made. The potential threats to internal validity can compromise the confidence that a relationship exists. Threats to statistical conclusion validity include low statistical power resulting from inadequate sample size and this will be addressed first. Other aspects that will be discussed are: blinding, method of analysis and attrition.

6.7.1 Sample size

Sample size calculations are beneficial as they have a high chance of detecting a significant effect if it occurs and provides confidence that if the effect is not detected it is because it does not exist (Field, 2013). In the development of this study, there had been no previous research to use as a reference point. This was particularly relevant when predicting the effect size, the power and sample size required to detect the effect. Initial calculations at the outset of this study were calculated based on the EORTC QLQ C30. In the absence of previous data, an effect size of 0.5 was used and informed by Cheung *et al.* (2005) and Cohen (1992). Therefore a power of 80% to detect a significance level (p=0.05) between the groups required a sample size of 64 in each arm. Allowing for attrition of 15%, 74 patients in each arm was needed. After the study started the primary outcome changed to changes in unmet needs. However, following advice from the statistician the original power calculation was not altered as recruitment had started. Therefore the calculation based on the EORTC QLQ C30 data, this raised the possibility of the study being under or over powered to detect the primary outcome. The results possibly reflect some of the uncertainty of estimating effect size in the absence of previous studies. In addition, an estimation of a moderate effect following the intervention, particularly when this affect has been achieved in few nursing studies, was possibly optimistic when this was a new area of enquiry.

In this study the results were unable to reject the null hypothesis. However not being able to reject it does not mean that it is true; rather, the low numbers made the study underpowered and there was not enough precision to allow the null hypothesis to be rejected.

6.7.2 Blinding

Randomisation is one of the strengths of the RCT and avoids bias in allocating interventions to the trial. It was well organised in this study. Subjects were allocated on a consecutive basis to the next group within the block. Statistical tests were used to compare the baseline variables of the two groups and no differences were found. Blinding the participants however to the group they were

allocated was impossible in this study. It was necessary to inform the participant who they would see at the clinic; the doctor or the nurse. However, the allocation sequence was concealed but was compromised by lack of blinding.

6.7.3 Intention to treat analysis

"Intention to treat" analysis was the intended strategy for this study at the outset. The strength of this approach is that all randomised participants are included in the analysis and retained in the group to which they were allocated (Gupta, 2011). One of the challenges using "intention to treat" is the need for complete data and missing data is a known problem in many trials, occurring in this study. The CONSORT Group (2010) recognise that strict intention to treat analysis is difficult to achieve due to the practical clinical scenario whereby non-compliance and protocol violations will occur. They therefore no longer include this in their checklist and instead favour a clear description of who is included in the analysis.

It was decided, due to missing outcomes data from some participants, to use a complete case analysis approach rather than imputation of missing data. While, the disadvantage may be that the sample size reduced further, there was no clear justification for imputation. It was important to understand the type of missing data and how this could relate to bias in the subsequent analysis. Analysis of completers and non-completers across demographic variables indicated that they did not differ and it is likely the data was missing randomly.

6.7.4 Attrition

"Attrition" refers to the dropout of participants in a study and is not uncommon in longitudinal studies and a source of potential bias. Attrition was 20% overall in this study, 22% in control group and 16% in the nurse group. Although it was considerably better than the studies by Boyes *et al.* (2006), Aranda *et al.* (2006) and Velikova *et al.* (2004) who had used PROMs to guide care and reported attrition levels of 40%, 50% and 46% respectively, it was recognised that this was not ideal. Studies that are longitudinal are particularly vulnerable to attrition and the timing of the questionnaires, one year apart in this study, probably contributed to this.

An additional problem in this study was that dropout rates differed between treatment arms, known as “differential dropout”. While this can bias results, a recent paper by Bell *et al*. suggests that “*unequal bias rates do not mean the results are biased and conversely equal dropout rates do not imply that results will not be biased”* (2013, p.1). The critical factor is the missingness of the data and the statistical analyses, with both areas considered and discussed above.

6.8 Comparisons with other research

As discussed in Chapter 1, this study was conceived through the personal experiences of the researcher and a systematic review in Chapter 3. There were no RCTs which sought to measure the effectiveness of using PROMSs to guide care by the SBCN on needs over time of women attending breast cancer follow-up in a hospital. Surprisingly, the paucity of evidence continues up to the writing of this thesis. However three studies, one in the UK and two out with the UK have contributed to the body of evidence about a woman’s unmet needs, anxiety and depression levels post-treatment since this study began and will be discussed.

Study 1: Beaver *et al.* (2009) “Comparing hospital and telephone follow-up after treatment for breast cancer: randomised equivalence trial”.

This study was not solely undertaken in the hospital environment like the present study but was an extended full RCT of the study reviewed in Chapter 3. The SBCN delivered a structured intervention over the telephone that aimed to meet the need for information and support of women receiving follow-up care compared to hospital-based standard care. This was an equivalent trial and found that telephone follow-up by SBCNs using a needs assessment questionnaire were as effective as hospital-based follow-up in its ability to meet the information needs of women. The results illustrate the difficulties comparing studies in this area: standard hospital follow-up in the study was offered more frequently than in the present study, participants with a high risk of recurrence were excluded and women no longer received a clinical examination in the telephone follow-up group. Despite this, the results are consistent with the present study, by

incorporating PROMs such as needs assessment questionnaires into follow-up consultations, women with breast cancer are afforded an opportunity to raise issues of importance to them rather than those of importance to the HCP.

Study 2: Vahdaninia, Omidvari & Montazeria (2010), "What do predict anxiety and depression in breast cancer patients? A follow - up study.
This study, undertaken in Iran, measured the possible predictors of having anxiety and depression among breast cancer patients post treatment (n=167) (3 and 18 months). The measures used were the HADS and EORTC C30, similar to the present study. The results indicated that at 18 months the percentage of participants with anxiety was 38.4% and depression was 22.2%. Regression analysis indicated that a significant risk factor for developing depression was fatigue and pain; and for anxiety, it was pain. Caution is needed in the interpretation of these results in relation to the present study for a number of reasons. First, 37% of the sample had metastatic disease and second, the context of the healthcare setting in Iran is very different from the Scottish NHS and it is unclear what impact that may have on individual's anxiety and depression levels post-treatment.

Study 3: Akechi *et al*. (2011) "Patient's perceived need and psychological distress and/or quality of life in ambulatory breast cancer patients in Japan"

This study investigated the association between patients' perceived needs and psychological distress, and or quality of life among Japanese breast cancer patients with a high level of unmet needs. The women were ambulatory and the majority had primary breast cancer (338 out of 408), which is consistent with the women in the present study. However it was unclear from the data presented by Akechi *et al* (2011) whether woman had completed primary treatments or whether women they were still receiving them. Women were invited to complete three questionnaires at one time point: the SCNS-SF34, the HADS, and the EORTC QLQ-C30. The SCNS-SF34 was the short version of the SCNS used by Girgis *et al*. (2000). The 10 most frequent unmet needs were reported, using a cut off of three or above to classify as unmet. The results are consistent with previous studies that reported the fear of cancer spreading as the most important unmet

need (63%) (Raupach & Hillier, 2002; de Bock *et al.* 2004b; Girgis *et al.* 2000; Thewes *et al.* 2004; McCaughan & McSorley, 2007; Beaver *et al.* 2006). In fact similarities were seen in the top 10 unmet needs between this study and the previous ones reviewed, reaffirming earlier findings that unmet needs are multifactorial.

An association between the unmet needs (score on SCNS-SF34) and psychological distress (HADS) and quality of life is reported. When psychologically distressed patients (HADS > 11) were compared to those without distress (HADS < 10), the distressed patients reported a higher number of unmet needs (18.9 v. 8.3). Similarly, when seriously psychologically distressed patients (HADS >20) were compared to those without distress (HADS<19), these patients experienced a much higher number of unmet needs (26.7 v. 11) while the cross-sectional design prevents any causal relationship between needs, psychological distress and quality of life being made. The findings are consistent with the present study that women with breast cancer report unmet needs but also the association between anxiety, depression, unmet needs and quality of life.

These studies provide an important addition to the literature reviewed in Chapter 3 and re-affirm that women attending follow-up continue to have high anxiety, depression and unmet needs. While the study by Beaver *et al.* (2009) indicated that needs can be assessed and met through telephone consultations by SBCNs compared to hospital follow-up, they were unable to demonstrate changes over time in these groups. There remains a dearth of studies that have measured the effectiveness of interventions to address needs and psychosocial issues at follow-up in the hospital setting. The present study incorporated the previous literature to inform the development of the study and the effectiveness of the intervention to achieve change.

6.9 Main strengths of the study

The main strength of this study was the method used, a RCT. It is considered the most appropriate method to measure cause and effect which is not achieved in other designs. To determine the effectiveness of the intervention used in this study, the RCT was deemed the most appropriate approach. The randomisation

approach was well set up and strategies used to maximise recruitment and retention were undertaken. The data should therefore be taken as useful preliminary data to inform future studies. Considering this research is a new area of enquiry, it may have been beneficial to have considered undertaking this study as an equivalence trial. An equivalence trial would have hypothesised that the intervention demonstrated equivalence with standard care.

A key strength of this study was that pilot work was undertaken. This informed the choice of questionnaires used, the acceptability of completing questionnaires in the particular population studied, the intervention and training of the SBCN.

Another key strength of this study was the choice of measurement tools used. The BCNQ was specifically designed to be used with survivors (post-primary treatment) rather than women immediately post-diagnosis or during treatment. It was able to distinguish between those expressing unmet needs and those who have none which is very important if healthcare resources can be focused towards those people who require help. The results have therefore provided a better understanding.

Another key strength was that the study was undertaken in the real clinic environment where follow-up care is delivered. Most of the evidence about using PROMs such as needs assessment tools and HADS, including some of the information provided by the NCSI, have not used them within a busy clinic and within a short appointment time.

6.9.1 Generalisability of results

The target population of this study was women with breast cancer attending follow-up clinics in a hospital. Although the sample size was not reached, the participants were representative of the breast cancer population in the UK. As the timing and purpose of follow-up care are influenced by the cultural background and medical system in each country, the findings may not be applicable to other populations in other countries. In addition, the use of multiple tests risked a chance significant finding being reported.

6.10 Main limitations of the study

All studies have limitations and these will be discussed further including strategies that were undertaken to minimise them. Reflecting on the learning the researcher gained throughout the research training and experience of undertaking the study, possible ways the researcher would strengthen the study for the future if repeated.

6.10.1 The intervention

The use of the BCNQ provided structure to the consultation; however this could be viewed as limiting opportunities to provide person-centred care. By combining a structured questionnaire with a person-centred conversation there was an opportunity for the woman to raise issues which may not have been captured within the BCNQ alone. The SBCN and the woman could then explore the options for the intervention, desire of the woman for assistance and the best way to provide it.

A deeper understanding of this person-centred conversation between the SBCN and the woman within the clinic may have been useful. Although the SBCN documented areas discussed and referrals made, the documentation of this did not align well with the BCNQ responses. In particular the notes appeared to focus primarily around symptom management and body image (see Section 5.12) rather than fears of recurrence, one of the top five needs expressed. Corter *et al.* (2013) suggests that there is an association between illness perceptions, side effects and fear of recurrence. The SBCN had to assess and use the information she received within a short time frame and may have combined areas where she saw natural associations. A more in-depth understanding of the relationship between the words documented and the needs expressed on the BCNQ and HADS would have been useful to understand whether the intervention was appropriate or whether further refinement of it was necessary to achieve differences compared to standard care.

6.10.2 The pilot work

The pilot work was undertaken to determine the best possible needs assessment tool to use, review the recruitment process and inform the development of the intervention. Despite eight women agreeing to participate, only four did. It may have been useful to have approached the non-responders at this stage to ascertain the reasons for non-response. It may have further informed the recruitment process. In addition, reviewing the BCNQ in the clinic rather than over the phone would have provided a better indication of how long it would take the nurse to review and deliver the intervention. This would have informed the training.

6.10.3 Recruitment

The recruitment of women into the trial was influenced by practical, logistical and ethical reasons. The participants in this study were regarded as 'vulnerable' and ethical approval was conditional on accessing participants by post to invite into the study. While this approach negated gatekeeping by HCPs involved in the women's' care, a process which occurs according to Patterson *et al.* whenever "*access to someone or something is allowed or denied by a third party*."(2011, p.2), it may have affected the timing and numbers of participants responding. The recruitment process depended on participants responding to recruitment materials by phone, post or email rather than within the clinical setting.

The researcher maximised the clarity of the process by providing comprehensive information, a clear statement that potential participants can refuse to participate or withdraw at any time and an explicit offer to answer questions or provide further information. The timing of the intervention was critical to its success. Because the study sought to undertake the intervention within the follow-up clinic, it was important that women were recruited prior to this clinic. The clarity of the information provided to women was reviewed by patients, HCP and the Ethics Committee and deemed appropriate. However, during the development of this thesis it became apparent that explaining a complex intervention can in itself be

complex. It may have been more effective to present the intervention diagrammatically rather than just in words or recruit face to face within the clinic. By providing recruitment details in writing an assumption is made that all the participants are literate and can clearly understand the concept under study. This may have improved recruitment.

A number responded after their follow-up consultation. This could have been self-selection; however Dellson *et al*. (2010) has suggested that recruitment can be impeded by feelings of context evoking insecurities, a sense of fear associated with words used and individual preferences. Studies, such as the one by Montgomery *et al*. (2008), report that the period leading up to the follow-up appointment is full of emotion, anticipation and expectation and may offer some explanation. This may be an area which warrants further exploration if PROMs are to be used widely in follow-up. Another limitation was the decision to stop recruitment before the required sample size had been reached. As the study was part of a doctoral thesis, a pragmatic decision was made to stop and ensure completion of the studies within the timeframe.

6.10.4 Outcome measurements

The BCNQ (Thewes, 2000) was used in the present study and had been used once before in this population. While it was an advantage, one disadvantage of this measure was that there is no comparative reference data of women with similar characteristics to compare against that of the general population. The review of alternative assessment tools was restricted to those previously used in the post-treatment breast cancer literature described in Chapter 3. It may have been useful to have also considered other cancer needs assessment tools although the integration of theory and choice of tool was directly linked to the individual requirements of the population under study. This was also true of the EORTC QLQ C30 and QLQ BR23, whereby the reference data available included women with breast cancer receiving treatment rather than having completed primary treatment. The reduction of perceived needs and improvement in quality of life is a core goal of policies that direct breast cancer services. As more

women survive it will become increasingly necessary to understand how these goals can be effectively achieved.

This study formed part of a part-time doctoral thesis and a pragmatic decision was made to gather data on two occasions, 12 months apart. However, the complexity of some of the unmet needs expressed which relate to sexuality, appearance and body image may follow a much longer recovery path. Some women were referred for further discussion about reconstructive surgery, and this takes time. Equally, the one year follow-up measurement point may have limited evidence of a short-lived effect seen at 3, 6 or 9 months.

