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The effectiveness of cognitive behavioural therapy for depression in women with breast cancer: a systematic review and meta-analysis

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Abstract

Background: Depression is a common co-morbidity in women with breast cancer. Previous systematic reviews investigating cognitive behavioural therapy (CBT) for depression in this population based their conclusions on findings from studies with varying and often limited specificity, quality and/or quantity of CBT within their interventions.

Aim: To determine the effectiveness of a specific, well-evidenced CBT protocol for depression in women with breast cancer.

Method: Online databases were systematically searched to identify randomised controlled trials (RCTs) testing CBT (aligned to Beck's protocol) as a treatment for depression in women with breast cancer. Screening, data extraction and risk of bias assessment were independently undertaken by two study authors. Both narrative synthesis and meta-analysis were used to analyse the data. The meta-analysis used a random effects model to compare CBT with non-active/active controls of depression using validated, self-report measures.

Results: Six RCTs were included in the narrative synthesis, and five in the meta-analysis ($n = 531$ participants). Overall, CBT demonstrated an improvement in depression scores in the CBT condition versus active and non-active controls at post-intervention (SMD = −0.93 [95% CI −1.47, −0.40]). Narratively, five out of six RCTs reported statistically significant improvements in depression symptoms for CBT over control conditions for women with breast cancer.

Conclusion: CBT aligned to Beck's protocol for depression appears effective for treating depression in women with breast cancer. However, further research is needed for women with stage IV breast cancer. The clinical recommendation is that therapists utilise Beck's CBT protocol for depression, whilst considering the complex presentation and adapt their practice accordingly.

Keywords: Breast cancer; CBT; Cognitive behavioural therapy; Depression; Oncology; Systematic review

Introduction

Breast cancer is the most common of all cancers, with over 2.3 million diagnoses and 685,000 deaths worldwide in 2020 (World Health Organization, 2021). Breast cancer is an umbrella term used for tumours that are found in the breast and includes different types of cancer that originate from the breast and either remain there or spread across the body (National Institute for Health and Care Excellence, 2009, 2018). A 5-stage classification system is utilised to categorise different severities of cancer. Broadly speaking, stages 0–III are considered less invasive and non-metastatic

(cancer is localised to the breast and might affect axillary lymph nodes), while stage IV is metastatic (cancer has spread to other areas in the body, for example the bones, liver or lungs). The treatment for stages 0–III focuses on removal of malignant tumours through a lumpectomy or mastectomy, which can be in conjunction with chemotherapy and/or radiotherapy. This can be followed with adjuvant treatment, which aims at reducing the risk of cancer recurrence. Adjuvant treatment usually lasts for 5–10 years (National Institute for Health and Care Excellence, 2018). Stage IV or metastatic cancer is incurable. The active treatment is similar to stages 0–III but additional treatment focuses on prolonging life (National Institute for Health and Care Excellence, 2009). Stages 0–III breast cancer sufferers experience few physical symptoms beyond localised changes such as lumps, skin irritation or discharge; stage IV sufferers might have additional symptoms such as pain, extreme fatigue, breathing problems and nausea, depending on location of metastases (National Institute for Health and Care Excellence, 2009, 2018). It is often the treatment and its side-effects that results in discomfort and distress. The treatment can result in dramatic bodily changes, possible amputation of breast, loss of hair and infertility. Furthermore, most patients experience serious side-effects such as nausea, joint pain, weight changes and tiredness (Binkley *et al.*, 2012). A lot of the younger patients' adjuvant treatments include medically induced menopause, resulting in side-effects such as severe hot flushes, aches and impact on sexual functioning (Hunter *et al.*, 2009).

It has been reported that with a prevalence of 15–20%, depression is likely to be more common in women with breast cancer compared with women without (Pitman *et al.*, 2018). However, as breast cancer is a broad diagnosis, the prevalence varies: in one study, patients with stages I–III of breast cancer showed a lower prevalence with 6.5% compared with 9.6% in stage IV patients (Kissane *et al.*, 1998). In a later study, the prevalence of depression was shown to be 33% of patients on diagnosis of breast cancer, which reduced to 15% at one year follow-up, but which increased to 45% for patients diagnosed with recurrent breast cancer (Burgess *et al.*, 2005).

Depression is a combination of a number of symptoms over a minimum of a two-week period (American Psychiatric Association, 2013). Some of these symptoms mirror the side-effects of the breast cancer treatment, such as fatigue, insomnia, poor concentration and weight change; others, such as low mood, feelings of worthlessness and inappropriate guilt and suicidal ideations, do not mirror this. Depression in women with breast cancer leads to reduced quality of life, functioning and increased distress (Calderon *et al.*, 2019; Purkayastha *et al.*, 2017). In addition, untreated depression in this population is associated with increased access to health care services, less acceptance of the cancer treatment and increased mortality rates (Beatty and Kissane, 2017). Depression accumulates the already devastating impact breast cancer (across all stages of the disease) has on women, and it is therefore important to identify effective treatment protocols for women with depression and breast cancer.

Despite evidence of the effectiveness of CBT for depression in general populations, the relatively limited evidence base in breast cancer patients is based on studies with substantial variation in what constitutes a CBT intervention. For example, one meta-analysis investigating the effectiveness of psychological interventions for depression in breast cancer patients included studies with very limited CBT components (Xiao *et al.*, 2017). Within their analysis, studies were classed as CBT even if they were short term (2–4 weeks) and contained little cognitive interventions alongside other treatments such as supportive counselling. Similarly, other studies (Jassim *et al.*, 2015; Matthews *et al.*, 2017) included a wide variation of interventions and approaches in their definition of CBT, such as cognitive existential therapy, memory and attention adaptation training, mindfulness stress management or psycho-education only. This lack of delineation as to what constitutes sufficient CBT leads to substantial, seemingly unrecognised heterogeneity within these reviews. This review therefore stipulates that the core intervention is CBT as per Beck's (Beck *et al.*, 1979) cognitive therapy (CT) protocol. This protocol has a strong evidence base (Beck and Dozois, 2011; Cuijpers *et al.*, 2013; Dobson et al., 2008; Hofmann *et al.*, 2012; Hollon *et al.*, 2005; Tolin, 2010) for people with depression in the wider population and is

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recommended in the clinical guidelines for depression in the UK (National Institute for Health and Care Excellence, 2022).

