Essential information

Title: How effective are self-management interventions in promoting health-related qualify of life in people after primary treatment for breast cancer? A critical evidence synthesis

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Highlights:

- SMIs are potentially effective after primary treatment for breast cancer, although effect sizes are small and inconsistent across HRQoL domains.
- SMIs predominantly promote recipients' physical and functional well-being, regardless of self-management skills applied.
- SMIs are mainly prescribed for 12 weeks, but optimal dosage cannot be confirmed currently.
- SMIs informed by CBT and/or offered through recipient education seem to be marginally more effective.

Abstract

Purpose: Self-management interventions (SMIs) are designed to empower people living beyond breast cancer and help them adjust to a new normal. This structured review aimed to critically appraise and synthesise up-to-date evidence on the effectiveness of SMIs to promote health-related quality of life (HRQoL) in people with breast cancer in the post-treatment period.

Methods: According to PRISMA statement guidelines, MEDLINE, EMBASE and CINAHL were searched for peer-reviewed publications of randomised controlled trials of SMIs. Pre-specified selection criteria were applied to all retrieved records. Methodological quality and risk of bias were evaluated by using the Caldwell framework and Cochrane Collaboration Risk of Bias tool, respectively. Findings were integrated into a narrative critical evidence synthesis.

Results: Nine eligible trials were identified that tested nine SMIs. Five SMIs were based on cognitive behaviour therapy (CBT). Eight SMIs targeted recipients' decision-making and taking-action skills. Across trials, gains in one to four domains of HRQoL were reported. SMIs predominantly promoted recipients' physical and functional well-being, regardless of methodological quality or self-management skills applied, but effect sizes were consistently small. SMIs were mainly prescribed for 12 weeks, but optimal dosage cannot be confirmed currently. SMIs informed by CBT and/or offered through recipient education were marginally more effective. Evidence derived from moderate-to-good quality trials.

Conclusions: SMIs are potentially effective after primary treatment for breast cancer, although effect sizes are small and inconsistent across HRQoL domains. More rigorous development and testing is required, while co-production from the early development stages or at the refinement phase is recommended.

Key words: breast cancer; survivors; self-management; intervention; effectiveness; health-related quality of life

1. Introduction

As a result of advances in early detection and treatment of breast cancer, a rising number of women and men will transit from being 'patients' to living beyond breast cancer (Harrow et al., 2014; Siegel et al., 2015). Completion of cancer treatment does not mean the end of the cancer experience. Variable deficits in health-related quality of life (HRQoL) might be experienced during treatment and carried over to the post-treatment period (Trusson, 2014). Such deficits might be difficult to turn around even a year post-treatment (Lee et al. 2011). Physical well-being can be influenced by lymphoedema, fatigue and sleep disorders, which restrict the ability to perform a series of daily tasks; anxiety and distress can reduce psychological well-being and put strains on family relations and social networks, which is a potential threat for social well-being (Ewertz and Jensen, 2011). Often, traditional medical follow-ups fail to meet people's post-treatment and medium-to-long-term supportive care needs. People living beyond breast cancer must be supported to develop the skills and confidence to monitor and manage their own health (Phillips and Currow, 2010) in addition or in conjunction to routine follow-up and potential survivorship care plans. Changing the emphasis of current follow-up from disease-monitoring to a more comprehensive model of aftercare is thus required (Eccles et al., 2013).

Enabling supported self-management in cancer care requires considerable effort and organisational changes, but promises to offer better disease and symptom control, smoother adjustment to life beyond cancer, and a model of care that is more streamlined to people's needs if and when these occur (Boger et al., 2015). Self-management interventions (SMIs) promise to offer ongoing and structured support to people living beyond cancer (Lorig and Holman, 2003). SMIs act as coaching means to provide the skills necessary to help people actively identify and effectively report challenges or even solve problems (Boger et al., 2015). In turn, SMIs can bring about modest improvements in self-efficacy, mood, physical symptoms and health service utilisation (Boger et al., 2015). SMIs typically incorporate five core skills: problem solving, decision making, resource utilisation, forming of a patient-healthcare provider partnership, and taking-action (Lorig and Holman, 2003). As such, SMIs have gradually come to be considered a key part of post-treatment, mainly because people are increasingly expected to assume responsibility to monitor their own health at home (Grady and Gough, 2014).

Diverse modes of delivery have been implemented to support testing the various SMIs in cancer care. To date, literature reviews in this area have either focused on one type of SMI or have only reviewed the effectiveness of one domain of HRQoL. Cheng et al. (2017) only reviewed home-based SMIs; Triberti et al. (2019) only evaluated e-health SMIs; Van Dijck et al. (2016) only considered the effects of physical self-management. Moreover, Boland et al. (2018) systematically reviewed SMIs regardless of cancer type. Although there are commonalities in terms of the impact that different types of cancer have on people, those living with and beyond breast cancer likely face unique issues, including sexual dysfunction, post-mastectomy/ lumpectomy psychological distress and body image changes, and premature aging due to endocrine effects (Fouladi et al., 2018; Stefanic et al., 2014). Such adverse experiences might pose a heavier burden compared to other types of cancer. SMIs developed for other types of cancer might have limited or unconfirmed application to people living beyond breast cancer. Given this knowledge gap, the authors set out to review the characteristics and effectiveness of the different SMIs specifically developed for and tested with people living beyond breast cancer. The aim of this review was to provide a critical synthesis of up-to-date evidence to identify how effective existing SMIs are in promoting HRQoL in people after primary treatment for breast cancer.