6.10.5 Health economics

Health economic data was not routinely collected as part of this study. Economic analyses of nursing interventions are not widely undertaken. However, the researcher recognises the importance of ensuring that healthcare interventions introduced into practice are cost-effective as well as being based on evidence. In undertaking follow-up care in this study, this was a transformation of the scope of the SBCN's role. While she focused on providing supportive care to women from diagnosis of breast cancer within the context of the multi-disciplinary team, she had not undertaken clinical examination and follow-up prior to the study commencing. The demands on follow-up services coupled with finite resources indicate that cost analysis of the intervention would have been beneficial. The cost of paper-based questionnaires, an experienced SBCN, training and lengthier appointments at the outset would all need to be factored into the costs compared to standard care. However, a balance is required between standardisation in the absence of individual context, professional autonomy and judgement.

6.11 The strengths and limitations of using the MRC framework

The use of the MRC framework to guide the study design and execution was extremely useful, particularly as a novice researcher. The MRC are a respected organisation and it challenged the researchers thinking to look beyond just defining the components of the intervention as standard towards considering how it was possible to define the standard steps in the process and describe the

context. In their discussion document, the MRC refer to constant and variable components in an intervention but they failed to define them, leaving this open to interpretation. However, the emergence of published examples of how it can, and could be applied to complex interventions aided the interpretation (Campbell *et al*. 2000; Byrne *et al*. 2006; Higginson *et al*. 2006). Hawes *et al.* (2004) referred to "constants" as functions that could be standardised and the variable aspects adapted to different contexts. The emergence of a graphical method for depicting the RCT of complex interventions provided further assistance (Perera *et al*. 2007). The use of the framework was coupled with the extension to the CONSORT statement (Boutron *et al*.2008) about the reporting of non-pharmacologic randomised trials. Again, the importance of describing context and process is highlighted.

One limitation of using the framework was that gaining a good understanding of it and adhering to the phases was time consuming and difficult at times. Craig *et al*. (2008) suggested in their updated version that more attention should be given to the exploratory/pilot work. The researcher used a systematic approach to develop an intervention informed by empirical evidence and established theory. The feasibility and acceptability as delivered by the SBCN was tested and led to a definitive RCT. This aimed to mitigate against results that showed no effect. However it is clear that other influences play a part and extensive learning was gained from this experience.

6.12 Conclusion

This chapter sought to analyse and interpret the findings and set them within the context of relevant literature and current work in the field of breast cancer follow-up. The clinical application of using the BCNQ and HADS has shown them to be a rapid and simple method of identifying women who required help with particular aspects related to their breast cancer diagnosis and treatment effects. This could be valuable in distinguishing those requiring help and those not, and initiate early interventions for those expressing high depressive, anxiety and psychosocial needs. The findings extend the knowledge of the perceived unmet needs of women attending follow-up care and unlike previous studies, and importantly,

sought to address these needs within a clinic environment. The intervention by the SBCN indicated that it was as effective as current standard care.

The findings resonate the direction of healthcare to offer person-centred services which meet the needs of patients; importantly, this study represents a model whereby an individual's needs can be assessed alongside a clinical examination within the context of a hospital setting. It illustrates that some of the tensions between the medical model and the provision of a person-centred holistic approach, can be allayed and need not be mutually exclusive. By offering all patients an equal opportunity to identify their need for help, services naturally become more equitable and place more responsibility on the individual. Further work is required to apply this approach across larger numbers of women. The women expressed significant anxiety and unmet needs. Perhaps the high use of healthcare services identified in this group reflects on-going needs and anxiety among them. Earlier psychosocial interventions in this group after primary treatment is completed may help further.

Chapter 7: Conclusion and recommendations

7.1 Introduction

The present study set out to measure the effectiveness of delivering follow-up care in a hospital setting to address the perceived needs, psychological state and quality of life of women with breast cancer. Follow-up care is an integral part of breast cancer services that are provided to women once primary treatment (chemotherapy, radiotherapy, surgery) is complete. Criticism about the benefits, or otherwise of follow-up has largely focused on gains associated with the identification of recurrences. However, the intensity of treatments used, and the range of side effects seen, have left many women unsure about what these symptoms are and how best to manage them moving forward. Attendance at the follow-up clinic provides an opportunity for women to gain psychosocial support from healthcare professional's familiar with breast cancer. Evidence suggests that while many women wish these clinics to continue, some are leaving these clinics with unmet needs. This juxtaposition between the goals of follow-up and the outcomes women report led the researcher to argue that an approach to follow-up care is required that should assess the perceived needs and psychological state of the woman in partnership with the HCP to improve outcomes. This gap identified in the field of study led to the following research question:

- What is the effectiveness of providing patient-reported needs, quality of life and psychosocial information to the SBCN at the follow-up clinic in reducing cancer needs and improving quality of life compared to standard care?

This final chapter draws conclusions from the preceding analysis and discussions, identifies the specific contribution to knowledge and identifies areas for future research. It also makes some recommendations for policy, education and clinical practice emerging from the research.

7.2 Conclusion

To answer the primary research question in this study, a randomised controlled trial was used. By measuring the primary outcome, changes in needs over time at baseline and 12 months using the breast cancer needs questionnaire (BCNQ), the hospital anxiety and depression scale (HADS), and quality of life questionnaires, QLQ C30 and BR23, the researcher was able to conclude that the intervention by the specialist breast care nurse was as effective as, and certainly no worse, than standard follow-up care. in reducing unmet needs, anxiety and depression, and improving quality of life among breast cancer participants.

The results indicated that patient-reported outcome measures (PROMs) such as the BCNQ and HADS can be used effectively and in a timely manner within a busy breast cancer follow-up clinic, to inform and guide interventions by the SBCN. The SBCN did not require an additional consultation; rather the use of these tools was integrated into the planned clinical appointment. The participants included in the study reflected the range of women seen within this clinic. Throughout Chapter 2, 3 and the exploratory work, the specific areas of importance to a women recovering from a diagnosis of breast cancer was reported. Although generic instruments are widely used, they fail to capture the unique psychological and physical needs associated with a mastectomy, reconstruction, arm/shoulder pain, menopausal symptoms and body, to name a few, that differ to other cancer groups.

The BCNQ demonstrated good validity and reliability. It identified both the women with unmet needs but also those who had no need for support. Although the SBCN found it easy to use and quick to scan for high expressed needs, the flexibility of the tool combined with a person centred conversation accommodated women with a higher need for help than others. The needs of women decreased over time in both groups but were not statistically significant at the end of the trial. Although the study was underpowered, the decrease was proportionally similar in both groups, suggesting a higher sample may not have achieved different results. The improvement in both groups suggests follow-up in the hospital setting

provides more benefit in relation to psychosocial support, rehabilitation and monitoring of side effects than previously reported.

Previous literature (Chapter 3) clearly indicated anxiety and depression continues to be high in a significant number of breast cancer survivors (McDowell, 2010) and high scores indicate psychological need. The HADS is not routinely used among women attending follow-up care but demonstrated good validity and reliability in this study. The data indicated that anxiety levels were high in both groups at the start of the trial but did decrease over time. Although there was no significant differences between the groups at the end of the trial, there was a sub-group of women who when assessed against the HADS scoring protocol, continued to record high scores. By combining this screening measure with the person centred conversation, a better understanding of what the score represented, was gained. This is particularly important as risk factors associated with anxiety and depression (see Section 2.5) is broad.

Depression scores across both groups were low at the start of the trial and did improve over time. Again, using the HADS score combined with the person centred conversation allowed the small group of women with high scores to be identified and assessed further. However, high scores were also reported in the control group for further evaluation. Depression emerged as being associated with changes in anxiety and need for support at time 1. It is therefore important these women are identified and supported appropriately.

The quality of life of participants in both groups was good to high. The interpretation of these scores quickly is often challenging for practitioners and therefore in this study, these questionnaires were not used to inform the person-centred conversation. All the results changed in the right direction, suggesting over time, quality of life improves in this group of women.

7.3 New knowledge from the findings

This research addressed a specific group of participants, women with breast cancer attending a hospital follow-up clinic. As discussed in Chapter 3 research

existed which reported multiple unmet needs of women with breast cancer post-treatment but not directly at the time when they would be receiving follow-up care, or, capturing this information in a systematic manner. There was also no evidence of nursing interventions used to address these unmet needs at follow-up and seek to improve patient outcomes. This study has contributed to the existing knowledge of women attending follow-up. In particular, the use of a specific breast cancer needs questionnaire that captured areas relevant to a women recovering from breast cancer and provided a broader overview of this population's psychosocial needs, than previously reported. It also provided further evidence of the utility of HADS to screen breast cancer survivors for psychological needs.

Follow-up care is offered uniformly to every woman irrespective of needs, age, disease and treatment plan, and the results indicated that although there were unmet needs across both groups at the start and end of the trial, a proportion of these women report no need for support across any of the areas assessed. This is an important aspect that has emerged from this study and provides the platform to make changes in follow-up services. It indicates that support from HCPs may no longer be required within a hospital clinic setting for some women and empowering them to move on in their lives is a positive rather than a negative outcome. To date, either all women are discharged at a set time point or all women continue indefinitely. This study's findings indicate that it is possible to use tools in practice to identify those with the greatest need for support and those who are coping well and no longer require specialist interventions, thus providing effective use of resources using a person-centred approach to follow-up care. These women may be suitable for discharge from follow-up care irrespective of time since diagnosis if clear mechanisms are in place to allow rapid access back to specialist services when concerns arise about a possible recurrence.

7.4 Specific contribution to knowledge

This study has provided a major contribution to the methodological evidence base about complex interventions in nursing practice. The findings showed that to measure the effectiveness of a nursing intervention during follow-up that focused on addressing unmet needs and encompassing a person centred approach, can

be studied using the RCT approach. The use of a RCT has benefits for the effective accumulation of knowledge within healthcare but its use to measure interventions by nurses is not widely used. It is certainly a new approach when combined with a person-centred conversation, as was the case with this study.

By using the MRC framework to guide the development and testing of the complex intervention in the follow-up setting, the research has been able to highlight both the diversity of needs among breast cancer survivors, but, also the means to address these needs in an individualised manner. The function and process of the intervention was standardised, however not the individual components. This enabled the intervention to be tailored to a woman's individual needs. In the pre-clinical (theoretical) phase, the intervention was based on the supportive care framework which drew on constructs such as human needs, coping, adaptation, personal experience and expectations.

There was no intervention guide prior to commencing this study. By drawing on qualitative and quantitative research, and theory within the context in which the intervention was implemented, the probability of success was maximised and a reproducible intervention was devised, one which can be used in future studies. In addition, there is now preliminary data, including standard deviations of a breast cancer survivor population's psychosocial needs which will serve as the basis for future studies, and offer a more precise sample size calculation in the future. The priori sample calculation for this study was based on the secondary outcome, quality of life, as there was no previous research that had measured changes in needs in this setting.

Policy, in particular the National Cancer Survivorship Initiative and the Transforming Care after Cancer, suggests interventions to meet the perceived needs of breast cancer survivors will increase and drive forward service re-design in follow-up care. It is important that theoretical and methodological aspects are considered in the development of interventions, but, also how the effectiveness of these interventions can be measured. This study adds considerably to this area of work. Of particular significance is the development within this study of an approach to assessing and addressing psychosocial needs within the context of a

"real life" clinic environment. By combining the use of PROMs, the clinical expertise of a SBCN and clinical examination, services can aid the recovery, support and adaptation of women as they survive breast cancer. While this approach was developed with the SBCN as the key professional, it may also be helpful, following adaptation, for use in primary care by GP's and other HCPs involved in the care of women post-treatment. While this work contributes to the existing knowledge of follow-up care in breast cancer, transferability of this approach to other cancer groups it also a possibility, where similar goals exist to address psychosocial needs, monitor for signs of recurrence and long-term morbidity. However, further research would be recommended.

7.5 Recommendations

The following recommendations were identified following the study which encompasses policy, practice, education and research.

7.5.1 Recommendations for policy

- The findings suggest using PROMs such as the BCNQ and the HADS offers promise in identifying unmet needs among those with breast cancer. At present no systematic approach is used and therefore patients may be under-reporting needs at clinics. With the identification of needs arguably comes the requirement to meet those needs: without the resources that are identified to meet the needs of cancer survivors, we could be raising expectations which cannot be met. These choices will be difficult, particularly in the field of breast cancer where there are high levels of need reported and large numbers of survivors.

- This study included training for the SBCN and suggested interventions to meet the needs of women were discussed. If widespread use of a needs assessment tool is integrated into practice, evidence of effective interventions, to meet needs, are required, so the HCPs can clearly signpost their patients towards them. There may also be a training requirement for HCPs to effectively use a needs assessment tool and its associated interventions.

- Women immediately post-treatment can expect to be seen by specialists in breast cancer for at least a couple of years**.** The findings suggest there is a requirement to consider the right time to introduce the BCNQ and HADS in a follow-up setting to understand the needs of these women as they recover and offer timely, appropriate interventions. A number of women beyond 3 years expressed high levels of need and may have benefited from an earlier opportunity to express their need for support.

7.5.2 Recommendations for practice

- If PROMS are to be used routinely in clinical practice, consideration is required about how this will be achieved to avoid high additional costs. Paper-based approaches are an option but assessment of psychosocial outcomes using electronic means may be the most cost effective approach to moving forward.

- If PROMs are to be used, there is a need to consider the cognitive ability of patients and how this may affect response rates.

- It would be premature to recommend the intervention for general clinical practice. The evidence is only preliminary and it is likely that some work would be required to translate it fully into clinical practice. The skill of the practitioner is likely to have an impact on the patient's reduction in needs, anxiety and depression, and therefore recognition of this is required or otherwise a dilution of effect may occur.

- The study has highlighted that the recording of psychosocial information within a follow-clinic, including interventions offered, is very limited. In particular linking the specific need reported by the woman and the actions or intervention initiated by the SBCN. If a stronger focus on these areas emerges, a standardised assessment and reporting mechanism is required. This would improve continuity between HCPs and directly link outputs to outcomes.

- If PROMS, such as the BCNQ and HADS are used regularly within follow-up clinics, reporting of this information, through formal gathering of datasets would be valuable. These data could inform future planning of services to support breast cancer survivors.

7.5.3 Recommendations for education

- In the development of this study it was apparent that there are inconsistencies in how SBCN are assessed for competence to undertake clinical examination within the whole context of "standard care". A consistent approach is required to assess the initial and on-going competence of nurses undertaking clinical examination and assessment within a follow-up clinic.

- This study identified the SBCN to undertake the intervention. However if different approaches are used in the delivery of follow-up care, multi-professional training and education will be required.

- The women in this study identified areas such as fear of recurrence, fatigue, pain and sexuality as areas of high need for support. There is a requirement to review education and support strategies used by SBCN's in relation to these areas on a regular basis.