Beck's cognitive model (Beck *et al.*, 1979) of depression identifies that child and young adulthood experiences lead to the development of enduring negative unconditional beliefs about ones-self, others, and the world. Conditional beliefs are formed to negotiate how to live with these unconditional beliefs, that are often rigid, unreasonable, and unmaintainable. Consistent, emotionally salient negative automatic thoughts arise due to the activation of this belief system influencing an individual's mood and behaviour, leading to a self-perpetuating cycle of depression. Beck's protocol (Beck *et al.*, 1979) works directly and indirectly on all levels of thinking. Given that the co-morbidity of breast cancer and depression is complex, it is acknowledged that a standard protocol needs to be augmented to address this complexity. One protocol that has considered this for people with cancer is the adjuvant psychological therapy (APT; Greer *et al.*, 1992, Moorey and Greer 2012). APT is a cancer-specific CBT protocol, which enhances Beck's cognitive model (Beck *et al.*, 1979) with a number of techniques such as: relaxation techniques; a focus on emotional expression; communication skills and setting new life goals. This protocol has shown to be effective to alleviate some of the emotional distress associated with cancer and to be suitable for depression and anxiety (Moorey and Greer, 2012). Although it is not targeting breast cancer specifically, the APT protocol's strength is in its flexibility, therefore allowing idiosyncratic adaptations. For example, for breast cancer patients APT might enhance Beck's approach with techniques targeting insomnia or sexual dysfunction. APT therefore falls within the remit of this study and would be one example of a suitable augmentation to Beck's protocol. Different approaches might enhance the protocol with a variety of interventions, for example relaxation techniques or life goal setting. In addition, cultural adaptations have been shown to be important for engagement and therapy outcome (Naeem *et al.*, 2023; Rathod *et al.*, 2019) and would therefore be considered important, additional adaptations to the treatment protocol.

To the authors' knowledge there is no systematic review that investigates an evidence-based CBT protocol for depression for breast cancer patients. As outlined above, there is a need for a standardised CBT treatment for this patient group, based on the prevalence and complexity of the presentation. This systematic review, therefore, explores the effectiveness of CBT for depression in women with breast cancer.

Method

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher *et al.*, 2009).

Eligibility criteria

A PICO (population, intervention, comparison, outcome) framework (Liberati *et al.*, 2009) defining the inclusion and exclusion criteria (Table 1) was followed to aid with a methodological search process.

Patients with all stages of breast cancer have been included as depression is common throughout all the stages (Kissane *et al.*, 1998). A minimum of six sessions, has been stipulated in line with NICE recommendations for depression in the UK (National Institute for Health and Care Excellence, 2022). For reasons detailed above, the primary treatment intervention is CBT for depression as per Beck (Beck *et al.*, 1979) with allowance for any appropriate augmentations to the protocol to meet cancer-specific needs. The primary outcome for this review is depression symptoms/diagnosis, and only randomised controlled trials (RCTs) are included to ensure quality standards (Clancy, 2002).

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Table 1. Inclusion and exclusion criteria

	Inclusion	Exclusion
Population	• Women • Stage 0–IV breast cancer	• Men • Other cancer patients • Children
Intervention	• Face-to-face, telephone, computer, or group therapy • Minimum of 6 sessions • The major psychological component being CBT for depression (as per Beck) and no other psychotherapy being delivered as part of the intervention	• 3rd wave CBT such as ACT, or mindfulness-based CBT • Behavioural therapy • cCBT not delivered by a therapist • CBT for palliative care
Comparison	• All types of control comparison, except a variation of CBT	• A variation of CBT as control group
Outcome	• Depression, evidenced by either a psychiatric assessment or validated psychometric measure	• Depression outcome being secondary to another outcome • Non-validated depression tool
Study design	• Randomised controlled trial (RCT)	• Non-experimental and quasi-experimental

Search strategy

The Cochrane Library, Embase, Medline, PsycInfo and PubMed online databases were searched using keywords for breast cancer, depression and CBT.

A combination of terms was employed, combined with the Boolean search modifier to facilitate relevant root/stem truncation search (see Table S1 in Supplementary material for search terms). The searches were conducted from 5 October 2020 to 20 December 2020, including the records of the mentioned databases from the time of their origin.

All records were imported into EndNote X9 (The EndNote Team, 2013) software. Screening of title and abstracts was undertaken independently by two authors (S.W. and S.M.). Once all potentially relevant studies were identified, full texts were independently appraised (S.W. and S.M.) for inclusion using the eligibility criteria. Disagreements on eligibility status of individual studies were handled by author T.C. Reference lists of included studies were hand searched to identify any further potentially eligible studies.

Data extraction

Data extraction was undertaken independently by two review authors (S.W. and S.M.), with any disagreements resolved by author T.C. Data were extracted into a pre-prepared Microsoft Excel document (Microsoft Corporation, 2018) (Tables 2 and 3) and covered the following categories: author and nationality of the study; participant demographics and characteristics; study design and duration; depression outcome; intervention; control group and study outcome. Methodological data were also extracted to advise the quality assessment.

Data synthesis

Narrative synthesis

A narrative synthesis was employed to summarise and present the data. The primary outcome (depression) was narrated into summaries of the following: CBT in comparison with a TAU group; CBT in comparison with an active comparison group.