2. Methods

A structured review was conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009).

2.1 Research question formation

To formulate the research question, the 'population, intervention, comparison, outcomes' (PICO) typology (Santos et al., 2007) was used. The PICO components considered are outlined below:

- Population: Adult men and women, diagnosed with eary-stage breast cancer and post-completion of primary treatment (surgery, chemotherapy or radiotherapy).
- Intervention: Different types of SMIs and different modes of delivery such as e-health, education or home-based practice.
- Comparison: Usual/standard care plans including wait list controls.
- Outcomes: Metrics of overall HRQoL and individual domains of well-being in the form of total and subscale scores derived from self-reported questionnaires.

Based on the above, the research question for this review was: "In adult men and women diagnosed with early-stage breast cancer and after completion of primary treatment, what is the effectiveness of the different types of SMIs on promoting self-reported HRQoL and well-being when compared to usual/standard care?"

2.2 Search strategy

Three major electronic databases (MEDLINE, EMBASE and CINAHL) were searched, using the keywords outlined in Table 1. The reference lists of eligible papers and key relevant articles on this topic were also examined for additional eligible studies. Searches were initially run in April 2019 and updated them in November 2019. No new eligible articles were found during this second iteration.

2.3 Eligibility criteria

Eligibility criteria were based on the PICO contents and objectives of this review. Inclusion criteria were as follows:

- People diagnosed with stage I-III breast cancer. As the lived experience of early-stage versus metastatic breast cancer can differ considerably (Vondeling et al.,2018), people with early-stage breast cancer were specifically targeted to create a more uniform sample.
- Men and women, aged ≥18 years, who had completed primary treatment for breast cancer, including surgery, chemotherapy or radiotherapy. According to Morgan (2009), 'cancer survivors' can be defined as those who have experienced cancer and are still alive, and this definition includes peoples at the post-treatment period.
- SMIs developed to promote at least one of participants'/recipients' core self-management skill.
- SMIs tested via a randomised controlled trial (RCT). RCTs are recognised as the 'gold standard' in evaluating the effectiveness of interventions against a controlled condition (Creswell et al., 2009). Waiting list controls were also considered.
- Metrics of overall HRQoL and domains of well-being (regardless of whether reported as primary or secondary outcomes) as measured via self-reported questionnaires with proven reliability and validity. Using high-quality, validated questionnaires caters for lower risk of measurement bias (El Fakir et al., 2014).
- Studies published in peer-reviewed journals and in English.
- Original research articles published within the past 10 years. Processing up-to-date evidence would increase the clinical usefulness and relevance of this review.

Articles were excluded for the following reasons:

- Study participants diagnosed with stage IV breast cancer, i.e. with metastatic disease, whereby breast cancer cells spread beyond the sentinel nodes of the breast and to other distant sites (Berman et al., 2013).
- Experimental studies without a control group. A control group refers to a group of participants whose performance regarding an outcome variable is used to evaluate the performance of the experimental group. If an experimental study does not include a control group, the risk of bias increases and the confidence in the true effectiveness of the intervention is compromised (Creswell et al., 2009).
- Studies involving samples with mixed cancer diagnoses, unless a separate analysis for people with breast cancer was reported.
- Literature reviews, qualitative studies, case studies commentaries and study protocols.

2.4 Review process and data extraction

Following article retrieval and de-duplication, the first author screened the retrieved articles for eligibility following a two-stage process. The first stage was to shortlist articles based on titles and abstracts. The second stage was the retrieval of potentially relevant articles in full-text. If studies were excluded after reading the full-texts, the reasons for doing so were recorded. Data from the final sample of eligible articles were then extracted. A bespoke evidence table was developed for this review to aid in the data extraction. The first author extracted all data, which were then double-checked by the second author.

2.5 Assessment of methodological quality and bias

The tool designed by Caldwell et al. (2011) was used to evaluate the methodological quality of the selected studies. Vader (1998) points out that core elements for assessing the quality of an RCT include the intervention design, internal validity, external validity, data analysis and ethical issues. This framework covered all these elements with 18 questions, and three possible answers for each question (no=0, partly=1, yes=2). Typically, the 'partly' score means that some information was provided, but only to a limited extent (Caldwell et al., 2011). The maximum value for each reviewed article was 36; higher scores indicated better methodological quality. Although there were no clear score ranges to indicate quality status, a score of >30 was considered as indicating methodologically robust studies, while scores between 25 and 30 were considered to indicate studies of moderate quality. No studies were excluded based on methodological quality. Details about quality assessment for the included articles can be found in Supplementary file 1.

Creswell (2009) points out that unexpected biases can lead to underestimation or overestimation of true intervention effects. The Cochrane Collaboration tool developed by Julian et al. (2011) was also used to assess the risk of bias in the included RCTs. Six domains were evaluated, namely: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants/personnel; 4) blinding of outcome assessment; 5) incomplete outcome data; 6) selective reporting. The risk of bias for each of these domains was determined to be low, high or unclear. 'Low' indicates that the risk of bias was acceptable, 'high' means that the risk of bias was high, and unclear means that there is insufficient information to make a judgement.