- The findings suggested that women require information and support to understand recurrence of breast cancer, genetics and new treatment developments alongside issues related to sexuality, body image and appearance. It is unclear if current educational models provide opportunities to consider patho-physiology of breast cancer and holistic aspects together. This study indicates that SBCNs undertaking follow-up require broad educational preparation.

7.5.4 Recommendations for future research

- The approach used in this study offers a promising way of meeting the needs of women in a person-centred way, in a breast cancer follow-up setting. The trial was undertaken in one cancer centre and future research should consider

a multi-centre trial. Although this study focused on the intervention delivered by the SBCN, it would be useful for future studies to capture more detail about standard care, delivered by doctors or SBCN.

- There is no data to date about the clinical interpretation of needs assessment data; when a score represents a problem, either in absolute terms or changes in an individual patients score over time. Further research is required in this area.

- The literature reviewed about the use of needs assessment tools to guide care within a follow-up clinic did not undertake any cost-benefit analysis. A study examining the costs over time of the intervention used in this study would be beneficial. It may also inform future strategies to meet the needs of breast cancer survivors.

- Although the results indicate the BCNQ is sensitive in identifying changes in unmet needs among breast cancer survivors, further psychometric testing is required on larger samples, over more geographical locations and over longer time periods.

7.6 Dissemination of Findings

The findings of this study will be disseminated through presentations and peer reviewed journals. Two opportunities arose to present some early discussion about the study and generated interest from SBCNs working in follow-up clinics in a hospital setting. Details of these can be found in at the beginning of this thesis. The importance of sharing the results with practitioners and policy makers is vital as the results have the potential to shift thinking and influence the planning of future follow-up services.

7.7 Final Summary

This chapter has provided a conclusion of the findings, a synopsis of the new knowledge gained and the specific contribution of this study. Follow-up care is a service which has continued to be delivered in the hospital setting in the same way, irrespective of whether a doctor or SBCN delivers the service. Diagnostic knowledge and treatment modalities have seen huge changes but this has not been translated to follow-up care. This study highlighted that an intervention by SBCN, guided by PROMs and a person centred conversation could be delivered in a follow-up clinic and within a short timeframe. The results imply that the intervention was as effective as, and certainly no worse than standard follow-up care. However the learning gained about the perceived needs and quality of life of this population has provided evidence that many of these women are recovering well and do not seek support while others are struggling. Prior to this study, little was known about the perceived needs and quality of life of women attending a follow-up care and the data can inform services in the future. Although these findings are preliminary, they suggest that future studies in follow-up care may benefit from this intervention approach.

References

Aaronson, N., Ahmedzai, S., Bergman, B., Bullinger, M., Cull, A., Duez, N.J., Filiberti, A., Flechtner, H., Fleishman, S.B., de Haes, J.C. *et al.*, 1993. The European Organisation for Research and Treatment of Cancer QLQ-C30: a quality of life instrument for use in international clinical trials in oncology. *Journal of National Cancer Institute*, **85** (5) pp.365-376.

Aapro, M., 2006. Breast Cancer: not a single disease. *European International Cancer Supplement*, 4 (4) pp. 1-3.

Adewuyi-Dalton, R., Ziebland, S., Grunfeld, E. & Hall, A., 1998. Patients' views of routine hospital follow-up: a qualitative study of women with breast cancer in remission. *Psycho-oncology*, **7** (5) pp.436-439.

Akechi, T., Okuyama, T., Endo, C., Sagawa, R., Uchida, M., Nakaguchi, T., Akazawa, T., Yamashita, H., Toyama, T. & Furukawa, T.A., 2011. Patient's perceived need and psychological distress and/or quality of life in ambulatory breast cancer patients in Japan. *Psycho-oncology*, **20** (5) pp.497-505.

Altman, D.G., Schulz, K.F., Moher, D., Egger, M., Davidoff, F., Elbourne, D., Gotzsche, P.C. & Lang, T. for the Consort Group, 2001. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Annals of internal medicine*, **134** (8) pp.663-694.

Andersson, M., Awada, A., Barrett-Lee, P., Ellis, P., Hupperets,P., Jackish, C., Kubista, E., Luck, H-J., Monnerat, C., Nitz, U., 2008. European oncologists' preferences for the management of breast cancer: case presentations and expert commentary. *The Breast*, **17** (52) pp. s1-s11.

Anderson,D,J., Yates, P., McCarthy, A., Lang, C,P., Hargreaves, M., McCarthy, N., Porter-Steele, J., 2011. Younger and older women's concerns about menopause after breast cancer. *European Journal of Cancer Care*, **20** pp. 785-794.

Anthony, D., 1999. *Understanding Advanced Statistics A guide for Nurses and Healthcare Researchers*. London: Churchill Livingstone.

Aranda, S., Schofield, P., Weih, L., Milne, D., Yates, P. & Faulkner, R., 2006. Meeting the support and information needs of women with advanced breast cancer: a randomized controlled trial. *British journal of cancer*, **95** (6) pp.667-673.

Armer, J.M., Henggler, M.H., Brooks, C.W., Zagar, E.A., Homan, S. & Stewart, B.R., 2008. The health deviation of post-breast cancer lymphedema: symptom assessment and impact on self-care agency. *Self-care, dependent-care & nursing*, **16** (1) pp.14-21.

Baildam, A., Keeling, F., Noble, M., Thompson, L., Bundred, N. & Hopwood, P., 2001. Nurse led follow-up for women treated for breast cancer: a randomised controlled trial. *European journal of of surgical oncology*, **27** (8) p.792.

Baum, M., 2002. The changing face of breast cancer – past, present and future perspectives. *Breast Cancer Research and Treatment*, **75** s1-s5.

Beaver, K. & Luker, K., 2005. Follow-up breast cancer clinics: reassuring for patients rather than detecting recurrence. *Psycho-oncology*, **14** (2) pp.94-101.

Beaver, K., Twomey, M., Witham, G., Foy, S. & Luker, K., 2006. Meeting the information needs of women with breast cancer: piloting a nurse-led intervention. *European journal of oncology nursing*, **10** (5) pp.378-390.

Beaver, K., Williamson, S. & Chalmers, K., 2009. Telephone follow-up after breast cancer treatment for breast cancer: views and experiences of patients and specialist breast cancer nurses. *Journal of clinical nursing*, **19** (19-20) pp.2916-2924.

Bell, M., Kenward, M,G., Fairclough, d, l., Horton, N,J., 2013. Differential dropout and bias in randomised controlled trials: when it matters and when it may not. *British Medical Journal*, **346** pp. 1-7.

Biglia, N., Cozzarello, M., Cacciari, F., Ponzone, R., Roagna, R., Maggiorotto, F. & Sismondi, P., 2003. Menopause after breast cancer: a survey on breast cancer survivors. *Maturitas*, **45** (1) pp.29-38.

Bjelland, I., Dahl, A.A., Haug, T. & Neckelmann, D. 2002. The validity of the hospital anxiety and depression scale. *Journal of psychosomatic research*, **52** (2) pp.69-77.

Black, S., 1998. Editorial. *Nurse researcher*, **6** (1) pp.3-4.

Bloom, J.R., Stewart, S.L., Johnston, M. & Banks, P., 1998. Intrusiveness of illness and quality of life in young women with breast cancer. *Psycho-oncology*, **7** (2) pp.89-100.

Blowers, E. & Foy, S., 2009. Breast cancer overview: current treatments. *Practice nursing*, **20** (6) pp.282-286.

Boehhmke, M.M. & Dickerson, S.S., 2006. The diagnosis of breast cancer: transition from health to illness. *Oncology nursing forum*, **33** (6) pp.1121-1127.

Bonevski, B., Sanson-Fisher, R., Girgis, A., Burton, L., Cook, P. & Boyes, A., 2000. Evaluation of an instrument to assess the needs of patients with cancer. *Cancer*, **88** (1) pp.217-225.

Boutron, I., Moher, D., Altman, D.G., Schulz, K.F. & Ravaud, P. for the CONSORT Group, 2008. Extending the CONSORT statement to randomised trials of non-pharmacologic treatment: explanation and elaboration. *Annals of internal medicine*, **148** (4) pp.295-309.

Bower, J,E., Ganz, P,A., Desmond, K,A., Rowland, J,H., Meyerowitz, B,E., Belin, T,R.,2000. Fatigue in breast cancer survivors: Occurrence, Correlates, and Impact on quality of life. American Society of Clinical Oncology, 18 (4) pp. 743-53.

Boyes, A., Newel, S., Girgis, A., McElduff, P. & Sanson-Fisher, R., 2006. Does routine assessment and real-time feedback improve cancer patients' psychosocial well-being? *European journal of cancer care*, **15** (2) pp.163-171.

Breast Cancer Care., 2012. Accessed from http://www.breastcancercare.co.uk on 22nd January 2014.

British Association of Surgical Oncology (BASO), 2005. Guidelines for the management of symptomatic breast disease. *European journal of cancer care*, **31** pp.S1-S21.

Brooks, J.J., 2006. A patient's journey: living with breast cancer. *British medical journal*, **333** (7557) pp.31-33.

Brown, L., Payne, S. & Royle, G., 2002. Patient initiated follow-up of breast cancer. *Psycho-oncology*, **11** (4) pp.346-355.

Burton, M., & Watson, M., 1998.Counselling people with cancer. Chichester: John Wiley.

Budin, W,C., Cartwright-Alcarase, F., Hoskins, C, N., 2008. The breast cancer treatment response inventory: development, psychometric testing, and

refinement for use in practice. Oncology Nursing Forum, **35** (2) pp. 209-215.

Byrne, M., Cupples, M,E., Smith, S,M., Leathem, C., Corrigen, M., Byrne, M,C., Murphy, A,W., 2006. Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK medical research council framework. *The American Journal of Managed Care,* **12** (5) pp. 261-266.

Campbell, M.,Fitzpatrick, R., Haines, A., Kinmonth, A,L., Sandercock, P., Spiegalhalter, D., Tyrer, P., 2000. Framework for design and evaluation of complex interventions to improve health. *BMJ*, **321** pp. 694-696.

Canadian Medical association, The steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer., 1998. Clinical practice guidelines for the care and treatment of breast cancer. *CMA*,**158** (suppl. 3), pp.1-83.

Cancer Australia., 2010. Clinical practice guidelines for management of early breast cancer: recommendations for follow-up of women with early breast cancer. Accessed from http://guidelines.canceraustralia.gov.au/guidelines/early_breast_cancer/ch01.php#Ch1053Se228454 on 9th February 2014.

Cancer Research UK, 2012. Breast cancer survival statistics. Accessed from http://www.cancerresearchuk.org/cancer-info/cancerstats/types/breast/survival/ on 18th January 2014.

Cardoso, F., Loibl, S., Pagani, O., Graziottin, A., Panizza, P., Martincich, L., Gentilini, O., Peccatori, F., Fourquet, A., Delaloge, S., Marott, L., Penault-Llorca, A,M., Rodger, A., Harbeck, N., 2012. The European Society of breast cancer specialists' recommendations for the management of young

women with breast cancer. *European Journal of Cancer*, **48** pp. 3355-3377.

Carey, M., Lambert, S., Smits, R., Paul, C., Sanson-Fisher, R. & Clinton-McHarg, T., 2012. The unfulfilled promise: a systematic review of interventions to reduce the unmet supportive care needs of cancer patients. *Support care cancer*, **20** (2) pp.207-219.

Carlson,L,E., & Bultz,B,D., 2004. Efficacy and medical cost offset of psychosocial interventions in cancer care: making the case for economic analyses. *Psycho-Oncology*, **13** (12) pp. 837-849.

Carlson, L.E., Waller, A. & Mitchell, A.J., 2012. Screening for distress and unmet needs in patients with cancer: review and recommendations. *Journal of clinical oncology*, **30** (11) pp.1160-1177.

Carroll, B.T., Kathol, R.G., Noyes, R. Jr, R., Wald, T.G. & Clamon, G.H., 1993. Screening for depression and anxiety in cancer patients using the hospital and anxiety depression scale. *General Hospital Psychiatry*, **15** (2) pp.69-74.

Carver, C,S., Smith, R,G., Petronis, V,M., Antoni, M,H., 2005. Quality of life among long-term survivors of breast cancer: different types of antecedents predict different classes of outcomes. *Psych-Oncology*, **15**, pp.749-758.

Cataliotti, L., et al on behalf of EUSOMA., 2007. Position paper, Guidelines on the standards for the training of specialized health professionals dealing with breast cancer. *European Journal of Cancer*, **43** pp. 660-675.

Cecil, R., Thompson, K. & Parahoo, K., 2006. The research assessment exercise in nursing: learning from the past, looking to the future. *Journal of clinical nursing*, **15** (4) pp.395–402.

Chapman, D., Cox, E., Britton, P.D. & Wishart, G.C., 2009. Patient-led breast cancer follow-up. *The breast*, **18** (2) pp.100-101.

Cheung, Y-B., Goh, C., Thumboo, J., Khoo, K-S. & Wee, J., 2005. Variability and sample size requirements of quality of life measures: a randomized study of three major questionnaires. *Journal of clinical oncology*, **23** (22) pp.4936-4944.

Clark, A.S. & Domchet, S.M., 2011. Clinical management of hereditary breast cancer syndromes. *Journal of mammary biology neoplasia*, **16** (1) pp.17-25.

Coates, V., 2010. The RCT: a very beautiful technique. The 2009 Janet Kinson lecture. *Practical Diabetes,* **27** (1) pp. 27-31.

Cochrane, A.L., 1972. *Effectiveness and efficiency: random reflections on health services*. Abington: The Nuffield Provincial Hospitals Trust. p.2.

Cohen, J.,1992. A power primer. *Psychological bulletin*, **112** (1) pp.155-159.

Collins, R.F., Bekker, H.L. & Dodwell, D.J., 2004. Follow-up care of patient's treatment for breast cancer: a structured review. *Cancer treatment reviews*, **30** (1) pp.19-35.

Consolidated Standards of Reporting Trials (CONSORT)., 2010. Accessed from http://www.consort-statement.org/consort-statement/further-explanations/box6_intention-to-treat-analysis/ on 9th February 2014.

Corter, A.L., Findlay, M., Broom, R., Porter, D. & Petrie, K.J., 2013. Beliefs about medicine and illness are associated with fear of recurrence in women taking adjuvant endocrine therapy with breast cancer. *British journal of health psychology*, **18** (1) pp.168-181.

Coyne, J.C., Palmer, S.P., Shapiro, P.J., Thompson, R. & De Michele, A., 2004. Distress, psychiatric morbidity, and prescriptions for psychotropic medication in a breast cancer waiting room sample. *General hospital psychiatry*, **26** (2) pp.121-128.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. & Petticrew, M., 2008. Developing and evaluating complex interventions: new guidance. Accessed from http://www.mrc.ac.uk/complexinterventionsguidance in July 2013.

Creswell, J, W., & Plano Clark., 2007. *Designing and conducting mixed methods research*. CA, USA: Sage Publications.