Meta-analysis

A random-effect meta-analysis (DerSimonian and Laird method) (Deeks *et al.*, 2002) was conducted to assess the effects of CBT on depression symptoms compared with non-active/active

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Table 2. Study and sample characteristics

Author (year)	**Country**	**Design** Trial arms	**Sample** Participants (*n*); mean age; ethnicity; status; depression severity[†]; recruitment setting	**Breast cancer diagnosis**	**Depression outcome** Outcome measure	**Follow-up** Immediate Post-intervention time point (weeks); follow-up (months)	**Drop-outs** Total (per condition) Post-intervention and follow-up	**Study results** Post-intervention depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/statistically not significant; *p*-value if available)	**Follow-up results** (months = *n*) Follow-up depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/not statistically significant; *p*-value if available)
Desautels *et al.* (2018)	Canada	RCT; 3	62; 57.1; 100% Caucasian; HADS-D score ≥7 or BDI-II ≥14; mild-moderate; hospital	Non-metastatic breast cancer diagnosis in past 2 years	HADS-D BDI II HDRS	8; 3; 6	PI; 5 (BLT: 4; CBT: 0; WLC:1) FU6; 3 (BLT: 0; CBT: 1; WLC: 2)	**BDI-II** BLT: 15.2 (2.1), $p<.01$ CBT: 9.8 (1.2), $p<.0001$ WLC: 17.7 (2.2), $p<.0001$ CBT-WLC: statistically significant CBT-BLT: not statistically significant BLT-WLC: statistically significant **HADS-D** BLT: 5.3 (0.8), $p<.0001$ CBT: 4.1 (0.6), $p<.0001$ WLC: 7.3 (0.8), not statistically significant CBT-WLC: statistically significant CBT-BLT: not statistically significant BLT-WLC: not statistically significant	Follow-up outcome and differences are not comparable due to reallocation of waiting list control participants to the active controls at post-waiting list time

(*Continued*)

Table 2. (*Continued*)

Author (year)	**Country**	**Design** Trial arms	**Sample** Participants (*n*); mean age; ethnicity; status; depression severity[†]; recruitment setting	**Breast cancer diagnosis**	**Depression outcome** Outcome measure	**Follow-up** Immediate Post-intervention time point (weeks); follow-up (months)	**Drop-outs** Total (per condition) Post-intervention and follow-up	**Study results** Post-intervention depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/statistically not significant; *p*-value if available)	**Follow-up results** (months = *n*) Follow-up depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/not statistically significant; *p*-value if available)
								HDRS BLT:9.2 (1.3), $p<.05$ CBT: 6.8 (0.9); $p<.0001$ WLC: 11.9 (2.1): not statistically significant CBT-BLT: statistically significant CBT-WLC: not statistically significant BLT-WLC: not statistically significant	
Edelman *et al.* (1999a)	Australia	RCT; 2	60; 48; unreported; unreported; unreported; hospital and media	Primary breast cancer patient (stages I and II) (diagnosed within last 12 months) –not receiving adjuvant treatment	POMS	12; 4	PI; 13 (CBT: 7; STG: 6) FU4; 10 (unreported)	**POMS depression subscale** CBT: 7.91 (2.21), unreported STG: 9.58 (2.04), unreported CBT-STG: not statistically significant, $p = .170$	**POMS depression subscale (4)** CBT: 13.1 (2.08), unreported STG: 13.56 (3.66), unreported CBT-STG: not statistically significant
Edelman *et al.* (1999b)	Australia	RCT; 2	124; 50; unreported; unreported; unreported; hospital and media	Metastatic breast cancer diagnosis (stage IV)	POMS	8; 3, 6	PI; 32 (unreported) FU; unreported	**POMS depression subscale** CBT: –3.07 (‡7.91)§, unreported NTC: 1.22 (‡7.24)§, unreported	**POMS depression subscale (3)** CBT: 0.42 (‡8.41)§, unreported NTC: 0.62 (‡7.22)§, unreported

(*Continued*)

Table 2. (*Continued*)

Author (year)	**Country**	**Design** Trial arms	**Sample** Participants (*n*); mean age; ethnicity; status; depression severity†; recruitment setting	**Breast cancer diagnosis**	**Depression outcome** Outcome measure	**Follow-up** Immediate Post-intervention time point (weeks); follow-up (months)	**Drop-outs** Total (per condition) Post-intervention and follow-up	**Study results** Post-intervention depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/statistically not significant; *p*-value if available)	**Follow-up results** (months = *n*) Follow-up depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/not statistically significant; *p*-value if available)
								CBT-NTC: statistically significant, $p = .008$	CBT-NTC: not statistically significant, $p = .911$ **POMS depression subscale (6)** CBT: −1.00 (‡7.93)§, unreported NTC: −0.64 (‡8.76)§, unreported CBT-NTC: not statistically significant, $p = .446$.
Qiu *et al.* (2013)	China	RCT; 2	62; 50.63; unreported; DSMV-IV criteria for major depressive disorder and HDRS score ≥17; moderate; mental health centre	Stages 0–IV breast cancer 6–36 months post-surgery, prior completion of radiation/ chemotherapy and no other active treatment apart from hormonal therapy	HDRS	10; 6	PI: 0; FU6: 8 (CBT: 2; NCT: 6)	**HDRS** CBT: 6.03 (‡2.82), $p < .001$ NTC:15.06 (‡5.09), $p < .001$ CBT-NTC: statistically significant, $p < .001$	**HDRS (6)** CBT: 7.5 (‡3.71), $p < .001$ NTC: 14.35 (‡5.21), $p < .001$ CBT-NTC: statistically significant, $p < .001$
Ren *et al.* (2019)	China	RCT; 3	392; 47.07; unreported; HDRS score >7 or HAMA-14 >7; mild; across 6 hospitals	Breast cancer 1 week to 1 year post-radical mastectomy	HDRS	12; 1; 3	PI; unreported FU3; 36 (CBT: 7; SCM: 8; UC: 21)	**HDRS** CBT: 5.7 (4.0), unreported SCM: 8.0 (3.2), unreported UC: 8.8 (4.2), unreported CBT-SCM: statistically significant, $p < .01$ CBT-UC: statistically significant, $p < .01$	**HDRS (3)** CBT: 4.4 (3.9), unreported SCM: 7.0 (3.3), unreported UC: 7.9 (4.4), unreported CBT-SCM: statistically significant, $p < .01$ CBT-UC: statistically significant, $p < .01$

(*Continued*)

Table 2. (*Continued*)