2.6 Data analysis synthesis

A narrative approach to this evidence synthesis was used, also creating thematic summaries of findings within similar context (Popay et al., 2006). Popay et al. (2006) point out that outcomes synthesised as a narrative are more contextualised and understandable to readers. Thematic summaries can offer detailed and focussed descriptions of evidence pertinent to specific outcomes within salient themes (Thomas et al., 2012). The thematic categories were informed by the different aspects of well-being reported in the reviewed articles, i.e. physical, psychological, cognitive, social, functional, and overall HRQoL. Moreover, to quantify the magnitude of the reported SMI effects and contextualise their

clinical importance, Cohen's *d* effect sizes (differences in mean HRQoL scores between intervention and control at post-treatment adjusting for baseline scores) were calculated, using the online formulae available at https://www.psychometrica.de/effect_size.html. By convention, d<0.20 indicated negligible intervention effect; d=0.20-0.49 'small' effect, d=0.50-0.79 'moderate' effect, and d≥0.80 'large' effect (Cohen, 1992). For readability purposes, references to 'participants' indicate participants in both the intervention and control groups, while references to 'recipients' indicate participants in the intervention group only. Moreover, the terms RCT and trial are used interchangeably to refer to the final sample of reviewed RCTs.

3. Results

3.1 Search results

The initial searches retrieved 503 articles. Once duplicates were removed (n=214), 289 articles were screened based on title and abstract. Subsequently, full-text versions of 54 potentially relevant articles were assessed for eligibility. Nine articles that reported on nine unique RCTs were included in the final sample (Figure 1). Table 2 outlines the methodological characteristics and quality of the selected RCTs.

3.2. Characteristics of the included RCTs and SMIs

Trial sample sizes ranged from 42 to 288 participants. The trials were conducted in the USA (n=4) and Oceania (n=1), as well as developed countries in Asia (n=2) and Europe (n=2). There were eight two-arm trials and one three-arm trial (Zick et al.,2016). Intervention duration ranged between 3 and 24 weeks. Admiraal et al. (2017) and Lee et al. (2014) used web-based platforms to deliver their interventions.

Chan et al. (2017) and Beatty et al. (2010) used structured education with group and self-study respectively, while Kvale et al. (2016) used single coaching sessions. Three SMIs employed a combination of two strategies, namely home-based practice with coaching or structured education (Lahart et al., 2016, Zick et al., 2016); Hoffman et al., 2012). Rogers et al. (2015) used structured education, home-based practice and coaching.

Three SMIs involved recipient self-study (Admiraal et al. 2017; Lee et al., 2014; Beatty et al., 2010); health care providers delivered the SMIs in the rest of reviewed RCTs. Five SMIs applied cognitive behaviour therapy (CBT) (Westbrook et al., 2016) as the foundation of the training (Chan et al., 2017; Hoffman et al., 2012; Roger et al., 2015; Lahart et al., 2016; Beatty et al., 2010).

3.3 Psychometric robustness of the outcome measures

Four trials used the generic European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) as their primary outcome measure (Admiraal et al., 2017; Beatty et al., 2010; Chan et al., 2017; Lee et al., 2014). Zick et al. (2016) and Kvale et al. (2016) used the Long-Term Quality of Life Instrument (LTQL) and the 36-Item Short Form Health Survey (SF-36), respectively.

Only three trials used a breast-cancer-specific Functional Assessment of Cancer Therapy-Breast (FACT-Breast) outcome measure (Hoffman et al., 2012; Rogers et al., 2015; Lahart et al., 2016). All outcome measures met the minimal standards for internal consistency (Cronbach's alpha coefficient ≥0.70), as well as content and construct validity (Aaronson et al., 1993; Hahn et al., 2015; Wyatt et al., 1996; Ware et al., 1998).

3.4 Risk of bias in the RCTs

Risk of bias evaluation is detailed in Table 2. Randomisation was conducted using a computer-generated randomisation list in all trials. Eight trials concealed the allocation

sequence until intervention began; Kvale et al. (2016) did not clarify whether allocation had been concealed. Absence of double-blinding and inadequate concealment of allocation effects may exert an influence according to the expectations of participants or clinicians (Creswell, 2009). Due to the unique nature of the SMIs, double-blinding was not practically feasible as participants could well guess the treatment allocation. The use of self-reported measures of HRQoL likely alleviated the effects of this type of bias as researchers did not interfere with participants' reporting during data collection.

Six trials employed an intention-to-treat analysis. Beatty et al. (2010) and Kvale et al. (2016) used linear mixed modelling and Admiraal et al. (2017) used multiple imputation analysis. These methods ensured that, despite participant withdrawal and missing data, all available research data were included in the final analysis to avoid overoptimistic estimates of the efficacy of the intervention (Galbraith et al., 2017; Gupta 2011; Van Buuren, 2007). In Lee et al. (2014), only two women missed the follow-up; because missing data were well-balanced between intervention and control group, it is unlikely that attrition biased findings of this trial. One trial was evaluated as high risk for selective reporting bias due to the results being contrary to expectations (Admiraal et al., 2017). All trials complied with CONSORT guidelines (Begg et al., 1996; Schulz et al., 2010). The CONSORT urges completeness, clarity and transparency in reporting for RCT, which reflects the actual trial design and conduct (Schulz et al. 2010).