Cruickshank, S., Kennedy, C., Lockhart, K., Dosser, I. & Dallas, L., 2008. *Specialist breast care nurses for supportive care of women with breast cancer*. Cochrane Database of Systematic Reviews. Accessed from http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005634/frame.html on 20th January 2014.

Cruickshank, S., & Hume, A., 2014. The experience of providing support about menopausal symptoms to women with breast cancer. European Journal of Oncology Nursing, 18 (1) pp. 110-117.

Cull, A., Stewart, M. & Altman, D.G., 1995. Assessment of and intervention for psychosocial problems in routine oncology practice. *British journal of cancer* **72** (1) pp.229-35.

Curran, S.L., Andrykowski, M.A. & Studts, J.L., 1995. Short form of the profile of mood states (POMS-SF): psychometric information. *Psychological assessment*, **7** (1) 80-83.

Davidson, P., Cockburn, J., Daly, J. & Fisher, R.S., 2004. Patient-centred needs assessment: rationale for a psychometric measure for assessing needs in heart failure. *Journal of cardiovascular nursing*, **19** (3) pp.164-171.

Davies, N.J. & Batechup, L., 2009. *Cancer follow-up: towards a personalised approach to aftercare services. A review of current practice and selected initiatives*. London: Macmillan Cancer Support. Accessed from http://www.ncsi.org.uk/wp-content/uploads/Follow-Up-Towards-a-Personalised-Approach-to-Aftercare.pdf on 3rd February 2014.

De Bock, G.H., Bonnema, J., van der Hage, J., Kievit, J. & van de Velde, C.J., 2004a. Effectiveness of routine visits and routine tests in detecting isolated locoregional recurrences after treatment for early stage invasive breast cancer: a meta-analysis and systematic review. *Journal of clinical oncology*, **22** (19) pp.4010-4018.

De Bock, G.H., Bonnema, J., Zwaan, R.E., van de Velde, C.J.H., Kievit, J. & Stiggelbout, A.M., 2004b. Patient's needs and preferences in routine follow-up after treatment for breast cancer. *British journal of cancer*, **90** (6) pp.1144-1150.

Degner, L.F., Davison, B.J., Sloan, J.A. & Mueller, B., 1998. Development of a scale to measure information needs in cancer care. *Journal of nursing measurement*, **6** (2) pp.137-153.

Delon, M., Wade Evans, A., Cooper, S., Walls, C., McGillycuddy, B., Martlew, B., 2008. Early post-op swelling and its association with lymphoedema. *Journal of Lymphoedema,* **3** (1) pp.26-30.

Dellson, P., Nilbert, M., Bendahl, P-O., Malmstrom, P. & Carlsson, C., 2011. Towards optimised information about clinical trials, identification and validation of key issues in the collaboration with cancer patient advocates. *European journal of cancer care*, **20** (4) pp.445-454.

Department of Health., 2011. *Improving outcomes: a strategy for cancer*. London: Department of Health.

Deshields, T., Tibbs, T., Fan, M-Y. & Yaylor, M., 2006. Differences in patterns of depression after treatment for breast cancer. *Psycho-oncology*, **15** (5) pp.398-406.

Dinh, P., Sotiriou, C., & Piccart, M., 2007. The evolution of treatment strategies: aiming at the target. *The Breast*, **18** pp. s10-s16.

Dixon, J.M. & Montgomery, D., 2008. Follow-up after breast cancer. *British medical journal*, **19** (336) pp.107-108.

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B. & Sutton, A., 2005. Synthesising qualitative and quantitative evidence: a review of possible methods. *Journal of health services research and policy*, **10** (1) pp.45-53.

Dutch Breast Cancer Federation., 2012 The Dutch breast cancer guideline, available from http://www.oncoline.nl/breastcancer on 16th February 2014.

Early Breast Cancer Trialists' Collaborative Group (EBCTCG), 2005. Effects of chemotherapy and hormonal therapy on recurrence and 15-year survival: an overview of the randomized trials. *Lancet*, **365** (9472) pp.1687-1717.

Early Breast Cancer Trialists' Collaborative Group (EBCTCG).,2011. Effect of radiotherapy after breast conserving on 10 year recurrence and 15 year breast cancer death: meta-analysis of individual patient data for 10,801 women in 17 randomised trials, *Lancet* **378** pp. 1707-1716.

Earnshaw, J.J. & Stephenson, Y., 1997. First two years of a follow-up breast clinic led by a nurse practitioner. *Journal of the Royal Society of Medicine*, **90** (5) pp.258-259.

Eccles, S.A., Thompson, M. *et al.*, 2013. Critical research gaps and translational priorities for the successful prevention and treatment of breast cancer. *Breast Cancer* Research, **15** (5) R92 pp.1-37. Accessed from http://breast-cancer-research.com/content/15/5/R92 on 25th January 2014.

Emens, L.A. & Davidson, N.E., 2003. The follow-up of breast cancer. *Seminars in oncology*, **30** (3) pp.338-348.

European Society for Medical Oncology., 2007. Primary breast cancer: ESMO clinical recommendations for diagnosis, treatment and follow-up. *Annals of oncology*, **18** (suppl. 2), pp.i5-i8.

Ewert, M., Jensen, A, B., 2011. Late effects of breast cancer treatment and potentials for rehabilitation. *Acta Oncologica*, **50** pp.187-193.

Fallowfield, L.J. & Baum, M., 1989. Psychological welfare of patients with breast cancer. *Journal of Royal Society of Medicine*, **82** (1) pp.4-5.

Fallowfield, L. & George, D., 2008. Introduction to the session on “Debate: extended follow-up of breast cancer patients in clinic wastes time for both patients and doctors”. *Breast cancer research*, **10** (suppl. 4) pp.1-2.

Farrell, G.A., 1991. How accurately do nurses perceive patients’ needs? A comparison of general and psychiatric setting. *Journal of advanced nursing*, **16** (9) pp.1062-1070.

Fayers, P., Aaronson, N., Bjordal, K., Curran, D., Groenvold, M., 1999. EORTC QLQC30 *Scoring manual plus supplementary modules*. EORTC Data Center, Brussels.

Ferrans, C.E., 2005. Definitions and conceptual models of quality of life. In Lipscomb, J., Gotay, C.C. & Snyder, C., 2005. *Outcomes assessment in cancer: measures, methods and applications*. Cambridge: Cambridge University Press. pp.14-30.

Fenlon, D,R., Corner, J,L., Haviland, J.,2009. Menopausal hot flushes after breast cancer. *European Journal of Cancer Care*, **18** pp.140–148.

Ferrell, B.R., Grant, M., Funk, B., Otis-Green, S. & Garcia, N., 1997. Quality of life in breast cancer. Part 1: physical and social well-being. *Cancer nursing*, **20** (6) pp.398-408

Ferrell, B.R., Grant, M., Funk, B., Otis-Green S. & Garcia, N., 1998. Quality of life in breast cancer. Part II: psychological and spiritual well-being. *Cancer nursing*, **21** (1) pp.1-9.

Ferrell, B.R., Grant, M., Garcia, N., Otis-Green, S. & Schaffner, M.L.J., 1996. Quality of life in breast cancer. *Cancer practice*, **4** (6) pp.331-340.

Field, A., 2005. *Discovering statistics using SPSS.* 2nd ed. London: Sage.

Field, A., 2013. *Discovering statistics using IBM SPSS statistics.* 4th ed. London: Sage publications.

Filippakis, G, M., Zografos, G.,2007. Contraindications of sentinel lymph node biopsy: Are there any really? *World Journal of Surgical Oncology,* **5** pp.1-11.

Fitch, M.I., 1994. *Providing supportive care for individuals living with cancer*. Taskforce report. Toronto: Ontario Cancer Treatment and Research Foundation.

Fitch, M,I., Porter, H, B., & Page, B,D., 2002. Pathway of care for cancer, p.15 IN Fitch, M.I., Porter, H.B. & Page, B.D., 2009. *Supportive care framework: a foundation for person-centred care*. Ontario: Pappin Communication.

Fitch, M.I., 2008. Supportive care framework. *Canadian oncology nursing journal*, **18** (1) pp.6-24.

Fitch, M.I., Porter, H.B. & Page, B.D., 2009. *Supportive care framework: a foundation for person-centred care*. Ontario: Pappin Communication.

Folkman, S., & Greer,S., 2000. Promoting psychological well-being in the face of serious illness: When theory, research and practice inform each other. Psycho-Oncology, **9** pp.11-19.

Franks, P., Williams, A & Moffatt, C., 2006. A review of the epidemiology of BCRL. *Journal of Lymphoedema*, **1** (1) pp. 66-70.

Fortner, B., Okon,T., Schwartzberg, L., Tauer, K. & Houts, A.C., 2003. The cancer care monitor: psychometric content evaluation and pilot testing of a computer administered system for symptom screening and quality of life in adult cancer patients. *Journal of pain and symptom management*, **26** (6) pp.1077-1092.

Ganz, P.A., Coscarelli, A., Fred, C., Kahn, B. & Polinsky, M.L., 1996. Breast cancer survivors: psychosocial concerns and quality of life. *Breast cancer research and treatment*, **38** (2) pp.183-199.

Ganz, P.A., Greendale, G.A., Peterson, L., Zibecchi, L., Kahn, B. & Berlin, T.R., 2000. Managing menopausal symptoms in breast cancer survivors: results of a randiomised controlled trial. *Journal of National Cancer Institute*, **92** (13) pp.1054-1064.

Ganz, P.A., Kwan, L., Stanton, A.L., Krupnick, J.L., Rowland, J.H., Meyerowitz, B.E., Bower, J.E. & Belin, T.R., 2004. Quality of life at the end of primary treatment of breast cancer: first results from the moving beyond cancer randomised trial. *Journal of National Cancer Institute*, **96** (5) pp.376-387.

Ganz, P.A., Schag, C.A.C., Lee, J.J. & Sim, M.S., 1992. The CARES: a generic measure of health related quality of life for patients with cancer. *Quality of life research*, **1** (1) pp.19-29.

Gerrish, K., & Lacey, A., 2006. *The research process in Nursing*. London: Blackwell.

Girgis, A., Boyes, A., Sanson-Fisher, R. & Burrows, S., 2000. Perceived needs of women diagnosed with breast cancer: rural versus urban location. *Australian and New Zealand journal of public health,* **24** (2) pp.166-173.

Gligorov, J., Pritchard, K. & Goss, P., 2007. Adjuvant and extended adjuvant used of aromatase inhibitors: reducing the risk of recurrence and distant metastasis. *The breast*, **16** (3) pp.S1-S9.

Goldhirsch, A., Glick, J,H., Coates,A,S., Thulmann,B., Senn, H-J., and panel members., 2005. Meeting highlights: International expert consensus on the primary therapy of early breast cancer. *Annals of Oncology*, **16** pp. 1569-1583.

Goldhirsch, A., Winer, E.P., Coates, A.S., Gelber, R.D., Piccart-Gebhart, M., Thurliman, B., Senn, H. & Panel Members, 2013. Personalising the treatment of women with early breast cancer: highlights of the St Gallen international expert consensus on the primary therapy of early breast cancer 2013. *Annals of oncology*, **24** (9) pp.2206-2013.

Gotay,C., 2006. Increasing trial generalizability. *Journal of clinical oncology*, **24** (6) pp.846-847.

Greendale, G.A., Lee, N.P. & Arriola, E.R., 1999. The menopause. *Lancet*, **353** (9152) pp.571-580.

Greenhalgh, T. & Peacock, R., 2005. Effectiveness and efficiency of search methods in systematic reviews of complex evidence: audit of primary sources. *British medical journal*, **331** (7524) pp.1064-1065.

Grov, E.K., Dahl, A.A., Moum, T. & Fosså, A., 2005. Anxiety, depression, and quality of life in caregivers of patients with cancer in late palliative phase. *Annals of oncology*, **16** (7) pp.1185-1191.

Grunfeld, E., Dhesy-Thind, S. & Levine, M., 2005. Clinical practice guidelines for the care and treatment of breast cancer (summary of the 2005 update). *Canadian medical association guidelines*, **172** (10) pp.1319-1320.

Grunfeld, E., Levine, M.N., Julian, J.A., Coyle, D., Szechtman, B., Mirsky, D., Verma, S., Dent, S., Sawka, C., Pritchard, K., Wood, M. & Whelan, T., 2006. Randomized trial of long-term follow-up for early stage breast cancer: a comparison of family physician versus specialist care. *Journal of clinical oncology*, **24** (6) pp.848-855.

Guba, E.G. & Lincoln, Y.S., 1998. Competing paradigms in qualitative research. In: Denzin, N.K. & Lincoln, Y.S., eds., 1998. *The landscape of qualitative research*. London: Sage. pp.195-220.

Gupta, S,K., 2011. Intention to treat concept: A review. Perspectives in Clinical Research, **2** (3) pp. 109-112.

Gustafson, D.H., 2005. Needs Assessment in Cancer. In: Lipscomb, J., Gotay, C.C. & Snyder, C., 2005. *Outcomes assessment in cancer: measures, methods and applications*. Cambridge: Cambridge University Press. pp.305-328.

Guyatt, G., Oxman, A., Akl, E.I., Kunz, R., Vist, R., Brozek, J., Norris, S., Falck-Ytter, Y., Glasziou, P., de Beer, H., Jaeschke, R., Rind, D., Meerpohl, J., Dahm, P. & Schunemann, H.J., 2011. GRADE guidelines: 1. Introduction - GRADE evidence profiles and summary of findings tables. *Journal of clinical epidemiology*, **64** (4) pp.383-394.

Hagedorm, M., Uijl, S.G., Van Somderen, E., Ranchor, A.V., Grol, B.M., Otter, R., Krol, B., Van den H.W., Sanderman, R., 2003. Structure and reliability of Ware's satisfaction questionnaire 111 (should be roman numerals but can't find it): patients satisfaction with oncological care in the Netherlands. *Medical Care*, **41** pp. 254-263.

Hall, A., A'Hern, R. & Fallowfield, l., 1999. Are we using appropriate self-report questionnaires for detecting anxiety and depression in women with early breast cancer? *European journal of cancer*, **35** (1) pp.79-85.

Halkett, G, K, B., 2007.The phenomenon of making decisions during the experience of early breast cancer. *European Journal of Cancer Care,* **16** pp. 322-330.

Harris, P., Remington P., Trentham-Dietz, A., Allen, C. & Newcomb, P., 2002. Prevalence and treatment of menopausal symptoms among breast cancer survivors. *Journal of pain and symptom management*, **23** (6) pp.501-509.

Hawe, P., Shiell, A., Riley, T., 2004. Complex interventions: how "out of control" can a randomised controlled trial be? *BMJ*, 328 pp.1561-1563.

Hicks C. & Hennessay, D., 1997. Mixed messages in nursing research: their contribution to the persisting hiatus between evidence and practice. *Journal of advanced nursing*, **25** (3) pp.595-601.

