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## Specialist breast care nurses for support of women with breast cancer (Review)

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## [Intervention Review]

# Specialist breast care nurses for support of women with breast cancer

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## ABSTRACT

### Background

Interventions by specialist breast cancer nurses (SBCNs) aim to support women and help them cope with the impact of the disease on their quality of life.

### Objectives

To assess the effects of individual interventions carried out by SBCNs on indicators of quality of life, anxiety, depression, and participant satisfaction.

### Search methods

In June 2020, we searched MEDLINE, Embase, CENTRAL (Trials only), Cochrane Breast Cancer Group's Specialist Register (CBCG SR), CINAHL, PsycINFO, World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and Clinicaltrials.gov.

### Selection criteria

We selected randomised controlled trials (RCTs) of interventions carried out by SBCNs for women with breast cancer, which reported indicators of quality of life, anxiety, depression, and participant satisfaction.

### Data collection and analysis

The certainty of the evidence was evaluated using the GRADE approach. A narrative description of the results including structured tabulation was carried out.

### Main results

We included 14 RCTs involving 2905 women. With the exception of one study (women with advanced breast cancer), all the women were diagnosed with primary breast cancer. Mean age ranged from 48 to 64 years.

### Psychosocial nursing interventions compared with standard care for women with primary breast cancer

Eight studies (1328 women, low-quality evidence) showed small improvements in general health-related quality of life or no difference in effect between nine weeks and 18 months. Six studies (897 women, low-quality evidence) showed small improvements in cancer-specific quality of life or no difference in effect between nine weeks and 18 months. Six studies (951 women, low-quality evidence) showed small improvements in anxiety and depression between nine weeks and 18 months. Two studies (320 women, low-quality evidence) measured satisfaction during survivorship; one study measured satisfaction only in the intervention group and showed high levels of satisfaction with care; the second study showed equal satisfaction with care in both groups at six months.

## Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer

Two studies (351 women, very-low quality evidence) measured general health-related quality of life. One study reported that psychological morbidity reduced over the 12-month period; scores were consistently lower in women supported by SBCNs alone compared to support from a voluntary organisation. The other study reported that at six months, women receiving psychosocial support by either SBCNs or psychologists clinically improved from "higher levels of distress" to "lower levels of distress".

One study (179 women, very-low quality evidence) showed no between-group differences on subscales at all time points up to six months measured using cancer-specific quality of life questionnaires. There were significant group-by-time changes in the global quality of life, nausea and vomiting, and systemic therapy side effects subscales, for women receiving psychosocial support by either SBCNs or psychologists at six months. There were improvements in other subscales over time in both groups. Systemic therapy side effects increased significantly in the psychologist group but not in the SBCN group. Sexual functioning decreased in both groups.

Two studies (351 women, very-low quality evidence) measured anxiety and depression. One study reported that anxiety subscale scores and state anxiety scores improved over six months but there was no effect on depression subscale scores in the SBCN group compared to the psychologist group. There was no group-by-time interaction on the anxiety and depression or state anxiety subscales. The other study reported that anxiety and depression scores reduced over the 12-month post-surgery period in the SBCN group; scores were consistently lower in women supported by SBCNs compared to support from a voluntary organisation.

## SBCN-led telephone interventions delivering follow-up care compared with usual care for women with primary breast cancer

Three studies (931 women, moderate-quality evidence) reported general health-related quality of life outcomes. Two studies reported no difference in psychological morbidity scores between SBCN-led follow-up care and standard care at 18 to 24 months. One trial reported no change in feelings of control scores between SBCN-led follow-up care and standard care at 12 months.

Two studies (557 women, moderate-quality evidence) reported no between-group difference in cancer-specific quality of life at 18 to 24 months. A SBCN intervention conducted by telephone, as a point-of-need access to specialist care, did not change psychological morbidity compared to routine clinical review at 18 months. Scores for both groups on the breast cancer subscale improved over time, with lower scores at nine and 18 months compared to baseline. The adjusted mean differences between groups at 18 months was 0.7 points in favour of the SBCN intervention ( $P = 0.058$ ). A second study showed no differences between groups for role and emotional functioning measured using cancer-specific quality of life questionnaires in a SBCN-led telephone intervention compared with standard hospital care, both with and without an educational group programme at 12 months. At 12 months, mean scores were 78.4 ( $SD = 16.2$ ) and 77.7 ( $SD = 16.2$ ) respectively for SBCN-led telephone and standard hospital follow-up. The 95% confidence interval difference at 12 months was -1.93 to 4.64.

Three studies (1094 women, moderate-quality evidence) reported no between-group difference in anxiety between 12 and 60 months follow-up. One of these studies also measured depression and reported no difference in depression scores between groups at five years (anxiety:  $RR\ 1.8$ ; 95%  $CI\ 0.6$  to  $5.1$ ; depression:  $RR\ 1.7$  95%  $CI\ 0.4$  to  $7.2$ ).

Four studies (1331 women, moderate-quality evidence) demonstrated high levels of satisfaction with SBCN-led follow-up care by telephone between 12 and 60 months.

## Psychosocial nursing interventions compared with usual care for women with advanced breast cancer

One study (105 women, low-quality evidence) showed no difference in cancer-specific quality of life outcomes at 3 months.

## Authors' conclusions

Evidence suggests that psychosocial interventions delivered by SBCNs for women with primary breast cancer may improve or are at least as effective as standard care and other supportive interventions, during diagnosis, treatment and survivorship. SBCN-led telephone follow-up interventions were equally as effective as standard care, for women with primary breast cancer.

## PLAIN LANGUAGE SUMMARY

### Specialist breast care nurses for supportive care of women with breast cancer

#### Review question

Which interventions carried out by specialist breast care nurses (SBCNs) improve quality of life outcomes for women with a diagnosis of breast cancer?

#### Why is this question important?

Breast cancer is a complex disease and the most common cancer among women globally. Survival has improved markedly over the last 20 years linked to treatment advances, improved screening and a multi-professional management approach. Breast cancer is not just a physical disease but also impacts on the psychological, emotional and social needs of an individual.

#### Specialist breast care nurses for support of women with breast cancer (Review)

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SBCNs are defined as nurses with 'advanced knowledge' who meet women at diagnosis and provide information and emotional support, patient advocacy, and continuity across the care pathway, seeking to address the multifactorial patient's needs. It is important to understand the effectiveness of these interventions which may include using a focussed intervention or the SBCN undertaking new roles within the multidisciplinary team.

### **How did we identify and evaluate the evidence?**

We searched the research literature for randomised controlled trials comparing a SBCN intervention with usual care or other supportive interventions. The primary outcome was quality of life and indicators assessed included general health-related quality of life, cancer-specific quality of life, anxiety and depression, and participant satisfaction. We summarised the evidence from all the studies and considered factors such as how the studies were conducted, and whether the results were consistent.

### **What did we find?**

We found 14 studies with a total of 2905 participants, and four ongoing studies. Thirteen studies involved women with primary disease and one study involved women with advanced disease (sometimes referred to as metastatic or secondary disease). We grouped the studies: psychosocial nursing interventions both in primary disease and in advanced disease and SBCN-led interventions delivering follow-up care.

#### **Psychosocial nursing interventions compared with standard care for women with primary breast cancer**

We included nine studies involving 1469 women. The studies tested different types of psychosocial interventions to improve quality of life such as anxiety, depression, distress, emotional and social functioning and physical symptoms; some of these studies measured outcomes up to 18 months using a range of different measurement tools. The evidence suggests that psychosocial interventions carried out by SBCNs for women with a primary diagnosis of breast cancer can improve quality of life and satisfaction with care.

#### **Psychosocial nursing interventions compared with standard care for women with advanced (metastatic) breast cancer**

There was only one study which showed that there was no difference in quality of life outcomes at three months following a brief psychosocial nursing intervention compared with standard care for 105 women with newly diagnosed advanced breast cancer.

#### **Specialist breast cancer nurse-led interventions delivering follow-up care for women with primary breast cancer**

We included four studies involving 1331 women that reported findings up to five years of follow-up. All four trials showed that SBCN-led follow-up care was equally as effective as standard care for women's quality of life and their satisfaction with care. Overall, the studies captured a specific time point in a person's care within a role that was multifactorial. No adverse effects or harms were reported. The evidence suggests that, when compared to usual care, SBCN interventions improve health-related quality of life, satisfaction with care, anxiety and depression. SBCN-led follow-up care interventions are equally as effective as usual care for women's quality of life and satisfaction of care. Overall, the quality of evidence ranged from a very low to moderate levels of certainty and we await the results of ongoing studies to strengthen our confidence in the findings.

There were no SBCN-led follow-up interventions for women with advanced breast cancer.

### **What does this mean?**

The evidence suggests that psychosocial interventions carried out by SBCNs for women with a primary diagnosis of breast cancer, may improve or are at least as effective as standard care for general health-related quality of life, cancer-specific quality of life, anxiety and depression outcomes and satisfaction with care. In future studies, the expertise of the SBCN needs to be better articulated for there to be a meaningful and successful translation to practice, and for SBCNs to have more impact in the area of psychosocial support. Qualification and training of the SBCN needs to be more clearly reported as well as the description of the intervention.

### **Study funding sources**

Two studies did not report on funding, eleven studies reported receiving funding from charities or government institutes, and one study reported that no funding had been received. Two studies reported on the role of the funders.

### **Search date**

11th June 2020.

## SUMMARY OF FINDINGS

### Summary of findings 1. Summary of findings

#### Psychosocial nursing interventions compared with standard care for women with primary breast cancer

**Patient or population:** women with primary breast cancer

**Settings:** hospital outpatients, specialist breast care units, community, surgical unit, medical oncology unit, home

**Intervention:** psychosocial nursing intervention

**Comparison:** standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Standard care	Psychosocial nursing intervention				
General health-related quality of life [assessed using a variety of scales, follow-up ranged between 9 weeks and 18 months]	not estimated	not estimated	Eight studies showed small improvements in general health-related quality of life or no difference in effect.	1328 (8 studies)	⊕⊕⊕⊖ <b>low</b> <sup>1</sup>	
Cancer-specific quality of life [assessed using a variety of scales, follow-up ranged between 9 weeks and 18 months]	not estimated	not estimated	Six studies showed small improvements in cancer-specific quality of life or no difference in effect.	897 (6 studies)	⊕⊕⊕⊖ <b>low</b> <sup>1</sup>	
Anxiety and depression [assessed using a variety of scales, follow-up ranged between 9 weeks and 18 months]	not estimated	not estimated	Six studies showed small improvements in anxiety and/or depression or no difference in effect. Four studies showed improvements in favour of the intervention group and two studies showed no difference between groups for anxiety or depression.	951 (6 studies)	⊕⊕⊕⊖ <b>low</b> <sup>1</sup>	

Service provision-patient perspective [follow-up ranged between 6 and 24 months]	not estimated	not estimated	Two studies showed satisfaction with psychosocial nursing interventions. One study measured satisfaction only in the intervention group and the second study compared satisfaction between the intervention and control group and showed no difference in satisfaction between groups.	320 (2 studies)	⊕⊕⊕⊕ <b>low</b> <sup>2</sup>
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\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Risk of bias and high risk of attrition bias

<sup>2</sup> High risk of attrition bias and imprecision

## Summary of findings 2. Summary of findings

### Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer

**Patient or population:** women with primary breast cancer

**Settings:** community, hospital (face-to-face and telephone)

**Intervention:** psychosocial nursing intervention

**Comparison:** other supportive care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Other supportive care	Psychosocial nursing intervention				

General health-related quality of life  [GHQ-28, IES, follow-up between 6 and 12 months]	not estimated	not estimated	<p>One study reported that psychological morbidity (GHQ-28) reduced over the 12-month period; scores were consistently lower in women supported by SBCNs alone compared to support from a voluntary organisation and compared to support from a voluntary organisation plus a SBCN (McArdle 1996).</p> <p>The other study reported that at six months, women receiving psychosocial support by either SBCNs or psychologists clinically improved from "higher levels of distress" to "lower levels of distress" on the 'intrusion' subscale of the IES. Intrusion and avoidance improved over time with clinical improvement in both groups. There was no group-by-time interaction (Arving 2007).</p>	351 (2 studies)	⊕⊕⊕⊕ <b>very low</b> 1
Cancer-specific quality of life  [EORTC QLQ-C30, EORTC- BR23, follow-up 6 months]	not estimated	not estimated	<p>One study showed no between-group differences on subscales at all time points up to six months (EORTC QLQ-C30, EORTC-BR23). There were significant group-by-time changes in the global QoL/health status, nausea and vomiting, and systemic therapy side effects subscales, for women receiving psychosocial support by either SBCNs or psychologists at six months. There were significant improvements in subscales over time in both groups, for role functioning, emotional functioning, social functioning, nausea and vomiting, pain, dyspnoea, insomnia and financial difficulties. There were significant improvements in subscales over time in both groups, for future perspectives, systemic therapy side effects, breast symptoms, and arm symptoms.</p> <p>Clinically significant changes: systemic therapy side effects increased significantly in the psychologist group but not in the SBCN group. Sexual functioning decreased in both groups. The number of clinically significant changes in group means in each category did not differ between the groups (Arving 2007).</p>	179 (1 study)	⊕⊕⊕⊕ <b>very low</b> 2
Anxiety and Depression [HADS, STAI, follow-up between 6 and 12 months]	not estimated	not estimated	<p>One study reported that anxiety subscale (HADS) and state anxiety (STAI) improved over 6 months but there was no effect on the depression subscale (HADS) in the SBCN group compared to the psychologist group. There was no group-by-time interaction for HADS or STAI subscales. No group differences were found in the proportions of patients who changed from being a 'case/doubtful case' to a 'noncase' for the HADS subscales (Arving 2007).</p> <p>The other study reported that anxiety and depression (HADS) reduced over the 12-month post-surgery period in the SBCN group; scores were consistently lower in women supported by SBCNs compared to support from a voluntary organisation and compared to support from a voluntary organisation plus SBCNs, particularly with regards to depression (McArdle 1996).</p>	351 (2 studies)	⊕⊕⊕⊕ <b>very low</b> 2
Service provision-patient perspective	Not reported				

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).



GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

1 Risk of bias and high risk of attrition bias and imprecision

2 Risk of bias and high risk of attrition bias and imprecision

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 30

EORTC-BR23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module with 23 questions

GHQ: General Health Questionnaire

HADS: Hospital Anxiety and Depression Scale

IES: Impact of Event Scale

STAI: Spielberger's State-Trait Anxiety Inventory

### Summary of findings 3. Summary of findings

#### Nurse-led interventions delivering follow-up care compared with usual care for women with primary breast cancer

**Patient or population:** women with primary breast cancer

**Settings:** hospital outpatient clinics, specialist breast care units, telephone, radiotherapy units, cancer information centre

**Intervention:** nurse-led interventions delivering follow-up care

**Comparison:** standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Standard care	Nurse-led interventions				
General health-related quality of life	not estimated	not estimated	Three studies of nurse-led follow-up care by telephone for women with primary breast cancer reported general health-related quality of life outcomes between 12 and 24 months from baseline.	931 (3 studies)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>	

[GHQ-12, Mastery Scale, follow-up ranged between 12 and 24 months]			Two studies reported no difference in psychological morbidity (GHQ-12) between SBCN-led follow-up care and standard care at 18 to 24 months. One trial reported no change in feelings of control (Mastery Scale) between SBCN-led follow-up care and standard care at 12 months.		
Cancer-specific quality of life  [FACT-G, FACT-B + ES, EORTC QLQ-C30, follow-up ranged between 12 and 18 months]	not estimated	not estimated	Two studies reported no difference in cancer-specific quality of life between SBCN-led follow-up care by telephone and standard care at 18 to 24 months.  A SBCN intervention conducted by telephone, as a point-of-need access to specialist care, did not change psychological morbidity (FACT-G also breast and endocrine subscales) compared to routine clinical review at 18 months (Sheppard 2009). No differences were found in relation to endocrine scores (P = 0.39). Scores for both groups on the breast subscale improved over time, with lower scores at 9 and 18 months compared to baseline. The adjusted mean differences between groups at 18 months was 0.7 points in favour of SBCN intervention (P = 0.06).  There were no differences between groups for role and emotional functioning (EORTC QLQ-C30) in a SBCN-led telephone intervention compared with standard hospital care, both with and without an educational group programme at 12 months (Kimmman 2011). At 12 months, mean scores (EORTC QLQ-C30) were 78.4 (SD = 16.2) and 77.7 (SD = 16.2) respectively for SBCN-led telephone and standard hospital follow-up. The 95% confidence interval difference at 12 months was -1.93 to 4.64.	557 (2 studies)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>
Anxiety and depression [HADS, STAI, follow-up ranged between 12 and 60 months]	not estimated	not estimated	Three studies reported no difference in anxiety between SBCN-led follow-up by telephone and standard care between 12 and 60 months follow-up. One of these studies (Koinberg 2004) which also measured depression (HADS) reported no difference in depression between groups at 5 years (anxiety: RR 1.8; 95% CI 0.6 to 5.1; depression: RR 1.7 (95% CI 0.4 to 7.2).	1094 (3 studies)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>
Service provision-patient perspective  [follow-up ranged between 12 and 60 months]	not estimated	not estimated	Four studies demonstrated high levels of satisfaction with SBCN-led follow-up care by telephone between 12 and 60 months. Women who received nurse-led telephone follow-up care reported equal or improved satisfaction with care compared to standard hospital follow-up.	1331 (4 studies)	⊕⊕⊕⊕ <b>moderate</b> <sup>1</sup>

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **RR:** Risk Ratio; **SD:** standard deviation.

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup>Risk of bias

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 30

FACT-B + E: Functional Assessment of Cancer Therapy plus breast and endocrine subscales

FACT-G: Functional Assessment of Cancer Therapy-General

GHQ: General Health Questionnaire

HADS: Hospital Anxiety and Depression Scale

STAI: Spielberger's State-Trait Anxiety Inventory

## Summary of findings 4. Summary of findings

### Psychosocial nursing interventions compared with usual care for women with advanced breast cancer

**Patient or population:** women with advanced breast cancer

**Settings:** outpatient clinics in 4 large urban hospitals (3 private, 1 public)

**Intervention:** psychosocial nursing intervention

**Comparison:** standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Standard care	Psychosocial nursing intervention				
General health-related quality of life	Not reported					
Cancer-specific quality of life [follow-up 3 months]	not estimated	not estimated	There was no difference in cancer-specific quality of life outcomes (EORTC QLQ-30 version 2.0, SCNS) at 3 months, following a brief psychosocial nursing intervention, compared with standard care for women with newly diagnosed advanced breast cancer (Aranda 2006).	105 (1 study)	⊕⊕⊕⊕ <b>low</b> <sup>1</sup>	
Anxiety and depression	Not reported					

Service provision (patient perspective)

Not reported

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Risk of bias and imprecision

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 3

SCNS: Supportive Care Needs Survey

## BACKGROUND

### Description of the condition

Breast cancer is a significant health problem worldwide, and a complex disease both physically and psychologically (WHO 2012). Dealing with the many challenges relating to a diagnosis of breast cancer, such as lengthy treatments and trying to combine recovery with family and work commitments, can have a significant and negative impact on women (Deshields 2006; Fallowfield 2002; Schultz 2005). Following diagnosis of breast cancer, an individual's quality of life can be challenged physically, psychologically and functionally. Depression and anxiety may result from the distress of diagnosis, fear of a life-threatening disease and tumour recurrence (Cruickshank 2019 NCT03763825). Breast surgery may impact psychologically on a woman's body image and sexuality. Side effects such as nausea and vomiting; hair loss and fatigue; secondary lymphoedema; and symptoms associated with therapy-induced menopause, such as hot flushes and emotional lability are just some of the physical consequences of breast cancer treatments (Fenlon 2017). To the individual patient, therefore, breast cancer is not only a medical problem, but also one which has serious psychological, emotional and social impact. Effective management requires a professional, person-centred and holistic approach.

### Description of the intervention

Maguire and colleagues (Maguire 1978) were the first to identify the specific emotional and psychological needs of women diagnosed with breast cancer and the need to offer both psychological as well as physical care to aid recovery. Their work laid the foundation for the development of the role of Breast Care Nurses (BCNs) in the United Kingdom. Other countries have also embraced this role. In North America, Australia and Scandinavia, BCNs or Specialist Breast Care Nurses (SBCNs) have been developing their roles over the past 20 to 30 years. Both terms (BCN and SBCN) are used interchangeably and, for the purposes of this review, we refer to both as SBCNs. Various educational models and postgraduate programmes have evolved to prepare SBCNs for their role (Eicher 2012; EUSOMA 2007; RCN 2007; RCN 2017; RCN 2019).

The roles and titles of SBCNs can vary across continents, with new titles such as advanced practitioners and navigators emerging (Smith 2017). Yates 2007 consulted stakeholders and undertook a focussed review of existing literature to develop competency standards for Australian SBCNs. They define 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 stages across the continuum of care, including diagnosis, treatment, rehabilitation and palliative care"

Illuminating and quantifying what the SBCNs do is difficult due to the variations in practice settings in which they are employed and training opportunities available. Yates 2007 identified five main domains of competency for SBCNs. These are supportive care, collaborative care, co-ordinated care, information provision and education and clinical leadership, which remain relevant in practice today (RCN 2019).

### How the intervention might work

Interventions which provide supportive care are not exclusive to nursing, hence the difficulties in establishing the impact of nurse-led interventions on patient outcomes (Corner 2003). Despite this, there is research evidence that the SBCN contributes to improvements in outcomes for women by providing information and support which promote continuity of care (Redman 2003; Yates 2007). Women themselves have reported positive outcomes from their interactions with the SBCN. In the study by Ahern 2016, there was a decreased number of unmet needs and increased self-efficacy among women who had contact with SBCNs. Likewise, in interviews with women with breast cancer conducted by Halkett 2007, interviewees repeatedly emphasised the importance of the role of the SBCN in providing support through communication, establishing rapport and an awareness of their needs. The availability of the SBCN and the provision of reassurance and practical information was seen to be particularly useful. The Specialist Breast Nurse Project Team (Liebert 2003) interviewed 176 women and found that they viewed SBCNs as good communicators who were skilled in explaining issues and who provided a significant link between them and their doctors (96%) and community health workers (86%). Continuity of care was rated as a major benefit by 88% of these women and 97% reported that they benefited from ongoing contact with the SBCN.

Supportive care in cancer has been defined as "the prevention and management of the symptoms and side effects of cancer and its treatment across the cancer continuum from diagnosis to end of life; it includes support for patients, their families, and their caregivers" (MASCC 2017). In terms of the SBCN role, supportive care interventions are aimed at improving women's quality of life. This supportive role reflects the ability of the SBCN to identify the complex and inter-related physical, psychological, social, sexual, cultural and spiritual needs of individual breast cancer patients. Needs identification at all stages of the illness, implementation of evidence-based interventions and psychosocial support in a responsive and flexible manner, provided in conjunction with anti-cancer treatment, are key (Liebert 2003; Watts 2011; Yates 2007).

Currently, SBCNs are mainly supported within better resourced healthcare systems where they are often the primary contact for women following a diagnosis of breast cancer. Working as part of a breast team is central to the work of SBCNs and, as such, they are a regular feature of the multidisciplinary healthcare team and decision-making within the teams (Goldhirsch 2013; Senikus 2015). National and clinical guidelines and commissioning service guidance recommend multidisciplinary teams (MDTs) as the best way to manage breast cancer and maximise outcomes (Calman 1995; Cancer Research UK 2017; Independent Cancer Taskforce 2015; Scottish Cancer Co-ordinating & Advisory Committee). They also recommend all patients have access to a SBCN to provide psychosocial support from diagnosis through treatment and follow-up (Grunfeld 2005; NICE 2018). The effectiveness of these teams comes from common goals and understanding among members as to the impact of the illness on each woman, recognising her circumstances, feelings, concerns and preferences for treatment and the contribution each can make (Mileshkin 2006). The SBCN is a well respected and well established entity within these teams (Cardoso 2019), and has been shown to impact positively on the overall quality of clinical care provided to women

and to exert a positive influence on the work of their teams and their medical colleagues (Haward 2003).

## Why it is important to do this review

The aim of this systematic review was to examine a range of quality of life outcome indicators (physical, psychological and psychosocial) in order to establish positive changes in outcomes for women which can be attributed to SBCN supportive care interventions thereby informing the future development of the SBCN role.

## OBJECTIVES

To assess the effects of individual interventions carried out by SBCNs on general health-related quality of life, cancer-specific quality of life, anxiety and depression, and participant satisfaction, for women with a diagnosis of breast cancer.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included randomised controlled trials (RCTs), including cluster- and cross-over RCTs. We excluded quasi-RCTs.

#### Types of participants

Women with a diagnosis of breast cancer. Eligible participants included women of any age, stage of disease, and receiving any treatment modality. Studies with male participants were excluded because breast cancer is an infrequent event in men with approximately 0.7% of all breast cancers diagnosed occurring in men. Clinicians have limited experience of male breast cancer and, therefore, treatment and management is modelled on the approach to females (Mattarella 2010; Nordman 2008).

#### Types of interventions

Any type of intervention that was delivered by SBCNs. A SBCN is defined for the purposes of this review as a registered nurse with a qualification or specialist knowledge in breast care (NHS 2005). The intervention could be delivered as a single or multicomponent intervention, in any setting including inpatients, outpatients and primary care, using any delivery method. Studies were excluded if participants with breast cancer were a subgroup and outcomes were not reported separately for this subgroup. Studies were also excluded if the SBCN was part of a MDT where the contribution of the SBCN component could not be assessed.

Examples of comparisons are as follows:

- SBCN versus no SBCN
- SBCN versus other supportive care interventions
- SBCN versus other care

#### Types of outcome measures

##### Primary outcomes

Quality of life is the primary outcome of this review, and indicators assessed in this review include any of the following:

- General health-related quality of life (any validated tool at any time point)

- Cancer-specific quality of life (any validated tool at any time point)
- Anxiety and depression (any validated tool at any time point)

##### Secondary outcomes

- Service provision (patient perspective, any validated tool at any time point)

## Search methods for identification of studies

### Electronic searches

This is the first update of the review that was originally published in issue 1, 2008. On 11 June 2020 we searched the following sources from inception of each database and placed no restrictions on the language of publication.

- Cochrane Breast Cancer Group's Specialised Register (CBCG SR). Details of the search strategies used by the group for the identification of studies and the procedure used to code references are outlined in this document: [https://breastcancer.cochrane.org/sites/breastcancer.cochrane.org/files/public/uploads/specialised\\_register\\_details.pdf](https://breastcancer.cochrane.org/sites/breastcancer.cochrane.org/files/public/uploads/specialised_register_details.pdf). Trials with the key words "specialist nurse", "nurse" and "supportive care" were extracted and considered for inclusion in the review.
- Cochrane Central Register of Controlled Trials (CENTRAL) only in the Cochrane Library. See [Appendix 1](#).
- MEDLINE (R) ALL via OvidSP – 1946-present (Epub Ahead of Print, In-Process & Other Non-Indexed Citations were not included). See [Appendix 2](#).
- Embase via OvidSP – 1947-present. See [Appendix 3](#).
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) via Ebsco – 1982-present. See [Appendix 4](#).
- PsycINFO via OvidSP – 1806-present. See [Appendix 5](#).

British Nursing Index (BNI) and Library and Info Science Abstracts (LISA) databases were searched for the 2008 review but were not searched for this update. Details of the search strategies for BNI and LISA databases can be found in the 2008 review.

### Searching other resources

We searched the WHO International Clinical Trials Registry Platform (ICTRP) Search Portal ([Appendix 6](#)) and ClinicalTrials.gov ([Appendix 7](#)). We searched the reference lists of key systematic reviews and references of included studies to identify other potentially eligible trials or ancillary publications.

## Data collection and analysis

### Selection of studies

For this first update, two review authors (TB, SC) independently assessed all the titles and abstracts retrieved by the electronic searches to identify potentially relevant studies. We obtained the full texts of all potentially relevant records. Two review authors (TB, SC), independently assessed the full-text reports of studies against a list of criteria for inclusion. We resolved any discrepancies through discussion.



## Data extraction and management

For trials that fulfilled our inclusion criteria, two review authors (TB, SC) independently abstracted key participant and intervention characteristics and outcomes using a standardised data extraction form. For this first update, we extracted information relevant to equity using PROGRESS-Plus (place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status, social capital, age, disability and sexual orientation). We also extracted information relevant to assessing risk of bias, source and involvement of funders, data on indicators of intervention process and evaluation, health promotion theory underpinning intervention design, modes of strategies, and attrition rates.

## Dealing with duplicate and companion publications

In the event of multiple publications and trial documents including protocols and trial registry information, we grouped these with the primary trial publication and listed them as secondary references. We extracted all available outcome data relevant to this review from any of the included publications and trial documents.

## Assessment of risk of bias in included studies

We assessed the risk of bias of included RCTs using Cochrane's 'Risk of bias' tool and the criteria specified in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2017). This included assessment of the following domains.