Sample sizes were informed by formal, a priori power calculation in all trials but Kvale et al. (2016). Where no justification was provided for the choice of sample size, the risk of missing an important intervention effect due to limited power increases (Creswell, 2009). No ad hoc power calculation was reported for any trial. Another potential bias was the use of convenient sampling in all trials, which may pose a threat to the internal validity of an RCT (Creswell 2009). Finally, although SMIs in Admiraal et al. (2017) and Lee et al. (2014) were web-based, internet access could be a restriction for specific population sub-groups, such as older people and those with low technology literacy and/or low income, thus impacting on the representativeness of the sample.

3.5 Overall methodological quality of the RCTs

Quality scores using Caldwell et al.'s (2011) framework ranged from 28 to 34 (see Table 2 and Supplementary file 1). In conjunction to risk of bias evaluation, the overall quality of the reviewed trials reveals moderate-to-high methodological quality.

3.6 Effectiveness of the SMIs

3.6.1 Physical well-being

Five in nine trials showed statistically significant effectiveness of SMIs on recipients' physical well-being (Chan et al., 2017; Hoffman et al., 2012; Lee et al., 2014; Rogers et al., 2015; Zick et al., 2016); three of these trials were based on CBT. All four trials were methodologically robust. Across trials however, effect sizes were negligible-to-small, ranging from 0.14 to 0.37 overall, and from 0.19 to 0.37 where statistical significance was also confirmed (Table 2). Relaxing acupressure with structured education had the largest effect on physical well-being at 6 weeks post-intervention and across trials (d=0.37) (Zick et al., 2016).

Chan et al. (2017) – effect size d=0.32 – were the only ones to consider the cultural context and lifestyle preferences of SMI recipients, which may have catered for greater acceptability of the SMI and easier integration to recipients' daily activities. Nonetheless, the short time-frame for intervention delivery (three weeks in Chan et al., 2017) might have prevented from larger intervention effects to show. The SMI tested in Kvale et al. (2016) was the only one to actively promote a partnership skill with healthcare providers that might have led to a follow-up more tailored to participants' physical needs; however, bias interfering with this trial might have led to lack of statistical significance and only small intervention effects (d=0.29).

3.6.2 Emotional well-being

Only three trials reported statistically significant improvements in emotional well-being (Hoffman et al., 2012; Kvale et al., 2016; Rogers et al. 2015) with only small effect sizes (*d*=0.23-0.32). Two of these trials employed CBT-based SMIs (Hoffman et al., 2012; Rogers et al. 2015), although the SMI by Hoffman et al. (2012) was associated with effectiveness of greater clinical importance. Hoffman et al. (2012) used a mindfulness-based method to urge participants to actively face their current health condition rather than avoid it. The remaining six trials yielded no statistically significant results, with negligible effect sizes.

Although Admiraal et al. (2017) and Chan et al. (2017) did use tailored psychological interventions with their participants, these were not linked to statistical significance or clinical importance. Ceiling effects at baseline might explain these findings. Several participants in Admiraal et al. (2017) reported no major psychological issues for which they needed additional support. In sub-group analyses though, the sub-group of distressed patients did seem to find greater benefit from the SMI (Admiraal et al., 2017).

3.6.3 Social well-being

Two trials reported statistically significant gains in intervention recipients' social well-being (Hoffman et al., 2012; Zick et al., 2016). Effect sizes were negligible (*d*=0.16-0.19). The rest of trials yielded no statistically significant or clinically important findings. Common self-management skills in Zick et al. (2016) and Hoffman et al. (2012) were decision-making, taking action and problem solving. Both SMIs were also delivered using education combined with home-based practice, which likely promoted problem-solving skills, helping participants to feel in control of issues within their social environment. In both trials, the SMIs were associated to significant gains in fatigue management and mood state, which might partially explain more positive scores on social well-being.

3.6.4 Functional well-being

Eight trials evaluated functional well-being (Table 2); five of them showed statistically significant improvement (Hoffman et al., 2012; Kvale et al., 2016; Lahart et al., 2016; Rogers et al., 2015; Zick et al., 2016) with small-to-moderate effect sizes (*d*=0.28-0.66). Only one SMI was associated with moderate effects (*d*=0.66) on functional well-being (Kvale et al., 2016).

There are two key points related to these positive effects. First, decision-making and taking-action were the two self-management skills that recipients were trained on across the four trials. Recipients could choose a suitable exercise level according to their physical situation before taking-action to finish the short-term plan. Second, in Rogers et al. (2015) and Lahart et al. (2016), SMIs focused on physical deficits, which might have helped in the management of breast cancer-specific symptoms to allow recipients to perform the usual tasks of daily living and carry out social roles. No trial specifically considered age-related implications when evaluating the recipients' functional well-being.

3.6.5 Cognitive well-being

In four trials, use of the EORTC QLQ-C30 allowed for evaluation of participants' cognitive well-being (Table 2). Only Beatty et al. (2010) reported statistically significant improvement associated with a moderate effect size (*d*=0.59) at 24 weeks post-intervention although no intervention effects were found at 12 weeks. Two factors might underpin these positive effects. First, delivery of the SMI involved self-study education, which might have promoted recipients' mental acuity. Second, participants had only recently completed treatment (previous 3 months), which might allow for any deficits in cognitive well-being to reverse more easily.