Author (year)	**Country**	**Design** Trial arms	**Sample** Participants (*n*); mean age; ethnicity; status; depression severity†; recruitment setting	**Breast cancer diagnosis**	**Depression outcome** Outcome measure	**Follow-up** Immediate Post-intervention time point (weeks); follow-up (months)	**Drop-outs** Total (per condition) Post-intervention and follow-up	**Study results** Post-intervention depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/statistically not significant; *p*-value if available)	**Follow-up results** (months = *n*) Follow-up depression outcomes (mean, standard error for each arm, *p*-value if available); difference between conditions (statistically significant/not statistically significant; *p*-value if available)
Savard *et al.* (2006)	Canada	RCT; 2	45; 51.57; Caucasian; mild-moderate; across 3 cancer clinics	Metastatic breast cancer (stage IV) but not with prognosis of less than 2 months	HADS-D BDI HDRS	8; 3, 6	PI: 16 (CBT: 10; WLC:6) FU3: 1 (unreported) FU6: 2 (unreported)	**BDI** CBT: 11.52 (1.40), unreported WLC: 15.93 (1.53), unreported CBT-WLC: not statistically significant, $p = .08$ **HADS-D** CBT: 5.19 (0.63), unreported WLC:5.83 (0.68), unreported CBT-WLC: not statistically significant, $p = .32$ **HDRS** CBT: 6.88(1.05), unreported WLC: 12.21(1.16), unreported CBT-WLC: statistically significant, $p = 0.01$	Follow-up outcome and differences are not comparable due to reallocation of waiting list control participants to the active control at post-waiting list time

BDI, Beck Depression Inventory; BDI-II, Beck Depression Inventory-II; BLT, bright light therapy; CBT, cognitive behavioural therapy; HADS-D, Depression subscale of the Hospital Anxiety and Depression Scale; HAMA-14, Hamilton Anxiety Rating Scale; HDRS, Hamilton Depression Rating Scale; POMS, Profile of Mood States; NTC, non-therapy control; RCT, randomised controlled trial; SCM, self-care management; STG, supportive therapy group; UC, usual care; WLC, waiting list control; †Calculated from studies; ‡standard deviation as standard error not available; §main change reported only.

Table 3. Intervention and control condition characteristics

Author (year)	CBT intervention (description of adaptations to Beck's cognitive protocol)	Protocol adherence Measure (y/n); adherence outcome	Format of intervention Group (*n*)/ individual; description of facilitator	Intervention specifics Number and frequency of sessions; session duration (minutes); booster sessions after completion of intervention (*n*)	Control condition(s)	Control condition(s) Frequency (per fortnight); session duration; treatment information
Desautels *et al.* (2018)	Re-defining life goals	Y; HDRS: inter-rater agreement 86.7% = excellent (on 43% of the assessment) CTSR rating 4.4 = proficient (on 18% of treatment session)	Individual; doctoral level student in clinical psychology	8 weekly sessions; 60; 0	BLT WLC	BLT: 14; 30 minutes exposure to 10000 lux light box WLC: 1; unreported; monitoring contact
Edelman *et al.* (1999a)	Assertive communication; deep relaxation	Unreported	Groups (8–9); two female CBT/cancer specialist therapists of whom at least one was a registered psychologist	12 weekly sessions; 120; 0	STG	2; 120 minutes; unstructured talking sessions
Edelman *et al.* (1999b)	Deep relaxation/ meditation, assertive communication	Unreported	Groups (unreported); registered psychologist with CBT training	8 weekly sessions; 120; 0	NTC	Unreported; unreported; community information support given
Qiu *et al.* (2013)	Interpersonal communication and progressive muscle relaxation	Y; unreported	Group (at least 5); experienced psychiatrist with training in CBT	10 weekly sessions; 120; 1	WLC	0; 0; educational booklet
Ren *et al.* (2019)	ABC framework, meditation, emotional regulation, social skills	Y; random selection and evaluation of 20% of sessions, indicated a 90% retained power to identify the effect sizes, with an α of 0.05	Group (6–8); trained therapist	9 sessions over 12 weeks; unreported; unreported	SCM UC	SCM: 9 sessions over 12 weeks; unreported; breast cancer treatment information, diet advice, rehabilitation training and recovery and complication information. UC: delivered by nurses
Savard *et al.* (2006)	Re-define life goals	Unreported	Individual; licenced psychologists experienced in CBT	8 weekly sessions; 60–90; 3	WLC	0; 0; 8 weeks wait then reassessment before receiving CBT

BLT, bright light therapy; CBT, cognitive behavioural therapy; CTSR, Revised Cognitive Therapy Scale; HDRS, Hamilton Depression Rating Scale; NTC, non-therapy control; SCM, self-care management; STG, supportive therapy group; UC, usual care; WLC, waiting-list control.

controls (due to small number of studies) at post-intervention and 4–6 months follow-up. Standardised mean differences (SMD) depression symptoms were computed to Hedges' *g* (as this corrects small number of comparisons). The SMD was interpreted using Cohen's approach where effect sizes of .20, .50 and .80 are considered small, moderate and large, respectively (Cohen, 1992). Where standard deviations (*SD*) were not available, these were imputed from standard errors and sample size. Change scores from baseline to post-intervention per arm were used in one case, where post-intervention estimates per arm were not reported. In this case, the SMD was standardised by imputing a uniform post-intervention *SD* based on the mean difference between groups at post-intervention, its respective *p*-value and the sample sizes of both arms. Stata software (version 17) was used to conduct the meta-analysis. Due to the small number of studies ($n < 10$), a formal investigation of heterogeneity and publication/small-study effect bias was precluded.

Quality assessment

The PEDro risk of bias tool (Herbert *et al.*, 1998) was employed to assess the methodological quality and risk of bias of the included studies. Each study was independently assessed by two review authors (S.W. and S.M.) with any disagreements resolved by author T.C.

Results

Study identification

The database searches identified 1003 records, which was reduced to 605 following removal of duplicates. Following the initial title and abstract screening, 13 potentially eligible studies were identified. Full texts screened identified six eligible studies that were included in the narrative synthesis, and five in the meta-analysis (see Fig. 1).

Study design

The date of publication ranged from 1999 to 2019, and all were published in English. Two studies were conducted in Australia (Edelman *et al.*, 1999a; Edelman *et al.*, 1999b), two in China (Qiu *et al.*, 2013; Ren *et al.*, 2019) and two in Canada (Desautels *et al.*, 2018; Savard *et al.*, 2006).