Hicks, D,G., Kulkarni, S.,2008. Trastuzumab as adjuvant therapy for early breast cancer. *Arch Pathology Laboratory Medicine,* **132** pp.1008-1015.

Hickey, A., Saunder, C., Partridge, A., Santoro, N., Joffee, h., Stearns, V., 2008. Practical clinical guidelines for assessing and managing menopausal symptoms after breast cancer. *Annals of Oncology*, **19** pp. 1669-1680.

Higgins, J.P.T. & Green, S,M., eds., 2011. *Cochrane handbook for systematic reviews of interventions,* version 5.1.0. London: The Cochrane Collaboration. Accessed from www.cochrane-handbook.org on 10th July 2012.

Higginson, I,J., Vivat, B., Silber, E., Saleem, T., Burman, R., Hart, S., Edmonds, P., 2006. Study protocol: delayed intervention randomised controlled trial within medical research council (MRC) Framework to assess the

effectiveness of a new palliative care service. *BMC Palliative Care*, 5 (7) pp.1-11.

Holmes, C.A. & Warelow, P.J., 1997. Culture, needs and nursing: a critical theory approach. *Journal of advanced nursing*, **25** (3) pp.463-470.

Holzner B., Kemmler, G., Kopp, M., Moschen, R., Schweigkofler, H., Dunser, M., Margreiter, R., Fleishhacker, W. & Sperner-Unterweger, B., 2001. Quality of life in breast cancer patients – not enough attention for long-term survivors. *Psychosomatics*, **42** (2) pp.117-123.

Horsburgh, D., 2003. Evaluation of qualitative research. *Journal of clinical nursing*, **12** (2) pp.307-312.

Houssami, N., Cuzick, J., Dixon, J,M., 2006. The prevention, detection and management of breast cancer. *Medical Journal of Australia*, **184** (5) pp. 230-234.

Hunter, M.S., Coverntry, S., Hamed, H., Fentiman, I., Grunfeld, E.A., 2009. Evaluation of a group cognitive behavioural intervention for women suffering from menopausal symptoms following breast cancer treatment. *Psych-Oncology.* **18** pp. 560-563

Ipsos Mori., 2011. National Cancer Survivorship Initiative Evaluation of adult cancer aftercare services – Wave 1 Report. Accessed from http://www.ipsos-mori.com/researchpublications/publications/1608/National-Cancer-Survivorship-Initiative-Wave-1-Evaluation.aspx on 9th February 2014.

IBM Corp, release., 2011. *IBM SPSS statistics for windows*, ver 20.0, NY: IBM Corp.

Information Services Division, Scotland., 2010. *Breast cancer statistics*. Edinburgh: NHS National Services Scotland. Accessed from

http://www.isdscotland.org/Health-Topics/Cancer/Cancer-Statistics/Breast/ on 25th January 2014.

Ingram, R., 1998. Power analysis and sample size estimation. *NT Research*, **3** (2) pp.132-138.

Isasi, C, R., Moadel, R,M., Donald Blaufox, M., 2005. A meta-analysis of FDG-PET for the evaluation of breast cancer recurrence and metastases. *Breast Cancer Research and Treatment*, **90** pp.105-112.

Jadad, A., 1998. *Randomised controlled trials: a user's guide*. London: British Medical Journal.

Judkins, A.F., Peterson, S.K. & Singletary, E.S., 1996. Satisfaction of breast cancer patients with a nonphysician-provider model of long term follow-up care. *Breast disease*, **9** (3) pp.139-144.

Karakoyun-Celik, O., Gorken, I., Sahin, S., Orcin, E., Alanyali, H. & Kinnay, M., 2010. Depression and anxiety levels in woman under follow-up for breast cancer: relationship to coping with cancer and quality of life. *Medicine oncology*, **27** (1) pp.108-113.

Kimman, M.L., Benedict, G.C., Boersma, L.J., Lambin, P. & Dirksen, C.D., 2010. Follow-up after treatment for breast cancer: one strategy fits all? An investigation of patient preferences using a discrete choice experiment. *Acta oncologica*, **49** (3) pp.328-337.

Kimman, M.L., Voogd, A.C., Dirksen, C.D., Falger, P., Hupperets, P., Keymeulen, K., Hebly, M., Dehing, C., Lambin, P. & Boersma, L.J., 2007. *Improving the quality and efficiency of follow-up after curative treatment for breast cancer – rationale and study design of the MaCare trial*. Accessed from http://www.biomedcentral.com/1471-2407/7/1 on 25th January 2014.

Kimman, M,L., Dirken, C,D., Voogd, A, C., Falger, P., Gijsen, B,C,M., Thuring,M., Lenssen, A., van der Ent, F., Verkeyn, J., Haekens, P., Hupperets, P., Nuytinck, J,K,S., van Riet, Y., Brenninkmeijer, S,J., Scheijmans, L,J,E,E., Kessels, A., Lambin, Ph., Boersma,L,J., 2011. Nurse-led telephone follow-up and an educational group programme after breast cancer treatment: Results of a 2x2 randomised controlled trial. *European Journal of Cancer*, **47** pp.1027-1036.

Knobf, M.T., 2001. The menopausal symptom experience in young mid-life women with breast cancer. *Cancer nursing*, **24** (3) pp.201-211.

Knobf, M,T., 2007. Psychosocial responses in breast cancer survivors. *Seminars in Oncology Nursing*, **23** (1) pp.71-83.

Koinberg, I.L., Engholm, G.B., Genell, A. & Holmberg, L., 2009. A health economic evaluation of follow-up after breast cancer surgery: results of an RCT study. *Acta oncologica*, **48** (1) pp.99-104.

Koinberg, I.L., Fridlund, B., Engholm, G.B. & Holmberg, L., 2004. Nurse-led follow-up on demand or by a physician after breast cancer surgery: a randomized study. *European journal of oncology nursing*, **8** (2) pp.109-117.

Lancaster, G.A., Dodd, S. & Williamson, P.R., 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*, **10** (2) pp.307-312.

Lee, T,S., Kilbreath, S,L., Refshauge, K, M., Herbert, R,D., Beith, J,M., 2008. Prognosis of the upper limb following surgery and radiation for breast cancer. *Breast Cancer Research Treatment*, **110** pp. 19-37.

Leining, M.G,. Gelber, S., Rosenberg, R., Przypyszny, M., Winer, E.P., Partridge A.H, (2006) Menopausal-type symptoms in young breast cancer survivors. *Annals Oncology*. **17** (12) pp.1777-82.

Lindop, E. & Cannon, S., 2001. Evaluating the self-assessed support needs of women with breast cancer. *Journal of advanced nursing*, **34** (6) pp.760-771.

Lipscomb, M., 2012. Questioning the use value of qualitative research findings. *Nursing philosophy*, **13** (2) pp.112–125.

Loftus, L.A. & Weston, V., 2001. The development of nurse-led clinics in cancer care, *Journal of clinical nursing*, **10** (2) pp.215-220.

Maddams, J., Brewster, D., Gavin, A., Stewart, J., Elliott, J., Utley, M. & Moller, H., 2009. Cancer prevalence in the United Kingdom: estimates 2008. *British Journal of Cancer*, **101** (3) pp.541-547.

Maguire,G,P., Lee, E,G., Bevington, D,J.,Kuchemann, C,S., Crabtree, R,J., Cornell, C,E., 1978. Psychiatric problems in the first year after mastectomy. *British Medical Journal*, **1** pp. 963-965.

Maguire, P., Brooke, M., Tait, A., Thomas, C. & Sellwood, R., 1983. The effect of counselling on physical disability and social recovery after mastectomy. *Clinical oncology*, **9** (4) pp.319-324.

Mann, E., Smith, M,J., Hellier, J., Balabanovic, J,A., Hamed, H., Grunfeld, E., Hunter, S., 2012. Cognitive behavioural treatment for women who have menopausal symptoms and breast cancer treatment, MENO1: a randomised controlled trial., 2012. *Lancet Oncology*, **13** pp. 309-318.

Manley, K. & McCormack, P., 2008. Person-centred care. *Nursing management*, **15** (8) pp.12-13.

Mansel, R,E., Fallowfield, L., Kissin, M., Goyal, A., Newcombe, R, G., Dixon, M, J., Yiangou, C., Horgan, K., Bundred, N.,Monypenny, I., England, D., Sibbering, M., Abdullah, T, L., Barr, L., Chetty, U., Sinnett, D, H., fleisig, A., Clark, D., Ell, P,J., 2006. Randomized multicenter Trial of Sentinel node biopsy versus standard axillary treatment in operable breast cancer: The

ALMANAC TRIAL. *Journal of the National Cancer Institute* **98** (2) pp.599-609.

Mantzoukas, S., 2008. A review of evidence-based practice, nursing research and reflection: leveling the hierarchy. *Journal of clinical nursing*, **17** (2) pp.214-223.

Marx, K., 1964. Precapitalist economic formations….Translated….by Jack Cohen. London: Lawrence & Wishart.

Maslow, A., 1943. A theory of human motivation. *Psychology review*, **50** (1943) pp.370-396.

Maslow, A,H., 1987. The theory of human motivation. **In**: Maslow, A,H., *Motivation and personality 3rd* ed. London: Harper & Row. Chapter 2 pp. 15-31

Matterella, A., 2010. Breast cancer in men. *Radiologic technology*, **8** (4) pp.361-378.

Maynard, A., 1999. Commentary: clinical governance: the unavoidable economic challenges. *Nursing times research*, **4** (3) pp.189-191.

McArdle, J,M., Hughson, A,V,M., McArdle, C,S.,Smith, C., 1990. Reduced psychological morbidity after breast conservation. *British Journal of Surgery,* **77** pp. 1221-1223.

McCaughan, E. & McSorley, O., 2007. Consumers' and professionals' perceptions of a breast cancer review clinic. *Journal of advanced nursing*, **60** (4) pp.419-426.

McCowan, C., Wang, S., Thompson, A, M., Makubate, B., Petrie, D, J., 2013. The value of high adherence to Tamoxifen in women with breast cancer: a community based cohort study. *British Journal of Cancer*, **109** pp.1172-1180.

McDowell, M.E., Occhipinto, S., Ferguson, M., Dunn, J. & Chambers, S.K., 2010. Predictors of change in unmet supportive care needs in cancer. *Psycho-oncology*, **19** (5) pp.508-516.

McIntosh, J., Fowler, C.A., 2011. Patient satisfaction with nurse-led follow-up for breast cancer: A questionnaire study. *The Breast Journal*, **17** (2) pp.213-214.

McKinley, E.D., 2000. Under toad days: surviving the uncertainty of cancer recurrence. *Annals of internal* medicine, **133** (60) pp.479-480.

McLachlan, S-A., Allenby, A., Mathews, J., Wirth, A., Kisane, D., Bishop, M., Beresford, J. & Zalcberg, J., 2001. Randomized trial of coordinated psychosocial interventions based on patient self-assessments versus standard care to improve the psychosocial functioning of patients with cancer. *Journal of clinical oncology*, **19** (21) pp.4117-4125.

McPhail, G., 1999. Menopause as an issue for women with breast cancer. *Cancer nursing*, **22** (2) pp.164-171.

Medical Research Council, 2000. *A framework for the development and evaluation of RCT's for complex interventions to improve health*. London: Medical Research Council.

Millar, K., Purushotham, A.D., McLatchie, E., George, W.D. & Murray, G.D., 2005. A 1-year prospective study of individual variation in distress, and illness perceptions, after treatment for breast cancer. *Journal of psychosomatic research*, **58** (4) pp.335-342.

Minstrel, M., Winzenberg, T., Rankin, N., Hughes, C. & Walker, J., 2008. Supportive care of rural women with breast cancer in Tasmania, Australia: needs over time. *Psycho-oncology*, **17** (1) pp.58-65.

Mitchell, A, J., Kaar, S., Coggan,C., Herdman, J., 2008. Acceptability of common screening methods used to detect distress & related mood disorders – preferences of cancer specialists and non-specialists, *Psycho-Oncology*, **17** pp. 226-236.

Mohler, R., Bartoszek, G., Kopke, S. & Meyer, G., 2010. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development. *International journal of nursing studies*, **49** (1) pp.40–46.

Molino, A., 2008. What is the best follow-up methodology in early breast cancer? *The breast*, **17** (1) pp.1-2.

Montazeria, A., Gillies, R., McEwen, J., 1996. Measuring quality of life in oncology: is it worthwhile? 1. Meaning, purpose and controversies, *European. Journal of Cancer*, **5** pp.159-67.

Montgomery, D.A., Krupa, K. & Cooke, T.G., 2007. Follow-up in breast cancer: does routine clinical examination improve outcome? A systematic review of the literature. *British journal of cancer*, **97** (12) pp.1632-1641.

Montgomery, D.A., Krupa, K., Wilson, C. & Cooke, T.G., 2008. Patients' expectations for follow-up in breast cancer – a preliminary, questionnaire-based study. *The breast*, **17** (4) pp.347-352.

Moss, L.S., Starbuck, M.F., Mayer, D.K., Harwood, E.B. & Glotzer, J., 2009. Trastuzumab-induced cardiotoxicity. *Oncology nursing forum*, **36** (6) pp.676-685.

Nagel, G.C., Schmidt, S., Strauss, B.M. & Katenkamp, D., 2001. Quality of life in breast cancer patients: a cluster analytic approach. Empirically derived subgroups of the EORTC-QLQ BR 23: a clinically oriented assessment. *Breast cancer research and treatment*, **68** (1) pp.75–87.

Nail, L, M., 2006. Cognitive changes in cancer survivors. *American Journal of Nursing*, **106** (3) (suppl) pp. 48-54.

National Breast Cancer Centre., 2005. *Specialist breast care nurse competency standards and educational requirements*. Australia: National Breast Cancer Centre.

National Cancer Intelligence Network., NCIN., 2011. The Second All Breast Cancer Report. NCSI.

National Cancer Comprehensive Network., NCCN, 2003. Distress Management Guidelines. *Journal National Comprehensive Cancer Network*, **1** (3) pp. 344-74.

National Comprehensive Cancer Network., 2014. *Practice guidelines in oncology* (NCCN Guidelines Breast Cancer v1.2014). Accessed from http://www.nccn.org/professionals/physician_gls/f_guidelines_nojava.asp# site on 25th January 2014.

National Cancer and Survivorship Initiative., 2014. Accessed from http://www.ncsi.org.uk/ on 18th February.

National Institute for Clinical Excellence (NICE), 2004. *Guidance on cancer services – improving outcomes in breast cancer.* Accessed from http://www.nice.org.uk/pdf/Improving_outcomes_breastcancer_manual.pdf on 25th January 2014.

National Institute for Clinical Excellence (NICE), 2009. *Early and locally advanced breast cancer: diagnosis and treatment* (NICE Guideline: CG80). Cardiff: National Collaborating Centre for Cancer. Accessed from http://www.nice.org.uk/CG80 on 25th January 2014.