3.6.6 Global HRQoL

Three trials showed statistically significant improvement of global HRQoL (Hoffman et al., 2012; Lahart et al., 2016; Rogers et al., 2015); effect sizes were small (*d*=0.23-0.40). Two main factors might have played a role to these positive effects. First, all three trials used multiple rather than single intervention delivery modes most commonly education and home-based practices. Delivery modes were chosen to be relatively brief and highly feasible, thus allowing easy practice at home and regular follow-up sessions. Second, all three trials targeted their recruitment on a sample size that was based on an a priori power calculation, which has likely increased the internal validity of the trial and its ability to detect a true difference between the experimental conditions. Of the remaining trials, where overall HRQoL scores were calculated, deficits in either or both of the aforementioned aspects could feasibly explain lack of statistically significant and/or clinically important findings.

4. Discussion

4.1 New evidence from this review

Evidence from the reviewed trials suggests gains in one to four domains of HRQoL of people with breast cancer in the post-treatment period. Current evidence on SMI effectiveness is nevertheless ambiguous. SMIs seem to predominantly promote recipients' physical and functional well-being, regardless of methodological quality or self-management skills applied. Effect sizes in relation to physical and functional well-being are consistently small regardless of statistical significance. The magnitude of SMI effects on emotional well-being and overall HRQoL is likely larger by a fraction, however only one in three trials reported statistically significant findings. The evidence on functional well-being is compromised by a smaller number of trials that did evaluate it. Effects on social or cognitive well-being cannot be confirmed. Prescription of SMIs for 12 weeks seems a popular choice, but whether it is optimal from an intervention effectiveness standpoint it cannot be confirmed currently. SMIs informed by CBT and/or offered through recipient education (particularly in combination with other training modes) seem to be marginally more effective.

4.2 Confidence in the evidence

Potential reasons affecting one's confidence in the available evidence include: (a) wide diversity in the tested SMIs in terms of nature, content, duration and delivery; (b) difficulty to verify recipient adherence to prescribed SMI; (c) differences in the proportion of older people and people with lower educational attainment levels among recruited participants compared to the general population of people with breast cancer; (d) unconfirmed feasibility of some of the SMIs in the post-treatment period; (e) use of generic rather than breast cancer-specific HRQoL tools that might have conflated SMI effects; (f) issues with randomisation and blinding that might have interfere with establishment of true SMI effectiveness; (g) evidence for some unplanned and therefore likely underpowered secondary analyses of data; (h) exclusive focus on women living beyond breast cancer and intervention settings in developed countries; and (i) wide variation in the definition of people living beyond cancer (referred to as 'breast cancer survivors', which might confuse evidence on SMI effectiveness due to differences in health status deficits at different time-points.

4.3 CBT-informed SMIs

SMIs informed by CBT seem to be more effective compared to other SMIs. CBT seems able to promote any domain of HRQoL regardless of type of SMI, particularly where skills around decision-making and taking-action are targeted. According to Nolte and Osborne (2013), people living beyond breast cancer must make day-to-day decisions in response to changes in their health condition; decision-making and taking-action skills can encourage them to actively monitor their health and then change their behaviour. The main goal of CBT in self-management is to promote recipients' level of activation and promote their confidence in managing their health condition (Hibbard et al., 2007). However, no trial measured

recipients' activation level prior to the SMI; therefore, a link between SMI effects and positive behaviour changes remains unclear (Hibbard et.al, 2007).

4.4 Education-delivering SMIs

Consistent with Howell et al. (2017), the overall quality of education-delivering SMIs was high enough to help effective monitoring of recipients' post-treatment health status. People living beyond cancer seem to agree that receiving information from healthcare professionals can facilitate decision-making to help them sustain positive self-management behaviours in the long run (Powers et al. 2017).

People living beyond breast cancer often find themselves emotionally challenged (Stanton and Bower, 2015). From an education perspective, mindfulness might be an effective and practical approach for an ongoing self-management of emotional issues (Haller et al., 2017). Mindfulness can help emotionally challenged people living beyond breast cancer to redirect their attention to other aspects of the present moment (e.g. breathing, walking or environmental sounds), thus avoiding rumination (Haller et al., 2017). Mindfulness training is consistent with CBT in several ways (Baer, 2003), enabling non-judgmental observation for early signs of a problem, promoting active management and reducing avoidance. Moreover, the likely effects of mindfulness as part of SMIs on the HRQoL of recipients' partners or family carers has been suggested as promoting relationship closeness and subsequent adjustment living beyond breast cancer (Carlson et al., 2013).

4.5 SMIs: Is there scope for web-based delivery?

With mixed evidence deriving from only two trials in this review, the true effectiveness of online SMIs remains unclear. Triberti et al. (2019) points out that one major advantage online SMIs is convenience for the recipient. Indeed, participants in two of the reviewed trials (Admiraal et al., 2017; Lee et al., 2014) found online delivery to be a particularly attractive feature compared to having to attend appointments in person, which might further underpin adjustment to a new reality that moves away from the clinical environment. Historically, web-based solutions have been challenged by low technology literacy among recipients (often but not exclusively linked to older age) and lack of clarity around compliance with the intervention. Low adherence rates could well hinder delivery fidelity and subsequently adversely impact on the effectiveness of SMIs. Ugalde et al. (2017) claim that actual use of online SMIs largely depends on the recipient's own attitude and motivation rather than on the SMI's technical properties. However, certain technical properties (e.g. user friendliness, ability to personalise SMI content) can be measures to improve consistent, long-term engagement with the intervention. Concerns also exist that online delivery might put a barrier on the formation of a collaborative and interactive relationship between recipients and healthcare professionals (Foster et al., 2016), however frequency of SMI delivery that is tailored to recipients' needs and boosted by using online, real-time calls/interaction with healthcare professionals might provide feasible solutions.