- Selection bias (random sequence generation and allocation concealment)
- Performance bias (blinding of participants and personnel)
- Detection bias (blinding of outcome assessment)
- Attrition bias (incomplete outcome data)
- Reporting bias (selective reporting of outcomes)
- Other possible sources of bias (serious issues not captured within the other bias domains such as contamination or inconsistencies with timing of interventions/comparisons)

For selective outcome reporting, we searched for both trial registrations and protocols. Where we were unable to find a trial registration or protocol, we recorded 'selective outcome reporting' as unclear. Two review authors (TB, SC) assessed each study as being at 'high', 'low' or 'unclear' risk of bias for each item. Review authors were not blinded with respect to study authors, institution or journal. We used discussion and consensus to resolve any disagreements. We did not exclude studies on the risk of bias basis, but sources of bias were reported when presenting the results of studies.

## Measures of treatment effect

We planned to calculate the mean difference (MD) for continuous variables (e.g. anxiety scores) where the same scale had been used for the same outcome; if different scales had been used, then we planned to calculate the standardised mean difference (SMD). We planned to calculate the relative risk (i.e. risk ratios (RRs)) for dichotomous variables (e.g. proportion of participants showing clinical improvement on a quality of life scale), with the uncertainty of the estimate expressed using 95% confidence intervals (CIs). We reported 'change scores' and 'post-intervention values' and 'difference in means' for continuous outcome data however, these were reported in the study. We planned to combine post-intervention and change from baseline values in meta-

analyses of MD and report change scores separately for meta-analyses of SMD. We planned to pool and analyse study effects wherever possible using meta-analyses, and to use random-effects estimates to account for potential heterogeneity amongst the studies. We planned that, where meta-analyses were not possible or appropriate, then we would describe results in a narrative format with accompanying tables.

## Unit of analysis issues

We planned to take into account the level at which randomisation occurred, such as cross-over trials, cluster-RCTs and multiple observations for the same outcome. For example, we planned to assess how a cluster-RCT accounted for clustering in its data analysis; if we judged that a cluster RCT did not account for clustering appropriately, then we planned to explore the impact of removing the study from any relevant meta-analyses, as a sensitivity analysis. No cross-over or cluster-RCTs were included in the update of this review (however, there is an ongoing cluster-RCT).

For RCTs with more than one intervention group, we planned to consider 1) if all the intervention groups were relevant to the review, and 2) if all the intervention groups were relevant for a specific meta-analysis. For studies with more than two arms of relevance to the same meta-analysis and with one control arm, we planned to include data from both treatment arms. To avoid double counting of participants, we planned to halve the number of participants in the control arm. For dichotomous outcomes, both the number of events and the total number of participants would have been divided up. For continuous outcomes, only the total number of participants would have been divided up (with means and standard deviations remaining unchanged). This method only partially overcomes the unit-of-analysis error (because the resulting comparisons remain correlated), however, we were interested in evaluating all types of SBCN intervention as well as SBCN interventions per se so we did not plan to pool any intervention group data within each study.

## Dealing with missing data

We did not impute any missing data. During the process of data extraction and assessing risk of bias for each study, we investigated attrition rates (e.g. dropouts, losses to follow-up, withdrawals), and methods of analysis (such as intention-to-treat and per-protocol analyses); and we critically appraised issues concerning missing data and use of imputation methods. We did not contact any of the included study authors to attempt to obtain missing data.

## Assessment of heterogeneity

We planned to consider random-effect meta-analysis and only where the participants, the interventions and the outcomes were similar. We planned to assess statistical heterogeneity between comparable studies using the Chi<sup>2</sup> test and the I<sup>2</sup> method (Higgins 2003). This provides an estimate of the percentage of variation in observed results thought unlikely to be due to chance. It was planned that a value equal or greater than 60% of the I<sup>2</sup> quantity and a Chi<sup>2</sup> test < 0.10 would indicate heterogeneity and potential reasons would be explored.

## Assessment of reporting biases

For this first update, we did not exclude studies of SBCN interventions that did not report on general or cancer-specific quality of life outcomes or anxiety or depression outcomes (where all other selection criteria were met). This first update suggested that studies of SBCN interventions were reporting the review outcomes.

We planned to use visual inspection of funnel plots (plots of the effect estimate from each study against the sample size or effect standard error) to indicate possible publication bias if there were at least 10 studies included in a meta-analysis. As meta-analyses were not conducted, reporting biases were not assessed.

## Data synthesis

We planned, wherever possible, to conduct pooled analysis and aggregation of data using a random-effect model, because we expected a certain degree of heterogeneity among trials. We did not feel it was appropriate to pool data in this first update and specific reasons for this are stated within each comparison in [Effects of interventions](#). A narrative description of the study results was carried out including structured tabulation of results across the studies using the comparisons used in the 'Summary of findings' tables in order to aid identification and verification of our interpretation of the study data.

## Subgroup analysis and investigation of heterogeneity

No subgroup analysis was undertaken. If sufficient data had been available we would have subgrouped according to stages across the continuum of care, including diagnosis, treatment, rehabilitation and palliative care.

## Sensitivity analysis

No sensitivity analysis was undertaken. If sufficient data had been available, we had planned to explore the impact of removing any studies that were judged as having 'high' risk of bias (on any of the

domains) including removing any cluster-RCTs from any relevant meta-analyses, as a sensitivity analysis.

## Summary of findings and assessment of the certainty of the evidence

We assessed the certainty in the evidence based on the five GRADE considerations of risk of bias, consistency of effect, imprecision, indirectness and publication bias ([Schünemann 2020](#)) for all the outcomes:

- General health related quality of life
- Cancer specific quality of life
- Anxiety and depression
- Service provision

and created 'Summary of findings' tables according to:

- population (women with primary or advanced breast cancer)
- type of intervention (psychosocial nursing intervention or nurse-led intervention delivering follow-up care)
- type of comparison (standard care or other supportive intervention)

# RESULTS

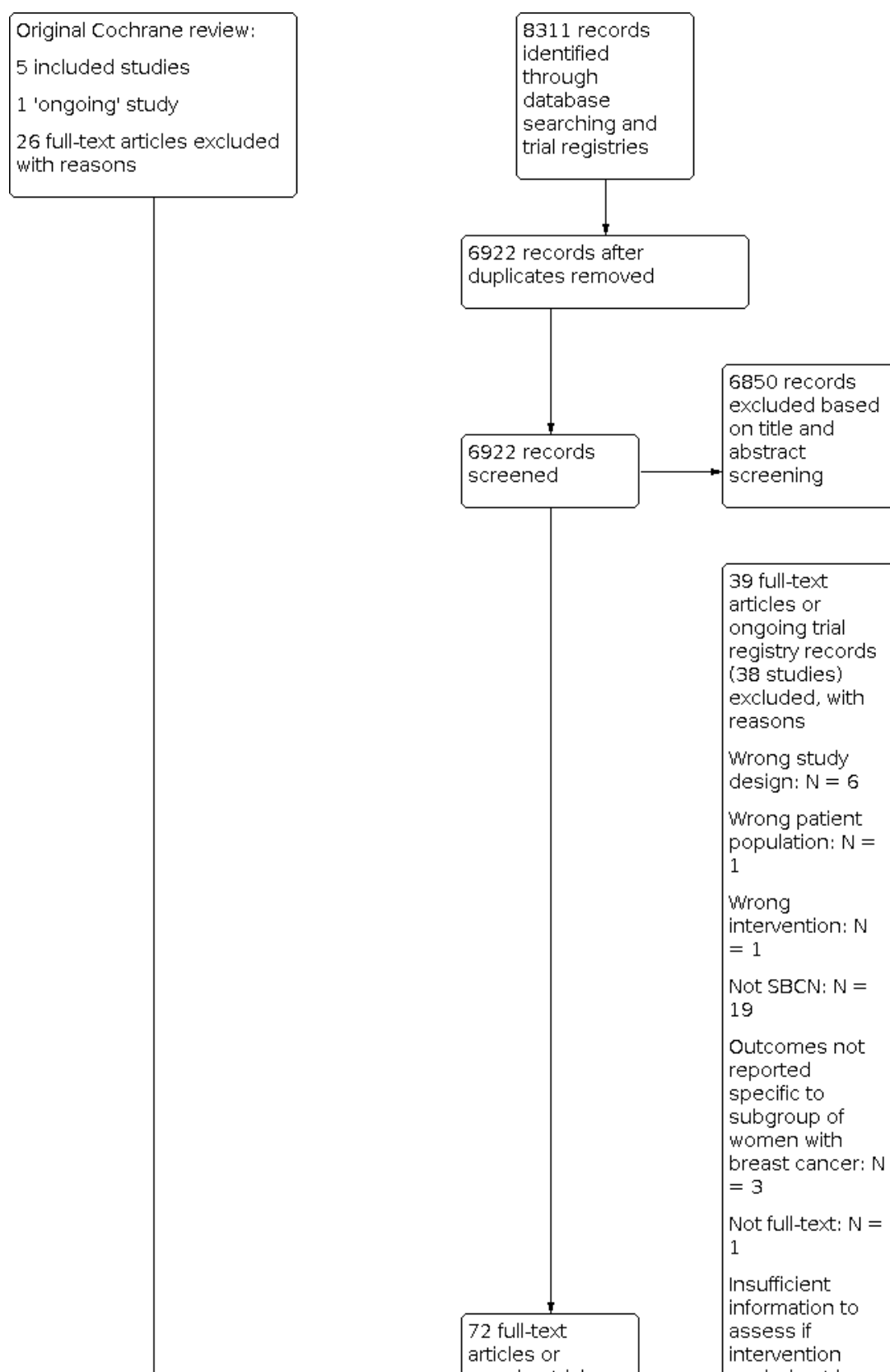
## Description of studies

### Results of the search

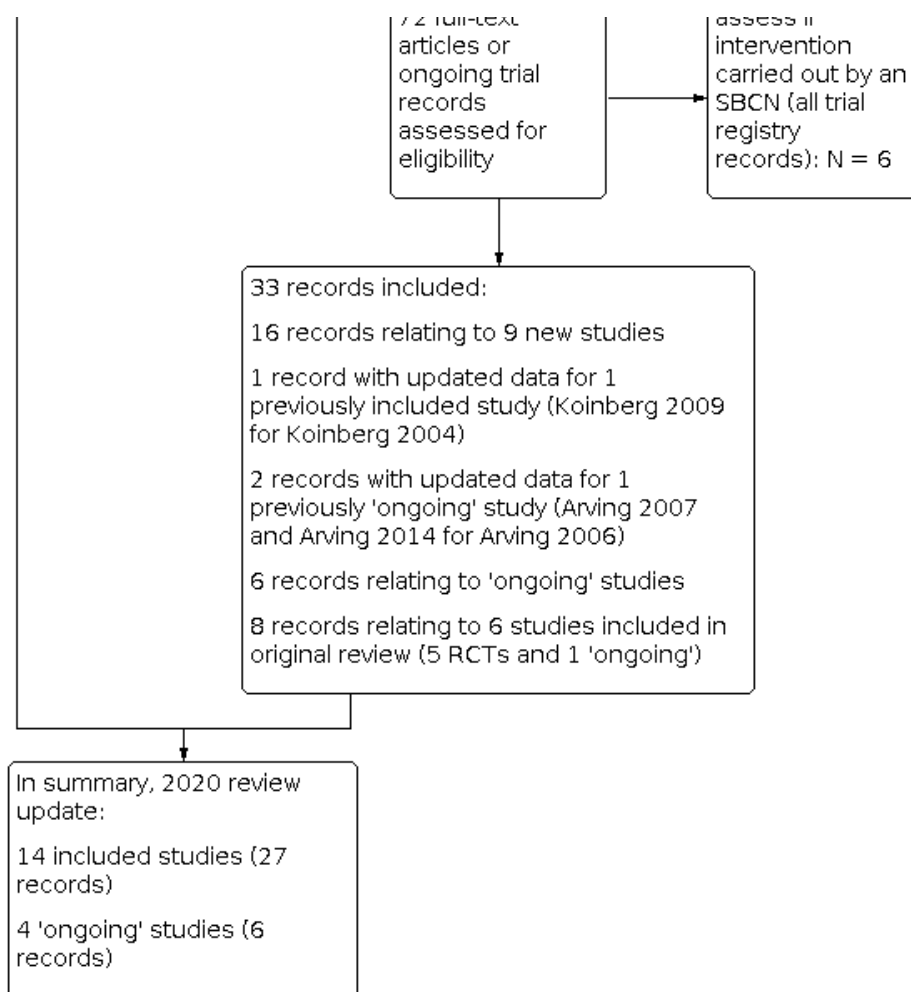
This is the first update of the review since the review was published in issue 1, 2008. This update searched each database from inception to June 2020 and retrieved 8311 records; after duplicates were removed, this left 6922 records. Seventy-two full-text articles or ongoing trial records were assessed for eligibility and from these we included nine new studies. With the inclusion of the five previously included studies from the original review, this makes a total of 14 included studies. We identified four ongoing studies. For a detailed description of the study flow, please see [Figure 1](#).



**Figure 1. Study flow diagram.**



**Figure 1. (Continued)**



### Included studies

We included 14 RCTs (Aranda 2006; Arving 2007; Beaver 2009; Fenlon 2020; Gomez 2019; Hershman 2013; Kim 2017; Kimman 2011; Koinberg 2004; Maguire 1980; McArdle 1996; Ritz 2000; Sheppard 2009; Wengstrom 1999), details of which can be found in the [Characteristics of included studies](#).

The following number of studies reported on PROGRESS Plus criteria at baseline. PROGRESS Plus includes: place of residence (two studies), race/ethnicity (three studies), occupation (seven studies reported on employment status, of which one study also reported on social class according to occupation), gender (12 studies), religion (three studies), education (eight studies), socioeconomic status (two studies reported on income), social capital (no studies), age (11 studies), disability (no studies) and sexual orientation (no studies). Eleven studies also reported on marital status. Four studies reported on differences in the PROGRESS Plus criteria in women according to whether they participated in the intervention or not. Three of these studies reported that participants were younger than nonparticipants (Kimman 2011; Ritz 2000; Sheppard 2009).

### *Psychosocial nursing interventions in primary disease during diagnosis, treatment or survivorship*

Nine studies with 1469 women were included (Arving 2007; Hershman 2013; Kim 2017; Maguire 1980; McArdle 1996; Ritz 2000; Wengstrom 1999).

Three studies included **interventions during time of diagnosis** (Maguire 1980; McArdle 1996; Ritz 2000).

Maguire 1980 conducted an RCT to determine whether counselling by a specialist nurse prevented the psychiatric morbidity associated with mastectomy and breast cancer. This study randomised 172 women with breast cancer, who had a modified radical mastectomy and full axillary clearance, to receive a counselling intervention carried out by the nurse in clinic within a few days of surgery and thereafter every two months at home for 12 to 18 months, or routine care from a surgical unit doctor in a University Hospital in North-West England.

McArdle 1996 conducted an RCT in three teaching hospitals and the community in Glasgow, to evaluate the additional effect of support from a nurse specialising in breast care and/or a voluntary support organisation such as Tak Tent compared with standard care, on the prevalence of psychological morbidity for women up to 12 months post-surgery. This study randomised 272 women prior

to surgery, to one of four groups: a) routine support from ward staff and an information booklet (Understanding Cancer of the Breast: BACUP); b) routine support plus support from a SBCN; c) routine support plus support from a voluntary organisation; or (d) routine support plus SBCN support plus support from a voluntary organisation. It was up to individual counsellors in the voluntary organisation to decide the level of support required which might include maintaining contact by telephone or post, arranging one-to-one meetings for counselling, or encouraging attendance at Tak Tent group meetings.

**Ritz 2000** randomised 211 women to an intervention delivered by an Advanced Practice Nurse (APN) plus standard care or standard care alone in an 'integrated healthcare system' in a suburban community of a large Midwestern metropolitan area in the US. The study aimed to assess whether additional input from the APN could improve quality of life outcomes while decreasing overall costs. The intervention was delivered by an APN within two weeks of diagnosis of breast cancer and for up to 12 months. The intervention provided written and verbal information about breast cancer, what to expect in consultations with physicians, decision-making support, answering questions and the presence of the APN at consultation to support the women. Subsequent contact was provided in a variety of settings, including hospital, telephone and community, to reinforce information, provide continuity and offer ongoing support.

Two studies included **interventions during treatment** (**Kim 2017**; **Wengstrom 1999**).

**Kim 2017** randomised 60 women attending one oncology outpatient clinic in a university hospital in south Korea for nine weeks intervention (including six weeks chemotherapy). The study aimed to develop a nurse-led psychological intervention programme and to evaluate its effects on psychological distress and quality of life in patients with breast cancer undergoing chemotherapy and at a high risk of depression. The nurse-led psychological intervention programme comprised seven weekly counselling sessions delivered face-to-face and by telephone to provide emotional support to patients and to enable them to express their feelings. After the study, the co-ordinator contacted patients by phone in the control group, checked their status, explained the programme to them and encouraged them to take part in it.

**Wengstrom 1999** randomised 134 women with breast cancer to a structured nursing intervention plus standard nursing care or standard nursing care alone after receiving curative radiotherapy in a university hospital in an urban area of Sweden. The goals of the intervention were to enhance and restore the women's ability for self-care; the nurse-led intervention consisted of 30 minutes once a week at week one (baseline) then at weeks three and five (end of radiotherapy) and follow-up at two weeks and again at three months. The structured nursing care intervention involved an additional individual session for each woman focussing on encouraging self-care actions to minimise, prevent or alleviate side effects of therapy, psychological support, education and guidance, and referral to the wider multiprofessional team. Standard care included a group information session for women containing information about treatment, routines and side effects, and contact with a nurse during the treatment period.

Four studies included **interventions during survivorship** (**Arving 2007**; **Fenlon 2020**; **Gomez 2019**; **Hershman 2013**).

**Arving 2007** randomised 179 women about to start adjuvant treatment (chemo, endocrine and/or loco-regional radiotherapy) in Sweden, to compare whether individual psychosocial support provided by oncology nurses specially trained in psychologic techniques was as effective as that given by psychologists and to compare these interventions to standard care over six months. Both psychosocial interventions used the same techniques such as relaxation, distraction, activity scheduling, and ways to improve communication, all derived from cognitive behavioural therapy (CBT) approaches. The number of sessions and the time interval between them varied according to the need and desire of the individual patients. Every session was scheduled to last for 45 to 60 minutes. Both interventions took place outside the hospital, some sessions (n = 91; 19%) were held by telephone because of long travelling distances and had essentially the same content as sessions held face-to-face.

**Hershman 2013** randomised 141 women who were within six weeks of completion of initial adjuvant treatment (radiation or chemotherapy) to a survivorship intervention in addition to standard care in a breast cancer-specific clinic in an a US University Medical Centre. Participants in the survivorship intervention met a nurse and nutritionist for one hour to receive a personalised treatment summary (in English or Spanish), surveillance recommendations, discussion of risk for late effects and toxicities, and screening and lifestyle recommendations based on guidelines from the American Society of Clinical Oncology. Both arms received the National Cancer Institute publication, "Facing Forward: Life after Cancer Treatment". This is a 24-page manual that summarises key issues of interest to cancer survivors during the re-entry phase, and contains sections on a number of issues after cancer treatment, including medical care, potential symptoms, emotions, social relationships, and dealing with practical matters, such as insurance and employment.

**Fenlon 2020** randomised 127 women, with primary breast cancer or ductal carcinoma in situ, who had completed primary treatment and were experiencing hot flushes and night sweats, to weekly group CBT sessions, lasting 90 minutes each, for six weeks, to improve well-being and manage hot flushes, night sweats and sleep.

**Gomez 2019** randomised 173 women with breast cancer, histologically documented between their first and third follow-up appointments, and who received anti-neoplastic treatment, to an educational nursing intervention to reduce cancer-related fatigue. There were two intervention groups, both of which included two in-person sessions at baseline and at three months to deal with fatigue; one intervention group also received telephone monitoring at six, nine and 12 months, to resolve doubts and reinforce education.

### ***Psychosocial nursing interventions in advanced disease***

One study **Aranda 2006** randomised 105 women with breast cancer that was newly diagnosed at an advanced stage, or that had recurred or progressed in the preceding 12 months, from outpatient clinics in four large urban hospitals (n = 3 public and n = 1 private) in Melbourne, Australia. The study examined the effectiveness of a brief, nurse-delivered intervention designed to address the

individual needs of women with advanced breast cancer. The SBCN intervention consisted of two interactions: a one-hour face-to-face session with a SBCN within 10 days covering: orientation, tailored responses, coaching and practising self-care and communication strategies, and concluding the session. Patients were encouraged to bring 'a significant other'. Each woman was given relevant information cards on self-care and communication strategies and a copy of her personal self-care plan. Women were also provided with a relaxation CD. One week after the first session there was a telephone follow-up with the SBCN to: (a) ask whether the suggested strategies had ameliorated the concerns; (b) elicit and respond to remaining concerns; (c) reinforce or modify planned self-care strategies or introduce new ones; and (d) prompt further questions/new concerns. Outcomes were measured at one month (after the intervention) and at three months post-baseline.

### **Nurse-led interventions delivering follow-up care**

Four studies with 1331 women were included (Beaver 2009; Kimman 2011; Koinberg 2004; Sheppard 2009).

Beaver 2009 randomised 374 women on completion of primary treatment (surgery, radiotherapy, chemotherapy), to compare telephone follow-up by specialist nurses with traditional hospital follow-up over a mean of 24 months. The study aimed to compare traditional hospital follow-up with telephone follow-up by specialist nurses after treatment for breast cancer. Participants received telephone appointments by SBCNs consistent with hospital policy (three months for two years; six-monthly for two years and annually for a further year). Each telephone appointment was allocated 30 minutes (20 minutes for the consultation and 10 minutes to dictate outcome). The structured and recorded telephone intervention used questions related to changes in condition, new symptoms, and information requirements about spread of disease, treatment and side effects, genetic risk, sexual attractiveness, self-care (diet, support groups, finances), and family concerns. Throughout the study, the same specialist nurse contacted each participant in the telephone group for all appointments.

The standard care was based at two sites: a district general hospital and a specialist breast care unit, both in North-West England. The district general hospital follow-up was consistent with hospital policy (three months for two years; six monthly for two years and annually for a further year). Standard care in the specialist breast care unit was annually for 10 years. Hospital consultations were generally unstructured but primarily consisted of a clinical examination, a check on whether hormone treatment was being taken as prescribed, and ordering mammograms if necessary. As per hospital policy, both study locations allocated 10 minutes for each individual hospital appointment. Hospital consultations could be conducted by various health professionals including consultant surgeons, consultant oncologists, registrars, more junior doctors, or specialist nurses. It was more usual at both locations, however, for junior medical staff to conduct hospital appointments (Beaver 2009).

Kimman 2011 randomised 320 women within six weeks after completion of treatment with curative intent from seven hospitals and two radiotherapy clinics in the Netherlands. The study aimed to investigate the impact of a SBCN-led telephone intervention compared with standard care both with and without an educational group programme (EGP) (held at cancer information centre)

delivered by a SBCN and a health care psychologist. There were four groups: standard care, SBCN-led telephone, standard care plus EGP and SBCN-led telephone plus EGP. The SBCN-led intervention consisted of a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews by a SBCN at the same time points as for usual follow-up. The EGP consisted of two interactive group sessions of 2.5 hours and attended by the woman's partner within three months of treatment. Standard care was hospital follow-up as usual - five outpatient clinic visits in the first 18 months (at 3, 6, 9, 12 and 18 months). Hospital follow-up was provided by a surgeon, medical oncologist, radiation oncologist and/or SBCN. All groups received follow-up as usual that took place in the hospital where surgery and chemotherapy were performed, alternating between the surgeon, medical oncologist and radiation oncologist.

Koinberg 2004 randomised 400 breast cancer patients with stage 1 or 2 disease to a SBCN intervention or standard care in three hospitals (two hospitals analysed,  $n = 264$ ) in Sweden with follow-up at five years. The study aimed to compare nurse-led follow-up on demand versus physician follow-up after breast cancer treatment. The SBCNs worked in a setting where they had rapid access to specialists in surgery and/or oncology within their own hospital. Standard follow-up care included examination by an oncologist or surgeon four times per year for the first two years, bi-annually for five years and yearly thereafter, plus yearly mammography. The SBCN intervention included follow-up by demand, managed by an experienced nurse specialist who saw the patient three months post-surgery. The Nurse Specialist gave the women information about recurrence, advice, and contact details, and they were asked to contact the nurse if there were concerns or symptoms related to the breast cancer. The Nurse also co-ordinated yearly mammography.

Sheppard 2009 randomised 237 women who had completed primary treatment (surgery, chemotherapy or radiotherapy) and were in year two post-diagnosis, from one large specialist breast unit in the UK. The study aimed to develop a model of care based on the concept of point-of-need access and investigate the efficacy of this model compared to routine clinical review; women were followed up for 18 months. The SBCN intervention was conducted by telephone and was a point-of-need access to specialist care via the SBCN. The control consisted of six-monthly follow-up appointments for clinical review at the hospital. Mammograms continued annually for both groups.

### **Training and experience of the SBCN**

We have summarised information regarding the experience and training of SBCNs in Table 1. Five studies (Kim 2017; Kimman 2011; Koinberg 2004; McArdle 1996; Sheppard 2009) reported some information relating to the clinical experience of the SBCNs but only three of these studies reported a qualification (Kim 2017; Kimman 2011; Sheppard 2009) of which only two (Kim 2017; Sheppard 2009) reported a minimum requirement of three years' experience. Six studies reported information on training received to carry out the intervention (Aranda 2006; Arving 2007; Beaver 2009; Kim 2017; Kimman 2011; Sheppard 2009). Sheppard 2009 reported a detailed training plan with objectives and outcome measures. Three studies did not report either the clinical experience of the SBCN or any training received by the SBCN relating to the intervention (Hershman 2013; Ritz 2000; Wengstrom 1999). Maguire 1980 did not

report any information on the clinical experience of the SBCN and reported 'brief training'.

### Ongoing studies

We identified four ongoing trials that appeared to meet our inclusion criteria. See [Characteristics of ongoing studies](#). All the ongoing studies reported a primary endpoint of interest (quality of life indicator or service provision) and will contribute to the findings of future updates.

### Excluded studies

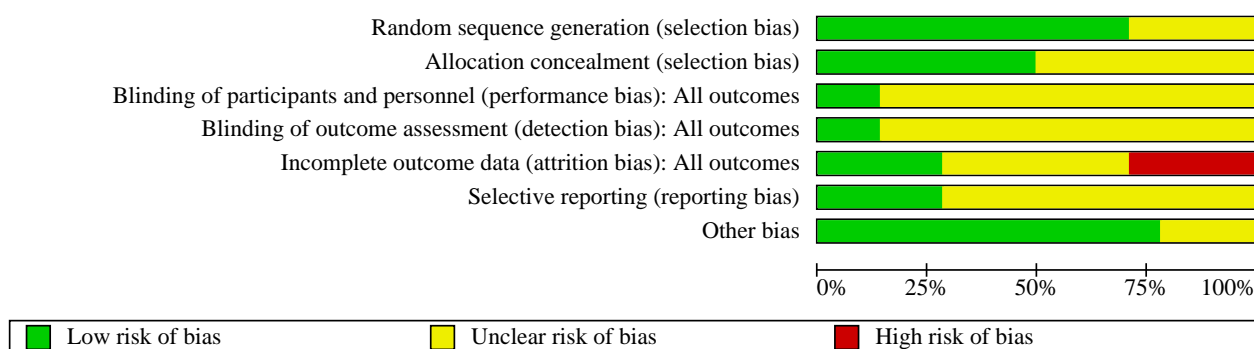
We excluded 26 studies in the original version of the review. We excluded 39 articles in this first update, making a total of

65 excluded articles (63 studies). See ['Characteristics of excluded studies'](#) for more information.

### Risk of bias in included studies

The [Characteristics of included studies](#) reports the risk of bias results for the 14 included RCTs. We present a 'Risk of bias' graph ([Figure 2](#)) with review authors' judgements about each 'Risk of bias' item presented as percentages across all included RCTs. We present a 'Risk of bias' summary ([Figure 3](#)), with review authors' judgements about each 'Risk of bias' item for each included study. When a study included insufficient information to allow us to make a judgement for a particular domain, we gave a rating of unclear.

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): All outcomes	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Other bias
Aranda 2006	+	+	?	+	?	?	+
Arving 2007	?	?	?	?	-	?	+
Beaver 2009	+	+	?	+	+	?	+
Fenlon 2020	+	+	?	?	+	+	+
Gomez 2019	?	?	?	?	-	?	?
Hershman 2013	+	+	+	?	?	+	+
Kim 2017	+	?	?	?	?	?	+
Kimman 2011	+	+	?	?	+	+	+
Koinberg 2004	+	+	?	?	?	?	?
Maguire 1980	+	?	?	?	?	?	+
McArdle 1996	?	?	?	?	?	?	?
Ritz 2000	?	?	?	?	-	+	+
Sheppard 2009	+	+	+	?	+	?	+
Wengstrom 1999	+	?	?	?	-	?	+



## Allocation

None of the 14 RCTs were rated as having 'high' risk of selection bias. Ten studies clearly specified sequence generation and were assessed as having 'low' risk of bias and there was insufficient information reported in four studies to enable us to make a judgement about sequence generation ('unclear' risk of bias).