All studies undertook individual randomisation, with two stating that they used block randomisation (Desautels *et al.*, 2018; Edelman *et al.*, 1999b).

Five studies (Desautels *et al.*, 2018; Edelman *et al.*, 1999b; Qiu *et al.*, 2013; Ren *et al.*, 2019; Savard *et al.*, 2006) compared CBT versus treatment as usual (TAU), with two studies (Ren *et al.*, 2019; Savard *et al.*, 2006) also having compared CBT versus an active control.

Participant characteristics

The sample sizes ranged from 45 to 392 participants. The mean ages of participants ranged from 47 to 57 years. All participants were recruited from either hospitals, cancer centres or through media, except for one study that recruited from a mental health centre (Qiu *et al.*, 2013).Two recruited from multiple sites (Ren *et al.*, 2019; Savard *et al.*, 2006).

Participants' stage of breast cancer diagnosis varied across the studies. Two studies only recruited stage IV/metastatic cancer (Edelman *et al.*, 1999b; Savard *et al.*, 2006). One study recruited women at stages I and II (Edelman *et al.*, 1999a) and another study recruited women at stages 0–III/non-metastatic cancer (Desautels *et al.*, 2018). The remaining two studies included all breast cancer diagnoses, with the majority in stages 0–III.

One study (Qiu *et al.*, 2013) stated a diagnosis of 'major depressive episode' as per the *DSM-IV* (American Psychiatric Association, 1994) as an eligibility criterion. Two studies (Desautels *et al.*, 2018;

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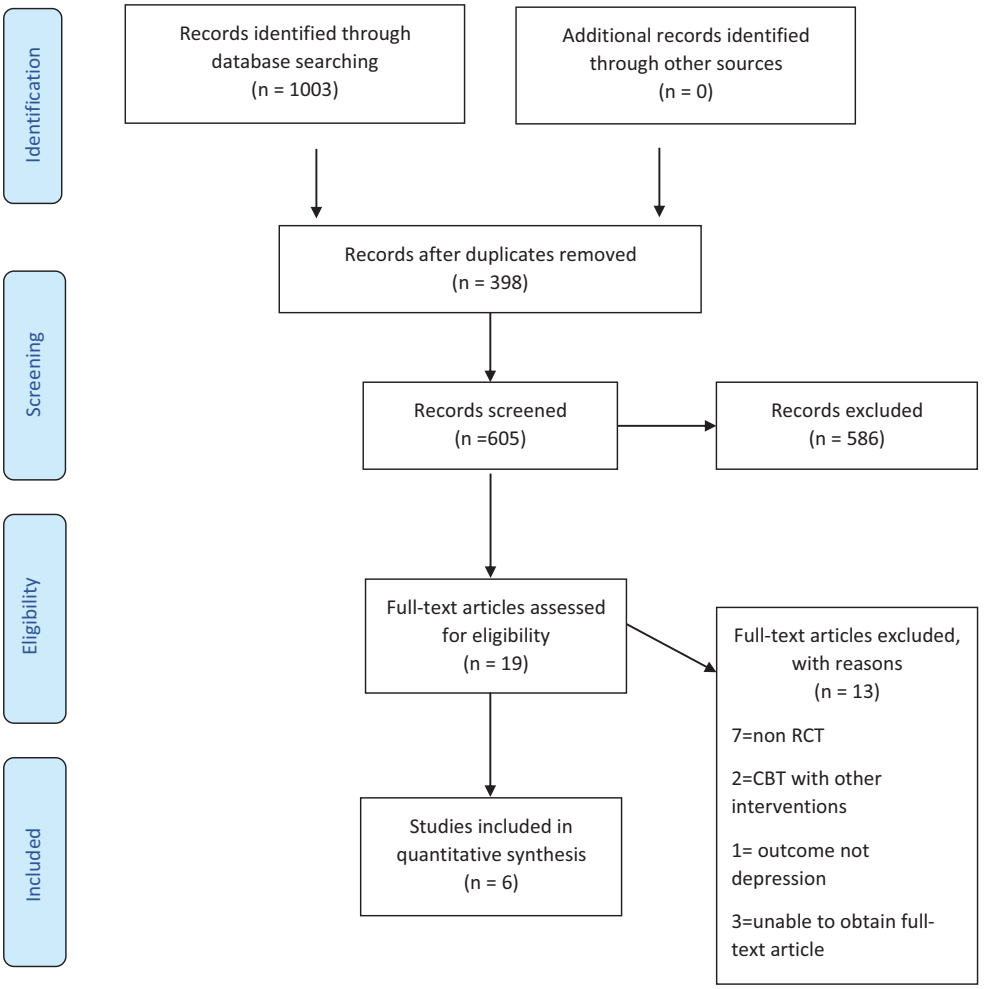

Figure 1. PRISMA flow diagram.

Savard *et al.*, 2006) required a mild to moderate level of depression, measured on either the BDI/BDI-II or the HADS-D. One study's eligibility criterion (Ren *et al.*, 2019) was to either score clinically on a depression or an anxiety measure; it was unreported what percentage of participants scored clinically on the depression measure. The remaining studies did not report any criterion relating to mental health status.

Outcome measures

Two studies used three validated depression measures each: HADS-D (Zigmond and Snaith, 1983), HDRS (Hamilton, 1960) and either BDI (Beck *et al.*, 1961) (Savard et al., 2006) or BDI-II (Beck *et al.*, 1996) (Desautels *et al.*, 2018). Two studies (Qiu *et al.*, 2013; Ren *et al.*, 2019) only used the HDRS (in these trials its alternative abbreviation 'HAMD-17' is used; for ease of this study it will be consistently referred to as HDRS). The remaining two studies used the depression subsection of the POMS (McNair *et al.*, 1981).

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Description of intervention and comparison conditions

Two studies conducted weekly individual CBT sessions over 8 weeks (Desautels *et al.*, 2018; Savard *et al.*, 2006). Four studies employed group CBT on a weekly basis with a duration of 8 (Edelman *et al.*, 1999b) to 12 weeks (Edelman *et al.*, 1999a).