4.6 Applying SMIs to match the post-treatment phase

Aligning target outcomes of a SMI to post-treatment phases and associated deficits in health status can theoretically be linked to greater SMI effectiveness (Howell et al., 2017). For instance, participants in Admiraal et al.'s (2017) psychoeducation programme had finished treatment within the previous six months, but self-reports of emotional issues were infrequent, which might explain why the trial was unable to show any viable SMI effectiveness. Henselmans et al. (2010) report that many people living beyond breast cancer (36%) appear to experience no distress at all during the first six months after treatment completion, yet distress increases a year later. Perhaps, SMIs that allow multiple components to be delivered in a phased fashion over time and be tailored to key health status deficits at said time-points might be linked to greater effectiveness. Longitudinal observational studies to describe over-time changes among people living beyond breast cancer could establish the level of need and help inform these SMIs.

4.7 Review strengths and limitations

Aside from a systematic approach to the search for and evaluation of available evidence, a strength of the present review is that it involved diverse, internationally tested self-management programmes targeting the core self-management skills, while it holistically looked at all domains of HRQoL. However, there are also some limitations. This review considered the effects of SMIs on recipients' HRQoL only, although evidence regarding other outcomes, such as cost-effectiveness, were not examined. Moreover, only articles published in English and only three of the major electronic databases were considered. Despite the small possibility that non-English publications or additional eligible trials were missed, this review was performed on a 'rapid' mode to allow for a timely and comprehensive critical evidence synthesis that could be of immediate use to clinicians, researchers and people living beyond cancer.

5. Implications

According to guidelines created by Runowicz et al. (2016), it is recommended that healthcare professionals offer self-management programmes to people living beyond breast cancer as an option for a proactive and supportive follow-up service, particularly where deficits in physical/functional well-being (and tentatively, emotional well-being) are experienced or anticipated. Attention to baseline activation levels and close follow-up may be needed to ensure engagement with and adherence to SMIs over time. Researchers are urged to consider discussion points outlined here to introduce methodological tweaks to the content of SMIs (e.g. use of all five core self-management skills in one SMI) and modes/timing/duration of delivery in order to ensure true alignment to recipients' ever-changing needs and adjustment challenges. Importantly, the authors wish to further bring SMIs to the attention of people living beyond breast cancer and their relatives to encourage them to seek information regarding availability, content and delivery options for SMIs according to their healthcare needs.

6. Conclusions

SMIs are potentially effective for supporting predominantly the physical/functional well-being of people after primary treatment for breast cancer, although effect sizes are small and inconsistent across HRQoL domains. However, the decision-making and taking-action skills delivered by SMIs are commensurate as both can help recipients to finish a behavioural change process. More rigorous development and testing is required, working together with people living with breast cancer from the early development stages or at the refinement phase for existing SMIs to ensure that SMIs 'talk' to likely recipients' 'activation' and 'motivation' levels.

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Table 1. Search strategy and keywords used in the electronic database searches