Neal, A.J. & Hoskins, P.J., 2009. Breast cancer. In: Neal, A.J. & Hoskins, P.J., 2003. *Clinical oncology: basic principles and practice*. 4th ed. London: Hodder Arnold. pp. 89-115.

NHS Education for Scotland., 2014.Person centred care accessed from http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-improvement/current-health-improvement-work/person-centredness.aspx on 18th February 2014.

NHS Information Centre for health and social care. 2011. National Mastectomy and breast reconstruction audit. Leeds: The NHS Information Centre.

NHS Improving Quality., 2014. Accessed from http://www.nhsiq.nhs.uk/ on 20th February 2014.

Nordman, I.C., Dalley, D.N., 2008. Breast cancer in men - should aromatase inhibitors become first line hormonal treatment? *The breast*, **14** (6) pp.562-569.

Noseworthy, J, H., Ebers, G, C., Vandervoort, M, K., Farquhar, R, E., Yetisir, E., Roberts, R., 1994. The impact of blinding on the results of a randomised, placebo-controlled multiple sclerosis clinical trial. *Neurology*, **44**, pp.16-20.

Nursing and Midwifery Council.,2008. NMC code of professional conduct: standards for conduct, performance and ethics. Accessed from http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/ on 7th February 2014.

Nursing and Midwifery Council.,2007. NMC Record Keeping guidance. Available from http://www.nmc-uk.org/Publications/Guidance/ on 7th February 2014.

Nursing and Midwifery Council., 2006a. Confidentiality. Available from http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-

practice/Regulation-in-Practice-Topics/Confidentiality/ on 7th February 2014.

Nursing and Midwifery Council., 2006b. Consent. Available from: http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Regulation-in-Practice-Topics/consent/ on 7th February 2014.

O'Cathain, A., Murphy, E. & Nicholl, J., 2008. The quality of mixed methods studies in health services research. *Journal of health services research & policy*, **13** (2) pp.92-98.

Office for National Statistics., 2008. *Cancer statistics registrations: registrations of cancer diagnosed in 2005, England* (Series MB1 number 36). London: Office for National Statistics.

Osaba, D., Bezak, A., Brundage, M., Zee, B., Dongsheng, T., Pater, J., for the quality of life committee of the NCIC CTG., 2005. Analysis and interpretation of health-related quality of life data from clinical trials: basic approach of the National Cancer Institute of Canada Clinical Trials Group. *European Journal of Cancer*, **41** pp. 280-287.

Osborne, R,H., Elsworth, G,R., Sprangers, M,A,G., Oort, F,J., Hopper, J,L., 2004. The value of the Hospital Anxiety and Depression Scale (HADS) for comparing women with early onset breast cancer with population-based reference women. Quality of Life Research, **13** pp.191-206.

Oxlad, M., Wade, T.D., Hallsworth, L.B. & Koczwara, B., 2008. "I'm living with a chronic illness, not . . . dying with cancer": a qualitative study of Australian women's self-identified concerns and needs following primary treatment for breast cancer. *European journal of cancer care*, **17** (2) pp.157-166.

Palacios, S., Henderson, V., Siseles, N., Tan, D. & Vilaseca, P., 2010. Age of menopause and impact of climacteric symptoms by geographical region.

Climateric: The Journal of the International Menopause Society, **13** (5) pp.419-428.

Parahoo, K., 1997. *Nursing research, principles, process and issues*. London: Macmillan.

Palmieri, C., Patten, D, K., Januszewski, A., Zucchini, G., Howell, S.J., 2014. Breast cancer: current and future endocrine therapies. *Mollecular and Cellular Endocrinology*, **381** (1) pp.695-723.

Patterson, S., Mairs, H., Borschmann, R., 2011. Successful recruitment to trials: a phased approach to opening gates and building bridges. *BMC Medical Research Methodology*, **11** pp.. 1-6.

Pelusi, J., 2006. Sexuality and Body Image: Research on breast cancer survivors documents altered body image and sexuality. *Cancer Nursing*, Supplement: **29** (2) pp. 32-38.

Pennery, E. & Mallet, J., 2000. A preliminary study of patients' perceptions of routine follow-up after treatment for breast cancer. *European journal of oncology nursing*, **4** (3) pp.138-47.

Perera, R., Heneghan, C. & Yudkin, P., 2007. Graphical method for depicting randomised trials of complex interventions. *British medical journal*, **334** (7585) pp.127-129.

Perreault, A., & Fothergill Bourbonnais, F., 2005. The experience of suffering as lived by women with breast cancer. *International Journal of Palliative Nursing*, **11** (10) pp. 510-519.

Pestalozzi, B.C., Luporsi-Gely, E., Jost, L.M. & Bergh, J., 2005. ESMO minimum clinical recommendations for diagnosis, adjuvant treatment and follow-up of primary breast cancer. *Annals of oncology*, **16** (suppl. 1) pp.i7-i9.

Pinto, A,C., de Azambuja E., 2011. Improving quality of life after breast cancer: Dealing with symptoms. *Maturitas*, **70** pp. 343-348

Plant, R., Lesser, H., Taylor-Gooby, P., 1980. *Political philosophy and social welfare: essays on the basis of welfare provision*. London: Routledge & Kegan Paul.

Pluye, P., Gagnon, M-P., Griffiths, F. & Johnson-Lafleur, J., 2009. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in mixed review studies. *International journal of nursing studies*, **46** (4) pp.529-546.

Polit, D.E. & Beck, C.T., 2004. *Nursing research principles and methods*. 7th ed. Philadelphia: Lippincott Williams and Wilkins.

Polit, D.F. & Sherman, R.E., 1990. Statistical power in nursing research. *Nursing research*, **39** (6) pp.365-369.

Poole, K. & Jones, A., 1996. A re-examination of the experimental design for nursing research. *Journal of advanced nursing*, **24** (1) pp.108-114.

Raupach, J. & Hiller, J.E., 2002. Information and support for women following the primary treatment of breast cancer. *Health expectations*, **5** (4) pp.289-301.

Reddy, M. & Given-Wilson, R., 2006. Screening for breast cancer. *Women's health medicine*, **3** (1) pp.22-27.

Richardson, A., Medina, J. & Brown, V., 2007. Patients' needs assessment in cancer care: a review of assessment tools. *Cancer*, **15** (10) pp.1125-1144.

Roche, N., 2006. Follow-up after treatment for breast cancer in young women with breast cancer. *The breast*, **15** (suppl. 2) pp.S71-S75.

Rojas, M.P., Telaro, E., Russo, A., Moschetti, I., Coe, L., Fossati, R., Palli, D., Roselli del Turco, M. & Liberati, A., 2009. *Follow-up strategies for women treated for early breast cancer*. Cochrane Database of Systematic Reviews (4). Accessed from http://dx.doi:10.1002/14651858.CD001768.pub2 on 10th July 2013.

Roger, A., Stebbing, J., Thompson, M., 2006. Breast Cancer (non-metastatic). *Clinical Evidence*, **15**, pp.1-34.

Rose, P,W., & Watson,E., 2009. What is the value of routine follow-up after diagnosis and treatment of cancer? British Journal of General Practice, 59 (564) pp. 482-483.

Royal College of Nursing, 2007. *Clinical standards for working in a breast specialty: RCN guidance for nursing staff*. Accessed from http://www.rcn.org.uk/publications on 9th February 2014.

Rutgers, E.J., 2004. Follow-up in breast cancer. *Expert review of anti-cancer therapy*, **4** (2) pp.212-218.

Ryan, L., Golden, A., 2006. 'Tick the box please': A reflexive approach to doing quantitative social research. *Sociology*, **40** (6) pp.1191-1200.

Sakorafas, G.H., Tsiotou, A.G. & Pavlakis, G., 2000. Follow-up after primary treatment for breast cancer. *Acta oncologica*, **39** (8) pp.935-940.

Sanson-Fisher, R.W., Carey, M. & Paul, C., 2009. Measuring unmet needs of those with cancer: a critical overview. *Cancer forum*, **33** (3) pp.198-201.

Sanson-Fisher, R., Girgis, A., Boyes, A., Bonevski, B., Burton, L., Cook, P. and the Supportive Care Review Group, 2000. The unmet supportive care needs of patients with cancer. *Cancer*, **88** (1) pp.226–237.

Schipper, H., Clinch, J., McMurray, A. & Levitt, M., 1984. Measuring the quality of life of cancer patients: the functional living index – Cancer: development and validation. *Journal of clinical oncology*, **2** (5) pp.472-483.

Schmid-Buchi, S., Halfens, R.J.G., Dassen, T. & van den Borne, B., 2008. A review of psychosocial needs of breast cancer patients and their relatives. *Journal of clinical nursing*, **17** (21) pp.2895-2909.

Schwartz, C.E., Mirjam, S. & Spranger, A.J., 2002. An introduction to QOL instruments in oncology: the value of measuring patient-reported outcomes. *The American journal of managed care*, **8** (18) pp.S550-S559.

Scottish Cancer Advisory Network, 2009. Accessed from http://www.scan.scot.nhs.uk/HealthProfessionals/Pages/default.aspx on 25th January 2014.

Scottish Executive., 2004. *Knowledge and Skills Framework*. Edinburgh, Department of Health.

Scottish Executive., 2006.*Radiotherapy activity planning for Scotland 2011-2015*. Edinburgh: NHS Scotland.

Scottish Government., 2008. *Better Cancer Care, An action plan*. Edinburgh: Scottish Government.

Scottish Government., 2009. *Cancer waiting times*. Accessed from http://www.scotland.gov.uk/News/Releases/2012/03/cancer-waiting-times-27032012 on 25th January 2014.

Scottish Government.,2010a. *The Healthcare Quality Strategy for NHSScotland*, Edinburgh: Scottish Government.

Scottish Government.,2010b. *Better Cancer Care Progress report*. Edinburgh: Scottish Government. Accesed from http://www.scotland.gov.uk/Topics/Health/Services/Cancer/Progress-Report-2010 on 22nd January 2014.

Scottish Government, 2012. Scottish index of multiple deprivation. Accessed from http://simd.scotland.gov.uk/publication-2012/ 9th February 2014.

Scottish Government, 2013. Transforming care after treatment. Accessed from http://www.scotland.gov.uk/Topics/Health/Services/Cancer/TCAT on 9th February 2014.

Scottish Intercollegiate Guideline Network., 2005. Management of breast cancer in women: a national guideline. (Guideline 84).

Scottish Intercollegiate Guideline Network, 2013. *Management of primary breast cancer*. Edinburgh: SIGN [SIGN Guideline: 134]. Accessed from http://www.sign.ac.uk/pdf/SIGN134.pdf on 25th January 2014.

Senn, H-J., 2006. Significance and usefulness of guidelines. *Breast care*, **1** (4) pp.220-222.

Shapiro,C,L., Recht, A., 2001.Side effects of adjuvant treatment of breast cancer. *The New England Journal of Medicine,* **344** (26) pp.1997-2009.

Sheppard, C., 2007. Breast cancer follow up: literature review and discussion. *European journal of oncology nursing*, **11** (4) pp.340-347.

Sheppard, C., Higgins, B., Wise, M., Yiangou, D., Dubois, D. & Kilburn, S., 2009. Breast cancer follow-up: a randomised controlled trial comparing point of need access versus routine 6-monthly clinical review. *European journal of oncology nursing*, **13** (1) pp.2-8.

Shuldham, C. & Hiley, C., 1997. Randomized controlled trials in clinical practice: the continuing debate. *NT research*, **2** (2) pp.128-135.

Shultz, P.N., Klein, M.J., Beck, M.L., Stava, C. & Sellin, R.V., 2005. Breast cancer: relationship between menopausal symptoms, physiologic health effects of cancer treatment and physical constraints on quality of life in long-term survivors. *Journal of clinical nursing*, **14** (2) pp.204-211.

Sibbald, B. & Martin, R., 1998. Understanding controlled trials: why are randomised controlled trials important? *British medical journal*, **316** (7126) p.201.

Skills for Health., 2006. Accessed from http://www.skillsforhealth.org.uk/ on 4th March 2014.

Slamon, DJ., Clark, GM.,Wong, SA.,1987. Human breast cancer: Correlation of relapse and survival with amplification of HER-2/neu proto-oncogene. *Science,* **235** pp.177.

Sloan, J.A., Aaronson, N., Cappelleri, J.C., Fairclough, D.L. & Varricchio, C., 2002. Clinical significance consensus meeting group: assessing the clinical significance of single items relative to summated scores. *Mayo clinic proceedings*, **77** (5) pp.479-87.

Sprangers, M.A., Groenvold, M. & Arraras, J.I., Franklin, J., te Velde, A., Muller, M., Franzini, L., Williams, A., de Haes, H.C., Hopwood, P., Cull, A. & Aaronson, N.K., 1996. The European Organisation for Research and Treatment of Cancer breast cancer-specific quality-of-life questionnaire module: first results from a three country field study. *Journal of clinical oncology*, **14** (10) pp.2756-2768.

Stanton, A.L., 2006. Psychosocial concerns and interventions for cancer survivors. *Journal of clinical oncology*, **24** (32) pp.5132-5137.

Stegall Moss, L., Fields Starbuck, M., Mayer, D,K., Brooks Harwood, E., Glotzer, J., 2009. Trastuzumab-Induced Cardiotoxicity. *Oncology Nursing Forum*, **36** (96) pp. 676-685.

Stephenson, J. & Imrie, J., 1998. Why do we need randomised controlled trials to assess behavioural interventions? *British medical journal*, **316** (7131) pp.611-613.

Stricker, C.T., 2007. Endocrine effects of breast cancer treatment. *Seminars in oncology*, **23** (1) pp.55-70.

Thewes, B., 2000. *Development of a breast cancer survivor's module*. Unpublished MPsych thesis: University of Sydney, Australia.

Thewes, B., Butow, P., Girgis, A. & Pendlebury, S., 2004. The psychosocial needs of breast cancer survivors: a qualitative study of the shared and unique needs of younger versus older survivors. *Psycho-oncology*, **13** (5) pp.177-189.

Thewes, B., Meiser, B., Rickard, J. & Friedlander, M., 2003. The fertility- and menopause-related information needs of younger women with a diagnosis of breast cancer: a qualitative study. *Psycho-oncology*, **12** (5) pp. 500-511.

Thompson, C., 2004. Fortuitous phenomena: On complexity, pragmatic randomised controlled trials, and knowledge for evidence-based practice. *Worldviews on Evidence-based Nursing*, **1** pp.9-17.

Thompson, H.S., Littles, M., Jacobs, S. & Coker, C., 2006. Post-treatment breast cancer surveillance and follow-up care experiences of breast cancer survivors of African descent: an exploratory qualitative study. *Cancer nursing*, **29** (6) pp.478-486.

Thompson, A,M., Wells, M., 2006. *Surgery* **IN** Kearney, N., Richardson, A., *Nursing patients with cancer principles and practice.* Edinburgh: Elsevier Churchill Livingstone.