All the studies stated that their protocol was based on Beck's CBT for depression model (Beck *et al.*, 1979). All studies were augmented with a variety of additional interventions. Four studies included sessions on assertiveness training/interpersonal communication and various relaxation techniques. Two studies added a session on re-defining life goals (Desautels *et al.*, 2018; Savard *et al.*, 2006).

Five studies had non-active control conditions that served to provide a variety of minimal support to the participants as follows: provision of community information (Edelman *et al.*, 1999b); educational booklet (Qiu *et al.*, 2013); monitoring of mood and risk (Desautels *et al.*, 2018); usual medical care (Ren *et al.*, 2019) and waiting list control (Savard *et al.*, 2006). Two studies had a third trial arm alongside the non-active control condition: bright light therapy (BLT) (Desautels *et al.*, 2018) and self-care management (SCM) (Edelman *et al.*, 1999a). One study used a supportive talking group (STG) as an active comparison. This unstructured talking group matched the experimental group in time and frequency.

Quality assessment

One study (Qiu *et al.*, 2013) scored 9/11 on the PEDro scale (Herbert *et al.*, 1998), indicating an 'excellent' level of quality. Three studies scored 'good' and the last two studies scored a 'fair' with 4/11 (Edelman *et al.*, 1999b) and 5/11 (Edelman *et al.*, 1999a). None of the studies blinded participants, however, this would be difficult to achieve when delivering therapy in comparison with a waiting list control. Only one trial (Ren *et al.*, 2019) blinded the therapist to the outcome data and the study hypothesis. The two lowest scoring studies did not conceal the allocation schedule, the assessors were not blinded, their key outcome measures were collected for fewer than 85% of participants and they did not specify if their analysis was based on the intention-to-treat. Two studies did not have a similar baseline across the comparison groups (Ren *et al.*, 2019; Savard *et al.*, 2006).

Meta-analysis of depression outcome

The assessment of CBT compared with non-active/active controls was conducted using standardised mean difference (SMD). Post-intervention data were used from five RCTs (see Fig. 2). CBT resulted in a statistically significant improvement in depression symptoms compared with controls with an SMD of –0.93 (95% CI –1.47, –0.40, $p<0.001$, $I^2 = 84.66$).

Meta-analysis of depression symptoms at longer term follow up (4–6 months) using data from four RCTs (Edelman *et al.*, 1999a; Edelman *et al.*, 1999b; Qiu *et al.*, 2013; Ren *et al.*, 2019) found that CBT resulted in a statistically significant improvement in depression symptoms compared with controls with an SMD of –0.65 (95% CI –1.20, –0.10, $p<0.05$, $I^2 = 83.2\%$).

Narrative synthesis of depression outcome

CBT versus treatment as usual

All studies with a TAU control reported a statistically significant group × time interaction for at least one of the clinical outcome measures used when CBT was compared with the control group. Savard *et al.* (2006) showed a statistically significant interaction on the HDRS only, and not on BDI and HADS-D. Desautels *et al.* (2018) showed that the interaction on the HDRS was non-significant, yet reported a statistically significant interaction on the BDI-II.

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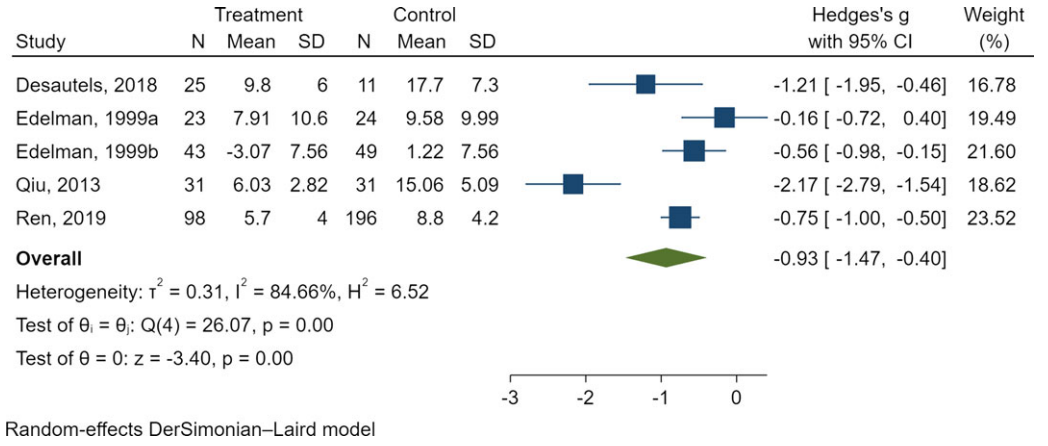

Figure 2. Forest plot.

At 6-month follow-up, Qiu *et al.* (2013) showed a statistically significant time × group interaction, while Edelman *et al.* (1999b) reported no difference at 6 months. For two studies (Desautels *et al.*, 2018; Savard et al., 2006) the follow-up outcome and differences were not comparable due to reallocation of waiting list control participants to the intervention group at post-intervention.

CBT versus active control

Ren *et al.* (2019) reported a statistically significant lower HDRS score in the CBT group compared with their active condition. However, Edelman *et al.* (1999a) did not find a significant difference in HDRS scores between CBT and STG. Desautels *et al.* (2018) found that the CBT group showed only statistically significant lower scores than their active condition on the HDRS but not on BDI-II or HADS-D.

At follow up, Ren *et al.* (2019) showed a statistically significant time × group difference between CBT and the active control at 3 months; however, this was not replicated in Edelman *et al.* (1999a) at their follow-up point of 4 months. Desautels *et al.* (2018) offered no follow-up comparison due to reallocation of waiting list participants to the intervention group.

Attrition/engagement/protocol adherence

Attrition rates at post-intervention ranged from 0% (Qiu *et al.*, 2013) to 36% (Savard *et al.*, 2006). Attrition rate at post-intervention was unreported for one study (Ren *et al.*, 2019) but their attrition rate at 3-month follow-up was 8%.