Seven studies clearly specified adequate methods for allocation concealment and were rated as having 'low' risk of bias; there was insufficient information reported in seven studies to enable us to make a judgement about allocation concealment ('unclear' risk of bias).

## Blinding

None of the 14 RCTs were rated as having 'high' risk of performance and detection bias. It was feasible to obscure how interventions were allocated from the outcome assessors and conceal allocation of interventions from the participants themselves.

We rated two studies as having 'low' risk of bias for blinding of participants and personnel; in the other 12 studies, blinding was not reported ('unclear' risk of bias).

We rated two studies (a different two studies that were blinded for participants and personnel) as having 'low' risk for blinding of outcome assessors; in the other 12 studies, blinding of outcome assessors was not reported ('unclear' risk of bias).

## Incomplete outcome data

We rated four studies as having 'high' risk for attrition bias; this was because of unbalanced baseline characteristics between groups and/or unbalanced completion rates across study groups which was not accounted for in the analyses. We rated four studies as having 'low' risk of bias from missing data. We based our decisions on the provision of an adequate description of participant flow through the study and with missing outcome data relatively low and balanced between groups and judged to be unlikely to be related to the outcomes of interest. We rated six studies as having 'unclear' for attrition bias, mainly because they did not adequately report reasons for dropouts or dropouts were unbalanced between groups and it was unclear how analyses accounted for this attrition.

## Selective reporting

None of the 14 RCTs were rated as having 'high' risk of reporting bias. We rated four studies as having 'low' risk of reporting bias. We rated ten of the studies as having 'unclear' risk of bias because a protocol was not available to assess whether all outcomes were reported as stated a priori.

## Other potential sources of bias

None of the 14 RCTs were rated as having 'high' risk of other potential sources of bias. Eleven studies were rated as having 'low' risk of other potential sources of bias, three studies were rated as having 'unclear' risk due to the timing of the intervention which differed between groups in one study and similar treatment between groups in one centre of another (multicentred) study.

## Effects of interventions

See: [Summary of findings 1](#) Summary of findings; [Summary of findings 2](#) Summary of findings; [Summary of findings 3](#) Summary of findings; [Summary of findings 4](#) Summary of findings

More detailed information on the interventions, outcome tools and outcomes can be found in [Table 2](#); [Table 3](#); [Table 4](#), respectively.

## Women with primary breast cancer

There were 13 studies of women with primary breast cancer, nine of which compared psychosocial nursing interventions with standard care and four studies that compared nurse-led follow-up with standard care.

## Psychosocial nursing interventions versus standard care

See: [Summary of findings 1](#).

General health-related quality of life and cancer-specific quality of life outcomes were measured across the trials, using a range of tools with different scales and at various time points. In some studies, only subscale scores were reported and not overall scores. These tools measured a variety of outcomes but not exactly the same underlying phenomena, and it was therefore not appropriate to conduct meta-analyses. The potential exception to this was for the outcomes of anxiety and depression which were measured using a range of tools; however, the most commonly used tool (Hospital and anxiety scale (HADS), used in three trials) reported two subscales, one each for anxiety and for depression and an overall score. Supportive actions for patients were based on the overall score of both subscales combined, as it was fundamentally used as a screening tool. Therefore, it was not appropriate to split anxiety and depression into two separate outcomes and pool the data for each outcome separately with data from tools that measured anxiety or depression separately. In addition, one of the three trials that used HADS was in a sample of women with higher levels of depression ([Kim 2017](#)).

## General Health-Related Quality of Life

Eight studies (1328 women, low-quality evidence) ([Arving 2007](#); [Fenlon 2020](#); [Gomez 2019](#); [Kim 2017](#); [Maguire 1980](#); [McArdle 1996](#); [Ritz 2000](#); [Wengstrom 1999](#)) compared psychosocial nursing interventions for women with primary breast cancer to standard care and reported a range of general health-related quality of life outcomes using different scales between nine weeks and 18 months from baseline at all three time points (during diagnosis, treatment and survivorship). All eight trials showed small improvements in general health-related quality of life or no effect. Overall, the majority of general health-related quality of life outcomes showed improvements over time for both intervention and standard care groups, including a range of physical, emotional and psychological aspects of quality of life.

**Psychiatric/psychological morbidity** appeared reduced with psychosocial nursing interventions compared with standard care in two studies ([Maguire 1980](#); [McArdle 1996](#)). [Maguire 1980](#) reported that 12 to 18 months after mastectomy there was much less psychiatric morbidity in the intervention group (12%), compared to 39% in the control group. The intervention led to recognition of psychiatric morbidity and prompted referral of 76% of those who required help, compared to 15% in the control group. [McArdle 1996](#) reported that psychological morbidity (28-item General health

questionnaire (GHQ)) reduced over the 12-month period; scores were consistently lower in women supported by SBCNs.

In [Fenlon 2020](#), women in the intervention group had improvement in **hot flushes and night sweats** at 26 weeks and in **sleep** at nine weeks (only measured at nine weeks) compared to standard care. In [Gomez 2019](#), women who received education plus telephone monitoring had less **fatigue** at 12 months compared to education only follow-up or standard care follow-up.

[Ritz 2000](#) demonstrated that additional input from an Advanced Practice Nurse (APN) improved quality of life in terms of **uncertainty of illness** (Mishel Uncertainty in Illness Scale (MUIS)), in women in the six months following diagnosis, but benefits were not sustained at 12 months; there was a greater beneficial effect in the APN intervention group for unmarried women than for married women.

Two studies reported on **mood**; at nine weeks (including six weeks chemotherapy), women at high risk of depression reported lower mood disturbance (Korean version of Profile Mood States - Brief (K-POMS-B)) compared to women in the standard care group ([Kim 2017](#)). [Ritz 2000](#) showed no differences in mood disturbance (POMS) between the intervention and control groups at any time point up to 12 months.

Two studies reported on **distress** (Impact of Event Scale (IES)): intervention women rated fewer distress reactions than those in the standard care group at three months in one study ([Wengstrom 1999](#)). At six months, women receiving psychosocial support from oncology nurses experienced less intrusion compared with the standard care group. More intervention participants as compared to the standard care group, improved clinically significantly from 'higher levels of distress' to 'lower levels of distress' but there was no group-by-time interactions ([Arving 2007](#)).

### Cancer-specific quality of life

Six studies (897 women, low-quality evidence) ([Arving 2007](#); [Hershman 2013](#); [Kim 2017](#); [Maguire 1980](#); [Ritz 2000](#); [Wengstrom 1999](#)) compared psychosocial nursing interventions for women with primary breast cancer and reported a range of cancer-specific quality of life outcomes between nine weeks and 18 months from baseline at all three time points (during diagnosis, treatment and survivorship). All six trials showed small improvements in cancer-specific quality of life or no effect. Overall, most cancer-specific quality of life outcomes showed improvements over time for both intervention and standard care groups.

In terms of **recovery after surgery** ([Maguire 1980](#)), more women in the SBCN group (n = 54, 72%) than in the control group (n = 42, 55%) were satisfied with their scar compared with 'neutral' or 'dissatisfied'. More women in the control group (n = 23, 33%) were dissatisfied with their prosthesis than women in the counselled group (n = 11, 15%). More women in the SBCN group (n = 51, 68%) than women in the control group (n = 40, 52%) had adapted to breast loss although some women in both the SBCN group (n = 8, 11%) and in the control group (n = 7, 9%) were unable to accept the loss of a breast. Differences in housework, social adjustment and return to work were all improved in the SBCN group as opposed to the control group. Women in both groups had a small but important minority (12%) who suffered from moderately severe or severe swelling in a limb 12 to 18 months after surgery ([Maguire 1980](#)).

There were no differences in **well-being** (Functional Assessment of Cancer Therapy - Fatigue (FACT-B)) between the intervention and standard care groups at six months in one study (only physical and functional subscales measured) ([Hershman 2013](#)) and at any time point up to 12 months in another study ([Ritz 2000](#)). At six months, there were no differences between the intervention and control groups for impact of cancer (IOC), and assessment of survivor concerns (ASC) in one study ([Hershman 2013](#)).

At nine weeks (including six weeks chemotherapy), women at high risk of depression showed an improved **global health status** (including physical role and emotional function) - also fewer symptoms of fatigue, nausea/vomiting, pain and insomnia - compared to women in the standard care group (European Organisation of Research and Treatment of Quality of Life Core Questionnaire - Core 30 (EORTC QLQ C-30)) ([Kim 2017](#)). At six months, there were improvements in the subscales of global Quality of life/health status, nausea and vomiting, and systemic therapy side effects for women who received individual psychosocial support provided by oncology nurses compared to standard care in one study ([Arving 2007](#)). Clinically significant changes in subscales were noted for emotional functioning, social functioning, nausea and vomiting, pain, dyspnoea, insomnia and financial difficulties. There were clinically significant changes in subscales for future perspectives, systemic therapy side effects, breast symptoms, and arm symptoms. However, there was no difference in perceived **side effects, global QoL or coping ability** (Oncology Treatment Toxicity Assessment Tool (OTTAT), Cancer Rehabilitation Evaluation System - shortened Form (CARES-sf)) in one study at three months of women receiving curative radiotherapy ([Wengstrom 1999](#)). When the sample was divided into two groups based on the median age (59 years), women older than 59 years had increased ability to cope with radiotherapy through stronger motivation to be emotionally involved.

### Anxiety and Depression

We reported the data for the HADS in [Table 5](#). Six studies (951 women, low-quality evidence) ([Arving 2007](#); [Hershman 2013](#); [Kim 2017](#); [Maguire 1980](#); [Fenlon 2020](#); [McArdle 1996](#)) compared psychosocial nursing interventions for women with primary breast cancer and reported anxiety and depression outcomes between nine weeks and 18 months using a range of measurement tools, from baseline at all three time points (during diagnosis, treatment and survivorship). All six trials showed small improvements in anxiety and/or depression or no effect. Four studies showed improvements in favour of the intervention group and two studies showed no difference between groups for anxiety or depression at six months.

One study reported subscales of anxiety and depression as part of the PSE ([Maguire 1980](#)). Twelve to eighteen months after mastectomy, 69 (92%) women in the SBCN group were anxiety-free as compared to 54 (70%) in the control group. Depression was also less in the SBCN group; depression was absent in 71 (95%) in the SBCN group compared to 54 (70%) in the control group. [McArdle 1996](#) reported that as anxiety and depression reduced over the 12 months post-surgery period; scores were consistently lower in women supported by SBCNs compared to standard care, particularly with regards to depression (GHQ, HADS). [Kim 2017](#) randomised 60 women undergoing chemotherapy and at a high risk of depression, to a six-week nurse-led CBT intervention or usual care. At nine weeks from baseline, anxiety and depression were



lower in the intervention group than in the control group (group:  $F = 5.25$ ,  $P = 0.03$  for anxiety,  $F = 10.56$ ,  $P < 0.01$  for depression). Significant group-by-time interactions were found for depression (group  $\times$  time:  $F = 8.33$ ,  $P < 0.01$ ); a decrease was observed in the intervention group, whereas a slight increase was observed in the control group over time (HADS). Fenlon 2020 reported improvements in anxiety (General Anxiety Disorder (GAD-7)) at nine weeks (only measured at nine weeks) (adjusted mean difference, intervention versus control:  $-1.54$ , CI  $-3.01$  to  $-0.07$ ,  $P = 0.041$ ) and in depression (PHQ-9) measured at 26 weeks (adjusted mean difference, intervention versus control:  $-2.86$ , CI  $-4.73$  to  $-0.98$ ,  $P = 0.003$ ).

At six months, there were no group-by-time interactions using the HADS or Spielberger's State Trait Anxiety Inventory (STAI) tools for women undergoing adjuvant treatment and receiving individual psychosocial support compared to standard care (Arving 2007) and no differences between the intervention and control groups for depression scores in another study (Centre for Epidemiologic Studies Depression Scale (CES-D)) (Hershman 2013).

### Service provision

Two studies (320 women, low-quality evidence) of psychosocial nursing interventions for women with primary breast cancer reported on patient satisfaction with the intervention, between six and 24 months from baseline. At six months, there was no difference in treatment satisfaction with a survivorship nursing intervention in addition to standard care in women who had undergone adjuvant treatment with radiation or chemotherapy (Hershman 2013). Women were highly satisfied with an individual psychosocial support intervention, provided by nurses, for up to 18 to 24 months from the start of adjuvant therapy - the standard care group were not assessed for satisfaction (Arving 2007). Ninety-five per cent of intervention women were satisfied with the number of sessions and 71% of intervention women were satisfied with the timing of the support. We rated Arving 2007 as having high risk of attrition bias; attrition was not statistically significant between the groups but was high at 33%. There was imbalance between the groups for baseline characteristics plus imbalance between groups for dropouts which was not accounted for in the analyses (completer analyses).

### Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer

See [Summary of findings 2](#).

General health-related quality of life was measured by the GHQ and the IES at six and 12 months. These tools did not measure the same underlying phenomena, and it was therefore not appropriate to conduct meta-analyses. Only one study (Arving 2007) reported cancer-specific quality of life outcomes using the EORTC QLQ-C30 and the breast cancer module. Two studies (Arving 2007; McArdle 1996) used the HADS tool to measure anxiety and depression but the comparison interventions were very different and so we did not pool the data.

### General Health-Related Quality of Life

Two studies (351 women, very low-quality evidence) (Arving 2007; McArdle 1996) compared psychosocial nursing interventions for women with primary breast cancer to other supportive care

interventions. McArdle 1996 reported that psychological morbidity (28-item GHQ) reduced over the 12-month period; scores were consistently lower in women supported by SBCNs alone compared to support from a voluntary organisation and compared to support from a voluntary organisation plus a SBCN. Arving 2007 reported that, at six months, women receiving psychosocial support by either SBCNs or psychologists clinically improved from 'higher levels of distress' to 'lower levels of distress' on the 'intrusion' subscale of the IES. Intrusion and avoidance improved over time with clinical improvement in both groups. There was no group-by-time interaction.

### Cancer-specific quality of life

One study (179 women, very low-quality evidence) (Arving 2007) compared psychosocial nursing interventions by an SBCN to that given by psychologists, for women with primary breast cancer. Arving 2007 showed no between-group differences on subscales at all time points up to six months (EORTC QLQ-C30, European Organisation of Research and Treatment quality of life questionnaire breast cancer module with 23 questions (EORTC-BR-23)). There were significant group-by-time changes in the global quality of life/health status, nausea and vomiting, and systemic therapy side effects subscales for women receiving psychosocial support by either SBCNs or psychologists at six months. There were significant improvements in subscales over time in both groups, for role functioning, emotional functioning, social functioning, nausea and vomiting, pain, dyspnoea, insomnia and financial difficulties. There were significant improvements in subscales over time in both groups, for future perspectives, systemic therapy side effects, breast symptoms, and arm symptoms. In terms of clinically significant changes, systemic therapy side effects increased significantly in the psychologist group but not in the SBCN group. Sexual functioning decreased in both groups. The number of clinically significant changes in group means in each category did not differ between the groups.

### Anxiety and Depression

We reported the data for the HADS in [Table 5](#). Two studies (351 women, very low-quality evidence) (Arving 2007; McArdle 1996) compared psychosocial nursing interventions for women with primary breast cancer to other supportive care interventions. Arving 2007 reported that anxiety subscale scores (HADS) and state anxiety scores (STAI) improved over six months but there was no effect on depression subscale scores (HADS) in the SBCN group compared to the psychologist group. There was no group-by-time interaction for HADS or STAI subscale scores. No group differences were found in the proportions of patients who changed from being a 'case/doubtful case' to a 'non-case' for the HADS subscale scores. McArdle 1996 reported that anxiety and depression (HADS) reduced over the 12-month post-surgery period in the SBCN group; scores were consistently lower in women supported by SBCNs compared to support from a voluntary organisation, particularly with regards to depression.

### Service provision

There were no data reported for this outcome. Arving 2007 reported satisfaction using an unvalidated questionnaire ([Table 4](#)).

### Nurse-led interventions delivering follow-up care versus standard care

See: [Summary of findings 3](#).

For general health-related quality of life, two studies used the GHQ-12 but the data were reported differently in each study. Two studies measured different phenomena of cancer-specific quality of life. Two studies measured anxiety using STAI but one of these studies had a factorial design. For these reasons, we did not pool any of the data.

### General Health-Related Quality of Life

Three studies, (931 women, moderate-quality evidence) of nurse-led follow-up care for women with primary breast cancer reported general health-related quality of life outcomes between 12 and 24 months from baseline (Beaver 2009; Kimman 2011; Sheppard 2009). Two studies reported no difference in psychological morbidity (GHQ-12) between nurse-led follow-up care and standard care at 18 to 24 months. One trial reported no change in feelings of control (Mastery Scale) between nurse-led follow-up care and standard care at 12 months. SBCN-led follow-up care was equally as effective as standard care for women with primary breast cancer.

A SBCN intervention conducted by telephone, as a point-of-need access to specialist care, did not change psychological morbidity (GHQ-12) compared to routine clinical review in 237 women who were followed up for 18 months (Sheppard 2009). The SBCN intervention was not associated with any deleterious effect on early detection of recurrence compared with routine clinical review. Aggregate psychological morbidity scores at nine and 18 months were similar to those obtained at baseline in both groups suggesting very little change over time. There was no significant change at 18 months between the two groups ( $P = 0.77$ ), with the observed difference, 0.2, less than 1%. Mean aggregate scores for general quality of life showed no significant change at 18 months between the two groups ( $P = 0.95$ ), with an adjusted mean difference of 0.1, well below 1%.

Structured telephone follow-up by SBCNs did not change psychological morbidity (GHQ-12) compared to standard hospital consultations in 374 women over 24 months follow-up (Beaver 2009). The numbers of clinical investigations ordered did not differ between the groups. Recurrences were few (4.5%), with no differences between groups for time-to-detection (median 39.0 (range 10-152) days in telephone SBCN group versus 60.5 (range 37-131) days in the standard hospital group).

There were no changes between groups for feelings of control (Mastery Scale) in a SBCN-led telephone intervention compared with standard care, both with and without an educational group programme delivered by a SBCN and a health care psychologist, in 320 women over 12 months (Kimman 2011).

### Cancer-specific quality of life

Two studies (557 women, moderate-quality evidence) of nurse-led follow-up care for women with primary breast cancer reported cancer-specific quality of life outcomes between 12 and 24 months from baseline (Kimman 2011; Sheppard 2009). Both trials reported no difference in psychological morbidity, role and emotional functioning, between nurse-led follow-up care and standard care. Nurse-led follow-up care was equally as effective as standard care for women with primary breast cancer.

A SBCN intervention conducted by telephone, as a point-of-need access to specialist care, did not change psychological morbidity

measured using the Functional Assessment of Cancer Therapy - General (FACT-G), also breast and endocrine subscales) compared to routine clinical review in 237 women who were followed up for 18 months (Sheppard 2009). No differences were found in relation to endocrine scores ( $P = 0.39$ ). Scores for both groups on the breast subscale improved over time, with lower scores at nine and 18 months compared to baseline. The adjusted mean difference between groups at 18 months was 0.7 points in favour of the SBCN intervention ( $P = 0.058$ ).

There were no differences between groups for role and emotional functioning (EORTC QLQ-C30) in a SBCN-led telephone intervention compared with standard hospital care, both with and without an educational group programme at 12 months (Kimman 2011). At 12 months, mean scores (EORTC QLQ-C30) were 78.4 (SD = 16.2) and 77.7 (SD = 16.2), respectively, for telephone and hospital follow-up. The 95% confidence interval difference at 12 months was -1.93 to 4.64. Overall, quality of life measured using the EORTC QLQ-C30, significantly improved over time ( $P = 0.01$ ) with no difference between follow-up with or without the educational group programme ( $P = 0.86$ ) and no interaction effect between the educational group programme and SBCN-led follow-up ( $P = 0.50$ ).

### Anxiety and Depression

We report the data for the HADS in Table 5. Three studies (1094 women, moderate-quality evidence) (Beaver 2009; Kimman 2011; Koinberg 2004) compared nurse-led follow-up care by telephone with standard care for women with primary breast cancer and reported anxiety and/or depression outcomes between 12 months and five years. One trial used HADS and two trials used STAI. All three studies reported no difference in anxiety between nurse-led follow-up by telephone and standard care between 12 and 60 months; one study also reported no difference in depression between groups at 60 months.

One study with 400 women (Koinberg 2004) showed no difference in anxiety or depression (HADS) between follow-up by demand, managed by a SBCN via telephone, compared with routine follow-up by a specialist oncology surgeon, for up to five years follow-up (60 months: anxiety: RR 1.8; 95% CI 0.6 to 5.1; depression: RR 1.7; 95% CI 0.4 to 7.2). Levels of reported anxiety and depression were low and varied between 4.4% and 11.6% for anxiety and 0.8% and 5.2% for depression, across both groups. Women receiving telephone follow-up by specialist nurses (foregoing clinic examinations and face-to-face consultations) were no more anxious than women receiving traditional hospital follow-up over 24 months (STAI) (Beaver 2009). There were no significant differences in anxiety (STAI) between women receiving telephone follow-up, with or without an educational group programme, compared with standard hospital follow-up over 12 months (Kimman 2011).

### Service provision

Four studies with 1331 women (moderate-quality evidence) of nurse-led follow-up care for women with primary breast cancer reported on satisfaction with service provision between 12 and 60 months from baseline (Beaver 2009; Kimman 2011; Koinberg 2004; Sheppard 2009). All four trials reported no difference or improvement in satisfaction with service provision between nurse-led follow-up care and standard care.

One study (Koinberg 2004) of follow-up by demand, managed by a SBCN via telephone, did not change satisfaction with care or access to medical care (SaaC) compared to routine follow-up by a specialist oncology surgeon during five years of follow-up with satisfaction in both groups ranked highly (93% to 100%) (satisfaction at five years: RR 0.1; 95% CI 0.0 to 0.9). In the SBCN group, there was a higher rate of mammographies but a similar rate of other imaging and laboratory tests compared to routine follow-up by a specialist oncology surgeon. There were 21% more primary contacts in the routine follow-up by a specialist oncology surgeon group. One study (Sheppard 2009) of a SBCN intervention conducted by telephone, as a point-of-need access to specialist care, showed that 95% of the women in the intervention group were happy to continue with a point-of-need access as follow-up care. One study (Beaver 2009), of a structured telephone follow-up by SBCNs, was associated with more satisfaction at the middle and end of the trial compared to standard hospital-based follow-up care. Structured telephone follow-up by SBCNs was not associated with a difference in information needs, compared to standard hospital consultations during 24 months follow-up. In both groups, needs reduced over time. One study (Kimmman 2011), of a SBCN-led telephone intervention compared with standard care, both with and without an educational group programme delivered by a SBCN and a health care psychologist, were associated with high patient satisfaction scores regarding access of care, technical competence, interpersonal aspects and general satisfaction at 12 months follow-up (Wares Patient Satisfaction Questionnaire, Kimmman 2011).

Three of these studies had low risk of bias in five of the seven domains. Koinberg 2004 was rated at low risk of bias in only two of the seven domains. The integrity of the study was unclear - there was ambiguity as to whether an intervention had taken place or not for some participants with verification of the consultation missing in some cases. Also, two study arms in one centre were excluded from the initial analyses because the arms received similar treatment (women randomised to the SBCN intervention were also scheduled to see a surgeon/oncologist each year).

### Women with advanced breast cancer

One study of women with advanced breast cancer compared a psychosocial nursing intervention with standard care (Aranda 2006).

### Psychosocial nursing interventions versus standard care

See: [Summary of findings 4](#).

### General health-related quality of life

There were no data for this outcome.

### Cancer-specific quality of life

One study of 105 women (low-quality evidence) showed that there was no difference in cancer-specific quality of life outcomes at three months following a brief psychosocial nursing intervention, compared with standard care for women with newly diagnosed advanced breast cancer (Aranda 2006). Aranda 2006 randomised 105 women with breast cancer that was newly diagnosed at an advanced stage, or that had recurred or progressed in the preceding 12 months, from outpatient clinics in four large urban hospitals in Australia. A brief nurse-delivered intervention designed to address the individual needs of women with advanced breast cancer did not change quality of life or unmet needs, compared to standard care.

Changes in the EORTC domain scores were not different between the intervention and standard care arms of the study at either one month or three months post-intervention (EORTC Q-C30 version 2). There were no differences between the intervention and standard care groups for the change in SCNS questionnaire domain scores in any of the domains. When data were stratified according to higher psychological needs (a score over 50) or lower needs (a score 50 or below), women with higher baseline needs reported a 19-point decrease in the intervention group compared to a 14-point decrease in the control group.

### Anxiety and depression

There were no data for this outcome.

### Service provision

There were no data for this outcome.

### Nurse-led interventions delivering follow-up care versus standard care

There were no data for this comparison.

## DISCUSSION

### Summary of main results

We included 14 RCTs: ten studies of psychosocial nursing interventions, of which nine studies (1469 women) were of women with primary disease during diagnosis, treatment or survivorship and only one study (105 women) was of women with advanced breast cancer. There were four studies (1331 women) of SBCN-led interventions delivering follow-up care. This review update provides low- to moderate-quality evidence of SBCN interventions. The evidence suggests that psychosocial interventions carried out by SBCNs for women with a primary diagnosis of breast cancer, may improve or are at least as effective **as standard care** for general health-related quality of life, cancer-specific quality of life, anxiety and depression outcomes and satisfaction with care.

The evidence suggests that psychosocial interventions carried out by SBCNs for women with a primary diagnosis of breast cancer, may improve or are at least as effective as **other supportive interventions** for general health-related quality of life, cancer-specific quality of life, anxiety and depression outcomes and satisfaction with care. Individual psychosocial support delivered by specially trained oncology nurses was equally as effective as that delivered by psychologists. Support by SBCNs alone may improve general health-related quality of life and anxiety and depression, compared to support from a voluntary organisation and also compared to support from a voluntary organisation plus a SBCN.

SBCN-led telephone follow-up interventions for women with a primary diagnosis of breast cancer are at least as effective as standard care for general health-related quality of life, cancer-specific quality of life, anxiety and depression outcomes and satisfaction with care.

One study (low-quality evidence) showed that there was no difference in cancer-specific quality of life outcomes at three months, following a brief psychosocial nursing intervention, compared with standard care for women with advanced breast cancer.

We did not pool the outcomes within any of the comparisons for a variety of reasons which differed within each comparison but included the following: only one study reporting an outcome, multiple studies of an outcome but with different comparison groups, outcome measures with different underlying phenomena, studies reporting effects for a mixture of scales and subscales and a mix of measures that lumped or split anxiety and depression. We carried out a narrative description of the study results including structured tabulation of results across the studies using the comparisons used in the 'Summary of findings' tables in order to aid identification and verification of our interpretation of the study data. The SISAQOL Consortium has recently recommended international standards for the analysis of quality-of-life and patient-reported outcome (PRO) endpoints in cancer randomised controlled trials (Coens 2020). Our findings from this update are consistent with the SISAQOL review that showed a need to improve standards in the analysis, interpretation, and reporting of PRO data in cancer RCTs and concluded that "lack of standardisation makes it difficult to draw robust conclusions and compare findings across trials".

### Overall completeness and applicability of evidence

This update has identified nine additional RCTs which has increased the evidence base for SBCN interventions beyond the diagnosis and treatment phase and now includes survivorship interventions and SBCN interventions for follow-up care in women with primary breast cancer. There is now one study of a SBCN intervention for women with newly diagnosed advanced breast cancer disease. This update increases the evidence base for SBCN interventions across the disease trajectory. The studies of SBCN interventions for follow-up care reported a wider range of outcomes compared to psychosocial nursing interventions, particularly around satisfaction with this different model of care. The ongoing studies included women with advanced breast cancer and so this will add additional evidence to the next review update for these women; in addition, the ongoing studies are investigating psychosocial interventions and have the potential to make a substantial contribution to the next update (Characteristics of ongoing studies). Since the search of clinical trials registries was carried out, we are aware of another ongoing pilot trial, the Mini-AFTERc study, which is a pilot trial of a brief cognitive behavioural communication intervention, designed to reduce fear of cancer recurrence in breast cancer patients (NCT03763825). This pilot will improve our understanding of the acceptability and fidelity of complex cognitive behavioural interventions delivered by SBCNs in real-time practice situations.

In terms of generalisability of the results across the patient population, four studies reported that nonparticipants were older than participants of the interventions; the mean ages of the women participating in these trials ranged from 55 to 60 years and the mean age of nonparticipants in these trials ranged from 60 to 73 years. This potentially limits the applicability of the interventions and associated changes in outcomes in women with breast cancer who are over 60 years of age. Despite all studies reporting at least one sociodemographic characteristic of the women at baseline, only two studies reported outcomes according to one of these characteristics. In terms of quality of life outcomes, Hershman 2013 reported that there was no interaction between treatment and ethnicity and Ritz 2000 reported that there was a greater beneficial effect in the APN intervention group for unmarried women than

for married women. We currently do not know whether or how these social determinants of health can influence the effectiveness of SBCN interventions. In addition, the majority of studies excluded women who could not speak the language of the country in which the study was set.