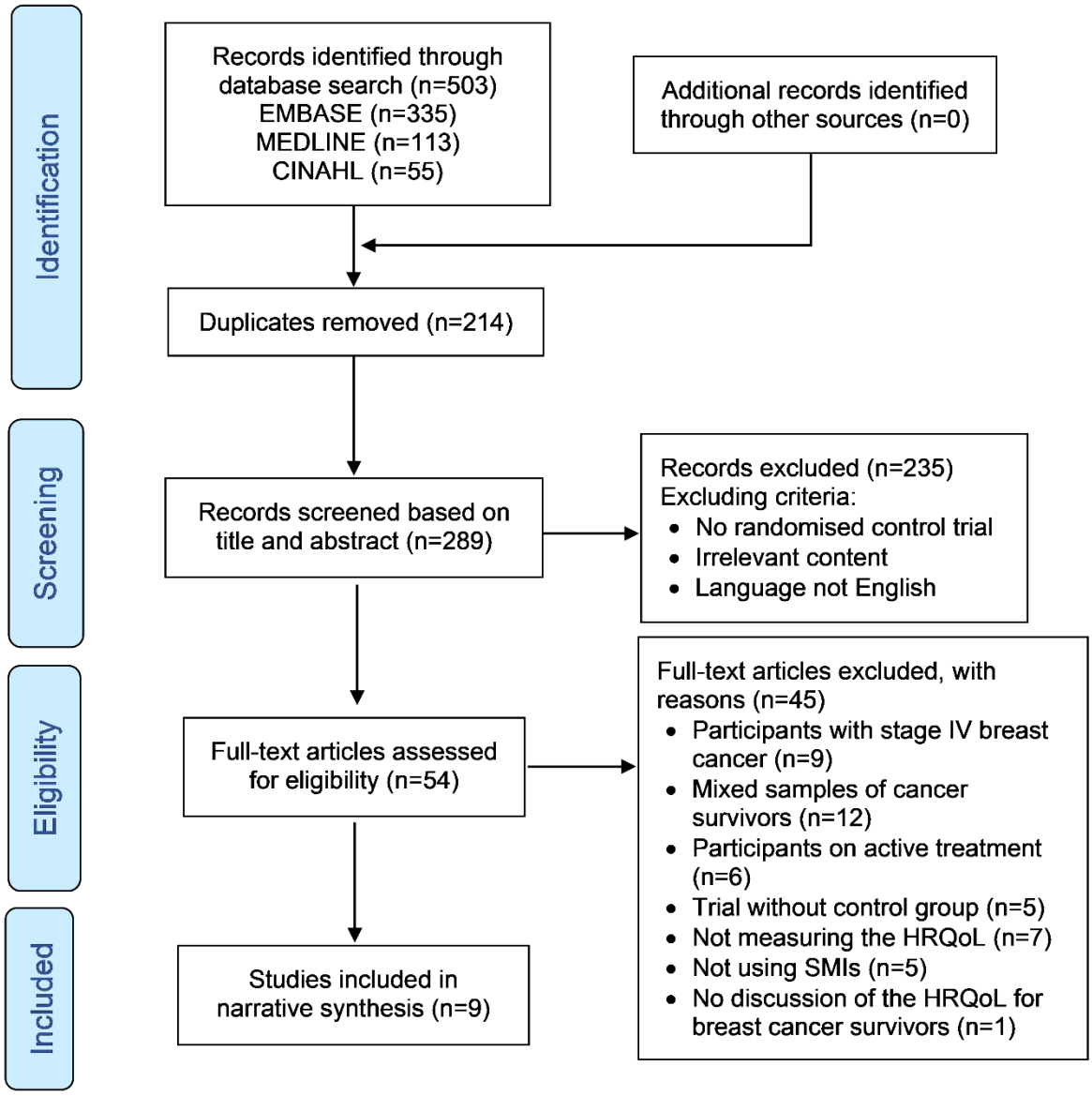
MEDLINE (select Ovid MEDLINE(R) 1946 to November Week 4 2019 database)	1. Breast neoplasms OR (breast adj5 (cancer* or carcinoma* or tumour* or tumor* or neoplas*)).tw. 2. (“Self management” or “self care” or “self-care” or “self-management”).tw. 3. Quality of life OR (“health related quality of life”).tw. 4. Searches 1-3 were combined with AND
EMBASE (select Embase 1996 to 2019 Week 47 databases)	1. Breast tumor OR (breast adj5 (cancer* or carcinoma*or tumour* or tumor* or neoplas*)).tw. 2. Self care OR (“self-management” or “self management” or “self-care).tw. 3. Health related quality of life OR quality of life 4. Searches 1-3 were combined with AND
CINAHL	1. (“Breast Neoplasms+”) 2. (“Self Care+”) OR (“Self-Management”) 3. (''Health and Life Quality+'') OR (''Quality of Life+'') OR (“Psychological Well-Being'') 4. Searches 1-3 were combined with AND

Table 2. Characteristics of reviewed RCTs

Author, year, origin	Admiraal et al. (2017), The Netherlands	Beatty et al. (2010), Australia	Chan et al. (2017), Singapore	Hoffman et al. (2012), USA	Kvale et al. (2016), USA	Lahart et al. (2016), UK	Lee et al. (2014), South Korea	Rogers et al. (2015) USA	Zick et al. (2016), USA
Study design	Two-arm RCT	Two-arm RCT	Two-arm RCT	Two-arm RCT	Two-arm RCT	Two-arm RCT	Two-arm RCT	Two-arm RCT	Three-arm RCT
Final sample size	Total=139 SMI=70 Control=69	Total=42 SMI=20 Control=22	Total=72 SMI=34 Control=38	Total=229 SMI=114 Control=115	Total=79, SMI=40 Control=39	Total=80 SMI=40 Control=40	Total=59 SMI=30 Control=29	Total=222 SMI=110 Control=112	Total=288 SMI1=98 SMI2=94 Control=96
Target sample size[a]	64 per arm	33 per arm	32 per arm	85 per arm	Not reported	40 per arm	29 per arm	97 per arm	100 per arm
Control group	Care as usual	Care as usual	Booklet on cancer self-management	Care as usual while on wait-list	Care as usual	Standard information on physical activity	Booklet on exercise and diet	Booklet on advice for physical activity	Care as usual
SMI group	Psycho-educational programme tailored to reported issues	Self-help workbook (10 chapters; 3 major components per chapter)	Multi-disciplinary, culturally adapted psycho-educational programme	Mindfulness-based stress reduction programme	Professional coaching to help patient develop survivorship care plan	Physical activity consultation with follow-up reinforcement telephone calls	Self-guided exercise and diet programme	Physical activity intervention and supervised exercise	Self-administered relaxing or stimulating acupressure
SMI underpinning framework	Problem-solving therapy	CBT; written emotional expression	CBT	CBT	Chronic care model; Care transitions intervention model	CBT	Trans-theoretical, model-based strategies	CBT; social cognitive theory	Traditional Chinese medicine
SMI delivery mode	Web-based education	Self-study involving reading and listening to audiotape	Face-to-face group education (three educational sessions)	Weekly face-to-face structured classes followed by home-based practice	Single face-to-face motivational interviewing session	Single face-to-face session followed by home-based practice	Web-based coaching	Face-to-face coaching, home-based practice, group sessions	Face-to-face structured education with home-based practice
Core SMI skill(s)	Problem-solving; normalisation; access to resources	Decision-making; taking-action	Decision-making; taking-action	Decision-making; taking-action; problem-solving	Decision-making; forming a partnership with the HCP; taking-action	Decision-making; taking-action; problem-solving	Decision-making; taking-action	Decision-making; taking-action	Decision-making; taking-action; problem-solving
SMI context	Within 6 months after curative primary treatment	Within 3 months after primary treatment	After completion of adjuvant chemotherapy	Within 2 and 24 months after primary treatment	Within 12 months after active treatment	Within 24 months after adjuvant treatment	Within 12 months after curative treatment	Within 8 weeks after completion of surgical procedures	Within 12 months after curative treatment
SMI duration	12 weeks	12 weeks	3 weeks	8 weeks	12 weeks	24 weeks	12 weeks	12 weeks	6 weeks
Assessment points	0, 6 and 12¶ weeks	0, 12¶ and 24 weeks	0 and 8¶ weeks	0, 8 and 12¶ weeks	0 and 12¶ weeks	0 and 24¶ weeks	0 and 12¶ weeks	0, 12¶ and 24 weeks	0, 6¶ and 10 weeks
HRQoL measure(s)	EORTC QLQ-C30	EORTC QLQ-C30	EORTC QLQ-C30	FACT-B	SF-36	FACT-B	EORTC QLQ-C30	FACT-B	LTQL