Three studies (Edelman *et al.*, 1999b; Qiu *et al.*, 2013; Ren *et al.*, 2019) did not report attendance data across the interventions. One study (Desautels *et al.*, 2018) reported the drop-out of four participants in the active control and one in the TAU group, but no drop-outs in the CBT group. Edelman *et al.* (1999a) reported seven drop-outs in the CBT group versus six in the active group. Finally, Savard *et al.* (2006) reported 10 drop-outs in the CBT condition versus six in TAU condition.

Half the studies (Desautels *et al.*, 2018; Qiu *et al.*, 2013; Ren *et al.*, 2019) reported adherence to protocol of which only two (Desautels *et al.*, 2018; Ren *et al.*, 2019) reported an adherence outcome, both reporting satisfactory adherence.

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Discussion

The aim of this study was to determine the effectiveness of a well-defined CBT protocol for depression for women with breast cancer. This is the first review that stipulates the CBT interventions in the included studies were delivered according to Beck's depression protocol (Beck *et al.*, 1979); a protocol with sound evidence base and theory (Beck and Dozois, 2011; Cuijpers *et al.*, 2013; Dobson *et al.*, 2008; Hofmann *et al.*, 2012; Hollon *et al.*, 2005; Tolin, 2010) which, in the UK, is also recommended in the clinical guideline for depression (National Institute for Health and Care Excellence, 2022).

CBT yielded a large treatment effect on depression symptoms for women with breast cancer. Importantly, the quality of most studies ranged from good to excellent, indicating high validity of the study and reliability in terms of their outcome. The two Edelman studies (Edelman *et al.*, 1999a; Edelman *et al.*, 1999b), however, were of low methodological quality, potentially increasing their risk of bias, especially allocation and detection bias. There was some variation in drop-out rates across the studies (ranging from 9 to 35% at post-intervention) which could imply attrition bias and potentially limit the generalisability of findings (Boland *et al.*, 2017). However, the majority of studies reported drop-out rates at post-intervention of less than 25%, and generally reported equal attrition across trial conditions, suggesting that drop-out was not likely due to unacceptability of the intervention. Considering this, the relatively high drop-out rates observed in two of the studies could have been due to a variety of factors, such as change in cancer symptomology or disease progression, rather than issue with the intervention itself.

Sample size across the individual studies varied, with two of the studies included in the meta-analysis self-reporting that they likely lacked statistical power, a finding common in mental health trials (Brown *et al.*, 2019). However, two of the studies included in the meta-analysis reported to be of sufficient power to detect statistical differences at the effect size that was found. Thus, despite the variation in sample size, it is felt that the pooled analysis is sufficient to make reasonable estimates of effectiveness. An important consideration for future trials, is that one study (Ren *et al.*, 2019) that reported a large sample size, perhaps achieved this by broadening their eligibility criteria. However, this likely resulted in a more heterogenic group of participants. It can be argued that increasing the sample size at the cost of broadening the inclusion range (by including all breast cancer stages as well as a mental health diagnosis of depression and/or anxiety) does not increase the reliability of the study (Porzsolt *et al.*, 2019). Based on this, it is recommended that future studies in this area include a depression severity eligibility criterion for study entry, as opposed to other symptomology such as anxiety.

The studies included some variation in the depression entry levels of their samples, ranging from non-clinical to mild to moderate depression. Furthermore, there was a range of depression severity within studies. Only one study (Qiu *et al.*, 2013) stated a *DSM–IV* diagnosis (American Psychiatric Association, 2013) of major depressive episode as an inclusion criteria. Another study (Desautels *et al.*, 2018) showed that only six of 62 participants would have met this criteria. Traditionally, research in CBT and depression in the wider population has found CBT as a stand-alone intervention to be most effective in mild to moderate depression (Elkin *et al.*, 1989). Conversely, more recent studies found good effectiveness in moderate to severe levels of depression, showing that depression severity did not affect treatment efficacy (DeRubeis *et al.*, 1999; Furukawa *et al.*, 2017). Nevertheless, it is recognised that more severe levels of depression need more intense treatment (National Institute for Health and Care Excellence, 2022). While less severe depression often responds well to 6–8 weeks of guided self-help based on CBT, for moderate to severe levels the recommendation is 16 or more weeks of CBT. There was no accounting for this in the included studies, potentially resulting in some participants receiving a sub-therapeutic level of CBT, while others might have received a higher intensity of CBT than required, therefore making the treatment more burdensome. However, despite the variation, the majority of samples consisted of women with elevated symptoms of depression, as assessed

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through either validated scales or through structured clinical interview, thus overall, it is felt that our results do reflect the effectiveness of CBT on a depressed population of breast cancer patients.

Whilst the six studies were all based on Beck's (Beck *et al*., 1979) protocol, each was augmented differently to address the complex needs of this population. For example, some studies added skills around assertiveness and communication as well as various relaxation techniques, while others focused on re-defining life goals. This seems to be broadly based on the adjuvant psychological therapy (APT) (Greer *et al*., 1992; Moorey and Greer, 2012), a CBT-based treatment protocol for cancer patients. APT is based on Beck's (Beck *et al*., 1979) approach and highlights the importance of working on the underlying beliefs system.

APT was initially developed almost 30 years ago, providing a protocol for cancer based on Beck's CT model. While it does not detail a specific protocol for different types of cancer, it provides flexibility to adapt the protocol according to individual needs. It certainly provides valid possible enhancements to the Beckian protocol for women with breast cancer and depression. It is important to consider that the medical side of breast cancer is a rapidly developing area and over the last 30 years, the 5-year survival rate has increased from 70 to 85% (Office for National Statistics, 2019; Quinn *et al*., 2008). This is partly due to increased screening for breast cancer and advances in treatment, which result in more people living longer with breast cancer. This means women spend more years receiving intensive medical treatment and with it having to deal with side-effects. Women commonly suffer with early menopausal symptoms, loss of fertility, exhaustion, insomnia and joint pain. These side effects have been linked to symptoms of depression and reduction in quality of life (Hunter *et al*., 2009). A study has shown that a CBT protocol for menopausal symptoms is effective in improving mood and quality of life within women suffering with early onset menopausal symptoms due to breast cancer treatment (Hunter *et al*., 2009). Similarly, research has shown that CBTi, a protocol for insomnia, has been effective in breast cancer sufferers not only to improve sleep but also to improve depression scores (Peoples *et al*., 2019). The included studies do not fully consider the complexity of symptoms within breast cancer patients and their protocols do not reflect the importance of augmenting the Beckian protocol with flexibility, to meet the myriads of individual needs across breast cancer patients. It is important to remember that stage IV patients are likely to present with difference in symptoms including more pain and discomfort from the disease in the first place and challenges of coming to terms with the incurability of the disease at that stage. All studies were conducted outside of the UK and none of them reported any cultural adaptations. Although this is certainly a limitation, it is felt that the findings and interpretations of the studies remain valid for UK populations; however, future studies should consider cultural sensitivity when working with non-Western populations.