### Quality of the evidence

The certainty of the evidence in this review was generally appraised as very low to moderate using the GRADE rating system (Schünemann 2020). The results were generally consistent, with the direction of findings following the same direction, with SBCN interventions doing as well, or better than, the comparators. We downgraded the quality of the evidence due to overall risk of bias and, in particular, attrition bias and also imprecision; for further details please refer to Summary of findings 1; Summary of findings 2; Summary of findings 3; Summary of findings 4.

### Potential biases in the review process

In this update, we have been specific about the types of outcome measures that were included: primary outcomes are general health-related quality of life, cancer-specific quality of life, and anxiety and depression; the secondary outcome is service provision from the patient perspective. This update included an electronic search of each database from inception to June 2020 and so we are confident that all relevant studies have been identified and included or identified as ongoing.

### Agreements and disagreements with other studies or reviews

Our review complements two recent reviews with broader remits; our review results are consistent with these other two review findings. A 2020 systematic review (Chan 2020) of interventions delivered by nurses with oncology experience for women with breast cancer concluded that "nurse-led surveillance interventions are as safe and effective as physician-led care" and that there was "strong evidence that nurse-led teaching, guidance and counselling and case management interventions are effective for symptom management". Our review complements a recent scoping review (Charalambous 2018) with a broader remit that included non-randomised trials and participants with any cancer, led or delivered by cancer nurses. The scoping review concluded that it had "captured the breadth and scope of cancer nurses in delivering interventions within a trial design. Cancer nurses are performing multiple and increasingly complex roles in a variety of settings across the care continuum". Our review complements this scoping review as it focussed on specialist breast cancer nurses and on the effectiveness of SBCN-led interventions in terms of indicators of quality of life outcomes.

## AUTHORS' CONCLUSIONS

### Implications for practice

The review highlighted the role of the SBCN as having evolved since its early focus on diagnosis to deliver supportive care interventions during treatment and follow-up, reflecting an increasingly complex care pathway. The SBCN continues to have an important role supporting women with early breast cancer but also can translate this role in advanced disease settings. The important role of the SBCN in the provision of complex interventions is evident in all the studies, however, this expertise needs to be better articulated



in the reporting to allow successful translation to practice. There are opportunities for the SBCN to improve the quality of life outcomes for women with early and advanced breast cancer and more clinically applied studies are needed to increase evidence in this area.

### Implications for research

Better reporting of the qualifications of the SBCN undertaking the intervention, the training required, and the context in which the intervention is delivered would enable replication and/or implementation into daily practice. Trial authors should consider using validated quality of life tools already available and widely used to improve opportunities to group trials together in a meta-analysis.

The following outcomes should be considered for inclusion and reported in future trials of SBCN-led interventions in early breast and secondary breast cancer studies.

- Measurement of participant-reported satisfaction
- Sociodemographic data using the PROGRESS Plus

- Measurement of resource use and cost-effectiveness analysis
- Trial authors should consider using the consolidated standards of reporting trials (CONSORT) to improve reporting of complex interventions

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Aranda 2006

##### Study characteristics

Methods	<p>Accrual: 105/172 (61%)</p> <p>Single/multicentre: multicentre</p> <p>Design: RCT</p> <p>Country: Australia</p> <p>Setting: outpatient clinics in 4 large urban hospitals (n = 3 public and n = 1 private) in Melbourne</p> <p>Follow-up period: 3 months (including 1 month intervention)</p>
Participants	<p>N (intervention baseline) = 59</p> <p>N (intervention follow-up) = 36 at 1 month, 30 at 3 months</p> <p>N (control baseline) = 46</p> <p>N (control follow-up) = 36 at 1 month, 30 at 3 months</p> <p>Mean (SD) age:</p> <p>Intervention: Median age 57 (range 34-85)</p> <p>Control: Median age 55 (range 36-82)</p> <p>Tumour stage/clinical condition: A diagnosis of breast cancer that was newly diagnosed at an advanced stage, recurred or progressed in the preceding 12 months;</p> <p>Stage N (%), I vs C: NR – see inclusion criteria</p> <p>Menopausal status N (%), I vs C: NR</p> <p>Years since breast cancer diagnosed:</p> <p>Median (range) years I vs C: 5 (0 – 27) vs 5 (0 – 26)</p> <p>Years since advanced breast cancer diagnosed:</p> <p>Median (range) years I vs C: 1 (0 – 7) vs 1 (0 – 14)</p> <p>Notable exclusion criteria: non-English speaking</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: all urban women</p> <p>Race/ethnicity: NR</p> <p>Occupation: NR</p> <p>Religion: NR</p> <p>Education: NS differences between groups <math>P &gt; 0.15</math></p> <p>Highest education N (%), I vs C:</p> <p>School certificate 18 (31) vs 12 (28)</p> <p>Higher school certificate 7 (12) vs 4 (9)</p> <p>Certificate/diploma 5 (8) vs 6 (14)</p>



**Aranda 2006** (Continued)

University degree/diploma 13 (22) vs 10 (23)

University higher degree 3 (5) vs 2 (5)

Other 13 (22) vs 9 (21)

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status, N (%), I vs C: NS differences between groups  $P > 0.15$

Never married 6 (10) vs 5 (11)

Married/de facto 35 (60) vs 32 (71)

Separated/divorced 9 (16) vs 6 (13)

Widowed 8 (14) vs 2 (4)

**Interventions**

Theoretical basis: FOCUS framework (Family involvement, Optimistic attitude, Coping effectiveness, Uncertainty reduction and Symptom management). Cognitive behavioural techniques and adult learning principles

Aim: to examine the effectiveness of a brief, nurse-delivered intervention designed to address the individual needs of women with advanced breast cancer

Intervention (1 and 3 months):

1. 1 hour face-to-face session with SBCN within 10 days covering: orientation, tailored responses, coaching and practising self-care and communication strategies, and concluding the session. Patients were encouraged to bring 'a significant other'. Each woman was given relevant information cards on self-care and communication strategies and a copy of her personal self-care plan. Women were also provided with a relaxation CD.

2. Telephone follow-up with SBCN 1 week after first session to: (a) ask whether the suggested strategies had ameliorated the concerns; (b) elicit and respond to remaining concerns; (c) reinforce or modify planned self-care strategies or introduce new ones; and (d) prompt further questions/new concerns

Control:

Standard care (no specific details): referral to a SBCN or cancer support nurse not affiliated with the study if appropriate

SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention:

2 training days, covered adherence to the research protocol, evidence-based best-practice medical and psychosocial management of women with advanced breast cancer. A team comprising SA, RF, DM, (authors), a medical oncologist, a radiation oncologist and two experienced BCNs provided training. Teaching included role plays about difficult situations that may arise. Constructive feedback and debriefing was provided.

**Outcomes**

Primary outcomes and tools:

Quality of life measured by European Organisation of Research and Treatment of Cancer Quality of Life Q-C30 (EORTC QLQ-C30) version 2.0

## Aranda 2006 (Continued)

Perceived needs in five core domains: psychological, health information, physical and daily living, patient care and support, and sexuality; measured by Supportive Care Needs Survey (SCNS)

Secondary outcomes and tools:

For each subscale score of the SCNS, each woman was categorised as having high baseline needs (> 50) or low baseline needs (50 and below)

### Notes

Trial registration link: NR

Funding source: Inner & Eastern Melbourne Breast Care Consortium, Breast Services Enhancement Program, Victorian Department of Human Services, Australia

Funding role: NR

Other: Baseline differences: undergoing current radiotherapy (93% (I) vs 73% (C),  $P = 0.01$ )

Family members were included in the intervention.

Patients who died, withdrew, or were lost to follow-up in the usual care arm had consistently lower baseline EORTC scores than those who died, withdrew, or were lost to follow-up in the intervention arm. However, these groups did not differ at baseline on the SCNS subscales.

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	For each study site, an even number of folded intervention (20) and control (20) cards were thoroughly shuffled then placed in consecutively numbered opaque sealed envelopes.
Allocation concealment (selection bias)	Low risk	Consecutively numbered opaque sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported. Baseline assessment carried out before randomisation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A research assistant not involved in intervention delivery administered all data collection.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons not provided for all dropouts and uneven between groups (65% vs 51%)
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.

## Arving 2007

### Study characteristics

#### Methods

Accrual: 179/288 (62%)

Single/multicentre: single centre

**Arving 2007** (Continued)

Design: RCT  
Country: Sweden

Setting: Both interventions took place outside the hospital, face-to-face or over the telephone.

Follow-up period: 6 months, (24 months for healthcare utilization and cost-utility analysis)

Participants	<p>N individual nurse support (INS) baseline = 60</p> <p>N INS follow-up = 40</p> <p>N individual psychological support (IPS) baseline = 60</p> <p>N IPS follow-up = 49</p> <p>N control (usual care) baseline = 59</p> <p>N control follow-up = 40</p> <p>Mean (range) age:</p> <p>INS Intervention: 55 (34-72)</p> <p>IPS Intervention: 55 (23-75)</p> <p>Control: 55 (25-87)</p> <p>Tumour stage/clinical condition: primary breast cancer patients about to start adjuvant treatment (chemo, endocrine and/or loco-regional radiotherapy)</p> <p>Stage N (%), INS vs IPS vs C:</p> <p>T1 43 (72) vs 44 (73) vs 43 (73)</p> <p>T2 12 (20) vs 11 (18) vs 12 (20)</p> <p>T3/T4 5 (8) vs 5 (8) vs 4 (7)</p> <p>N0 41 (68) vs 28 (47) vs 30 (51), P = 0.05.</p> <p>Menopausal status N (%), INS vs IPS vs C:</p> <p>Premenopausal 16 (27) vs 21 (35) vs 18 (30)</p> <p>Notable exclusion criteria: ongoing psychiatric illness, previous cancer diagnosis or inability to speak and understand Swedish</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: INS vs IPS vs C, n (%)</p> <p>Uppsala town 32 (53) vs 33 (55) vs 39 (66)</p> <p>Rural district 28 (47) vs 27 (45) vs 20 (34)</p> <p>Race/ethnicity: NR</p> <p>Occupation: NR</p> <p>Religion: NR</p> <p>Education: NR</p> <p>Socioeconomic status: NR</p> <p>Social capital: NR</p>
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**Arving 2007** (Continued)

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status: INS vs IPS vs C, n (%)

Married/cohabitant 48 (80) vs 46 (77) vs 42 (71)

Single, divorced, widowed 12 (20) vs 14 (23) vs 15 (25)

Missing information 0 vs 0 vs 2 (3)

**Interventions**

Theoretical basis: cognitive behavioural therapy (CBT)

Aim: to compare if individual psychosocial support to breast cancer patients provided by oncology nurses specially trained in psychological techniques was as effective as that given by psychologists and to compare them to standard care

Intervention:

Both interventions used the same techniques such as relaxation, distraction, activity scheduling, and ways to improve communication, all derived from CBT.

In the first session, the patient was asked to relate her disease history using an interview guide covering the following areas: worry/anxiety; depression; sleep disturbances; view of prognosis and future; social situation and support from spouse, family and friends in general and with respect to the disease in particular; communication with hospital staff; the impact of disease/treatment on the patient's activity level such as working capacity, leisure time activities, and management of household tasks. The assessment also included an estimation of the extent to which problems were expected to occur in the near future, for example, if the patient was waiting for test results or was to go through burdensome treatments.

At the end of the first session, it was jointly decided whether further sessions were warranted. The number of sessions and the time interval between them varied according to the need and desire of the individual patients. Every session was scheduled to last for 45 to 60 minutes. The patient's problems were identified, and strategies such as problem-solving, relaxation and distraction techniques, ways to improve communication, and activity scheduling that could help her to manage these were taught to the patient. Patients were given oral and written instructions on how to practice these strategies at home and were asked to report the outcome during the follow-up sessions. Some sessions (n = 91; 19%) were held by telephone because of long travelling distances and had essentially the same content as sessions held face-to-face. At the termination of the intervention, the patient was encouraged to contact the investigators again, should new problems arise.

(1) individual psychosocial support by x 2 oncology nurses specially trained in psychological techniques (individual nurse support = INS)

(2) individual psychosocial support by x 2 psychologists (IPS)

Control: Standard care included regular contact with the patient's oncologist and medical staff. Contact with psychiatrists, physiotherapists, or counsellors was not offered regularly but was arranged if the patient's physician or other medical staff judged this to be necessary or if the patient herself made a specific request.

SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention: 4 x 3-hour lectures over 4 months covering knowledge and skills to assess and treat common psychosocial problems in cancer patients, with a follow-up meeting 5 months later

## Arving 2007 (Continued)

The 2 psychologists who performed the IPS had theoretical knowledge about cancer diseases and treatments, and had experience of counselling. Both nurses and psychologists received supervision every third week by a psychologist or a nurse with extensive experience of psychosocial support to cancer patients.

Outcomes	<p>Primary outcomes and tools:</p> <p>Cancer specific Quality of Life using the European Organisation for Research and Treatment of Cancer Quality of Life Study Group Core Quality of life questionnaire with 30 questions (EORTC QLQ-C30),</p> <p>Breast Cancer Module with 23 questions (BR-23),</p> <p>Hospital Anxiety and Depression Scale (HADS),</p> <p>Spielberger's State-Trait Anxiety Inventory (STAI),</p> <p>Impact of Event Scale (IES)</p> <p>Secondary outcomes and tools: utilisation of psychosocial support offered in routine care (hospital records)</p> <p>Cost-utility analysis (Arving 2014) - hospital billing system provided cost estimates. Quality adjusted life years (QALYs) were calculated using health-related quality of life data from the EORTC QLQ C-30 translated into the Euro Quality of Life 5-Dimensional classification.</p>
Notes	<p>Trial registration link: NR</p> <p>Funding source: grants from the Swedish Cancer Society</p> <p>Funding role: NR</p> <p>Other:</p> <p>Arving 2006 did not report data for control group and only reported satisfaction outcome data for the x 2 randomised groups so not extracted</p> <p>Baseline differences: statistically significantly higher proportion randomised to INS were diagnosed in stage N0 as compared with the remaining groups. Patients that declined to be in the study appeared older compared to patients in study groups.</p> <p>About one-third of the patients in the control group used the psychosocial support provided in routine care, being a statistically significantly higher proportion than in the intervention groups.</p> <p>Arving 2014 reported data on occupation (employed; working at home/unemployed/student; retired) at baseline but not full numbers of participants provided in main paper so not extracted here</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomised in blocks of 9 into 1 of 3 alternatives. No further information reported
Allocation concealment (selection bias)	Unclear risk	Insufficient information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported. Baseline assessments carried out before randomisation
Blinding of outcome assessment (detection bias)	Unclear risk	Blinding not reported. Baseline assessments carried out before randomisation

**Arving 2007** (Continued)

## All outcomes

Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was not statistically significant between groups but was high at 33%. Imbalance between groups at baseline plus imbalance between groups for dropouts which was not accounted for in the analyses (completer analyses of all 4 assessments)
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.

**Beaver 2009**
**Study characteristics**

Methods	<p>Accrual: 374/629 (60%)</p> <p>Single/multicentre: multicentre (2)</p> <p>Design: RCT</p> <p>Country: United Kingdom</p> <p>Setting: telephone (intervention group), district general hospital outpatients or specialist breast care unit outpatients (control) in North-West England</p> <p>Follow-up period: mean 24 months (range 2-43)</p>
Participants	<p>N (intervention baseline) = 191</p> <p>N (intervention follow-up) = 154</p> <p>N (control baseline) = 183</p> <p>N (control follow-up) = 145</p> <p>Mean (SD) age:</p> <p>Intervention: 63.9 (10.1)</p> <p>Control: 64.0 (11.1)</p> <p>Tumour stage/clinical condition: completion of primary treatment (surgery, radiotherapy, chemotherapy), no evidence of recurrent disease, low to moderate risk of recurrence according to the Nottingham prognostic indicator (including grade 1, 2 and low risk grade 3); women with grade I and grade II tumours if the tumour size was <math>\leq 50</math> mm with three or fewer nodes affected. Women with grade III tumours were included only if they were postmenopausal, tumour size was <math>\leq 50</math> mm, no nodes were affected, oestrogen receptor status was positive, and HER2 status was negative.</p> <p>Participants were a median of 20 months from diagnosis, although most (63%) were 24 months or less from diagnosis.</p> <p>Stage N (%), I vs C: NR - low to moderate risk of recurrence</p> <p>Menopausal status N (%), I vs C: NR</p> <p>Notable exclusion criteria: inflammatory carcinomas and sarcomas, difficulty hearing</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: NR</p>

**Beaver 2009** (Continued)

Race/ethnicity: NR

Occupation:

Employment status, I vs C, n (%)

Employed full time: 29 (15) vs 28 (16)

Employed part time: 29 (15) vs 29 (16)

Retired: 121 (64) vs 115 (64)

Unemployed: 2 (1) vs 5 (3)

Long-term sick: 7 (4) vs 3 (2)

Other: 2 (1) vs 1 (1)

Religion: NR

Education: NR

Socioeconomic status:

Social class, I vs C, n (%)

Managers and senior officials: 19 (12) vs 13 (8)

Professional: 18 (11) vs 15 (10)

Associate professionals/technical: 20 (12) vs 20 (13)

Administrative/secretarial: 35 (22) vs 48 (31)

Skilled trades: 7 (4) vs 11 (7)

Personal service: 23 (14) vs 9 (6)

Sales/customer services: 13 (8) vs 12 (8)

Process, plant, and machine operatives: 2 (1) vs 4 (3)

Elementary occupations: 25 (15) vs 25 (16)

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status, I vs C, n (%)

Married/cohabiting: 123 (64) vs 117 (64)

Divorced/separated: 21 (11) vs 15 (8)

Widowed: 39 (20) vs 38 (21)

Never married: 8 (4) vs 13 (7)

Interventions

Theoretical basis: NR

## Beaver 2009 (Continued)

**Aim:** To compare traditional hospital follow-up with telephone follow-up by specialist nurses after treatment for breast cancer

**Intervention:**

Telephone follow-up by BCNs either from the district general hospital or the specialist breast care unit. Participants received telephone appointments by BCNs consistent with hospital policy (3 months for two years; six monthly for two years and annually for a further year). Each telephone appointment was allocated 30 minutes (20 minutes for the consultation and 10 minutes to dictate outcome). Structured and recorded telephone intervention with questions related to changes in condition, new symptoms, and information requirements about spread of disease, treatment and side effects, genetic risk, sexual attractiveness, self-care (diet, support groups, finances), and family concerns.

Throughout the study, the same specialist nurse contacted each participant in the telephone group for all appointments.

**Control:**

District General hospital follow-up consistent with hospital policy (3 months for two years; six monthly for two years and annually for a further year). Specialist breast care unit: reviewed annually for 10 years. Hospital consultations were generally unstructured but primarily consisted of a clinical examination, a check on whether hormone treatment was being taken as prescribed, and ordering mammograms if necessary. As per hospital policy, both study locations allocated 10 minutes for each individual hospital appointment. Hospital consultations could be conducted by various health professionals including consultant surgeons, consultant oncologists, registrars, more junior doctors, or specialist nurses. It was more usual at both locations, however, for junior medical staff to conduct hospital appointments.

Both arms received a mammogram annually.  
SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention: 4 x half-day training sessions on the administration of the telephone intervention with subsequent feedback and debriefing sessions throughout the study period. Seven nurses received training, although one nurse at the district general hospital and three nurses at the specialist breast unit conducted most telephone appointments.

Outcomes	<p>Primary outcomes and tools:</p> <p>Psychological morbidity measured by Spielberger state trait anxiety inventory (STAI),</p> <p>General Health questionnaire (GHQ-12)</p> <p>Secondary outcomes and tools: Need for information, satisfaction, and time to detection of recurrent disease, clinical investigations ordered. Cost minimisation analysis (<a href="#">Beaver 2009b</a>)</p>
Notes	<p>Trial registration link: National Cancer Research Institute, 1477</p> <p>Funding source: Medical Research Council (UK) and a project grant from the Rosemere Cancer Foundation (UK)</p> <p>Funding role: The funding agencies had no role in the design and conduct of the study, in the collection, analysis and interpretation of the data, or in the preparation, review or approval of the manuscript.</p> <p>Other:</p> <p>Women who refused to take part differed from participants in study site, social class, and follow-up status. Patients at the specialist breast unit (71%) were more likely to want to participate than those at the district general hospital, participants from higher social classes (professional occupations) were more likely to want to participate than those from lower social classes and participants with three to 12 months between visits were more likely to participate than those on six monthly follow-up.</p>

### Risk of bias

**Beaver 2009** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequences were computer-generated with randomly varying block sizes.
Allocation concealment (selection bias)	Low risk	Researchers contacted a central randomisation service to discover individual group randomisation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported for participants. Breast care nurses had no involvement in randomisation or data collection procedures.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The analyst was blinded to study group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropouts were equally balanced (19.4% vs 20.8%), reasons for dropouts provided in flow diagram. Both intention-to-treat and analyses adjusted for treatment received, were carried out. Difference between dropouts and non-dropouts was associated with time from diagnosis and time from first visit after treatment.
Selective reporting (reporting bias)	Unclear risk	Trial registration number was reported but could not identify this trial in the database
Other bias	Low risk	The study appeared to be free of other sources of bias.

**Fenlon 2020**
**Study characteristics**

Methods	<p>Accrual: 127/130 (98%)</p> <p>Single/multicentre: multicentre (6)</p> <p>Design: RCT</p> <p>Country: United Kingdom</p> <p>Setting: group session or via telephone if missed session (intervention group), NHS Hospitals in England and Wales</p> <p>Follow-up period: 26 weeks</p>
Participants	<p>N (intervention baseline) = 63</p> <p>N (intervention follow-up) = 61</p> <p>N (control baseline) = 67</p> <p>N (control follow-up) = 66</p> <p>Mean (SD) age:</p> <p>Intervention: 53.5 (9.8)</p> <p>Control: 55.2 (10.2)</p> <p>Tumour stage/clinical condition: females 16 yrs and older, with primary breast cancer or ductal carcinoma in situ, who had completed primary treatment, experiencing seven or more hot flushes and night</p>

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**Fenlon 2020** (Continued)

sweats/week, with an overall rating of 4/10 or above on the Hot Flush Problem Rating scale. 85-94% participants had received radiotherapy and 50-62% had received chemotherapy.

Stage N (%), I vs C: NR

Time since last period (years; median [IQR]); I: 4.0 (1.0-8.0); C: 4.0 (1.0-8.0)

Notable exclusion criteria: metastatic disease and male

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity, White n (%); I: 58 (96.7%); c: 62 (95.4%)

Occupation: NR

Employment status, Employed n (%): I: 34 (56.7%); C: 40 (60.6%)

Religion: NR

Education, Educated 16+ years of age n (%): I: 38 (64.4%); C: 30 (46.2%)

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact could be anticipated:

Married/living with partner n (%); I: 43 (72.9%); C: 54 (84.4%)

**Interventions**

Theoretical basis: drew on Hunter and Mann's theoretical model of HFNS, based on symptom perception, self-regulation and cognitive behavioural theories to explain women's cognitive appraisal and behavioural reactions to symptoms

Aim: To evaluate the effectiveness of SBCN-led group CBT on reducing the impact of HFNS in women with breast cancer 26 weeks after randomisation

Intervention:

weekly group CBT sessions, lasting 90 minutes each, for six weeks, following the structured manual, which included a psycho-education and the cognitive behavioural model; stress management; paced breathing; cognitive and behavioural strategies to improve well-being and for managing hot flushes, night sweats and sleep; and maintaining changes. CBT targeted the cognitive and behavioural elements, manual included Power Point slides, homework sheets, and a paced breathing relaxation CD

Control:

standard NHS care differed between sites since there is no current UK standard of care. Women were generally given ad hoc advice about HFNS, typically only if they raised the issue. Offered a version of self-help CBT after the final assessment at week 26  
SBCN (provider) clinical experience: 4/11 BCNs had prior experience of delivering group sessions and 8 had received advanced communication skills training. 3 had received training in counselling, only one had experience or training in CBT.

SBCN (provider) training for this intervention: 11 BCNs underwent the training (all female, aged 45-48 years), trained by a clinical psychologist over two days, using the training manual to deliver the CBT

**Fenlon 2020** (Continued)

intervention. The manual contains detailed session content; presentation slides and handouts. BCNs received ongoing supervision of their delivery of group CBT from the trainer by email or telephone as required.

Nine BCNs completed pre and post-questionnaires. The average confidence for skills to run group CBT (scale 1-10) was 5.3 before and 7.7 post-training. Their views of how effective training would be was on average 6.7 pre and 8.2 post-training. Their average confidence in using the CBT model with participants for stress and hot flushes increased from 5.2 before to 8.1.

Outcomes	<p>Primary outcomes and tools:</p> <p>hot flushes (HFNS Rating scale &amp; HFNS Belief and Behaviour Scale) at 26 weeks</p> <p>Secondary outcomes and tools: depression (patient health questionnaire), general anxiety disorder (GAD-7) sleep (Pittsburgh Sleep Quality Index), impact of hot flushes on daily activities and overall QoL (Hot Flash Related Daily Interference Scale) and quality of life (EQ-5D-5l)</p>
Notes	<p>Trial registration link: International Standard Randomized Controlled Trial Number 12824632</p> <p>Funding source: sponsored by the University of Southampton and co-ordinated by the Southampton Clinical Trials Unit, commissioned by Breast Cancer Now</p> <p>Funding role: The commissioning board commented on study design, but no further part in management or analysis</p> <p>Other: extracted from article which was accepted for publication and undergone full peer review; original intention was to include FACT-ES to explore quality of life but this was withdrawn later to shorten the questionnaire and improve response rate. Health economic analysis (EQ-5D) and process evaluation (normalisation process theory) will be reported in additional publication.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Individual randomisation was conducted by an independent statistician, allocating participants in a 1:1 ratio, stratified by site, with fixed block size.
Allocation concealment (selection bias)	Low risk	Independent statistician
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/130 dropouts - low attrition
Selective reporting (reporting bias)	Low risk	Protocol published. All outcomes stated in protocol either reported in paper or will be reported in subsequent publications.
Other bias	Low risk	Study appeared to be free of other sources of bias.