Author, year, origin	Admiraal et al. (2017), The Netherlands	Beatty et al. (2010), Australia	Chan et al. (2017), Singapore	Hoffman et al. (2012), USA	Kvale et al. (2016), USA	Lahart et al. (2016), UK	Lee et al. (2014), South Korea	Rogers et al. (2015) USA	Zick et al. (2016), USA
Physical well-being[b]	-0.33[§^]	12w: -1.78^ 24w: 0.14^	0.32*	0.30**	0.29^	0.14^	Unable to calculate *d*[c,*]	12w: 0.28** 24w: 0.19*	0.37[d,*] 0.21[e,^]
Emotional well-being[b]	0.15^	12w: -0.37^ 24w: -1.51^	0.03^	0.32**	0.29*	0.05^	Unable to calculate *d*[c,^]	12w: 0.23** 24w: 0.12^	Domain not assessed
Social well-being[b]	0.03^	12w: -1.52^ 24w: -0.05^	0.04^	0.16*	0.21^	-0.32^	Unable to calculate *d*[c,^]	12w: 0.19^ 24w: 0.23^	0.19[d,*] 0.09[e,^]
Functional/role well-being[b]	-0.18^	Domain not assessed	0.05^	0.32***	0.66**	0.34*	Unable to calculate *d*[c,^]	12w: 0.37*** 24w: 0.15^	0.28[d,*] 0.11[e,^]
Cognitive well-being[b]	0.22^	12w: 0.13^ 24w: 0.59**	0.12^	Domain not assessed	Domain not assessed	Domain not assessed	Unable to calculate *d*[c,^]	Domain not assessed	Domain not assessed
Global HRQOL[b]	-0.07^	12w: -0.01^ 24w: 0.14^	0.11^	0.40***	Domain not assessed	0.23*	Unable to calculate *d*[c,^]	12w: 0.30*** 24w: 0.20*	Domain not assessed
Caldwell's framework score	29/36	29/36	32/36	32/36	28/36	33/36	30/36	34/36	30/36
Random sequence generation bias	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Allocation concealment bias	Low risk	Low risk	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk	Low risk
Blinding of participants and personnel bias	High risk	High risk	High risk	Low risk	Unclear risk	High risk	Low risk	Low risk	High risk
Blinding to outcome assessment bias	High risk	High risk	Unclear risk	High risk	High risk	High risk	High risk	Unclear risk	High risk
Incomplete outcome data bias	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Selective reporting bias	High risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk

[a]Based on a reported a priori power calculation.
[b]Cells report Cohen's *d* and p-value of comparison test control v. intervention from baseline to post-intervention.
[c]Standard deviation was not reported, therefore we were unable to calculate effect size *d*.
[d]Control v. relaxing acupressure.
[e]Control v. stimulating acupressure.
Abbreviations: CBT - Cognitive Behavioural Therapy; EORTC-QLQ C30 - European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; FACT-B - Functional Assessment of Cancer Therapy-Breast; HRQoL - Health-related quality of life; LTQL - Long-Term Quality of Life Instrument; SF-36 - 36-Item Short Form Health Survey; SMI - Self-management intervention; ^p>0.05; *p<0.05; **p<0.01; ***p<0.001
[§]A positive effect size indicates improvement in the mean scores of the experimental group relative to the control group. A negative effect size indicates deterioration in the mean scores of the experimental group relative to the control group.
¶Primary end-point.


Identification
Screening
Eligibility
Included
Records identified through database search (n=503)
EMBASE (n=335)
MEDLINE (n=113)
CINAHL (n=55)
Additional records identified through other sources (n=0)
Duplicates removed (n=214)
Records screened based on title and abstract (n=289)
Records excluded (n=235)
Excluding criteria:
No randomised control trial
Irrelevant content
Language not English
Full-text articles assessed for eligibility (n=54)
Full-text articles excluded, with reasons (n=45)
Participants with stage IV breast cancer (n=9)
Mixed samples of cancer survivors (n=12)
Participants on active treatment (n=6)
Trial without control group (n=5)
Not measuring the HRQoL (n=7)
Not using SMIs (n=5)
No discussion of the HRQoL for breast cancer survivors (n=1)
Studies included in narrative synthesis (n=9)