The two studies that focused on stage IV (metastatic) breast cancer showed a more complex outcome pattern than the others. Edelman *et al*. (1999b) showed a significant outcome at post-treatment but not at 3- or 6-month follow-up; however, this study also had several limitations. The other study showed a significant outcome only on one and not the other two outcome measures used. There is notably less research available that focuses on psychological interventions for metastatic breast cancer, yet this client group experiences high distress levels and low quality of life (Reed *et al*., 2012). Studies examining the effectiveness of CBT for depression in people with advanced cancer in general found CBT to be less effective than in people with less advanced cancer (Mustafa *et al*., 2013; Serfaty *et al*., 2020). For example, the CanTalk study (Serfaty *et al*., 2020) provided 12 weeks of 1:1 CBT to people with advanced stage breast cancer and found CBT to be ineffective in treating their depression. Several reasons were identified as to why CBT might be less effective in this patient group. For example, stage IV cancer sufferers undergo more intensive medical treatment, they experience more pain, hospitalisation is more common and ultimately participants are more likely to die during the study (Savard *et al*., 2006; Serfaty *et al*., 2020). These factors could potentially lead to lack of engagement with CBT, which could result in increased drop-out rates and poorer outcomes. This was observed in the two stage IV studies (Edelman *et al*., 1999b; Savard *et al*., 2006) included in this review; most participants dropped out from the

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studies due to it being too burdensome, illness or death. This raises the question whether metastatic breast cancer patients would benefit more from a different psychological intervention in comparison with non-metastatic breast cancer patients.

Study limitations

The depression levels between and within the included studies varied greatly. Some participants showed levels of severe depression while others did not have a clinical level of depression. This is problematic as it is difficult to generalise the outcome of the studies in that context. It has shown to be effective for women with depression and breast cancer, but it is unclear due to the within-study range of depression, whether CBT is more or less effective depending on the severity of depression.

The meta-analysis outcome should be considered with caution given the limited number of studies, most of which consisted of small samples. Additionally, there was substantial heterogeneity within the analysis, likely stemming from variation between studies in baseline depression severity and cancer status (metastatic/primary breast cancer), and from the inclusion of one study with an active control condition.

Recommendations for further research

Ongoing research needs to consider the drastic medical improvements in the field of breast cancer and the new demands this poses to breast cancer sufferers that now live longer with the impact of this disease. There is scope for the development of and research in a breast cancer-specific CBT protocol for depression, which further augments Beck's (Beck *et al.*, 1979) protocol, allowing for the flexibility to address specific symptoms such as menopausal symptoms, insomnia or sexual dysfunction.

Furthermore, the question was raised whether patients with metastatic breast cancer would benefit more from a different intervention or treatment approach. Studies focusing on different psychological approaches or incorporating third wave CBT approaches may show a more beneficial outcome for women with metastatic breast cancer. Third wave CBT approaches such as acceptance and commitment therapy (ACT) (Hayes *et al.*, 2011) or mindfulness-based cognitive therapy (Williams and Penman, 2011) move away from Beck's (Beck *et al.*, 1979) original approach that attempts to correct the dysfunctional belief system. These approaches do not focus on the content of thoughts but on understanding and accepting cognitive processes and the transient nature of thoughts. There is also a focus on living life according to meaningful values and practising acceptance (Hayes *et al.*, 2011). These approaches may be more effective when dealing with the terminal nature of the illness. A feasibility study for a RCT employing ACT within advanced cancer patients was successfully completed (Serfaty *et al.*, 2019), suggesting that this patient group will be able to meet the demands of this therapy. Similarly, mindfulness-based interventions are showing potential benefits for advanced cancer sufferers (Tan *et al.*, 2022; Zimmermann *et al.*, 2018).

Furthermore, despite the positive findings of the studies over a variety of cultural contexts, it is surprising that no explicit cultural adaptations were incorporated, especially given that CBT is traditionally based on western cultural values and ideas (Naeem *et al.*, 2023). As such, it is likely that meaningfully adapting the protocols where appropriate to the needs and nuances of the cultures that are being tested would likely bolster the effectiveness of the intervention. To this end, future trials testing CBT for this population should consider this in the design of their interventions.

Clinical implications

This review provides evidence that CBT for depression (Beck *et al.*, 1979), can be helpful for treating depression in women with breast cancer and should therefore be considered as an effective treatment for this patient group. The evidence was more robust for stages 0–III breast

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cancer patients, less so for stage IV. The protocol has to be augmented appropriately and individually, with additional interventions to meet the complex and varied needs of this population. Additionally, practitioners need to consider the impact of medication side-effects, alongside actual and perceived losses contributing to the depression diagnosis and adapt their practice accordingly. For women with stage IV breast cancer and depression, clinical judgement needs to be made and a more idiosyncratic approach should be considered, possibly including third wave approaches such as ACT or mindfulness. There is also emerging evidence of effectiveness of behavioural activation (a CBT technique) in the cancer population (Hirayama *et al.*, 2023; Hopko *et al.*, 2011; Hopko *et al.*, 2013).

Conclusion

There is evidence that CBT is likely to be effective in reducing depression symptoms for women with breast cancer. However, the evidence is less robust for patients with stage IV breast cancer, highlighting the need for further research in this patient group to inform clinical guidance.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1352465824000092

Data availability statement. All extracted data can be found in the cited articles.

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