**Gomez 2019**
**Study characteristics**

Methods	<p>Accrual: 173/NR</p> <p>Single/multicentre: single</p> <p>Design: RCT</p> <p>Country: Spain</p> <p>Setting: medical oncology unit of hospital in Malaga</p> <p>Follow-up period: 12 months</p>
Participants	<p>N (intervention1 baseline) = 61</p> <p>N (intervention1 follow-up) = NR</p> <p>N (intervention2 baseline) = 55</p> <p>N (intervention2 follow-up) = NR</p> <p>N (control baseline) = 56</p> <p>N (control follow-up) = NR</p> <p>Mean (SD) age:</p> <p>Intervention1: 58.6</p> <p>Intervention2: 56.5</p> <p>Control: 59.8</p> <p>Tumour stage/clinical condition: patients with breast cancer histologically documented between their first and third follow-up appointments who received antineoplastic treatment including biological therapies except hormone therapy, at least 18 years of age. 70-83% participants received radiotherapy (69.6% control, 80.3% I1, 80.9% I2 received radiotherapy)</p> <p>Stage N (%), I vs C: NR</p> <p>Menopausal status N (%), I vs C: NR</p> <p>Notable exclusion criteria: serious concomitant diseases, diagnosed and treated for other types of cancer before, brain metastases</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: NR</p> <p>Race/ethnicity: NR</p> <p>Occupation: NR</p> <p>Employment status: NR</p> <p>Religion: NR</p> <p>Education: NR</p> <p>Socioeconomic status:NR</p> <p>Social capital: NR</p> <p>Age: see above</p> <p>Disability: NR</p>

**Gomez 2019** (Continued)

	<p>Sexual orientation: NR</p> <p>Any other dimension of disadvantage or inequity for which a health impact may be anticipated: NR</p>
Interventions	<p>Theoretical basis: NR</p> <p>Aim: To evaluate the effectiveness of structured nursing intervention to improve cancer-related fatigue in breast cancer patients during their monitoring period</p> <p>Intervention1:</p> <p>Education (at baseline and 3 months, dealing with fatigue) plus telephone monitoring (at 6, 9 and 12 months, resolved doubts and reinforced education) conducted by nurse at oncological nursing unit</p> <p>First session:</p> <ol style="list-style-type: none"> <li>1. What is fatigue?</li> <li>2. Self-care: fatigue</li> <li>3. Rest</li> <li>4. Exercising tips</li> <li>5. Endurance exercises</li> <li>6. Toning exercises</li> <li>7. Stretching</li> <li>8. Cognitive restructuring process</li> </ol> <p>Second session:</p> <ol style="list-style-type: none"> <li>1. Characteristics of automatic thoughts</li> <li>2. Cognitive restructuring</li> <li>3. Emotion management</li> <li>4. Emotions</li> <li>5. Relaxation</li> <li>6. Relaxation techniques through breathing</li> </ol> <p>Intervention2:</p> <p>Education (as above, at baseline and 3 months, dealing with fatigue) conducted by nurse at oncological nursing unit</p> <p>Control:</p> <p>Usual practice - regular pattern for medical appointment with their oncologist</p> <p>SBCN (provider) clinical experience: NR</p> <p>SBCN (provider) training for this intervention: NR</p>
Outcomes	<p>Primary outcomes and tools:</p> <p>Cancer-related fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue, FACIT)</p> <p>Secondary outcomes and tools: sleep (Oviedo Sleep Questionnaire, OSQ), anxiety and depression (Goldberg Anxiety and Depression Scales, GADS), pain (Visual Analogue Scale)</p> <p>At 3, 6, 9 and 12 months follow-up</p>
Notes	<p>Trial registration link: NR</p> <p>Funding source: V HOSPIRA SEEO (Spanish Society of Oncology Nursing) GRANT 2016</p> <p>Funding role: NR</p> <p>Other: Baseline difference between groups for radiotherapy. Paper translated into English from Spanish by the first author. There were dropouts in all groups but it was not reported clearly (n = 14, n = 12, n = 39 reported for correlation of paired samples - FACIT scale).</p>

**Risk of bias**

**Gomez 2019** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Study authors reported measuring fatigue, sleep, anxiety and depression, and pain at baseline and 3, 6, 9 and 12 months after the intervention. However, within the results section, they did not include these data, and only reported fatigue at 12 months.
Selective reporting (reporting bias)	Unclear risk	Protocol was not available.
Other bias	Unclear risk	Not reported

**Hershman 2013**
**Study characteristics**

Methods	Accrual: 141/317 (44%)  Single/multicentre: single centre Design: RCT Country: United States  Setting: breast cancer-specific clinic, Columbia University Medical Center  Follow-up period: 6 months
Participants	N (intervention baseline) = 66 N (intervention follow-up) = 50 N (control baseline) = 60 N (control follow-up) = 57  Mean (SD) age: Intervention: 53.7 (12.1) Control: 54.9 (10.9)  Tumour stage/clinical condition: Women who had a history of stage 0–III breast cancer and were within 6 weeks of completion of initial adjuvant, treatment (radiation or chemotherapy);  Stage N (%), I vs C:

**Hershman 2013** (Continued)

Stage 0: 2 (2.8) vs 1 (1.4)

Stage I: 33 (46.5) vs 35 (50.0)

Stage II: 27 (38.0) vs 25 (35.7)

Stage III: 9 (12.7) vs 9 (12.9)

Menopausal status N (%), I vs C:

Premenopausal 9 (13.6) vs 9 (15)

Notable exclusion criteria: received surgery alone without adjuvant therapy or had a significant psychiatric illness that precluded completion of questionnaire

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: I vs C, n (%)

Race:

Caucasian: 38 (59.4) vs 35 (58.3)

Black, African-American or Carribean: 15 (23.4) vs 18 (30.0)

Asian: 1 (1.6) vs 3 (5.0)

American Indian: 1 (1.6) vs 0

Other: 9 (14.1) vs 4 (6.7)

Ethnicity:

Non-Hispanic: 32 (48.5) vs 33 (55.0)

Hispanic: 34 (51.5) vs 27 (45.0)

Occupation:

Employment:

Full-time: 22 (33.3) vs 21 (35.6)

Part-time/self-employed: 9 (13.6) vs 11 (18.6)

Unemployed: 9 (13.6) vs 7 (11.9)

Other: 26 (39.4) vs 20 (33.9)

Religion:

Catholic: 38 (58.5) vs 33 (56.9)

Protestant/Christian: 7 (10.8) vs 12 (20.7)

Jewish: 10 (15.4) vs 7 (12.1)

Other: 10 (15.4) vs 6 (10.3)

Education:

Grade school: 10 (15.1) vs 11 (18.6)

High school: 17 (25.8) vs 15 (25.4)

College: 25 (37.9) vs 19 (32.2)



**Hershman 2013** (Continued)

Graduate school: 14 (21.2) vs 14 (23.7)

Socioeconomic status:

Income:

0-\$30,000: 22 (38.6) vs 22 (42.3)

\$30,000-60,000: 9 (15.8) vs 5 (9.6)

\$60,000-100,000: 11 (19.3) vs 12 (23.1)

> \$100,000: 15 (26.3) vs 13 (25.0)

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status:

Single: 17 (25.8) vs 12 (20.3)

Married/living with partner: 38 (57.5) vs 31 (52.5)

Divorced/separated: 7 (10.6) vs 13 (22.0)

Widowed: 4 (6.1) vs 3 (5.1)

Primary language:

English: 43 (65.1) vs 36 (60.0)

Spanish: 23 (34.9) vs 24 (40)

Also Hispanic women were significantly less educated, less likely to be married or living with a partner, less likely to have full-time employment, had lower household income compared to non-Hispanic women.

**Interventions**

Theoretical basis: NR

Aim: To evaluate the effect of an in-person survivorship intervention

Intervention:

Survivorship Intervention Group (SI)

Participants met a nurse and nutritionist for 1 hour to receive a personalised treatment summary (in English or Spanish), surveillance recommendations, discussion of risk for late effects and toxicities, and screening and lifestyle recommendations based on guidelines from the American Society of Clinical Oncology

Control:

Participants received the National Cancer Institute (NCI) publication only  
Both arms received the NCI publication, "Facing Forward: Life after Cancer Treatment". It is a 24-page manual that summarises key issues of interest to cancer survivors during the re-entry phase, and contains sections on a number of issues after cancer treatment, including medical care, potential symptoms, emotions, social relationships, and dealing with practical matters, such as insurance and employment.

SBCN (provider) clinical experience: NR

**Hershman 2013** (Continued)

SBCN (provider) training for this intervention: NR

Outcomes	<p>Primary outcomes and tools:</p> <p>Health worry and impact of cancer using Impact of Cancer (IOC) and assessment of survivor concerns (ASC);</p> <p>Secondary outcomes and tools: Treatment satisfaction using functional assessment of chronic illness therapy-treatment satisfaction patient satisfaction (FACIT-TS-PS);</p> <p>Physical and functional well-being subscales of the Functional Assessment of Cancer Therapy (FACT);</p> <p>Center of epidemiological studies depression scale (CES-D);</p> <p>Memorial Symptoms Assessment Scale</p>
Notes	<p>Trial registration link: NCT00821288</p> <p>Funding source: grant from Susan G. Komen for the Cure (DISP0706868) and the Breast Cancer Research Foundation (DLH)</p> <p>Funding role: NR</p> <p>Other:</p> <p>Hispanic women were over-sampled to achieve a roughly equal number of Hispanic and non-Hispanic participants.</p> <p>Reported outcomes by ethnicity</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation was generated with a block randomisation list created via a computer-generated sequence for each of the stratification groups and placed in sealed sequential envelopes.
Allocation concealment (selection bias)	Low risk	Allocation was generated with a block randomisation list created via a computer-generated sequence for each of the stratification groups and placed in sealed sequential envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Single-blinded. Participants were told they were in a cancer survivors study prior to randomisation. Researchers were blinded to randomisation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding was unclearly reported in the paper.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Although there was reporting of reasons for non-participation (immediately after randomisation) in the study flow diagram, the reasons for dropouts from baseline to follow-up were not reported.
Selective reporting (reporting bias)	Low risk	The study protocol was available (NCT00821288) and outcomes stated in protocol were reported in the paper.
Other bias	Low risk	The study appeared to be free of other sources of bias.

## Kim 2017

### Study characteristics

Methods	<p>Accrual: 60/70 eligible (86%)</p> <p>Single/multicentre: single centre</p> <p>Design: RCT</p> <p>Country: South Korea</p> <p>Setting: Oncology outpatient clinic in a university hospital</p> <p>Follow-up period: 9 weeks (included 6 weeks chemotherapy)</p>
Participants	<p>N (intervention baseline) = 30</p> <p>N (intervention follow-up) = 29</p> <p>N (control baseline) = 30</p> <p>N (control follow-up) = 24</p> <p>Mean (SD) age:</p> <p>Intervention: 47.9 (8.4)</p> <p>Control: (48.1 (6.9)</p> <p>Tumour stage/clinical condition:</p> <p>Women with breast cancer who had undergone chemotherapy at a university hospital in Seoul (i) had been diagnosed with stage I to III breast cancer and were undergoing adjuvant chemotherapy; (ii) were at a high risk of depression, as determined by a score of <math>\geq 16</math> on the Center for Epidemiologic Studies Depression scale (CES-D); (iii) were <math>\geq 20</math> years old; (iv) could read, understand and write in Korean</p> <p>The average CES-D score (range: 0–60) for depressive symptoms was 26 for the patients in the present study (range: 19–32).</p> <p>Stage N (%), I vs C:</p> <p>I: n = 3 (10%) vs n = 6 (20%)</p> <p>II: n = 19 (63%) vs n = 15 (50%)</p> <p>Menopausal status N (%), I vs C:</p> <p>Yes: n = 6 (20%) vs n = 7 (23%)</p> <p>No: n = 24 (80%) vs n = 23 (77%)</p> <p>Notable exclusion criteria: none</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: NR</p> <p>Race/ethnicity: NR</p> <p>Occupation:</p> <p>Employment N (%), I vs C:</p> <p>Employed: 9 (30) vs 13 (43)</p> <p>Religion: N (%), I vs C:</p> <p>Yes: 26 (87) vs 22 (73)</p>

## Kim 2017 (Continued)

Education: N (%), I vs C:

≤ middle school: 6 (20) vs 5 (17)

High school: 9 (30) vs 16 (53)

≥ college: 15 (50) vs 9 (30)

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status N (%), I vs C:

Married: 29 (97) vs 28 (93)

Interventions	<p>Theoretical basis: NR</p> <p>Aim: To develop a nurse-led psychological intervention programme and to evaluate its effects on psychological distress and quality of life in patients with breast cancer undergoing chemotherapy and at a high risk of depression</p> <p>Intervention:</p> <p>The nurse-led psychological intervention programme comprised seven weekly counselling sessions delivered face-to-face and telephonically. These aimed to provide emotional support to patients and to enable them to express their feelings.</p> <p>Control:</p> <p>After the study, the co-ordinator telephonically contacted patients in the control group, checked their status, explained the programme to them and encouraged them to take part in it.</p> <p>SBCN (provider) clinical experience: Intervention was implemented by a co-ordinator nurse who had obtained certification in advanced practice nursing (and was thus also a nurse practitioner) in oncology nursing and had 3 years of experience in consultation with patients with cancer.</p> <p>SBCN (provider) training for this intervention: the co-ordinator nurse underwent a 20-hr AAA (i.e. awareness, adoption and application) coaching programme and obtained the Korean Associate Coach certificate.</p>
Outcomes	<p>Primary outcomes and tools:</p> <p>Affective mood disturbance was measured using the Korean version of Profile of Mood States-Brief (K-POMS-B), which is a short version of the original 65-item POMS.</p> <p>Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS), which was translated into Korean and validated in nonpsychiatric Korean individuals.</p> <p>For quality of life, the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life questionnaire—Core Questionnaire (QLQ-C30, version 3.0) was used, which was developed to assess cancer patients' quality of life and has been translated into Korean.</p> <p>Secondary outcomes and tools: Primary and secondary outcomes not reported</p>
Notes	<p>Trial registration link: NR</p> <p>Funding source: This study was part of a research project for a doctoral dissertation and had no funding sources.</p>

## Kim 2017 (Continued)

Funding role: This study was part of a research project for a doctoral dissertation and had no funding sources.

Other: none

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned using random numbers generated on a website, <a href="http://randomization.com/">http://randomization.com/</a>  Stratified according to surgery and menopausal status prior to randomisation
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts were reported but not reasons nor how dropouts were accounted for in the analyses.
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.

## Kimman 2011

### Study characteristics

Methods	<p>Accrual: 320/881 (36%)</p> <p>Single/multicentre: multicentre</p> <p>Design: RCT</p> <p>Country: Netherlands</p> <p>Setting: 7 hospitals and 2 radiotherapy clinics in the south of the Netherlands. The educational group programme (EGP) was held at cancer information centres. Centres were specialised in providing support to (ex-)cancer patients and their relatives through education and organising activities.</p> <p>Follow-up period: 12 months, (18 months subsample for cost analysis)</p>
Participants	<p>N (telephone + EGP baseline) = 77</p> <p>N (telephone + EGP follow-up) = 74</p> <p>N (telephone baseline) = 85</p> <p>N (telephone follow-up) = 76</p>

**Kimman 2011** (Continued)

N (hospital + EGP baseline) = 79

N (hospital + EGP follow-up) = 75

N (hospital control baseline) = 79

N (hospital control follow-up) = 74

Mean (SD) age:

N (telephone + EGP) = 55.4 (9.2)

N (telephone) = 55.5 (9.0)

N (hospital + EGP) = 55.3 (11.5)

N (hospital control) = 57.2 (9.8)

Tumour stage/clinical condition: recruited within 6 weeks after completion of treatment with curative intent

Stage N (%), Telephone + EGP vs Telephone vs Hospital + EGP vs Hospital control:

Stage I: 42 (56.8) vs 48 (63.2) vs 43 (57.3) vs 48 (64.9)

Stage IIa: 17 (23.0) vs 17 (22.4) vs 19 (25.3) vs 16 (21.6)

Stage IIb: 8 (10.8) vs 5 (6.6) vs 5 (6.7) vs 3 (4.1)

Stage III: 5 (6.8) vs 6 (7.9) vs 7 (9.3) vs 6 (8.1)

Unknown: 2 (2.7) vs 0 vs 1 (1.3) vs 1 (1.4)

Menopausal status: NR

Notable exclusion criteria: Evidence of distant metastases and/or participation in another clinical trial or medical illness requiring more frequent follow-up

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: NR

Occupation:

Paid employment: N (%)

Telephone + EGP = 26 (35.1)

Telephone = 28 (36.8)

Hospital + EGP = 32 (42.7)

Hospital control = 29 (39.2)

Religion: NR

Education: N (%)

Low/middle/high:

Telephone + EGP = 28 (37.8)/29 (39.2)/17 (23.0)

Telephone = 29 (38.2)/27 (35.5)/20 (26.3)

Hospital + EGP = 23 (30.7)/31 (41.3)/21 (28.0)



**Kimman 2011** (Continued)

Hospital control = 22 (29.7)/31 (41.9)/21 (28.4)

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status (not extracted - only reported by aggregating x 2 groups that received hospital follow-up compared to telephone follow-up (also 2 groups aggregated))

**Interventions**

Theoretical basis: basic theory underlying the EGP is the transaction process theory of stress

Aim: to investigate the impact of these interventions on cancer-specific QoL and costs and thus to determine which of these follow-up strategies is the most cost-effective

Intervention:

Telephone + educational group programme intervention:

Nurse-led telephone follow-up: a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews by breast care nurse at the same time points as for usual follow-up. Telephone follow-up was provided by SBCN.

The EGP consisted of two interactive group sessions of 2.5 hours and attended by partner +/- within three months of treatment.

Telephone intervention:

Nurse-led telephone follow-up: a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews by breast care nurse at the same time points as for usual follow-up. Telephone follow-up was provided by SBCN.

Standard care hospital + educational group programme intervention:

Hospital follow-up as usual - five outpatient clinic visits in first 18 months (at 3, 6, 9, 12 and 18 months)  
Hospital follow-up was provided by surgeon, medical oncologist, radiation oncologist and/or SBCN.  
The EGP consisted of two interactive group sessions of 2.5 hours and attended by partner +/- within three months of treatment.

Control: standard care hospital intervention:

Hospital follow-up as usual - five outpatient clinic visits in first 18 months (at 3, 6, 9, 12 and 18 months)  
Hospital follow-up was provided by surgeon, medical oncologist, radiation oncologist and/or SBCN.

All groups received follow-up as usual that took place in the hospital where surgery and chemotherapy were performed, alternating between the surgeon, medical oncologist and radiation oncologist.

SBCN (provider) clinical experience: The telephone follow-up was performed by the nurse practitioner (NP) or SBCN working at this hospital. 'A Nurse Practitioner (NP) is a registered nurse who has acquired (at masters level) the expert knowledge base, complex decision-making skills and clinical competencies for expanded practice. The SBCN is a qualified nurse who has had specialist training in breast care and who guides the patient throughout treatment. In this paper, the term SBCN is used and refers to both types of nurses'.

SBCN (provider) training for this intervention: BCNs were informed of the most recent developments in breast cancer treatment and follow-up, developed a semistructured questionnaire for support during

**Kimman 2011** (Continued)

the telephone interview, and practiced their telephone communication skills with a breast cancer patient.

Outcomes	<p>Primary outcomes and tools:</p> <p>Cancer specific QoL measured by EORTC QLQ-C30</p> <p>Secondary outcomes and tools:</p> <p>Perceived behavioural control measured by Dutch version of Mastery Scale</p> <p>Anxiety measured by Dutch version of State Trait Anxiety Inventory (STAI)</p> <p>Patients satisfaction measured by PSQ-NI</p> <p>Generic health-related quality of life measured by EuroQol-5D (5Q-5D)</p> <p>Cost-effectiveness analysis (societal perspective): costs were measured using cost diaries and hospital registrations. Quality-adjusted life years (QALYs) were measured using the EQ-5D. Outcomes were expressed in incremental cost-effectiveness ratios (ICERs) and cost-effectiveness acceptability curves.</p>
Notes	<p>Trial registration link: ISRCTN 74071417</p> <p>Funding source: Netherlands Organisation for Health Research and Development (Grant no. 945-04-512)</p> <p>Funding role: NR</p> <p>Other:</p> <p>Participants were significantly younger than non-participants: mean age 60 years, <math>P &lt; 0.001</math>; Kimman 2010 assessed satisfaction by aggregating x 2 groups that received hospital follow-up compared to telephone follow-up.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by minimisation was performed by the independent Comprehensive Cancer Centre Limburg using a computerised randomisation programme.
Allocation concealment (selection bias)	Low risk	Randomisation by minimisation was performed by the independent Comprehensive Cancer Centre Limburg.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition (6%) balanced across groups with reasons reported
Selective reporting (reporting bias)	Low risk	The study protocol was available (ISRCTN 74071417) and published (Kimman 2007). All outcomes reported in the protocol were reported in subsequent papers.

**Kimman 2011** (Continued)

Other bias	Low risk	The study appeared to be free of other sources of bias.
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**Koinberg 2004**
**Study characteristics**

Methods	<p>Accrual: 400/NR</p> <p>Single/multicentre: multicentre</p> <p>Design: RCT</p> <p>Country: Sweden</p> <p>Setting: 3 hospitals, (2 hospitals analysed, N = 264), BCNs worked in a setting where they had rapid access to specialists in surgery and/or oncology within their own hospital.</p> <p>Follow-up period: 5 years</p>
Participants	<p>N (intervention baseline) = NR</p> <p>N (intervention follow-up) = 133</p> <p>N (control baseline) = NR</p> <p>N (control follow-up) = 131</p> <p>Mean (SD) age:</p> <p>Intervention: 60.0 (10.3)</p> <p>Control: 58.8 (10.1)</p> <p>Tumour stage/clinical condition: women with newly diagnosed breast cancer, classified as UICC stage I or stage II (the intervention was a follow-up intervention post-surgery)</p> <p>Stage (%), I vs C:</p> <p>Tumor stage I:</p> <p>45.1% vs 45.5%</p> <p>Tumor stage II:</p> <p>54.9% vs 54.5%</p> <p>Menopausal status: NR</p> <p>Notable exclusion criteria: none</p> <p>PROGRESS categories assessed at baseline:</p> <p>Place of residence: NR</p> <p>Race/ethnicity: NR</p> <p>Occupation: NR</p> <p>Religion: NR</p> <p>Education: NR</p> <p>Socioeconomic status: NR</p> <p>Social capital: NR</p>

**Koinberg 2004** (Continued)

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status I vs C, %

Married or living with a partner: 66.6 vs 71.7

Living alone: 15.5 vs 13.0

Widowed: 17.1 vs 15.3

**Interventions**

Theoretical basis: NR

Aim: to compare nurse-led follow-up on demand versus physician follow-up after breast cancer treatment

Intervention:

Specialist nurse intervention with check-ups on demand. A nurse with specialist experience in breast cancer met patients approximately 3 months following surgery. Women received information about recognising recurrence, aspects of self-care and time to talk about psychosocial aspects. Women advised to contact the nurse if symptoms arose which were perceived as due to breast cancer. Mammography carried out yearly arranged by the nurse. Blood tests, chest x-ray or other imaging performed on clinical indication

Control:

Routine follow-up visits to a physician. Clinical examination/hospital visit 4 times per year following first 2 years, bi-annual for 5 years, yearly after 5 years. Mammography carried out yearly. Blood tests, chest x-ray or other imaging performed on clinical indication  
SBCN (provider) clinical experience: "We emphasise that the nurses in the study had great experience of and specific training in dealing with breast cancer patients."

SBCN (provider) training for this intervention: NR

**Outcomes**

Primary outcomes and tools:

Quality of life measured by:  
Hospital Anxiety and Depression (HAD) Scale  
Satisfaction and accessibility (SaaC) scale

Secondary outcomes and tools: Number of contacts with the health care services, number of diagnostic procedures, and time to recurrence or death via medical record review; cost minimisation study from public health perspective (Koinberg 2009)

**Notes**

Trial registration link: NR

Funding source: CTRF, Sweden (cancer and traffic federation) and by County Council of Halland, Sweden.

Funding role: NR

Other: at one of the centres, the women randomised to the nurse-based system were scheduled to see a surgeon or oncologist each year in conjunction with the mammography. Before the data were scrutinised and any analyses undertaken, the 135 women from this clinic were excluded, since we deemed the two study arms at this centre to be too similar. However, after all analyses and the first interpretation of data, all analyses were run with the third centre included.

**Risk of bias**

**Koinberg 2004** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was achieved by means of telephone contact with an external secretariat. The random selection was computer-generated and stratified by centre. The block size was unknown to the study co-ordinators at the centres.
Allocation concealment (selection bias)	Low risk	Randomisation was achieved by means of telephone contact with an external secretariat. The random selection was computer-generated and stratified by centre. The block size was unknown to the study co-ordinators at the centres.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not reported. It was unclear how many nurses/physicians the patients might see. In addition, no detail was provided about what would happen if a participant in the physician group wished to see a nurse and this was the same nurse as involved in the study.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding was not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Numbers of dropouts and reasons were not reported. The recurrences or deaths were reported in both groups but it was unclear if these participants were included in the analysis.
Selective reporting (reporting bias)	Unclear risk	No protocol was available and primary outcome was not clearly stated.
Other bias	Unclear risk	There was a monitoring procedure which highlighted ambiguity as to whether an intervention had taken place or not for some participants/verification of the consultation was missing in some cases. Also, 2 study arms in one centre were excluded from initial analyses because the 2 study arms received similar treatment (women randomised to the nurse-based system also scheduled to see a surgeon/oncologist each year).

**Maguire 1980**
**Study characteristics**

Methods	Accrual:172/NR  Single/multicentre: single centre Design: RCT Country: United Kingdom  Setting: home and clinic (intervention group), surgical unit, University Hospital of South Manchester, England  Follow-up period: 12-18 months post-mastectomy
Participants	N (intervention baseline) = NR  N (intervention follow-up) = 75  N (control baseline) = NR  N (control follow-up) = 77  Mean (SD) age:

**Maguire 1980** (Continued)

Intervention: NR

Control: NR

Tumour stage/clinical condition: Breast cancer patients who had a modified radical mastectomy and full axillary clearance.

Stage: NR

Menopausal status: NR

Notable exclusion criteria: NR

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: NR

Occupation: NR

Religion: NR

Education: NR

Socioeconomic status: NR

Social capital: NR

Age: NR

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated: NR

**Interventions**

Theoretical basis: NR

Aim: to determine whether counselling by a specialist nurse prevented the psychiatric morbidity associated with mastectomy and breast cancer

Intervention:

Nurse-led counselling service. Woman seen by nurse within a few days of surgery and thereafter every 2 months at home. Follow-up for 12-18 months after mastectomy

Control:

Routine care from surgical unit

SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention: 'brief training'

**Outcomes**

Primary outcomes and tools:

Anxiety, depression and sexual problems (present state examination);

Mood (linear analogue scales);

Semi-structured interview to assess physical and social recovery in three areas: swelling, pain and disability; reaction to scar, breast loss and prosthesis; house work, social adjustment, return to work;

Secondary outcomes and tools: Primary and secondary outcomes not reported

**Notes**

Trial registration link: NR

Funding source: North-west Regional Health Authority



**Maguire 1980** (Continued)

Funding role: NR

Other: baseline sociodemographic characteristics not reported

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Using a random numbers table half the weeks during a 24-month period were designated as counselling weeks and the other half as control weeks."
Allocation concealment (selection bias)	Unclear risk	Method of concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Dropouts (n = 20/170) were reported and were relatively low and reasons for dropouts also reported but not according to study group. Completer analyses conducted
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.

**McArdle 1996**
**Study characteristics**

Methods	Accrual: 272/311 (87%)  Single/multicentre: multicentre Design: RCT Country: United Kingdom  Setting: 3 x teaching hospitals in Glasgow and community  Follow-up period: 12 months post-surgery
Participants	N (routine care + SBCN + support from voluntary organisation baseline) = 69  N (routine care + SBCN + support from voluntary organisation follow-up) = NR  N (routine care + SBCN baseline) = 70  N (routine care + SBCN follow-up) = NR  N (routine care + support from voluntary organisation baseline) = 66  N (routine care + support from voluntary organisation follow-up) = NR  N (controls baseline) = 67

**McArdle 1996** (Continued)

N (controls follow-up) = NR

Median (SD) age:

Routine care + SBCN + support from voluntary organisation: median 57

Routine care + SBCN: median 55

Routine care + support from voluntary organisation: median 56

Control: median 59

Tumour stage/clinical condition: undergoing breast cancer surgery;

Stage: NR

Menopausal status: NR

Notable exclusion criteria: aged less than 70, non-English speaking, deafness, low intellect - no criteria for assessment given; psychiatric illness/cognitive impairment

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: NR

Occupation:

Employment: none/part-time/full-time, N

Routine care + SBCN + support from voluntary organisation: 38/16/15

Routine care + SBCN: 40/19/11

Routine care + support from voluntary organisation: 38/16/12

Control: 42/15/2

Religion: protestant/catholic/other or none, N

Routine care + SBCN + support from voluntary organisation: 51/13/5

Routine care + SBCN: 54/15/1

Routine care + support from voluntary organisation: 48/16/2

Control: 51/14/2

Further education: none/university/college, N

Routine care + SBCN + support from voluntary organisation: 51/17/1

Routine care + SBCN: 51/18/1

Routine care + support from voluntary organisation: 51/15/0

Control: 50/15/2

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

## McArdle 1996 (Continued)

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status, married/divorced/widowed/unmarried, N

Routine care + SBCN + support from voluntary organisation: 53/3/10/3

Routine care + SBCN: 50/6/6/8

Routine care + support from voluntary organisation: 45/7/8/6

Control: 39/6/14/8

### Interventions

Theoretical basis: Training in counselling was based on the transactional analysis theory

Aim: To evaluate the effect of support from a nurse specialising in breast care and a voluntary support organisation on prevalence of psychological morbidity after surgery for breast cancer

Intervention:

#### **SBCN + standard care (SC)**

Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP)

The SBCN adopted an informal approach and did not wear a uniform. Before surgery, she explained the preoperative and postoperative routine and provided information about the type of surgery, the likely appearance of the wound, and symptoms such as numbness in the arm. She ensured that those patients who needed a prosthesis received one promptly. She encouraged patients to use their arm freely after surgery and to return to all normal activities. If further treatment (radiotherapy, chemotherapy, or tamoxifen) was prescribed she informed the patients of its nature, duration, and possible side effects. She offered patients the option of a joint interview with their husband or other relatives. She avoided giving false reassurance about the prognosis but intervened if a patient was unduly pessimistic. She corrected misconceptions such as the belief that the cancer arose from erroneous behaviour by the patient. She allowed patients to express emotions such as grief freely and listened sympathetically to sexual problems such as feeling undesirable. She gave reassurance that such feelings were understandable. She emphasised that the patients would be seen again at their subsequent clinic visits and that they could make an appointment to see her at any time. The patients were given a contact telephone number. The initial interview lasted 20-30 minutes; the length of subsequent interviews was dictated by need and unavoidable external pressures on time.

#### **Voluntary organisation (Tak Tent) + SC**

Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP)

Tak Tent offered three types of support: information, counselling, and regular group meetings with fellow cancer sufferers. Usually cancer patients self-referred to Tak Tent and sought help from the counselling service or participated in the regular group meetings. For the purpose of this study, Tak Tent agreed to function in an atypical fashion: patients allocated to receive support from Tak Tent were given an introductory leaflet and subsequently contacted by one of the counsellors after discharge from hospital. It was up to individual counsellors to decide the level of support required. These might include maintaining contact by telephone or post, arranging one-to-one meetings for counselling, and encouraging attendance at Tak Tent group meetings. Counsellors underwent 200 hours of training.