Tolaney, S. & Winer, P.E., 2007. Follow-up care of patients with breast cancer. *The breast*, **16** (3) pp.S45-S50.

Tomey, A.M. & Alligood, M.R., 2002. *Nursing theorists and their work*. St Louis, NO: Mosby.

Torgeson, D. & Roland, M.,1998. Understanding controlled trials: what is Zelen's design? *British medical journal*, **316** (7131) p.606.

Van der Groep, P., van der Wall, E. & van Diest, P., 2011. Pathology of hereditary breast cancer. *Cell biology*, **34** (2) pp.71-88.

van Hezewijk, M., van den Akker, M., van der Helde, C.J.H., Scholten, A.N. & Hille, E.T.M., 2012. Costs of difference follow-up strategies in early breast cancer: a review of the literature. *The breast*, **21** (6) pp. 693-700.

Vahdaninia, M., Omidvan,S., & Montazeri, A., 2009. What do predict anxiety and depression in breast cancer patients? A follow-up study. *Social psychiatry and psychiatric epidemiology*, **45** pp. 355-361.

Veronesi, U., Cascinelli, N,M., Bufalino, R.,1983. Risk of internal mammary lymph node metastases and its relevance on prognosis in breast cancer, *Annals of Surgery*,**198** pp.681-84.

Veronesi U., Viale, G., Rotmensz, N., Goldhirsh, A., 2006. Rethinking TNM : breast cancer TNM classification for treatment decision-making and research. *Breast*, **15** (1) pp. 3-8.

Velikova, G., Booth, L., Smith, A.B., Brown, P.M., Lynch, P., Brown, J.M. & Selby, P.J., 2004. Measuring quality of life in routine oncology practice improves

communication and well-being: a randomised controlled trial. *Journal of clinical oncology*, **22** (4) pp.714-724.

Vivar, C.G. & McQueen, A., 2005. Informational and emotional needs of long-term survivors of breast cancer. *Journal of advanced nursing*, **51** (5) pp.520-528.

Walshe, J.M., Dendulur,i N. & Swain, S.M., 2006. Amenorrhea in premenopausal women after adjuvant chemotherapy for breast cancer. *Journal of clinical oncology*, **24** (36) pp.1-11.

Watson, E.K., Rose, P.W., Neal, R.D., Hubert-Williams, N., Donnelly, P., Hubbard, G., Elliott, J., Campbell, C., Weller, D. & Wilkinson, C., 2012. Personalised cancer follow-up: risk stratification, needs assessment or both? *British journal of cancer,* **106** (9) pp.1-5.

Watson, M., Greer, S. & Rowden, L., 1991. Relationships between emotional control, adjustment to cancer and depression and anxiety in breast cancer patients. *Psychological medicine*, **21** (1) pp.51-57.

Watson, R., 2003. Scientific methods are the only credible way forward for nursing research. *Journal of advanced nursing*, **43** (3) pp.219–220.

Watson, R., 2012. Editorial: NHS Research Ethics Committees: for those protection? *Journal of clinical nursing*, **21** (15-16) pp.2097-2098.

Weaver, K. & Olson, J.K., 2006. Understanding paradigms used for nursing research. *Journal of advanced nursing*, **53** (4) pp.459-469.

Weigelt, B., Peterse, J.L. & van ’t Veer, L.J., 2005. Breast cancer mets: markers and models. *Cancer*, **5** (8) pp.591-602.

Welford, C., Murphy, K. & Casey, D., 2011. Demystifying nursing research terminology. Part 1. *Nurse researcher*, **18** (4) pp.38-43.

Wells, M., Williams, b., Treweek, S., Coyle, J., Taylor, J., 2012. Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. *Trials*, **13** 95. Accessed from http://www.trialsjournal.com/content/13/1/95 on 9th February 2014.

Welsh Cancer Intelligence and Surveillance Unit, 2008. *Cancer incidence in Wales*. Cardiff: Welsh Cancer Intelligence and Surveillance Unit.

Wen, K.Y. and Gustafson, D.H., 2004. Needs assessment for cancer patients and their families. *Health quality of life outcomes*, **2** (11) pp.1-12.

Wilkinson, J.E., 2011. Using qualitative methodologies to evaluate randomized controlled trials: an ontological and epistemological paradox or a pragmatic recognition that context matters? *Worldviews on evidence-based nursing*, **8** (2) pp.63-65.

World Health Organization Quality of Life Group., 1995. The World Health Organisation quality of life assessment (WHOQOL): Position paper from the World Health Organization. *Social Science & Medicine*, **42** (10) pp.1403-1409.

Zabora, J., 2001. The prevalence of psychological distress by cancer site. *Psych-oncology*, **10** (1) pp.19-28.

Zebrack, B.J., Ganz, P.A., Bernaards, C.A., Peterson, L. and Abraham, L., 2006. Assessing the impact of cancer: development of a new instrument for long-term survivors. *Psycho-oncology*, **15** (5) pp.407-421.

Zigmond, A.S. & Snaith, R.P., 1983. The hospital anxiety and depression scale. *Acta psychiatrica scandinavica*, **67** (6) pp.361-370.

Appendix 1: Researchers reflections of the research process

The researcher's experience of the field of breast cancer gave her a unique understanding of how the service operated and of the different staff members who may interact with the study participants. It also challenged her to develop objectivity as a researcher, so necessary in the research field. Wells *et al.* (2012) supports reflexivity within RCTs, suggesting it allows a greater understanding of the complexity and background activity which contextualises real-life situations. The researcher shares this view and that of Ryan & Golden, that "*reflexivity adds a necessary insight into the complex dynamics that do exist between researchers and participants in quantitative research'* (2006, p.1194). While some may suggest the use of reflexivity may challenge the validity of quantitative research, the researcher would contend it does the opposite: it provides openness about how, where and by whom the data were collected, firmly locating the researcher as a participant in the dynamic inter-relationship of the research process.

The researcher embarked on this research with a passion for the subject area following many years working in the field of breast cancer, surgical and chemotherapy services. This has kept her going. Balancing the demands of a full-time job as a lecturer, her part-time PhD study and family commitments were a constant challenge throughout the period, balancing tensions and difficulties in equal measure. The researcher once read that patience, flexibility and humility are important characteristics to a successful PhD: she would add perseverance.

Patience was required at the outset, balancing the needs of the clinical area where the study was to be undertaken and the time pressures of the PhD. Systems for identifying the participants for the study, the recruitment process and the intervention required careful negotiation and preparation, and as time passed, flexibility was required.

The researcher is an optimist and always considered the study was achievable. However, over time she underestimated the enormity of the task of running a complex RCT and working full-time. While she was able to keep all the balls juggling successfully the study proceeded well. Unfortunately, between November

2009 and October 2011 the researcher suffered a series of losses which included: her husband losing his job and relocating to Wales; both children leaving home; the sudden death of her father; and the deaths of two very close friends. While she does not wish to dwell on the detail of these losses, the cumulative emotional effect impacted on her ability to successfully juggle all the balls all of the time. This impacted solely on the distribution of the satisfaction with care questionnaires and therefore this data is not available, forming a deviation from the original protocol.

Recovery came and her optimism returned, aided by the enthusiasm of the SBCN, supervisors and the knowledge that the research would contribute to HCP's understanding of managing unmet need within a hospital follow-up setting.

The limitations and strengths associated with this study reflect the challenges experienced undertaking a complex intervention within a real clinic environment. There were both practical and methodological issues which, as a novice, the researcher was aware of at different stages in the research process.

From a practical perspective, identifying clinic space for the SBCN and support for her dictation following the clinic was a surprising obstacle. This was largely out of the researcher's control and while passionate about her study, it took time to negotiate as it was not a priority. Between the training of the nurse, delays in receiving ethical permission and this issue, recruitment did not begin until November 2008, two years and five months after the researcher's PhD started.

Despite having worked in the NHS for over 20 years, the researcher displayed a naivety in expecting that the electronic patient records to identify patients would be easy to navigate. They were difficult to use, compounded by the introduction of a new system half-way through the study period and recruitment process. This required each patient to be identified individually, their survival status established and study details sent to large numbers of women. This was hugely time consuming and on-going for 18 months. In hindsight, the paperwork should have been sent out at least 12 weeks prior to the clinic, and may have reduced the

numbers of patients contacting the researcher after they had received their follow-up and therefore ineligible to participate.

Randomisation, central to the mechanics of a trial, was decided prior to the study commencing, indeed great thought went into how this would occur and how blinding of participants could be maximised. While the system worked well, contacting potential participants, getting their agreement to participate, randomisation and re-scheduling clinics appointments took longer than first thought. This was further compounded because the researcher was not able to give 100% of her time to the study due to working full-time. However the learning curve has been steep and rewarding, her skills in the use of statistical packages and interpretation of statistics have, and will be hugely beneficial in the future. It has been quite a journey.

Appendix 2: Example of Medline search strategy (1996 - 2013)

1	exp Breast Neoplasm/
2	(breast$ or mammary$).tw.
3	(cancer or tumor$ or tumour$ or carcinoma$ or sarcoma$ or neoplasm$ or adenocarcinoma$ or metastasis or poly$).tw.
4	2 and 3
5	(breast adj mass).tw.
6	(cystosarcoma adj Phylloides tumour)>tw.
7	(carcinoma, intraductal, noninfiltrating).tw.
8	(paget's disease, mammary midline heading).tw.
9	Or/4-8
10	1 or 9
11	Exp Neoplasm Recurrence, Local/
12	Recur.tw.
13	relaps$.tw.
14	or/11-13
15	(patients$adj follow up).tw.
16	(surveillance adj patient$).tw.
17	Or/15-16
18	Exp Diagnostic imaging/
19	Magnetic resonance imaging.tw.
20	Positron emission tomography.tw.
21	Exp RADIOGRAPHY/
22	x-ray.tw.
23	ultraso$
24	mammogra$.tw.
25	or/18-24
26	10 and 17 and 24
27	10 and 14 and 24
28	10 and 17
29	or/26-28
30	Limit 29 to yr=1996-2013
31	from 30 keep 1-10
32	from 30 keep 1-200
	Nursing and follow-up
1	Exp Breast Cancer/
2	Follow.af.
3	1 and 2
4	Exp Cancer Services/exp cancer nursing/
5	4 and 2
6	3 or 5
	Needs assessment (major concept)
1	exp*Needs Assessment/4288
2	exp*neoplasms/
3	1 or 2
4	Limit 3 to yr=1993-2013
5	From 4

Appendix 3: Breast cancer needs questionnaire

In the last month, what was your level of need for help with:		**No need**		**Some need**		
		Not applicable	**Satisfied**	**Low need**	**Moderate need**	**High need**
1.	Coping with problems with your prosthesis	1	2	3	4	5
2.	Wanting more information about finding a good breast prothesis	1	2	3	4	5
3.	Wanting help in coping with the amount of breast that was removed	1	2	3	4	5
4.	Coping with changes to your self-image as a result of breast surgery	1	2	3	4	5
5.	Dealing with your partner's reaction to your breasts	1	2	3	4	5
6.	Coping with fear about the reaction of future partner's to your breasts.	1	2	3	4	5
7.	Coping with lymphoedema	1	2	3	4	5
8.	Coping with what having breast cancer might mean for your daughters or sisters	1	2	3	4	5
9.	Being informed about your daughters and/or sister's risk of developing breast cancer	1	2	3	4	5
10.	Dealing with lack of energy or tiredness	1	2	3	4	5
11.	Pain or discomfort in the arm near to your surgery	1	2	3	4	5
12.	Pain or discomfort in the area of your affected breast	1	2	3	4	5
13.	Dealing with menopausal symptoms, which have occurred as a result of your treatment	1	2	3	4	5
14.	Dealing with anger and confusion about why this has happened to you	1	2	3	4	5

15.	Dealing with fears about the cancer spreading or returning	1	2	3	4	5
16.	Trying to find meaning in this experience	1	2	3	4	5
17.	Coping with changes to your usual routine and lifestyle	1	2	3	4	5
18.	Dealing with the impact of cancer on your career	1	2	3	4	5
19.	Accepting changes in your appearance	1	2	3	4	5
20.	Coping with changes in your sexuality or to your sexual relationships	1	2	3	4	5
21.	Finding assistance for your partner to come to terms with your cancer	1	2	3	4	5
22.	Coping with the impact your cancer is having on your relationship (both for you and/or your partner)	1	2	3	4	5
23.	Coping with changes with others attitudes and behaviour towards you	1	2	3	4	5
24.	Finding a support group which addresses your particular needs	1	2	3	4	5
25.	Meeting other breast cancer survivors who are your age	1	2	3	4	5
26.	Being informed about the possible effects of the cancer on the length of your life	1	2	3	4	5
27.	Being informed about the causes, preventions and treatment of lymphoedema	1	2	3	4	5
28.	Being informed about the latest developments in treatment and prevention of breast cancer	1	2	3	4	5
29.	Being informed about insurance issues	1	2	3	4	5
30.	Being informed about the impact of cancer treatment on your	1	2	3	4	5

	fertility					
31.	Being informed about the causes and possible triggers of breast cancer	1	2	3	4	5
32.	Being informed about the impact of the cancer or treatment on your ability to breast-feed children	1	2	3	4	5
33.	Being informed about using contraception following treatment	1	2	3	4	5
34.	Receiving information and advice about your diet	1	2	3	4	5
35.	Receiving information which is specific to women of your age	1	2	3	4	5
36.	Feeling able to ask your cancer specialists for information about a range of issues not just medical issues	1	2	3	4	5
37.	Having one doctor who knows all about your condition, treatment and follow-up	1	2	3	4	5
38.	Being able to negotiate with your specialists about the frequency or length of follow-up appointments	1	2	3	4	5
39.	Being able to negotiate with your specialists about the location of your follow-up appointments (eg whether the appointments occur at the treatment centre or in a separate clinic)	1	2	3	4	5
40.	Having access to health professionals (eg. general practitioners, dieticians, physiotherapists) who specialise in dealing with people who are cancer survivors (or people who are recovering from cancer)	1	2	3	4	5

Centre for Health Research & Psycho-oncology (2003) Recent Survivors of Breast Cancer Survey.

Appendix 4: HADS

HAD Scale

SC

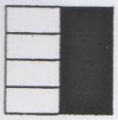
Name:

Date:

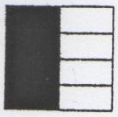
Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.
This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.
Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

I feel tense or 'wound up':
- Most of the time .....
- A lot of the time .....
- Time to time, Occasionally .....
- Not at all .....



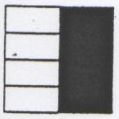
I still enjoy the things I used to enjoy:
- Definitely as much .....
- Not quite so much .....
- Only a little .....
- Hardly at all .....



I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly .....
- Yes, but not too badly .....
- A little, but it doesn't worry me .....
- Not at all .....

I can laugh and see the funny side of things:
- As much as I always could .....
- Not quite so much now .....
- Definitely not so much now .....
- Not at all .....