#### **SBCN + voluntary organisation (Tak Tent) + SC**

Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP).

As above.

#### **Control (SC)**

Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP).

SBCN (provider) clinical experience: The nurse (first author) had previous ward experience in managing breast cancer patients after surgery. In addition, she had extensive experience of documenting the prevalence of psychological morbidity in breast cancer patients with self-rating scales and talking to

## McArdle 1996 (Continued)

breast cancer patients as part of a study comparing psychological morbidity in patients undergoing either mastectomy or breast conservation.

SBCN (provider) training for this intervention: NR

Outcomes	<p>Primary outcomes and tools: 28-term general health questionnaire; Hospital Anxiety and Depression (HAD) Scale;</p> <p>Secondary outcomes and tools: Primary and secondary outcomes not reported</p>
Notes	<p>Trial registration link: NR Funding source: The Cancer Research Campaign</p> <p>Funding role: NR</p> <p>Other: informed consent was not sought.</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Before surgery, patients were randomised by telephone. No further details reported
Allocation concealment (selection bias)	Unclear risk	Method of concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	47/272 (17%) dropout rate, reasons for dropouts reported but missing outcome data were higher in the routine care group (30%) compared with the 3 other groups (10/12/16%). Consent was not obtained prior to randomisation, with some women unwilling to receive the support offered, and this may have contributed to the attrition rate. No one refused to see the nurse, but 12 participants did not want to be approached by the voluntary organisation (VO). Of those who did have contact with the VO, a further 17 did not wish further contact.
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Unclear risk	The time of intervention delivery differed in each group - SBCN saw the patients in the perioperative period whereas the voluntary organisation saw them after discharge. Also, ethical approval by participants was not sought.

## Ritz 2000

### Study characteristics

**Ritz 2000** (Continued)

Methods	<p>Accrual: 211/296 eligible (71%)</p> <p>Single/multicentre: single centre</p> <p>Design: RCT</p> <p>Country: USA</p> <p>Setting: integrated healthcare system in a suburban community of a large Midwestern metropolitan area</p> <p>Follow-up period: 12 months (outcomes), 24 months (costs)</p>
Participants	<p>N (interventions baseline) = 106</p> <p>N (interventions follow-up) = NR</p> <p>N (controls baseline) = 105 (decreased to 104 as 1 patient was re-staged to a noncancerous condition)</p> <p>N (controls follow-up) = NR</p> <p>Mean (SD) age:</p> <p>Intervention: 55.7</p> <p>Control: 55.3</p> <p>Tumour stage/clinical condition: newly diagnosed breast cancer</p> <p>Stage NR, mean tumor size (cm, I vs C): 2.0 vs 2.1</p> <p>Grade N (%), I vs C:</p> <p>Grade 1: n = 14 (14%) vs n = 16 (15%)</p> <p>Grade 2: n = 55 (52%) vs n=41 (39%)</p> <p>Grade 3: n = 29 (27%) vs n = 45 (43%)</p> <p>Grade 4: n = 7 (7%) vs n = 2 (2%)</p> <p>Menopausal status: NR</p> <p>Notable exclusion criteria: Unable to read and write in English, history of cancer, co-morbidities that limited functional ability, severe psychiatric illness</p> <p>PROGRESS categories assessed at baseline: I vs C:</p> <p>Place of residence: NR</p> <p>Race/ethnicity:</p> <p>White: n = 103 (97%) vs n = 101 (97%)</p> <p>Asian: n = 2 (2%) vs n = 1 (1%)</p> <p>African American: n = 1 (1%) vs n = 1 (1%)</p> <p>American Indian: n = 0 vs n = 1 (1%)</p> <p>Occupation: NR</p> <p>Religion: NR</p> <p>Education:</p> <p>Mean years education: 14.1 years vs 14.3 years</p>

**Ritz 2000** (Continued)

Socioeconomic status:

Income:

Under \$31,000: n = 24 (23%) vs n = 26 (25%)

\$31,000-\$50,999: n = 22 (21%) vs n = 22 (21%)

\$51,000-\$70,999: n = 21 (20%) vs n = 7 (7%)

\$71,000-\$90,999: n = 11 (10%) vs n = 17 (16%)

\$91,000 or more: n = 18 (17%) vs n = 14 (14%)

Not provided: n = 10 (9%) vs n = 18 (17%)

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Marital status [TB1]

Single, never married: n = 11 (10%) vs n = 15 (14%)

Married: n = 74 (70%) vs n = 70 (67%)

Divorced: n = 8 (8%) vs n = 9 (9%)

Widowed: n = 13 (12%) vs n = 10 (10%)

Insurance:

Health maintenance organisation: n = 60 (57%) vs n = 53 (51%)

Non-HMO: n = 22 (21%) vs n = 26 (25%)

Medicare/medical assistance: n = 24 (23%) vs = 25 (24%)

**Interventions**

Theoretical basis: Brooten's cost quality model (uses advance practice nurse's interventions to facilitate early hospital discharge) and Oncology Nursing Societies standards of advanced practice served as conceptual framework

Aim: To evaluate quality of life and cost outcomes of advanced practice nurses' interventions with women diagnosed with breast cancer

Intervention:

Standard medical care plus Advanced Practice Nurse (APN) care. APN contact made within 2 weeks of diagnosis, included written and verbal information about breast cancer, what to expect in consultations with physicians, decision-making support, answering questions, and presence for support. Subsequent contacts were made at scheduled clinic visits or by telephone, home visits or patient-initiated visits to reinforce information, provide continuity of care and ongoing supports. 1 of 2 APNs on call 8 a.m. to 8 p.m. Monday to Friday and 8 a.m. to noon on weekends

Control:

Standard medical care described as routine medical care but not defined  
SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention: NR



## Ritz 2000 (Continued)

Outcomes	<p>Primary outcomes and tools:</p> <p>Aspects of quality of life measured by: Mishel Uncertainty in Illness Scale (MUIS); Profile of Mood States (POMS);</p> <p>Functional Assessment of Cancer Therapy (FACT-B);</p> <p>Cost data from hospital &amp; clinic billing system;</p> <p>Secondary outcomes and tools: Primary and secondary outcomes not reported</p>
Notes	<p>Trial registration link: NR</p> <p>Funding source: NR</p> <p>Funding role: NR</p> <p>Other: Participants were significantly younger than non-participants and were more likely to have invasive disease. Unable to collect some costs such as anaesthesiologists, emergency room physicians and radiation oncologists but included length of hospitalisation and number of visits to a healthcare provider. Intervention group more likely to have lower histology (<math>P = 0.04</math>) and receive adjuvant hormone therapy (<math>P = 0.03</math>) than women in the control group. Reports all outcomes by marital status</p>

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The women were assigned randomly, no other details reported
Allocation concealment (selection bias)	Unclear risk	The method of concealment was not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant difference between groups at baseline for disease and treatment characteristics. Imbalance between groups both at baseline and 24-month follow-up for completion of Quality of Life questionnaires: intervention versus control 95% vs 76% at baseline and 76% versus 52% at follow-up - analyses focussed on QoL outcomes up to 12 months only
Selective reporting (reporting bias)	Low risk	The study protocol was not available but there was a study report for the US Army Medical Research and Materiel Command which reported the same outcomes as the published paper.
Other bias	Low risk	The study appeared to be free of other sources of bias.

## Sheppard 2009

### Study characteristics

Methods	Accrual: 237/328 eligible (72%)
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**Sheppard 2009** (Continued)

Single/multicentre: single centre  
Design: RCT  
Country: UK

Setting: telephone vs hospital – specialist breast unit in Portsmouth, one of the largest breast units within the UK

Follow-up period: 18 months

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**Participants**

N (intervention baseline) = NR

N (intervention follow-up) = 107

N (control baseline) = NR

N (control follow-up) = 107

Mean (SD) age:

Intervention: 57 (11)

Control: 58 (10.7)

Tumour stage/clinical condition: All participants completed primary treatment; surgery, chemotherapy and radiotherapy. Year 2 post-breast cancer diagnosis

Stage N (%), I vs C: NR

Grade N (%), I vs C:

DCIS (in-situ tumours): 9% vs 14%

Grade 1: 37% vs 42%

Grade 2: 39% vs 30%

Grade 3: 15% vs 14%

Node involvement: 21% vs 23%

Menopausal status: NR

Notable exclusion criteria: receiving primary endocrine treatment only

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: NR

Occupation: NR

Religion: NR

Education: NR

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

**Sheppard 2009** (Continued)

Married/partner, I vs C: 63% vs 80%

Interventions	<p>Theoretical basis: NR</p> <p>Aim: to develop a model of care based on the concept of point-of-need access and investigate the efficacy of this model compared to routine clinical review</p> <p>Intervention:</p> <p>Telephone - Point-of-need access to specialist care via the SBCN – patients given details how to contact the SBCN if concerned and all outstanding appointments were cancelled</p> <p>Control:</p> <p>Hospital - 6-monthly follow-up appointments for clinical review</p> <p>Mammograms continued annually for both groups</p> <p>In addition to their routine review, a total of 68 contacts were made in the control group equating to an incidence rate of 0.42 contacts per person-year, compared to 61 contacts in the point-of-need access group with an incident rate of 0.38 contacts per person-year.</p> <p>SBCN (provider) clinical experience: see training below</p> <p>SBCN (provider) training for this intervention: two BCNs underwent training in clinical examination, physical assessment and subsequent management of symptoms:</p> <p>Training plan</p> <p>Learning timescales and objectives</p> <p>Prior learning: Prior learning and experience assessed to identify learning needs. Breast care nurse must have a minimum of 3 years experience within the role and have completed a level 3 module in breast care nursing or cancer nursing. Outcome measure: Certificate of level 3 relevant learning; 3 years within the role.</p> <p>3-month objectives: To successfully complete a minimum level 3 physical assessment and history-taking module. To undertake observation of consultant oncologist and surgeon during follow-up clinics. Outcome measure: Certificate of completion, recorded observation of practice</p> <p>6-month objectives: To undertake additional learning regarding benign breast disease to include presentation, investigation and management. To undertake additional learning regarding metastatic disease, signs, assessment of symptoms, and investigation. To understand the management of side effects of cancer treatments and advise patient regarding management strategies recognising the need for potential change in treatment. To maintain a portfolio of learning and reflection. Outcome measures: Evidence of learning available within portfolio. Evidence of effective patient management within portfolio. Demonstration of appropriate investigations and interpretation of results</p> <p>9-month objectives: To undertake assessment of patients under supervision of a consultant. Record learning and maintain a portfolio. Outcome measure: Records of patient assessment with reflection on learning</p> <p>12-month objectives: To be able to successfully manage a follow-up patient clinic independently with availability of supervision from senior consultant where appropriate for complex cases. Outcome measures: Formal assessment of competence undertaken by consultant. Completed portfolio with a range of evidence to demonstrate competency</p>
Outcomes	<p>Primary outcomes and tools:</p> <p>Psychological morbidity measured by General Health Questionnaire (GHQ-12);</p> <p>Quality of life Measured by Functional Assessment of Cancer Therapy (FACT) with addition of breast and endocrine subscales (FACT-B/ES);</p>

## Sheppard 2009 (Continued)

Secondary outcomes and tools: Assessment of fear measured using a three-item questionnaire developed by authors of FACT (not validated); isolation measured by single question at 9 and 18 months; recurrence events recorded

### Notes

Trial registration link: study commenced in 2005, prior to the requirement for trial registration.  
Funding source: Wessex Cancer Trust

Funding role: NR

Other: Mean age of non-participation was 71 years, compared to a mean age of 57 years in the participant group. Data regarding other demographic characteristics was not collected however 30 of the non-participants did complete the GHQ-12 questionnaire. Overall, the mean scores for non-participants was 21.1 which was slightly lower than for the participant group ( $P = 0.02$ )

### Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomised using a sequential series of sealed envelopes containing computer-generated random assignments produced externally.
Allocation concealment (selection bias)	Low risk	Central allocation
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patient and research nurse blinded to group assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition balanced across groups with reasons reported
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.

## Wengstrom 1999

### Study characteristics

Methods	<p>Accrual: 134/175 (77%)</p> <p>Single/multicentre: single centre</p> <p>Design: RCT</p> <p>Country: Sweden</p> <p>Setting: Radiation therapy department, Karolinska Hospital</p> <p>Follow-up period: 3 months (included 5 weeks radiation treatment)</p>
Participants	N (intervention baseline) = 67

**Wengstrom 1999** (Continued)

N (intervention follow-up) = 67

N (control baseline) = 67

N (control follow-up) = 66

Mean (SD) age:

Intervention: 58 (39-76)

Control: 61 (range 37-83)

Tumour stage/clinical condition: A diagnosis of breast cancer including chest wall and lymph nodes receiving radiotherapy treatment for cure

Stage N (%), I vs C: NR

Menopausal status N (%), I vs C: NR

Notable exclusion criteria: inability to speak or understand the Swedish language and previous radiation

therapy experience

PROGRESS categories assessed at baseline:

Place of residence: NR

Race/ethnicity: NR

Occupation:

N (%), I vs C:

Employed: n = 39 (58%) vs n = 32 (47%)

Unemployed: n = 3 (5%) vs n = 1 (2%)

Retired: n = 25 (37%) vs n = 34 (52%)

Sick leave: n = 31 (46%) vs n = 23 (35%)

Religion: NR

Education:

N (%), I vs C:

High School: n = 37 (56%) vs n = 37 (56%)

College: n = 6 (9%) vs n = 7 (11%)

University: n = 24 (35%) vs n = 23 (33%)

Socioeconomic status: NR

Social capital: NR

Age: see above

Disability: NR

Sexual orientation: NR

Any other dimension of disadvantage or inequity for which a health impact may be anticipated:

Family situation, N (%), I vs C:

**Wengstrom 1999** (Continued)

Living with family: n = 42 (63%) vs n = 49 (74%)

Single/widow: n = 25 (37%) vs n = 18 (26%)

**Interventions**

Theoretical basis: Orem's self-care theory

Aim: to investigate whether a nursing intervention, aiming at enhancing the patient's ability for self-care, would have an effect on the subjective distress, side effects and quality of life as perceived by breast cancer patients receiving radiation therapy when compared to patients receiving standard care

RT dose N (%), I vs C:

46 Gy: n = 37 (55%) vs n = 52 (77%)

50 Gy: n = 28 (42%) vs n = 14 (21%)

Booster: n = 2 (3%) vs n = 1 (2%)

Intervention:

Nurse-led intervention - 30 minutes once a week at week 1 baseline then at weeks 3 and 5 (end of RT) and follow-up at 2 weeks and again at 3 months. Nurse-led intervention as a complement to standard nursing care in the radiotherapy department. First intervention at baseline, emphasis on oral and written cognitive information about simulation and treatment routines - this session lasted 45 minutes. During this time there was also time for the patients to talk about their personal fears or anxiety concerning the treatment and/or other issues. The following interventions took 30 min and were individualised concerning education and information depending on the patient needs. During these interventions, the purpose of the instruction was to prepare the patient for the possible side effects of treatment. Support and guidance and provision of self-care actions pertaining to what the patient herself could do to prevent, alleviate or minimise the side effects of therapy were given. The purpose of this guidance was to give the patient the ability and necessary skills to take action to sustain self-care at a sufficient level for the patient, thus liberating the patient from dependency on the nurse.

Psychological support and strategies for coping with emotional reactions such as anxiety, depression and insecurity were included. This support consisted of, for example, explicit instructions on how simulation and treatment felt, what sensations the patient might experience, what the role of the health-care staff would be, to what degree the patient could influence the experience (e.g. by listening to music during treatment).

Education and guidance to help the patient to modify her body image, and to revise routines in her daily life in order better to cope with the effects of illness and treatment were also given. This guidance and education included information about different possibilities of breast prostheses, how to cope when changing clothes: bathing suits in public, education on how to perform breast self examination (BSE) was also offered as a way for the patient to get to know her body again.

Depending on the patient's need, the nurse provided an informational and educational update regarding the treatment and the side effects. For every patient, a nursing-care journal was kept in order to document the nursing care given. The nurse also arranged contacts with other healthcare professionals such as, for example, physiotherapists and nutritionists if needed during and after the course of the treatment. The patients were encouraged to call the nurse if any problems arose during the treatment period or follow-up time.

Control:

Standard nursing care - there was no systematic routine assessment of patients' needs or nursing care in the department during or after completion of the course of radiation treatment. One information session with the primarily responsible nurse after the simulation of the treatment. This session contained information about treatment, routines and side effects.

SBCN (provider) clinical experience: NR

SBCN (provider) training for this intervention: NR

**Outcomes**

Primary outcomes and tools:

**Wengstrom 1999** (Continued)

Subjective distress, side effects and quality of life measured by:  
Instruments Impact of Event Scale (IES scale) a self-reported questionnaire containing 15 items including 7 items under the heading intrusion and 8 items of avoidance.

Oncology Treatment Toxicity Assessment Tool (OTTAT) a self-reported instrument containing 37 items to assess cancer-related symptoms including side effects of treatments. Every item was rated on a 5-point scale from none to intolerable.

Cancer Rehabilitation Evaluation System (CARES-sf) is a shortened version of a standardised and comprehensive rehabilitation and QoL questionnaire used for cancer patients. This consisted of 59 items and patients were asked to complete a minimum of 37 to a maximum of 57 items. The ratings change on this from a 5-point scale from 0 (does not apply) to 4 (applies very much). This item is multidimensional with reliability, validity and internal consistency previously documented.

Secondary outcomes and tools: Primary and secondary outcomes not reported. However 'coping ability' was assessed in Wengstrom 2001 using the Wheel questionnaire. 'Coping' refers to the attempt to reduce, ward off or to incorporate an existing or expected demand by means of cognition- or emotion-related effort or by action. The questionnaire assesses 'structure', 'motivation', 'emotional balance' and 'coping'.

**Notes**

Trial registration link: NR

Funding source: King Gustav: V jubilee fund (grants nos. 96–522, 97–509)

Funding role: NR

Other: The group of patients who declined to participate had a mean age of 73 years which was older than participants.

At baseline, there was a significant difference in QoL between the groups indicating that the patients in the intervention had a poorer QoL. There was a significant difference in radiation dose between groups but this was controlled for in subsequent analyses. Wengstrom 2001 reported on coping ability using the Wheel Questionnaire which showed no effect of the intervention so authors divided the sample into 2 age groups by the median age of the sample (59 years). In summary, the results showed that the intervention provided patients older than 59 years with a stronger motivation to be emotionally involved.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A numbered envelope was opened containing the information about which group the patient was randomised to.
Allocation concealment (selection bias)	Unclear risk	A numbered envelope was opened containing the information about which group the patient was randomised to but there were no further details.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	There was insufficient information reported about attrition in the primary paper (Wengstrom 1999), however in a later paper (Wengstrom 2001) uneven dropouts (higher in the control) were reported.
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available.
Other bias	Low risk	The study appeared to be free of other sources of bias.



AAA: Awareness, Adoption and Application  
 APN: Advanced Practice Nurse  
 ASC: Assessment of Survivor Concerns  
 BACUP: Understanding cancer of the breast  
 BCN: Breast Care Nurse  
 BSE: Breast Self Examination  
 C: Comparator  
 CARES-sf: Cancer Rehabilitation Evaluation System-shortened form  
 CBT: Cognitive Behavioural Therapy  
 CES-D: Center for Epidemiologic Studies Depression scale  
 EGP: Education Group Programme  
 EORTC QLQ-BR23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module with 23 questions  
 EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 30  
 EQ-5D(-5l): European Quality of Life - five dimension scale  
 EUROQoL-5D: Generic health-related quality of life  
 FACIT-TS-PS: Functional Assessment of Chronic Illness Therapy-Treatment Satisfaction-Patient Satisfaction  
 FACT(-B)(-ES): Functional Assessment of Cancer Therapy plus breast and endocrine subscales  
 FOCUS: Family involvement, Optimistic attitude, Coping effectiveness, Uncertainty reduction and Symptom management  
 GAD-7: General Anxiety Disorder  
 GADS: Goldberg Anxiety and Depression Scales  
 GHQ-12: General Health Questionnaire (12-item)  
 HADS: Hospital Anxiety and Depression Scale  
 HER2: Human Epidermal Growth Factor Receptor 2  
 HFNS: Hot flushes and night sweats  
 HMO:  
 I: Intervention  
 I1: Intervention 1  
 I2: Intervention 2  
 ICER: Incremental Cost-Effectiveness Ratio  
 IES: Impact of Event Scale  
 INS: Individual Nurse Support  
 IOC: Impact of Cancer scale  
 IPS: Individual Psychological Support  
 IQR: interquartile range  
 K-POMS-B: Korean version of Profile of Mood States-Brief  
 MUIS: Mishel Uncertainty in Illness Scale  
 NCI: National Cancer Institute  
 NHS: National Health Service  
 NR: Not reported  
 NS: Not significant  
 OSQ: Oviedo Sleep Questionnaire  
 OTTAT: Oncology Treatment Toxicity Assessment Tool  
 POMS: Profile of Mood States  
 PROGRESS: Place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic status, social capital, age, disability and sexual orientation  
 PSQ-NI: Patient Satisfaction Questionnaire  
 QALY: Quality-adjusted life years  
 QoL: Quality of life  
 RCT: Randomised controlled trial  
 RT: Radiotherapy  
 SaaC: Satisfaction and Accessibility Scale  
 SBCN: Specialist Breast Care Nurse  
 SC: Standard Care  
 SCNS: Supportive Care Needs Survey  
 SD: Standard deviation  
 SI: Survivorship Intervention  
 STAI: Spielberger's State-Trait Anxiety Inventory  
 T1/2/3/4: Tumour size  
 Tak Tent: Take Care, Old Scots expression  
 UICC: Union for International Cancer Control  
 VO: Voluntary Organisation

vs: Versus

**Characteristics of excluded studies** *[ordered by study ID]*

Study	Reason for exclusion
<a href="#">Abazari 2019</a>	2020 update - not SBCN
<a href="#">Allen 2002</a>	Not a nursing intervention
<a href="#">Ambler 1999</a>	Wrong study design
<a href="#">Angelis 2019</a>	2020 update - wrong study design (retrospective)
<a href="#">Arathuzik 1994</a>	2020 update - not SBCN
<a href="#">Asano 2020</a>	2020 update - not SBCN
<a href="#">Badger 2020</a>	2020 update - not SBCN
<a href="#">Bakitas 2009</a>	2020 update - outcomes not reported specific to subgroup of women with breast cancer
<a href="#">Barbor 2019</a>	2020 update - wrong study design
<a href="#">Berger-Hoger 2019</a>	2020 update - not SBCN
<a href="#">Bordeleau 2003</a>	The study did not include disaggregated data for nursing outcomes.
<a href="#">Brown 2002</a>	Not a nursing intervention
<a href="#">Cal 2020</a>	2020 update - not SBCN
<a href="#">Cameron 2019</a>	2020 update - not SBCN
<a href="#">Chan 2020</a>	2020 update - wrong study design
<a href="#">Cimprich 1993</a>	Wrong study design
<a href="#">Cleeland 1996</a>	Insufficient data
<a href="#">Del Valle 2018</a>	2020 update - not SBCN
<a href="#">Giese-Davis 2002</a>	Not a nursing intervention
<a href="#">Given 2008</a>	2020 update - not SBCN (subgroup analysis of breast cancer participants from a larger trial)
<a href="#">Goodwin 2003</a>	Not SBCN
<a href="#">Gorham 2020</a>	2020 update - not SBCN
<a href="#">Helgeson 1999</a>	The study did not include disaggregated data for nursing.
<a href="#">Hughes 2000</a>	Wrong study design
<a href="#">Hughes 2019</a>	2020 update - wrong study design
<a href="#">Hunter 2020</a>	2020 update - not SBCN

Study	Reason for exclusion
<a href="#">Hussain 2020</a>	2020 update - wrong study design
<a href="#">Ironson 2002</a>	Not SBCN
<a href="#">Kirshbaum 2017</a>	2020 update - wrong intervention - open access model of care but no details about what the intervention women received
<a href="#">Klafke 2019</a>	2020 update - wrong patient population
<a href="#">Kolcaba 1999</a>	Wrong study design
<a href="#">Krikorian 2019</a>	2020 update - not SBCN
<a href="#">Larsson 1992</a>	Wrong study design
<a href="#">Lev 2001</a>	The study did not include disaggregated data for nursing.
<a href="#">Liu 2019</a>	2020 update - not SBCN
<a href="#">Maguire 1985</a>	Not a nursing intervention
<a href="#">McHale 2020</a>	2020 update - wrong study design
<a href="#">Mock 1997</a>	Not SBCN intervention - individualised, self-paced, home-based walking exercise programme
<a href="#">Motzer 1997</a>	Reported recruitment and retention outcomes only
<a href="#">NCT00182234</a>	2020 update - trial registration related to <a href="#">Sussman 2018</a> which was excluded as no outcomes reported specific to subgroup of women with breast cancer
<a href="#">NCT00903305</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT00964522</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT01555645</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT02228200</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT02935920</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT03726801</a>	2020 update - insufficient data to assess if intervention carried out by a SBCN
<a href="#">NCT03930797</a>	2020 update - not SBCN
<a href="#">NCT03964896</a>	2020 update - wrong study design
<a href="#">NCT03975621</a>	2020 update - not SBCN
<a href="#">NCT04022772</a>	2020 update - not SBCN
<a href="#">NCT04173897</a>	2020 update - not SBCN
<a href="#">Ploos van Amstel 2016</a>	2020 update - not SBCN
<a href="#">Rolnick 1999</a>	Not a nursing intervention

Study	Reason for exclusion
<a href="#">Samarel 2002</a>	The study did not include disaggregated data for nursing.
<a href="#">Sameral 1998</a>	Wrong study design
<a href="#">Sandgren 2000</a>	Not a nursing intervention
<a href="#">Sandgren 2003</a>	Not a nursing intervention
<a href="#">Sussman 2018</a>	2020 update - outcomes not reported specific to subgroup of women with breast cancer
<a href="#">Targ 2002</a>	Not a nursing intervention
<a href="#">Vos 2004</a>	Not a nursing intervention
<a href="#">Williams 2004</a>	Not SBCN intervention; the intervention was audiotapes and the interviewers were senior-level nursing students
<a href="#">Wyatt 2004</a>	Not a SBCN
<a href="#">Yu 2020</a>	2020 update - not SBCN

SBCN:

### Characteristics of ongoing studies *[ordered by study ID]*

#### [Becker 2017](#)

Study name	CONNECT (Care management by Oncology Nurses to address supportive care needs) intervention
Methods	Cluster-RCT
Participants	Adults with metastatic solid tumors
Interventions	Oncology nurse-led palliative care versus usual care. Oncology nurses are trained to provide symptom management and emotional support, engage patients and families in advance care planning, and co-ordinate appropriate care using evidence-based care management strategies.
Outcomes	Quality of life (primary outcome), symptom burden, and mood; caregiver burden and mood; and healthcare resource use
Starting date	July 2016
Contact information	schenkery@upmc.edu
Notes	NCT02712229

#### [Komatsu 2016](#)

Study name	A nurse-led medication self-management programme in cancer patients
Methods	Open-label multicentre RCT (first phase of two-phase mixed-method study)

### Komatsu 2016 (Continued)

Participants	Patients with metastatic breast cancer, who have been newly prescribed an oral chemotherapy or a targeted therapy agent
Interventions	Medication self-management support programme group versus conventional care group; nurses will provide patients in the intervention group with information by using the teach-back method, help patients set a goal based on their preferences, and solve problems through follow-up counselling.
Outcomes	Primary outcome measure is adherence to medication; secondary outcome measures include self-efficacy, quality of life, psychological distress, severity and interference of symptoms, patient satisfaction, emergency department visits, and hospital admissions.
Starting date	February 2015
Contact information	hkomatsu@sfc.keio.ac.jp
Notes	UMIN000016597

### Rawther 2017

Study name	Nurse Navigator Programme
Methods	Stratified RCT
Participants	Newly diagnosed women with breast cancer
Interventions	Nurse navigator intervention versus control
Outcomes	Anxiety, psychological distress and quality of life
Starting date	October 2014
Contact information	shejilasajeev@gmail.com
Notes	CTRI/2015/09/006192

### Saltbaek 2019

Study name	MyHealth: specialist nurse-led follow-up in breast cancer
Methods	RCT
Participants	Female patients treated for early stage breast cancer
Interventions	Nurse-led follow-up programme based on Guided Self-Determination method, collection of patient-reported outcomes, and patient navigation versus routine oncologist-led follow-up
Outcomes	Primary outcome is breast cancer-specific health-related quality of life; secondary outcomes include time to detection of recurrence, health behaviours and status, depression, anxiety, and fear of recurrence.
Starting date	January 2017

### Specialist breast care nurses for support of women with breast cancer (Review)

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**Saltbaek 2019** (Continued)

Contact information lesa@cancer.dk

Notes NCT02949167

RCT: randomised controlled trial

**ADDITIONAL TABLES**
**Table 1. Experience and training of the SBCN**

Study	SBCN clinical experience	SBCN training of the intervention
Aranda 2006	NR	2 training days: covered adherence to the research protocol, evidence-based best-practice medical and psychosocial management of women with advanced breast cancer. A team comprising SA, RF, DM, (authors), a medical oncologist, a radiation oncologist and two experienced BCNs provided training. Teaching included role plays about difficult situations that may arise. Constructive feedback and debriefing was provided.
Arving 2007	NR	SBCNs received 4 x 3-hour lectures over 4 months covering knowledge and skills to assess and treat common psychosocial problems in cancer patients, with a follow-up meeting 5 months later.  The 2 psychologists who performed the individual psychological support had theoretical knowledge about cancer diseases and treatments, and had experience of counselling.  Both nurses and psychologists received supervision every third week by a psychologist or a nurse with extensive experience of psychosocial support to cancer patients.
Beaver 2009	NR	4 x half-day training sessions on the administration of the telephone intervention with subsequent feedback and debriefing sessions throughout the study period. Seven nurses received training, although one nurse at the district general hospital and three nurses at the specialist breast unit conducted most telephone appointments.
Fenlon 2020	4/11 SBCNs had prior experience of delivering group sessions and 8 had received advanced communication skills training. 3 had received training in counselling; only one had experience or training in CBT.	Trained by a clinical psychologist over two days, using the training manual to deliver the CBT intervention. The manual contained detailed session content; presentation slides and handouts. SBCNs received ongoing supervision of their delivery of group CBT from the trainer by email or telephone as required.
Gomez 2019	NR	NR
Hershman 2013	NR	NR
Kim 2017	Certification in advanced practice in oncology nursing and had 3 years of experience in consultation with patients with cancer	20-hr AAA (i.e., awareness, adoption and application) coaching programme and obtained the Korean Associate Coach certificate.

**Table 1. Experience and training of the SBCN** *(Continued)*

Kimman 2011	"A Nurse Practitioner [NP] is a registered nurse who has acquired (at masters level) the expert knowledge base, complex decision-making skills and clinical competencies for expanded practice. The SBCN is a qualified nurse who has had specialist training in breast care and who guides the patient throughout treatment."	SBCNs (and NPs) are informed on the most recent developments in breast cancer treatment and follow-up, develop a semistructured questionnaire for support during the telephone interview, and practice their telephone communication skills with a breast cancer patient.
Koinberg 2004	"We emphasise that the nurses in the study had great experience of and specific training in dealing with breast cancer patients."	NR
Maguire 1980	NR	"brief training"
McArdle 1996	The nurse (first author) had previous ward experience in managing breast cancer patients after surgery. In addition, she had extensive experience of documenting the prevalence of psychological morbidity in breast cancer patients with self-rating scales and talking to breast cancer patients as part of a study comparing psychological morbidity in patients undergoing either mastectomy or breast conservation.	NR
Ritz 2000	NR	NR
Sheppard 2009	SBCN must have a minimum of 3 years experience within the role and have completed a level 3 module in breast care nursing or cancer nursing.	<p>2 SBCNs underwent training in clinical examination, physical assessment and subsequent management of symptoms:</p> <p>Training plan.</p> <p>Learning timescales and objectives.</p> <p>Prior learning: Prior learning and experience assessed to identify learning needs. Breast care nurse must have a minimum of 3 years experience within the role and have completed a level 3 module in breast care nursing or cancer nursing. Outcome measure: Certificate of level 3 relevant learning; 3 years within the role.</p> <p>3 months objectives: To successfully complete a minimum level 3 physical assessment and history taking module. To undertake observation of consultant oncologist and surgeon during follow-up clinics. Outcome measure: Certificate of completion, recorded observation of practice.</p> <p>6 months objectives: To undertake additional learning regarding benign breast disease to include presentation, investigation and management. To undertake additional learning regarding metastatic disease, signs, assessment of symptoms, and investigation. To understand the management of</p>



**Table 1. Experience and training of the SBCN** (Continued)

		<p>side effects of cancer treatments and advise patient regarding management strategies recognising the need for potential change in treatment. To maintain a portfolio of learning and reflection. Outcome measures:</p> <ul style="list-style-type: none"> <li>• Evidence of learning available within portfolio.</li> <li>• Evidence of effective patient management within portfolio.</li> <li>• Demonstration of appropriate investigations and interpretation of results.</li> </ul> <p>9 months objectives: To undertake assessment of patients under supervision of a consultant. Record learning and maintain a portfolio. Outcome measure: Records of patient assessment with reflection on learning.</p> <p>12 months objectives: To be able to successfully manage a follow-up patient clinic independently with availability of supervision from senior consultant where appropriate for complex cases. Outcome measures:</p> <ul style="list-style-type: none"> <li>• Formal assessment of competence undertaken by consultant.</li> <li>• Completed portfolio with a range of evidence to demonstrate competency.</li> </ul>
Wengstrom 1999	NR	NR

AAA: Awareness, Adoption and Application

BCN: Breast Care Nurse

CBT: Cognitive Behavioural Therapy

NP: Nurse Practitioner

NR: Not reported

SBCN: Specialist Breast Care Nurse

**Table 2. Descriptions of interventions**

Study	Intervention	Control
Aranda 2006	<p>A one-hour face-to-face session within 10 days of recruitment and included orientation, tailored responses, coaching and practicing self-care and communication, and concluding the session. Patients were encouraged to bring 'a significant other'. Each woman was given relevant information cards on self-care and communication strategies and a copy of her personal self-care plan. Women were also provided with a relaxation CD.</p> <p>Telephone follow-up with SBCN 1 week after first session to: (a) ask whether the suggested strategies had ameliorated the concerns; (b) elicit and respond to remaining concerns; (c) reinforce or modify planned self-care strategies or introduce new ones; and (d) prompt further questions/new concerns.</p>	Standard care (no details) plus referral to breast care nurses/cancer nurse if appropriate
Arving 2007	<p>Intervention 1: individual psychosocial support by x 2 oncology nurses specially trained in psychologic techniques - one face-to-face session and follow-up sessions (0-16 sessions, mean = 3.8)</p> <p>Intervention 2: individual psychosocial support by x 2 psychologists - one face-to-face session and follow-up session (0-23 sessions, mean = 4.5)</p> <p>Both interventions used the same techniques such as relaxation, distraction, activity scheduling, and ways to improve communication, all derived from CBT.</p> <p>In the first session, the patient was asked to relate her disease history using an interview guide covering the following areas: worry/anxiety; depression; sleep disturbances; view of prognosis and future; social situation and support from spouse, family and friends in general and with respect to the disease in particular; communication with hospital staff; the impact of disease/treatment on the patient's</p>	Standard care included regular contact with the patient's oncologist and medical staff. Contact with psychiatrists, physiotherapists, or counsellors was not offered regularly but was arranged if the patient's physician or other medical staff judged this to be necessary or if the pa-

**Table 2. Descriptions of interventions** (Continued)

activity level such as working capacity, leisure time activities, and management of household tasks. The assessment also included an estimation of the extent to which problems were expected to occur in the near future, for example, if the patient was waiting for test results or was to go through burdensome treatments.

At the end of the first session, it was jointly decided whether further sessions were warranted. The number of sessions and the time interval between them varied according to the need and desire of the individual patients. Every session was scheduled to last for 45 to 60 minutes. The patient's problems were identified, and strategies such as problem-solving, relaxation and distraction techniques, ways to improve communication, and activity scheduling that could help her to manage these were taught to the patient. Patients were given oral and written instructions on how to practice these strategies at home and were asked to report the outcome during the follow-up sessions. Some sessions ( $n = 91$ ; 19%) were held by telephone because of long travelling distances and had essentially the same content as sessions held face-to-face. At the termination of the intervention, the patient was encouraged to contact the investigators again, should new problems arise.

tient herself made a specific request.

#### Beaver 2009

Telephone follow-up by SBCNs either from the district general hospital or the specialist breast care unit. Participants received telephone appointments by SBCNs consistent with hospital policy (3 months for two years; six-monthly for two years and annually for a further year). Each telephone appointment was allocated 30 minutes (20 minutes for the consultation and 10 minutes to dictate outcome). Structured and recorded telephone intervention with questions related to changes in condition, new symptoms, and information requirements about spread of disease, treatment and side effects, genetic risk, sexual attractiveness, self-care (diet, support groups, finances), and family concerns. Throughout the study, the same specialist nurse contacted each participant in the telephone group for all appointments.

Mammogram annually

District general hospital follow-up consistent with hospital policy (3 months for two years; six-monthly for two years and annually for a further year). Specialist breast care unit: reviewed annually for 10 years. Hospital consultations were generally unstructured but primarily consisted of a clinical examination, a check on whether hormone treatment was being taken as prescribed, and ordering mammograms, if necessary. As per hospital policy, both study locations allocated 10 minutes for each individual hospital appointment. Hospital consultations could be conducted by various health professionals including consultant surgeons, consultant oncologists, registrars, more junior doctors, or specialist nurses. It was more usual at both locations, however, for junior medical staff to conduct hospital appointments. Mammogram annually

#### Fenlon 2020

Weekly group CBT sessions, lasting 90 minutes each, for six weeks, following the structured manual, which included a psycho-education and the cognitive behav-

Standard NHS care differed between sites

**Table 2. Descriptions of interventions** (Continued)

	<p>journal model; stress management; paced breathing; cognitive and behavioural strategies to improve well-being and for managing hot flushes, night sweats and sleep; and maintaining changes. CBT, targeted the cognitive and behavioural elements, manual included Power Point slides, homework sheets, and a paced breathing relaxation CD.</p>	<p>since there is no current UK standard of care. Women were generally given ad hoc advice about HFNS, typically only if they raised the issue. Offered a version of self-help CBT after the final assessment at week 26</p>
Gomez 2019	<p>Intervention 1: education (at baseline and 3 months, dealing with fatigue) plus telephone monitoring (at 6, 9 and 12 months, resolved doubts and reinforced education)</p> <p>Intervention 2: education (as above, at baseline and 3 months, dealing with fatigue)</p>	<p>Usual practice - regular pattern for medical appointment with their oncologist</p>
Hershman 2013	<p>Participants met a nurse and nutritionist for 1 hour to receive a personalised treatment summary (in English or Spanish), surveillance recommendations, discussion of risk for late effects and toxicities, and screening and lifestyle recommendations based on guidelines from the American Society of Clinical Oncology. Participants received the received the NCI publication, "Facing Forward: Life after Cancer Treatment". It is a 24-page manual that summarises key issues of interest to cancer survivors during the re-entry phase, and contains sections on a number of issues after cancer treatment, including medical care, potential symptoms, emotions, social relationships, and dealing with practical matters, such as insurance and employment.</p>	<p>Participants received the National Cancer Institute publication, "Facing Forward: Life after Cancer Treatment" only. It is a 24-page manual that summarises key issues of interest to cancer survivors during the re-entry phase, and contains sections on a number of issues after cancer treatment, including medical care, potential symptoms, emotions, social relationships, and dealing with practical matters, such as insurance and employment.</p>
Kim 2017	<p>Seven-weekly counselling sessions delivered face-to-face and by telephone by SBCN to provide emotional support to patients and to enable them to express their feelings.</p>	<p>After the study, the coordinator telephonically contacted patients in the control group, checked their status, explained the programme to them and encouraged them to take part in it.</p>
Kimman 2011	<p>Intervention 1: Telephone + educational group programme (EGP)</p> <p>SBCN-led telephone follow-up: a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews at the same time points as for usual follow-up. The EGP consisted of two interactive group sessions of 2.5 hours and attended by partner +/- 3 months of treatment.</p> <p>Intervention 2: Telephone intervention</p>	<p>Hospital follow-up as usual - five outpatient clinic visits in first 18 months (at 3, 6, 9, 12 and 18 months). Hospital follow-up was provided by surgeon, medical oncologist,</p>

**Table 2. Descriptions of interventions** (Continued)

	<p>SBCN-led telephone follow-up: a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews at the same time points as for usual follow-up.</p> <p>Intervention 3: Standard care hospital + EGP</p> <p>Hospital follow-up as usual - five outpatient clinic visits in first 18 months (at 3, 6, 9, 12 and 18 months). Hospital follow-up was provided by surgeon, medical oncologist, radiation oncologist and/or SBCN. The EGP consisted of two interactive group sessions of 2.5 hours and attended by partner +/- 3 months of treatment.</p> <p>All groups received follow-up as usual that took place in the hospital where surgery and chemotherapy were performed, alternating between the surgeon, medical oncologist and radiation oncologist.</p>	<p>radiation oncologist and/or SBCN.</p>
Koinberg 2004	<p>SBCN with check-ups on demand. A nurse with specialist experience in breast cancer met patients approximately 3 months following surgery. Women received information about recognising recurrence, aspects of self-care and time to talk about psychosocial aspects. Women advised to contact the nurse if symptoms arose which were perceived as due to breast cancer. Mammography carried out yearly arranged by the nurse. Blood tests, chest x-ray or other imaging performed on clinical indication.</p>	<p>Routine follow-up visits to a physician. Clinical examination/hospital visit 4 times per year following first 2 years, bi-annual for 5 years, yearly after 5 years. Mammography carried out yearly. Blood tests, chest x-ray or other imaging performed on clinical indication.</p>
Maguire 1980	<p>SBCN-led counselling service. Woman seen by nurse within a few days of surgery and thereafter every 2 months at home. Follow-up for 12-18 months after mastectomy</p>	<p>Routine care by surgical unit</p>
McArdle 1996	<p>Intervention 1: SBCN + standard care (SC)</p> <p>Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP)</p> <p>The SBCN adopted an informal approach and did not wear a uniform. Before surgery, she explained the preoperative and postoperative routine and provided information about the type of surgery, the likely appearance of the wound, and symptoms such as numbness in the arm. She ensured that those patients who needed a prosthesis received one promptly. She encouraged patients to use their arm freely after surgery and to return to all normal activities. If further treatment (radiotherapy, chemotherapy, or tamoxifen) was prescribed, she informed the patients of its nature, duration, and possible side effects. She offered patients the option of a joint interview with their husband or other relatives. She avoided giving false reassurance about the prognosis but intervened if a patient was unduly pessimistic. She corrected misconceptions such as the belief that the cancer arose from erroneous behaviour by the patient. She allowed patients to express emotions such as grief freely and listened sympathetically to sexual problems such as feeling undesirable. She gave reassurance that such feelings were understandable. She emphasised that the patients would be seen again at their subsequent clinic visits and that they could make an appointment to see her at any time. The patients were given a contact telephone number. The initial interview lasted 20-30 minutes; the length of subsequent interviews was dictated by need and unavoidable external pressures on time.</p> <p>Intervention 2: Voluntary organisation (Tak Tent) + SC</p> <p>Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP)</p>	<p>Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP)</p>

**Table 2. Descriptions of interventions** (Continued)

	<p>Tak Tent offered three types of support: information, counselling, and regular group meetings with fellow cancer sufferers. Usually cancer patients self referred to Tak Tent and sought help from the counselling service or participated in the regular group meetings. For the purpose of this study, Tak Tent agreed to function in an atypical fashion: patients allocated to receive support from Tak Tent were given an introductory leaflet and subsequently contacted by one of the counsellors after discharge from hospital. It was up to individual counsellors to decide the level of support required. These might include maintaining contact by telephone or post, arranging one-to-one meetings for counselling, and encouraging attendance at Tak Tent group meetings. Counsellors underwent 200 hours of training.</p> <p>Intervention 3: SBCN + voluntary organisation (Tak Tent) + SC</p> <p>Routine support from ward staff and information booklet (Understanding Cancer of the Breast: BACUP). As above</p>	
Ritz 2000	<p>Standard medical care plus Advanced Practice Nurse (APN) care. APN contact made within 2 weeks of diagnosis; included written and verbal information about breast cancer, what to expect in consultations with physicians, decision-making support, answering questions, and presence for support. Subsequent contacts were made at scheduled clinic visits or by telephone, home visits or patient-initiated visits to reinforce information, provide continuity of care and ongoing supports. 1 of 2 APNs on call 8 a.m. to 8 p.m. Monday to Friday and 8 a.m. to noon on weekends</p>	<p>Standard medical care described as routine medical care but not defined</p>
Sheppard 2009	<p>Point-of-need access to specialist care via the SBCN (telephone). Patients given details how to contact the SBCN if concerned and all outstanding appointments were cancelled.</p> <p>Mammograms continued annually.</p>	<p>Hospital - 6-monthly follow-up appointments for clinical review. Annual mammogram</p>
Wengstrom 1999	<p>SBCN-led intervention - 30 minutes once a week at week 1 baseline then at weeks 3 and 5 (end of radiotherapy) and follow-up at 2 weeks and again at 3 months. SBCN-led intervention as a complement to standard nursing care in the radiotherapy department. First intervention at baseline, emphasis on oral and written cognitive information about simulation and treatment routines - 45-minute session. During this time there was also time for the patients to talk about their personal fears or anxiety concerning the treatment and/or other issues. The following interventions took 30 min and were individualised</p> <p>concerning education and information depending on the patient needs. During these interventions, the purpose of the instruction was to prepare the patient for the possible side effects of treatment. Support and guidance and provision of self-care actions pertaining to what the patient herself could do to prevent, alleviate or minimise the side effects of therapy were given. The purpose of this guidance was to give the patient the ability and necessary skills to take action to sustain self-care at a sufficient level for the patient, thus liberating the patient from dependency on the nurse.</p> <p>Psychological support and strategies for coping with emotional reactions such as anxiety, depression and insecurity were included. This support consisted of, for example, explicit instructions on how simulation and treatment felt, what sensations the patient might experience, what the role of the healthcare staff would be, to what degree the patient could influence the experience (e.g. by listening to music during treatment). Education and guidance to help the patient to modify her body image, and to revise routines in her daily life in</p> <p>order better to cope with the effects of illness and treatment were also given. This guidance and education included information about different possibilities of breast prostheses, how to cope when changing clothes: bathing suits in public; education on how to perform breast self examination (BSE) was also offered as a way</p>	<p>Standard nursing care - there was no systematic routine assessment of patients' needs or nursing care in the department during or after completion of the course of radiation treatment. One information session with the primarily responsible nurse after the simulation of the treatment. This session contained information about treatment, routines and side effects.</p>

**Table 2. Descriptions of interventions** (Continued)

for the patient to get to know her body again. Depending on the patient's need, the nurse provided an informational and educational update regarding the treatment and the side effects. For every patient, a nursing-care journal was kept in order to document the nursing care given.

The nurse also arranged contacts with other healthcare professionals such as, for example, physiotherapists and nutritionists if needed during and after the course of the treatment. The patients were encouraged to call the SBCN if any problems arose during the treatment period or follow-up time.

APN: Advanced Practice Nurse  
BACUP: Understanding cancer of the breast:  
BSE: Breast Self Examination  
CBT: Cognitive Behavioural Therapy  
EGP: Education Group Programme  
HFNS: Hot flushes and night sweats  
NCI: National Cancer Institute  
SBCN: Specialist Breast Care Nurse  
SC: Standard Care  
Tak Tent: Take Care, Old Scots expression

**Table 3. Outcome measures**

Tool abbreviation	Tool	Study
<b>General health-related quality of life outcomes</b>		
EQ-5D	European Quality of Life - five dimension scale	Kimman 2011
GHQ-12	General HealthQuestionnaire (12-item)	Beaver 2009; Sheppard 2009
GHQ-28	General HealthQuestionnaire (28-item)	McArdle 1996
HFBBS	Short Form Hot Flush Beliefs and Behaviours Scale	Fenlon 2020
HFNS	Hot Flushes and Night Sweats rating scale	Fenlon 2020
HFRDIS	Hot flash related daily interference scale	Fenlon 2020
IES	Impact of Event Scale	Arving 2007; Wengstrom 1999
K-POMS-B	Korean version of Profile of Mood States-Brief	Kim 2017
MS	Mastery Scale (perceived feelings of control)	Kimman 2011
MUIS	Mishel Uncertainty in Illness Scale	Ritz 2000
POMS	Profile of Mood States	Ritz 2000
PSQI	Pittsburgh Sleep Quality Index	Fenlon 2020
<b>Cancer-specific quality of life outcomes</b>		
ASC	Assessment of Survivor Concerns questionnaire	Hershman 2013

**Table 3. Outcome measures** (Continued)

CARES	Cancer Rehabilitation Evaluation System-shortened form	Wengstrom 1999
EORTC QLQ-BR-23	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module with 23 questions	Arving 2007
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 30	Aranda 2006; Aranda 2006; Kim 2017; Kimman 2011
FACIT	Functional Assessment of Chronic Illness Therapy-Fatigue	Gomez 2019
FACT-B	Functional Assessment of Cancer Therapy-Breast	Hershman 2013*; Ritz 2000
FACT-B/ES	Functional Assessment of Cancer Therapy plus breast and endocrine sub-scales	Sheppard 2009
IOC	Impact of Cancer scale	Hershman 2013
OTTAT	Oncology Treatment Toxicity Assessment Tool	Wengstrom 1999
SCNS	Supportive Care Needs Survey	Aranda 2006
<b>Anxiety and Depression outcomes</b>		
CES-D	Center for Epidemiologic Studies Depression scale	Hershman 2013
GAD-7	General Anxiety Disorder	Fenlon 2020
HADS	Hospital Anxiety and Depression Scale	Arving 2007; Kim 2017; Koinberg 2004; McArdle 1996
PHQ	Patient Health Questionnaire	Fenlon 2020
PSE	Present State Examination (anxiety, depression, and sexual problems)	Maguire 1980
STAI	Spielberger's State-Trait Anxiety Inventory	Arving 2007; Beaver 2009; Kimman 2011

\*Physical and functional well-being subscales only

**Table 4. Study results**

Study	Outcome	Results
<b>Psychosocial nursing interventions versus standard care for women with primary breast cancer</b>		
Arving 2007	General health-related quality of life	No group-by-time interactions for Impact of Event Scale (IES)  More intervention patients as compared to standard care group improved clinically significantly from "higher levels of distress" to "lower levels of distress" on IES scale (P = 0.04)  At six months, women receiving psychosocial support from oncology nurses experienced less intrusion compared with the standard care group.



**Table 4. Study results** (Continued)

Cancer-specific quality of life	<p>European Organisation of Research and Treatment of Cancer Quality of Life Q-C30 (EORTC QLQ-30 version 2.0)</p> <p>Statistically significant group by time interactions for subscales "Global QoL/health status" (<math>F_{6,378} = 2.18</math>; <math>P = 0.04</math>), "Nausea and vomiting" (<math>F_{6,375} = 3.41</math>; <math>P &lt; 0.00</math>), "Systemic therapy side effects" (<math>F_{6,375} = 2.44</math>; <math>P = 0.02</math>). Clinically significant changes in subscales noted; emotional functioning, social functioning, nausea and vomiting, pain, dyspnoea, insomnia and financial difficulties (<math>P &lt; 0.00</math>).</p> <hr/> <p>European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module with 23 questions (EORTC BR-23)</p> <p>Clinically significant changes in subscales noted; future perspectives, systemic therapy side effects, breast symptoms, arm symptoms (<math>P &lt; 0.00</math>)</p>
Anxiety and depression	<p>No group-by-time interactions for Hospital Anxiety and Depression Scale (HADS).</p> <p>No group differences were found in proportions of patients who changed from being a "case/doubtful case" to a "noncase".</p> <p>Statistically significant differences at baseline were found in HADS anxiety subscale (10.0 vs 6.0 (<math>P = 0.01</math>)).</p> <hr/> <p>No group-by-time interactions for Spielberger's State-Trait Anxiety Inventory (STAI)</p>
Satisfaction	<p>Patient Satisfaction questionnaire - extended version of the Individual psychological support (IPS) for cancer patients - not reliability tested or validated.</p> <p>The standard care group were not assessed for satisfaction. Women were highly satisfied with an individual psychosocial support intervention, provided by SBCN, for up to 18-24 months from the start of adjuvant therapy. Ninety-five per cent of intervention women were satisfied with the number of sessions and 71% of intervention women were satisfied with the timing of the support.</p>
Fenlon 2020	<p>General health-related quality of life</p> <p>Short Form Hot Flush Beliefs and Behaviours Scale (HFBBS)</p> <p>Negative beliefs about HFNS improved for all subscales in the SBCN group, as did positive coping behaviour; there was a significant between-group difference at both 9 and 26 weeks.</p> <hr/> <p>Hot Flushes and Night Sweats rating scale (HFNS)</p> <p>HFNS -problem rating score at 26 weeks: adjusted mean difference, intervention versus control: -1.96, CI -3.68 to -0.23, <math>P = 0.039</math>). Significant improvement also at 9 weeks and excluding patients with &lt; 4 CBT sessions/telephone calls, and also excluding one cohort of 2 patients.</p> <p>Total HFNS frequency at 26 weeks: adjusted mean difference, intervention versus control: -20.22, CI -34.46 to -4.93, <math>P = 0.010</math>). Significant improvement also at 9 weeks.</p> <hr/> <p>Hot Flash Related Daily Interference Scale (HFRDIS) at 26 weeks: adjusted mean difference, intervention versus control: -21.36, CI -29.79 to -12.94, <math>P &lt; 0.0001</math>). Significant improvement also at 9 weeks</p> <hr/> <p>Pittsburgh Sleep Quality Index (PSQI) measured at 9 weeks only: adjusted mean difference, intervention versus control: -0.67, CI -0.94 to -0.39, <math>P &lt; 0.0001</math></p>

**Table 4. Study results** (Continued)

	Anxiety and depression	<p>Depression - Patient Health Questionnaire (PHQ-9) measured at 26 weeks only: adjusted mean difference, intervention versus control: -2.86, CI -4.73 to -0.98, P = 0.003)</p> <hr/> <p>Anxiety - General anxiety disorder (GAD-7) measured at 9 weeks only: adjusted mean difference, intervention versus control: -1.54, CI -3.01 to -0.07, P = 0.041)</p>
Gomez 2019	Cancer-specific quality of life	<p>Functional Assessment of Chronic Illness Therapy (FACIT)</p> <p>Fatigue - FACIT scale average:</p> <p>I1: 23.35</p> <p>I2: 17.13</p> <p>C: 22.73</p> <p>Significant BASELINE differences in the correlation between groups C and I1, with inverse correlation (<math>r = -0.311</math>). Non-significant correlation between groups C and I2 and between groups I1 and I2.</p> <p>12 months: significant differences comparing the averages of each group from baseline to 12 months: I1 N = 14, correlation 0.55, P = 0.043; I2 N = 12, correlation = -0.75, P = 0.005; C, N = 39, correlation = 0.55, P = 0.000.</p> <p>Significant changes between baseline and 12 months for all 3 groups; FACIT scale averages reduced in I1 from 27.79 to 18.07 (n = 14); increased in I2 from 14.00 to 16.92 (N = 12) and reduced in C from 23.23 to 20.03 (N = 39)</p>
Hershman 2013	Cancer-specific quality of life	<p>No differences between groups on the physical and functional well-being subscales of the Functional Assessment of Cancer Therapy (FACT-TS-PS)</p> <hr/> <p>At baseline, the control group had a higher score on the physical health awareness scale (more health awareness) of the Impact of Cancer (IOC) scale. Mean existential negative outlook subscale of IOC was higher in the control group compared to intervention group at 3 months (3.10 vs. 2.67, P = 0.04). Change from baseline was not significant between groups.</p> <hr/> <p>At 3 months, there were no statistically significant between-group differences on the Assessment of Survivor Concerns (ASC) cancer worry subscale.</p> <p>The association between the individual ASC health worry item at 3 months and the intervention showed that the relationship between intervention and less health worry remained significant (P = 0.04); however the relationship between Hispanic ethnicity and health worry was no longer significant (P = 0.12).</p>
	Anxiety and depression	No differences between groups for total and subscale scores for Center of Epidemiological Studies Depression scale (CES-D). Hispanic women had higher (worse) scores on the CES-D scale.
	Satisfaction	<p>Memorial Symptoms Assessment Scale treatment satisfaction.</p> <p>At 6 months, there was no difference in treatment satisfaction with a survivorship nursing intervention in addition to standard care in women who had undergone adjuvant treatment with radiation or chemotherapy.</p>
Kim 2017	General health-related quality of life	<p>European Organisation of Research and Treatment of Cancer Quality of Life Q-C30 (EORTC QLQ-30)</p> <p>Global health status or quality of life was significantly higher in the intervention than in the control group over time (group: F = 8.78, P = 0.01)</p>