Worrying thoughts go through my mind:
- A great deal of the time .....
- A lot of the time .....
- From time to time but not too often ...
- Only occasionally .....

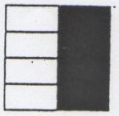


I feel cheerful:
- Not at all .....
- Not often .....
- Sometimes .....
- Most of the time .....

I can sit at ease and feel relaxed:
- Definitely .....
- Usually .....
- Not often .....
- Not at all .....

I feel as if I am slowed down:
- Nearly all the time .....
- Very often .....
- Sometimes .....
- Not at all .....

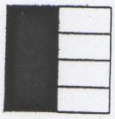
I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all .....
- Occasionally .....
- Quite often .....
- Very often .....



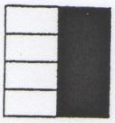
I have lost interest in my appearance:
- Definitely .....
- I don't take so much care as I should.....
- I may not take quite as much care .....
- I take just as much care as ever .....

I feel restless as if I have to be on the move:
- Very much indeed .....
- Quite a lot .....
- Not very much .....
- Not at all .....

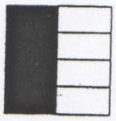
I look forward with enjoyment to things:
- As much as ever I did .....
- Rather less than I used to .....
- Definitely less than I used to .....
- Hardly at all .....



I get sudden feelings of panic:
- Very often indeed .....
- Quite often .....
- Not very often .....
- Not at all .....



I can enjoy a good book or radio or TV programme:
- Often .....
- Sometimes .....
- Not often .....
- Very seldom .....



Do not write below this line

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Appendix 5: EORTC QLQ C30 and BR23

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: _____

Your birthdate (Day, Month, Year): _____

Today's date (Day, Month, Year): 31 _____

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

ENGLISH

EORTC QLQ - BR23

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
31. Did you have a dry mouth?	1	2	3	4
32. Did food and drink taste different than usual?	1	2	3	4
33. Were your eyes painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you had any hair loss: Were you upset by the loss of your hair?	1	2	3	4
36. Did you feel ill or unwell?	1	2	3	4
37. Did you have hot flushes?	1	2	3	4
38. Did you have headaches?	1	2	3	4
39. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
40. Have you been feeling less feminine as a result of your disease or treatment?	1	2	3	4
41. Did you find it difficult to look at yourself naked?	1	2	3	4
42. Have you been dissatisfied with your body?	1	2	3	4
43. Were you worried about your health in the future?	1	2	3	4

During the past four weeks:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
44. To what extent were you interested in sex?	1	2	3	4
45. To what extent were you sexually active? (with or without intercourse)	1	2	3	4
46. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	1	2	3	4

Please go on to the next page

During the past week:	Not at All	A Little	Quite a Bit	Very Much
47. Did you have any pain in your arm or shoulder?	1	2	3	4
48. Did you have a swollen arm or hand?	1	2	3	4
49. Was it difficult to raise your arm or to move it sideways?	1	2	3	4
50. Have you had any pain in the area of your affected breast?	1	2	3	4
51. Was the area of your affected breast swollen?	1	2	3	4
52. Was the area of your affected breast oversensitive?	1	2	3	4
53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	1	2	3	4

Appendix 6: Key Instruments used in Health related quality of life research in breast cancer										
Type of construct measured	**EORTC QLQ-C30**	**EORTC BR-23**	**FACT-G**	**FACT-B**	**CARES**	**POMS**	**HADS**	**SF-36**	**FLIC**	**RSCL**
Physical functioning	5		2		4			10		4
Role - physical	2		3		7			5	4	4
Mental Health										
Psychological								3	4	8
distress/adjustment	4	1	7	2	5					
anxiety						9	7			
depression						15	7			
anger-hostility						12				
anxiety re cancer, treatment		1			4				2	
anxiety in medical situations					8					
psychological well-being								2		
role-emotional			2		2			3		
social	2		6		14			2	2	
energy/fatigue	3		1		3	15		4		2
cognitive	2				3	7				
sleep	1		1		1					2
pain	2		1		4			2		1
general health/global QOL	2	1	6	1				4	3	
Health change								1	2	
body image		2		1	3					
sexual interest, function/attractiveness		5	1	2	8					1
clothing					3					
nausea/vomiting	2		2		6				2	2
hair loss		2		1	1					1
appetite/taste/dry mouth/swallowing	1	2			3					1
other GI symptoms	2				1					3
shortness of breath	1			1						1
arm symptoms		3		1						
breast symptoms		4								
hot flashes		1								
ostomy/prosthesis problems					2					
other physical symptoms		1			4					8
medical interaction			2		11					
patient compliance					4					
relationship with partner					18					
interaction with children					3					
dating problems					5					
employment concerns					7					
hardship due to cancer (self)	1				3				1	
hardship (family)									2	
Not scored						7				
Total items	30	23	34	10	139	65	14	36	22	38

Appendix 7: Data collection sheet

Demographic and clinical characteristics of the participants in the study

Age	
Surgery	Mastectomy
	Wide local excision
Axillary surgery	Sample
	Clearance
	Sentinal node biopsy
Reconstruction	Yes/no
Time since diagnosis	
Side of primary	Left
	Right
Pathological tumour size	0-0.9
	1.0-1.9
	2.0-2.9
	>3.0
Tumour grade	1
	2
	3
	Unknown
Histological type	ductal
	Lobular
	Not reported
Node status	Positive
	negative
	unknown
Her2 status	Positive
	Negative
	Unknown
ER status	Positive
	Negative
	Unknown
Adjuvant treatment	None
	Endocrine therapy
	Chemotherapy
	Radiotherapy
	Herceptin

Appendix 8: Letter of invitation to take part in the study

Dear ……

You have an appointment to attend St John's Hospital Breast Clinic in the next few weeks/months.

We have become aware that many questions can arise leading up to and during the follow-up clinic appointment and we want to improve the care we provide. We are therefore undertaking a research study during this period to look at different ways of providing follow-up care to patients, within the breast clinic.

Taking part in our research study would help us to improve our care and we would value your contribution. An information sheet about the study is provided.

If you would be interested in taking part, complete the tear off slip below and send back in the stamped addressed envelope to Napier University to Sue Cruickshank who is co-ordinating the study. Alternatively you can phone her on 0131 455 5705. A member of the research team will get back to you. This is not the consent form to participate in the study.

Yours Sincerely

Mr Mathew Barber, Consultant Surgeon
Dr Frances Yuille, Consultant Clinical Oncologist
Rosie Small, Breast Care Nurse Specialist
Sue Cruickshank, Researcher, Napier University

Name:

Contact Details:

I am interested in taking part in the follow-up study.

Appendix 9: Information for participants about the study

Follow-up of breast cancer patients: a randomised controlled trial of a nursing intervention

PATIENT INFORMATION SHEET

You are being invited you to take part in a research study. The study is being carried out by staff at Napier University, School of Nursing and the breast cancer team at St John's Hospital, West Lothian. Before you make a decision it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and discuss it with family, friends, your GP or the independent person if you wish. Please ask your doctor or nurse if there is anything you do not understand or if you want more information. Take your time to decide.

Why is the study being done?

Follow-up care has traditionally focused on the the chances of cancer returning. While this is very important, it does not always answer all the questions that women may have. Other research studies have found that nurses can provide useful follow-up care. This research aims to investigate whether offering women a chance to talk about the needs that are important to them, before they come to the clinic allows the time spent in the clinic to be more effective.

How was I selected?

You have been diagnosed with breast cancer and are being offered or have been having follow-up care

How will you get in touch with me?

The initial contact will be by your doctor or nurse. They will tell you about the study and if you agree, you will meet the researcher, Sue Cruickshank.

What am I being asked to do?

We want to compare two different ways of providing follow-up care to women following a diagnosis of breast cancer. Whichever one you are allocated, you will be asked to fill in some questionnaires about your concerns and your quality of life.

Follow-up by the doctor: This is the standard follow-up care offered at St Johns hospital and is in common use in most breast services. You will see a doctor at regular intervals, undergo a clinical examination and have a mammogram yearly. You will be asked to fill in some questionnaires before the clinic appointment and at regular intervals which will only be seen by the researcher.

Follow-up by the breast care nurse: You will see a breast care nurse, undergo a clinical examination and have a mammogram yearly. Plus, you will be asked to fill in some questionnaires prior to your appointment. This will give you an opportunity to describe your concerns. This information will be available to the

nurse during the clinic appointment and she will then put together a plan that best suits your needs. This may include referral to other health professionals, more information or some additional support. She will contact you a month later to see how you are getting on.

How will my follow-up be chosen?

Everyone who agrees to take part in this research study will be allocated to one of two groups. Every patient has an equal chance of being in each group. It is important that the two groups of patients are as similar to each other as possible. This is because we need to be sure that if one group fares better than the other, it is because of the follow-up, and not because the groups are different from each other in some way. The only way to make sure that the groups of patients are as similar as possible is to allocate patients to a group *at random.* A computer programme is used to make sure it is done properly. We do not use any information about you or your breast cancer to allocate you to one of the groups.

We will look at how both groups get on and compare them. This will tell us which way is better to provide follow-up care.

What if I do not wish to take part?

If you do not wish to take part in this research, you will be offered the usual follow-up care delivered by the doctor.

What will happen to me if I take part?

If you agree to take part in this research, you will be asked to fill in some questionnaires before coming to the clinic. Before every appointment you will be sent another one. You will also be asked to fill in some short questionnaire booklets asking about your quality of life and general health, before attending the follow-up appointment and then at 12 months

The information will be kept and analysed anonymously. However, if we find that those in the doctor group have scored a particularly high score on either, the

anxiety and depression scale then with your permission we will inform your doctor or GP.

If you decide to take part you are still free to withdraw at any time andwithout giving a reason. This will not affect the standard of care you receive.

What will happen to the results of the research study?

The results will be published in a professional journal. You will not be identified in any report or publication. We will write to you when the results are known to ask if you would like to see them. The letter will explain how to get a copy. The anonymous data or part of the data from the quality of life questionnaire will be passed onto the EORTC Quality of Life Group.

Confidentiality

Your medical notes will need to be seen by authorised members of the research team, so that they can collect and check information needed for this research study. Your name, date of birth and NHS number will be passed to the research nurse. You will be given a unique registration number, which will be used together with your initials and date of birth on forms that the Research Staff uses. All information about you will be treated as strictly confidential and nothing that might identify you will be seen by anyone else.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be asked to sign a consent form. You will be given a copy of the consent form to keep, together with this information sheet. Your GP will be told if you are taking part in this research, unless you specifically request that he/she is not told.

What are the benefits and risks of taking part?

We hope that the information we gain will benefit patients who attend follow-up in the future but here is no guarantee that you as an individual will benefit directly from taking part.

Thank you for reading this

Researcher

Susanne (Sue) Cruickshank
Lecturer in Cancer Nursing
School of Nursing, Midwifery and Social Care
Napier University
74 Canaan Lane
Edinburgh
EH9 2TB
Tel: 0131 455 5705 (answer phone)
Email: s.cruickshank@napier.ac.uk

If you wish to speak to someone independent of the research team you can contact:

Juliet MacArthur
Senior Nurse – Research
NHS Lothian
Western General Hospital
Crewe Road
Edinburgh
Tel: 0131 537 2090
Email: Juliet.MacArthur@luht.scot.nhs.uk

Appendix 10 - Consent form

Patient Identification Number for this study:

Consent Form for patients

Title of study: Follow up care of breast cancer patients: a randomised controlled trial of a nursing intervention

Name: _____

Address: _____

_____

I confirm I have read and understood the information

I confirm I have had an opportunity to ask questions and discuss the study before taking part.

I confirm that my participation is voluntary and that I am aware I may withdraw from the study at any point, without explanation and with no adverse affect to the care I receive

I understand that sections of my medical notes will be looked at by members of the research team.

I agree to take part in the above study

Name: _____ Date:_____

Signature: _____ Date: _____

Researcher's signature: _____ Date: _____

One copy to researcher, one copy for participant, 1 copy for hospital notes
The participants General Practitioner will be notified of inclusion in the study

Appendix 11: Exploratory factor analysis results of BCNQ: rotated component matrix

	Component*				
	1	2	3	4	5
Coping with the impact your cancer is having on your relationship (both for you and/or your partner)	.873				
Accepting changes to your appearance	.821				
Meeting other breast cancer survivors who are your age	.728			.330	
Coping with changes with others attitudes and behaviour towards you	.706	.500			
Coping with changes in your sexuality or to your sexual relationships	.696				
Finding assistance for your partner to come to terms with your cancer	.694	.306			
Coping with changes to your usual routine and lifestyle	.655	.470		.382	
Dealing with anger and confusion about why this has happened to you	.617	.549			
Coping with changes to your self-image as a result of breast cancer	.610	.439			
Dealing with fears about the cancer spreading or returning	.591	.379	.304		
Coping with fear about the reaction of future partner's to your breasts	.555		.319		
Dealing with the impact of cancer on your career	.517				
Being informed about using contraception following treatment	.501			.337	
Dealing with lack of energy or tiredness	.472	.461			
Being informed about the impact of the cancer treatment on your ability to breast-feed children					
Having one doctor who knows all about your condition, treatment and follow-up					
Being able to negotiate with your specialists about the frequency or length of follow-up appointments		.764			
Wanting more information about finding a good breast protesis		.685			
Coping with problems with your prosthesis		.681			
Having access to health professionals (eg general practitioners, dieticians. physiotherapists) who specialise in dealing with people who are cancer survivors (or people who are recovering from cancer)		.660		.426	

	Component*				
	1	2	3	4	5
Feeling able to ask your cancer specialists for information about a range of issues not just medical issues		.648			
Trying to find meaning in this experience	.581	.641			
Being able to negotiate with your specialists about the location of your follow-up appointments (e.g. whether the appointments occur at the treatment centre or in a separate clinic)		.618		.312	
Being informed about the possible effects of the cancer on the length of your life		.540		.343	
Wanting help in coping with amount of breast that was removed			.667		
Coping with lymphoedema			.659		
Pain or discomfort in the arm near to your surgery	.336		.637		
Pain or discomfort in the area of your affected breast	.400		.611		
Dealing with your partner's reaction to your breasts	.342		.578		
Being informed about the causes, preventions and treatment of lymphoedema		.433	.502	.330	
Dealing with menopausal symptoms, which have occurred as a result of your treatment			.404		
Receiving information which is specific to women of your age				.782	.312
Receiving information and advice about your diet				.731	
Being informed about the causes and possible triggers of breast cancer				.540	.491
Being informed about your daughters and/or sister's risk of developing breast cancer		.384		.448	
Coping with what having breast cancer might mean for your daughters or sisters					.882
Being informed about the impact of cancer treatment on your fertility					.864
Being informed about insurance issues	.481				.513
Being informed about the latest developments in treatment and prevention of breast cancer		.374	.418	.459	.470
Extraction Method: Principal Component Analysis Rotation Method: Varimax with Kaiser Normalization * Rotation converged in 12 iterations.					