**Table 4. Study results** (Continued)

		<p>Korean version of Profile of Mood States- Brief ( K-POMS-B)</p> <p>Mood disturbance was significantly lower in the intervention group than control (F=5.44, P = 0.02). Changes were significantly different between two groups (group x time: F = 3,77, P = 0.03)</p>
	Anxiety and depression	Anxiety and depression lower in intervention group compared to control (group F = 5,25, P = 0.03 for anxiety, F = 10.56, P < 0.01 for depression)
Maguire 1980	Cancer-specific quality of life	<p>Semi-structured interview shortly after surgery, 3, and 12-18 months following surgery to assess physical and social recovery in three areas: swelling, pain and disability; reaction to scar, breast loss and prosthesis; house work, social adjustment, return to work.</p> <p>More SBCN women than control were satisfied with scar (P &gt; 0.05), had adapted to breast loss (P &gt; 0.05), social adjustment (P &gt; 0.05).</p>
	Anxiety and depression	<p>Anxiety, depression and sexual problems (present state examination).</p> <p>No difference between SBCN group and control group at 3 months.</p> <p>Comparisons between SBCN and control groups at 12-18 months for anxiety states (P &lt; 0.01), depressive illness (P &lt; 0.001) and sexual problems (P &lt; 0.02)</p>
McArdle 1996	General-health related quality of life	<p>General Health Questionnaire (GHQ)</p> <p>SBCN vs standard care unadjusted P values were 0.050 (28 general health questionnaire), 0.131 (anxiety and insomnia), 0.866 (severe depression), 0.184 (somatic symptoms), 0.014 (social dysfunction).</p>
	Anxiety and depression	Hospital Anxiety and Depression Scale (HADS). SBCN vs standard care unadjusted P values were 0.770 (HAD - anxiety) and 0.002 (HAD - depression).
Ritz 2000	General health-related quality of life	<p>Mishel Uncertainty in Illness Scale (MUIS).</p> <p>Uncertainty was significantly reduced in intervention group (P = 0.043) at baseline, 1 month (P = 0.001), 3 months (P = 0.026) and 6 months (P = 0.011) but not at 12 months (P = 0.589).</p>
		<p>Profile of Mood States (POMS).</p> <p>No significant differences between groups in levels of mood (P = 0.953) however, unmarried women showed a decrease in mood disturbance in the intervention group at 1 month (P = 0.011) and 3 months (P = 0.043). Additionally, women with no family history of breast cancer showed a decrease in mood disturbance at 1 month (P = 0.002), 3 months (P = 0.010) and 6 months (P = 0.004).</p>
	Cancer-specific quality of life	<p>Functional Assessment of Cancer Therapy (FACT-B).</p> <p>There was no statistical difference between intervention and control groups for well-being but unmarried women in the intervention group reported higher levels of well-being at 1 month (P = 0.036).</p>
Wengstrom 1999	General health-related quality of life	Impact of Event Scale (IES scale): a self-reported questionnaire containing 15 items including 7 items under the heading intrusion and 8 items of avoidance. Patients in the intervention group rated fewer distress reactions than the control (P < 0.05) - CI not provided.
	Cancer-specific quality of life	Oncology Treatment Toxicity Assessment Tool (OTTAT): a self-reported instrument containing 37 items to assess cancer-related symptoms including side effects of treatments. Every item is rated on a 5-point scale from none to intolerable. The On-

**Table 4. Study results** (Continued)

		<p>cology Treatment Toxicity Assessment Tool showed no significant effect between the two groups in perceived side effects - P value and CI not provided.</p> <p>Cancer Rehabilitation Evaluation System (CARES-sf) is a shortened version of a standardised and comprehensive rehabilitation and QoL questionnaire used for cancer patients. This consisted of 59 items and patients were asked to complete a minimum of 37 to a maximum of 57 items. The ratings change on this from a 5-point scale from 0 (does not apply), to 4 (applies very much). This item is multidimensional with reliability, validity and internal consistency previously documented.</p> <p>While the intervention group scored higher at baseline on the CARES-sf global score, the intervention had no measurable effect on global QoL - P value and CI not provided.</p>
<b>Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer</b>		
Arving 2007	General health-related quality of life	Impact of Event Scale (IES). At six months, women receiving psychosocial support by either SBCNs or psychologists clinically improved from "higher levels of distress" to "lower levels of distress" on the 'intrusion' subscale of the IES. Intrusion and avoidance improved over time with clinical improvement in both groups. There was no group-by-time interaction.
	Cancer-specific quality of life	No between-group differences on subscales at all time points up to six months (EORTC QLQ-C30, EORTC-BR-23). There were significant group-by-time changes in the global quality of life/health status, nausea and vomiting, and systemic therapy side effects subscales, for women receiving psychosocial support by either SBCNs or psychologists at six months. There were significant improvements in subscales over time in both groups, for role functioning, emotional functioning, social functioning, nausea and vomiting, pain, dyspnoea, insomnia and financial difficulties. There were significant improvements in subscales over time in both groups, for future perspectives, systemic therapy side effects, breast symptoms, and arm symptoms. In terms of clinically significant changes: systemic therapy side effects increased significantly in the psychologist group but not in the SBCN group. Sexual functioning decreased in both groups. The number of clinically significant changes in group means in each category did not differ between the groups.
	Anxiety and depression	Hospital Anxiety and Depression Scale (HADS). Anxiety subscale improved over 6 months but there was no effect on the depression subscale (HADS) in the SBCN group compared to the psychologist group. There was no group-by-time interaction for HADS subscales. No group differences were found in the proportions of patients who changed from being a 'case/doubtful case' to a 'noncase' for the HADS subscales.
		<p>Spielberger's State-Trait Anxiety Inventory (STAI)</p> <p>State anxiety improved over 6 months in the SBCN group compared to the psychologist group. There was no group-by-time interaction for STAI subscales.</p>
	Satisfaction	<p>Patient Satisfaction questionnaire - extended version of the Individual Psychological Support (IPS) for cancer patients - not reliability tested or validated.</p> <p>Women were highly satisfied with an individual psychosocial support intervention, provided by SBCN or psychologists, for up to 18-24 months from the start of adjuvant therapy. Ninety-five per cent of intervention women were satisfied with the number of sessions and 71% of intervention women were satisfied with the timing of the support.</p>
McArdle 1996	General health-related quality of life	General Health Questionnaire (GHQ) scores

**Table 4. Study results** (Continued)

		SBCN vs voluntary organisation unadjusted P values were 0.002 (28 general health questionnaire), 0.005 (anxiety and insomnia), 0.020 (severe depression), 0.006 (somatic symptoms), 0.010 (social dysfunction).
	Anxiety and depression	Hospital Anxiety and Depression Scale (HADS). SBCN vs voluntary organisation unadjusted P values were 0.020 (HAD - anxiety) and < 0.001 (HAD - depression).
<b>Nurse-led interventions delivering follow-up care compared with usual care for women with primary breast cancer</b>		
Beaver 2009	General health-related quality of life	General Health Questionnaire (GHQ-12) results were highly skewed with over 49% of scores within a group being 0 at each time point. Those scores greater than 4 were consistently higher in the hospital group at the start but not significant.
		Information needs (questionnaire)  The highest need was genetic risk, the lowest, information on sexual attractiveness. In both groups, needs reduced over time and there was no difference between the groups.
	Anxiety and depression	Spielberger's State-Trait Anxiety Inventory (STAI)  No significant differences between start and end of trial. The 95% confidence intervals for the differences between mean values from start and middle of trial: -0.66 and between start and end of trial -0.24.
	Satisfaction	No significant differences in satisfaction with information received, between the groups, at the beginning of the study shown. The telephone groups showed significantly more satisfaction at the middle and end of the trial ( $P < 0.001$ ).
Kimman 2011	General health-related quality of life	Mastery Scale (MS) - Perceived feelings of control  No significant differences between SBCN-led intervention and standard hospital follow-up, with or without educational group programme (EGP)
	Cancer-specific quality of life	European Organisation of Research and Treatment of Cancer Quality of Life (EORTC QLQ-30).  At 12 months, mean scores were 78.4 (SD = 16.2) and 77.7 (SD = 16.2) respectively for SBCN telephone and standard care hospital follow-up. The 95% confidence interval difference at 12 months after treatment was -1.93 to -4.64. Overall, HRQoL significantly improved over time ( $P = 0.01$ ).  Similarly, no significant difference in HRQoL between follow-up with or without educational group programme (EGP) ( $P = 0.86$ ). No significant interaction effect between EGP and nurse-led follow-up with respect to HRQoL ( $P = 0.50$ )
		Emotional and role functioning subscales of the European Organisation of Research and Treatment of Cancer Quality of Life (EORTC QLQ-30)  No significant differences between the SBCN-led intervention and standard hospital follow-up, with or without the educational group programme (EGP)
	Anxiety and depression	Spielberger's State-Trait Anxiety Inventory (STAI)  No significant differences between the SBCN-led intervention and standard hospital follow-up, with or without the educational group programme (EGP)
	Satisfaction	Wares Patient Satisfaction Questionnaire  The SBCN-led telephone follow-up had no statistically significant influence on general patient satisfaction ( $P = 0.379$ ), satisfaction with technical competence

**Table 4. Study results** (Continued)

(P = 0.015), and satisfaction with interpersonal aspects (P = 0.662). Access to care was significantly higher for patients receiving telephone follow-up (P = 0.015) (not deemed clinically relevant by study authors).		
Koinberg 2004	Anxiety and depression	<p>Hospital Anxiety and Depression Scale (HADS)</p> <p>A relative risk (RR) with a 95% confidence interval for the nurse group (NG) over the physician group (PG) was used as a reference. There were no statistically significant differences between the groups for either anxiety or depression.</p> <p>Anxiety</p> <p>6 months - RR 1.8 (95% CI 0.7 to 4.8)</p> <p>18 months - RR 1.2 (95% CI 0.4 to 3.1)</p> <p>24 months - RR 2.3 (95% CI 0.8 to 6.9)</p> <p>60 months - RR 1.8 (95% CI 0.6 to 5.1)</p> <p>Depression</p> <p>6 months - RR 1.0 (95% CI 0.6 to 16.4)</p> <p>18 months - RR 0.5 (95% CI 0.0 to 5.8)</p> <p>24 months - RR 1.0 (95% CI 0.1 to 7.2)</p> <p>60 months - RR 1.7 (95% CI 0.4 to 7.2)</p>
	Satisfaction	<p>Satisfaction and accessibility (SaaC) scale</p> <p>6 months - RR 0.6 (95% CI 0.1 to 3.9)</p> <p>18 months - RR 1.0 (95% CI 1.0 to 1.0)</p> <p>24 months - RR 0.3 (95% CI 0.0 to 1.2)</p> <p>60 months - RR 0.1 (95% CI 0.0 to 0.9)</p>
Sheppard 2009	General health-related quality of life	<p>GHQ-12, containing 12 questions</p> <p>Psychological morbidity was scored in two ways. Responses to each of the 12 questions on GQ-12 were aggregated to provide a maximum score of 48. Second, an official GHQ scoring mechanism was used (0, 0.1, 1) classifying responses as positive or negative.</p> <p>Aggregate psychological morbidity scores at 9 and 18 months were similar to those obtained at baseline in both groups suggesting very little change over time.</p> <p>There was no significant change at 18 months between the two groups (P = 0.77), with the observed difference, 0.2, less than 1%.</p>
	Cancer-specific quality of life	<p>Functional Assessment of Cancer Therapy plus breast and endocrine subscales (FACT-B + ES)</p> <p>Mean aggregate scores for general quality of life showed no significant change at 18 months between the two groups (P = 0.95), with adjusted mean difference of 0.1 well below 1%.</p> <p>No differences were found in relation to endocrine scores (P = 0.388). Scores for both groups on the breast subscale improved over time, with lower scores at 9 and 18 months compared to baseline. The adjusted mean differences between groups at 18 months were 0.7 points in favour of SBCN (P = 0.058).</p>
	Satisfaction	<p>95% of the women in the SBCN intervention group were happy to continue with a point-of-need access as follow-up care.</p>
<b>Psychosocial nursing interventions compared with usual care for women with advanced breast cancer</b>		
Aranda 2006	Cancer-specific quality of life	<p>European Organisation of Research and Treatment of Cancer Quality of Life Q-C30 (EORTC QLQ-30 version 2.0)</p>

**Table 4. Study results** (Continued)

Changes (decreases) noted in the EORTC domain scores were not significantly different between the intervention and usual care arms of the study at either 1 month or 3 months post-intervention.

Differences in EORTC domain scores at 3 months adjusted for baseline score:

Differences between baseline and 3 months I vs C, mean (SD):

EORTC functional scales

Physical functioning 17.9 (23.1) vs 21.6 (20.3)

Role functioning 1.5 (33.9) vs 0.0 (32.9)

Emotional functioning 5.4 (25.6) vs 3.7 (20.6)

Cognitive functioning 2.0 (19.1) vs 0.8 (22.4)

Social functioning 10.8 (29.3) vs 2.4 (32.2)

General quality of life -33.6 (36.6) vs -22.6 (39.1)

For EORTC subscales, a negative score indicates that function has decreased.

No significant differences between the intervention and standard care group for the change in Supportive Care Needs Survey (SCNS) questionnaire domain score in any of the domains.

Difference in SCNS domain scores at 3 months adjusted for baseline score:

SCNS need scales:

Psychologic needs -6.5 (21.7) vs -2.8 (18.5)

Health information needs -11.7 (25.7) vs -9.4 (23.4)

Physical and daily living needs -3.6 (22.6) vs -2.0 (16.4)

Patient care and support needs -4.0 (9.4) vs -1.6 (16.2)

Sexuality needs -6.8 (25.1) vs -9.8 (28.5)

For SCNS subscales, a negative score indicates that needs have decreased.

ASC: Assessment of Survivor Concerns questionnaire

CARES: Cancer Rehabilitation Evaluation System-shortened form

CES-D: Center for Epidemiologic Studies Depression scale

EORTC QLQ-BR-23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer Module with 23 questions

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire Core 30

EQ-5D: European Quality of Life - five dimension scale

FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue

FACT-B: Functional Assessment of Cancer Therapy-Breast

FACT-B/ES: Functional Assessment of Cancer Therapy plus breast and endocrine subscales

GAD-7: General Anxiety Disorder

GHQ-12: General Health Questionnaire (12-item)

GHQ-28: General Health Questionnaire (28 item)

HADS: Hospital Anxiety and Depression Scale

HFBBS: Short Form Hot Flush Beliefs and Behaviours Scale

HFNS: Hot Flushes and Night Sweats rating scale

HFRDIS: Hot flash related daily interference scale

IES: Impact of Event Scale

IOC: Impact of Cancer scale



K-POMS-B: Korean version of Profile of Mood States-Brief  
MS: Mastery Scale (perceived feelings of control)  
MUIS: Mishel Uncertainty in Illness Scale  
OTTAT: Oncology Treatment Toxicity Assessment Tool  
PHQ: Patient Health Questionnaire  
POMS: Profile of Mood States  
PSE: Present State Examination (anxiety, depression, and sexual problems)  
PSQI: Pittsburgh Sleep Quality Index  
SCNS: Supportive Care Needs Survey  
STAI: Spielberger's State-Trait Anxiety Inventory

**Table 5. Hospital Anxiety and Depression Scale**

<b>Anxiety measured by HADS</b>				
<b>Psychosocial nursing interventions compared with standard care for women with primary breast cancer</b>				
Study	SBCN-led intervention (mean ± SD)	Standard of care (mean ± SD)	Time point assessed	Other relevant info
Arving 2007	4 ± 4	6 ± 4	6 months	Statistically significant improvements over time ( $P < 0.01$ ). No group x time interactions
Kim 2017	7.1 ± 3.2	9.4 ± 3.9	9 weeks	Group $F = 5.25$ , $P = 0.03$ ; time $F = 11.18$ , $P < 0.01$ ; group x time $F = 2.26$ , $P = 0.09$
McArdle 1996	4.4 ± 3.6	4.8 ± 4.7	12 months	$P = 0.093$ and “consistently lower in the group offered breast care nurse alone compared to all other groups”
<b>Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer</b>				
Study	SBCN-led intervention (mean ± SD)	Other active intervention (mean ± SD)	Time point assessed	Other relevant info
Arving 2007	4 ± 4	4 ± 4	6 months	Statistically significant improvements over time ( $P < 0.01$ ). No group x time interactions
McArdle 1996	4.4 ± 3.6	6.3 ± 5.0	12 months	“consistently lower in the group offered breast care nurse alone compared to all other groups”
<b>Nurse-led interventions delivering follow-up care compared with usual care for women with primary breast cancer</b>				
Koinberg 2004			60 months	(RR 1.8; 95% CI 0.6 to 5.1)
<b>Depression measured by HADS</b>				
<b>Psychosocial nursing interventions compared with standard care for women with primary breast cancer</b>				
Study	SBCN-led intervention (mean ± SD)	Standard of care (mean ± SD)	Time point assessed	Other relevant info
Arving 2007	3 ± 3	4 ± 4	6 months	No statistically significant improvements over time. No group x time interactions

**Table 5. Hospital Anxiety and Depression Scale** (Continued)

Kim 2017	6.1 ± 2.6	9.1 ± 3.9	9 weeks	Group F = 10.56, P < 0.01; time F = 2.30, P = 0.11; group x time F = 8.33, P < 0.01
McArdle 1996	1.4 ± 1.8	3.0 ± 4.0	12 months	P = 0.003 and “consistently lower in the group offered breast care nurse alone compared to all other groups”
<b>Psychosocial nursing interventions compared with other supportive care interventions for women with primary breast cancer</b>				
Study	SBCN-led intervention (mean ± SD)	Other active intervention (mean ± SD)	Time point assessed	Other relevant info
Arving 2007	3 ± 3	3 ± 3	6 months	No statistically significant improvements over time. No group x time interactions
McArdle 1996	1.4 ± 1.8	3.2 ± 3.2	12 months	“consistently lower in the group offered breast care nurse alone compared to all other groups”
<b>Nurse-led interventions delivering follow-up care compared with usual care for women with primary breast cancer</b>				
Koinberg 2004			60 months	(RR 1.7; 95% CI 0.4 to 7.2)

21-point scale: high scores indicate high levels of symptoms

CI: Confidence interval

HADS: Hospital Anxiety and Depression Scale

RR: relative risk

SBCN: Specialist Breast Care Nurse

SD: Standard Deviation

## APPENDICES

### Appendix 1. Cochrane Central Register of Controlled Trials (CENTRAL)

#1	MeSH descriptor: [Breast Neoplasms] explode all trees
#2	MeSH descriptor: [Nurse Clinicians] explode all trees
#3	MeSH descriptor: [Nurse's Role] explode all trees
#4	MeSH descriptor: [Oncology Nursing] explode all trees
#5	MeSH descriptor: [Nurse Practitioners] explode all trees
#6	#1 or #2 or #3 or #4 or #5
#7	breast near nurs*
#8	#6 or #7
#9	support* near (care or caring)

(Continued)

#10

#8 and #9

## Appendix 2. Search strategy for MEDLINE (via OvidSP)

1	exp breast neoplasms/
2	(breast adj6 cancer\$).tw.
3	(breast adj6 neoplasm\$).tw.
4	(breast adj6 carcinoma\$).tw.
5	(breast adj6 tumo?r\$).tw.
6	or/1-5
7	randomized controlled trial.pt.
8	controlled clinical trial.pt.
9	randomized.ab.
10	placebo.ab.
11	Clinical Trials as Topic/
12	randomly.ab.
13	trial.ti.
14	(crossover or cross-over).tw.
15	Pragmatic Clinical Trials as Topic/
16	pragmatic clinical trial.pt.
17	or/7-16
18	6 and 17
19	Animals/ not Humans/
20	18 not 19
21	exp breast neoplasms/nu
22	exp nurse clinicians/
23	exp nurse's role/
24	exp oncologic nursing/

(Continued)

25	exp nurse practitioner/
26	(cancer adj25 nurs\$).ti,ab,sh.
27	(breast adj25 nurs\$).ti,ab,sh.
28	(support\$ adj25 (care or caring)).ti,ab,sh.
29	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30	exp palliative care/
31	palliat\$.ti,ab,sh.
32	30 or 31
33	20 and 29
34	20 and 32
35	33 or 34

### Appendix 3. Search strategy for Embase (via OvidSP)

1	Randomized controlled trial/
2	Controlled clinical study/
3	Random\$.ti,ab.
4	randomization/
5	intermethod comparison/
6	placebo.ti,ab.
7	(compare or compared or comparison).ti.
8	(open adj label).ti,ab.
9	((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
10	double blind procedure/
11	parallel group\$1.ti,ab.
12	(crossover or cross over).ti,ab.
13	((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)).ti,ab.
14	(assigned or allocated).ti,ab.

(Continued)

15	(controlled adj7 (study or design or trial)).ti,ab.
16	(volunteer or volunteers).ti,ab.
17	trial.ti.
18	or/1-17
19	exp breast/
20	exp breast disease/
21	(19 or 20) and exp neoplasm/
22	exp breast tumor/
23	exp breast cancer/
24	exp breast carcinoma/
25	(breast\$ adj5 (neoplas\$ or cancer\$ or carcin\$ or tumo\$ or metasta\$ or malig\$)).ti,ab.
26	21 or 22 or 23 or 24 or 25
27	exp nurse/
28	exp nursing/
29	exp nurse practitioner/
30	exp oncology nursing/
31	(cancer adj25 nurs\$).ti,ab,sh.
32	(breast adj25 nurs\$).ti,ab,sh.
33	breast nurse.tw.
34	specialist breast care nurse.tw.
35	(specialist breast care adj6 nurse).tw.
36	supportive care intervention.tw.
37	(support\$ adj25 (care or caring)).ti,ab,sh.
38	27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
39	exp palliative care/
40	palliat\$.ti,ab,sh.
41	39 or 40
42	38 or 41

(Continued)

43	18 and 26 and 42
44	limit 43 to (human and embase)

#### Appendix 4. Search strategy for CINAHL (via Ebsco)

S1	MH "Clinical Trials+"
S2	PT Clinical trial
S3	TX clinic* n1 trial*
S4	TX ( (singl* n1 blind*) or (singl* n1 mask*) ) or TX ( (doubl* n1 blind*) or (doubl* n1 mask*) ) or TX ( (tripl* n1 blind*) or (tripl* n1 mask*) ) or TX ( (trebl* n1 blind*) or (trebl* n1 mask*) )
S5	TX randomi* control* trial*
S6	MH "Random Assignment"
S7	TX random* allocat*
S8	TX placebo*
S9	MH "Placebos"
S10	MH "Quantitative Studies"
S11	TX allocat* random*
S12	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11
S13	MH "Breast Neoplasms+"
S14	TX breast cancer
S15	TX breast carcinoma
S16	TX breast tumour
S17	TX breast tumor
S18	TX breast neoplasm
S19	S13 OR S14 OR S15 OR S16 OR S17 OR S18
S20	(MH "Breast Neoplasms+/NU")
S21	(MH "Clinical Nurse Specialists")
S22	(MH "Nursing Role")
S23	(MH "Oncologic Nursing+")

(Continued)

S24	(MH "Nurse Practitioners+")
S25	TX (cancer n6 nurs*)
S26	TX (breast n6 nurs*)
S27	TX ((specialist breast care) n6 nurs*)
S28	TX supportive care intervention
S29	TX (support n6 (care or caring))
S30	S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29
S31	(MH "Palliative Care")
S32	(MH "Hospice and Palliative Nursing")
S33	(MH "Hospice Care")
S34	TX ((palliat*) or (hospice*))
S35	S31 OR S32 OR S33 OR S34
S36	S30 OR S35
S37	S12 AND S19 AND S36

## Appendix 5. Search strategy PsycINFO (via OvidSP)

1	exp Treatment Effectiveness Evaluation/
2	exp Treatment Outcomes/
3	exp Placebo/
4	exp Followup Studies/
5	placebo*.tw.
6	random*.tw.
7	comparative stud*.tw.
8	(clinical adj3 trial*).tw.
9	(research adj3 design).tw.
10	(evaluat* adj3 stud*).tw.
11	(prospectiv* adj3 stud*).tw.

(Continued)

12	((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).tw.
13	or/1-12
14	exp Breast Neoplasms/
15	(breast adj6 cancer\$).tw.
16	(breast adj6 neoplasm\$).tw.
17	(breast adj6 carcinoma\$).tw.
18	(breast adj6 tumour\$).tw.
19	(breast adj6 tumor\$).tw.
20	14 or 15 or 16 or 17 or 18 or 19
21	exp NURSING/
22	exp NURSES/
23	(nurs\$ adj6 practitioner\$).tw.
24	(cancer adj6 nurs\$).tw.
25	(breast adj6 nurs\$).tw.
26	(specialist breast care adj6 nurs\$).tw.
27	supportive care intervention.tw.
28	(support adj6 (care or caring)).tw.
29	or/21-28
30	exp Palliative Care/
31	exp HOSPICE/
32	(palliat\$ or hospice\$).tw.
33	or/30-32
34	29 or 33
35	13 and 20 and 34

## Appendix 6. WHO ICTRP

### Basic Searches:

1. Specialist breast care nurses for supportive care of women with breast cancer
2. Breast cancer AND specialist breast care nurse



3. Breast cancer AND breast care nurse
4. Breast cancer AND breast nurse
5. Breast cancer AND oncology nurse
6. Breast cancer AND nurse AND supportive care

**Advanced Searches (last searched 6 May 2019):**

1. Title: Specialist breast care nurses for supportive care of women

Recruitment Status: All

2. Condition: breast cancer or breast carcinoma or breast neoplasm or breast tumour or breast tumor

Intervention: breast care nurse\* OR breast cancer nurse\* OR breast nurse\*

Recruitment Status: All

3. Intervention: breast care nurse\* OR breast cancer nurse\* OR breast nurse\*

Recruitment Status: All

4. Condition: breast cancer or breast carcinoma or breast neoplasm or breast tumour or breast tumor

Intervention: specialist care nurse%

Recruitment Status: All

5. Condition: breast cancer or breast carcinoma or breast neoplasm or breast tumour or breast

Intervention: supportive care OR supportive caring OR supportive care intervention%

Recruitment Status: All

**Appendix 7. ClinicalTrials.gov**

**Basic Searches:**

1. Specialist breast care nurses for supportive care of women with breast cancer
2. Breast cancer AND specialist breast care nurse
3. Breast cancer AND breast care nurse
4. Breast cancer AND breast nurse
5. Breast cancer AND oncology nurse
6. Breast cancer AND nurse AND supportive care

**Advanced Searches:**

1. Search Terms: Specialist breast care nurses for supportive care of women

Recruitment: All Studies

Study Results: All Studies

Study Type: All Studies

Gender: All Studies

2. Conditions: breast cancer or breast carcinoma or breast neoplasm or breast tumor

Interventions: breast care nurse\* OR breast cancer nurse\* OR breast nurse\*

Recruitment: All Studies

**Specialist breast care nurses for support of women with breast cancer (Review)**

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[Study Results: All Studies](#)

[Study Type: All Studies](#)

[Gender: All Studies](#)

3. [Interventions:](#) breast care nurse\* OR breast cancer nurse\* OR breast nurse\*

[Recruitment:](#) All Studies

[Study Results:](#) All Studies

[Study Type:](#) All Studies

[Gender:](#) All Studies

4. [Conditions:](#) breast cancer or breast carcinoma or breast neoplasm or breast tumor

[Interventions:](#) specialist care nurse\*

[Recruitment:](#) All Studies

[Study Results:](#) All Studies

[Study Type:](#) All Studies

[Gender:](#) All Studies

5. [Conditions:](#) breast cancer or breast carcinoma or breast neoplasm or breast tumor

[Interventions:](#) supportive care OR supportive caring OR supportive care intervention\*

[Recruitment:](#) All Studies

[Study Results:](#) All Studies

[Study Type:](#) All Studies

[Gender:](#) All Studies

## WHAT'S NEW

Date	Event	Description
11 June 2020	New citation required and conclusions have changed	The search was updated to June 2020. Some amendments were made to update the search strategies. Nine new RCTs have been included bringing the total included studies to 14. Additional detail has been extracted about the context of the interventions including the setting and participant characteristics. We have assessed risk of bias using the Cochrane 'Risk of bias' tool and we have assessed the certainty of evidence using the GRADE approach. There have been changes to the composition of the authorship team since the last review was published.

## HISTORY

Protocol first published: Issue 1, 2006

Review first published: Issue 1, 2008

Date	Event	Description
11 June 2008	Amended	Converted to new review format.
12 November 2007	New search has been performed	First publication review
19 June 2006	New search has been performed	First publication protocol

## CONTRIBUTIONS OF AUTHORS

MN and SC developed the protocol for this review. TB and SC carried out screening and data extraction of this first update. All authors reviewed drafts and were responsible for the writing of the final review.

## DECLARATIONS OF INTEREST

TB: None known.

SC: None known.

MN: None known.

## SOURCES OF SUPPORT

### Internal sources

- University of Stirling, UK

We acknowledge in-kind support from the University of Stirling to enable the update of this review.

### External sources

- No sources of support supplied

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The primary outcome is still quality of life but amended to reflect different types of outcome measures. In the original protocol, 'quality of life' was defined in its broadest sense, as quality of life affected by a diagnosis of breast cancer. All the quality of life 'outcomes' in the list were intended as indicators of quality of life rather than stand-alone outcomes. In this update, we have amended the types of outcome measures: primary outcomes are general health-related quality of life, cancer-specific quality of life, and anxiety and depression; the secondary outcome is service provision (from the patient perspective).

## INDEX TERMS

### Medical Subject Headings (MeSH)

Anxiety [nursing]; Breast Neoplasms [\*nursing] [psychology]; Depression [nursing]; \*Oncology Nursing; \*Quality of Life; Randomized Controlled Trials as Topic

### MeSH check words

Female; Humans