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Review article

A systematic review of the quality of randomized controlled trials of psychological treatments for emotional distress in breast cancer

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ABSTRACT

Objective: Meta-analyses of trials of psychological treatments for emotional distress in breast cancer (BCa) conclude that efficacious treatments exist. Subsequently, their implementation in routine care is widely promoted by health policy. However, the methodological quality of these trials has not been systematically evaluated. The present review investigates this issue.

Method: A systematic search identified randomized controlled trials of psychological treatments for emotional distress in BCa. The Psychotherapy Outcome Study Methodology Rating Form was used to assess the quality of trials. Generic design elements, including representativeness of sample, control of concomitant treatments, reporting clinical significance outcomes, and design elements specific to psychotherapy trials, including manualisation, therapist training, and therapist adherence and competence were evaluated.

Results: 91 trials were eligible. Overall, methodological quality was low. Generic design elements were limited in most trials: 15% specified as an inclusion criterion that participants were distressed; 10% controlled for concomitant treatments; and 11% reported the clinical significance of findings. Design elements specific to psychotherapy trials were also implemented poorly: 51% used treatment manuals; 8% used certified trained therapists; and monitoring of adherence and competence occurred in 15% and 4%, respectively.

Conclusion: The methodological quality of psychological treatment trials for emotional distress in BCa is improving. However, if relevant health policies are to be adequately empirically informed, trials of greater methodological rigour are essential. Trials should include participants with clinical levels of distress, control for concomitant treatments and report the clinical significance of findings. Trialists must also consider the specific requirements of psychotherapy trials.

1. Introduction

Improvement in detection methods and advances in treatment have increased survival in breast cancer (BCa), with an estimated 3.5 million BCa survivors in the United States [1]. Around half of all newly diagnosed BCa patients report clinical levels of anxiety and/or depression based on either diagnostic criteria or cut-off points reflecting caseness on self-report or clinician administered questionnaires [2–4]. For most, distress naturally diminishes over time. However, some patients continue to experience distress. According to DSM III-R criteria [5], around 25% of patients experience clinical levels of anxiety and/or depression in each of the second, third, and fourth years, and 15% in the fifth year after diagnosis [3]. Emotional distress in BCa reduces quality of life, limits daily functioning, increases economic burden on health care systems, and decreases adjuvant treatment compliance [6–9].

Many randomized controlled trials (RCTs) have therefore examined the efficacy of psychological treatments for emotional distress in BCa across the disease trajectory (i.e. shortly after diagnosis, during treatment, and survivorship). Two Cochrane reviews and several additional meta-analyses of RCTs evaluating the efficacy of psychological treatments compared to controls produce small to modest effect sizes, with most concluding that efficacious treatments exist [10–17]. Health care policies in the United States, England, and Canada have therefore specified that psychological treatments should be available to BCa patients as part of their routine care. However, the methodological quality of RCTs for BCa patients experiencing emotional distress has yet to be

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comprehensively evaluated. In the present review, this limitation is addressed.

It is widely recognised that poor quality trials often overestimate treatment effects [18–23]. For example, meta-analysis report larger effect sizes in RCTs that do not use intention to treat analyses [21,23–25], adequate randomization [21,24], and blind outcome assessors [21,26].Whilst many meta-analyses highlight that poor quality RCTs overestimate treatment effects, an additional concern is that poor quality undermines the confidence in the conclusions that can be drawn from RCTs [27–29]. For example, if concomitant treatments are not controlled for, it is difficult to determine the impact of the specific intervention being assessed; if an RCT is underpowered, between group effects may be undetected; and if psychometrically valid outcome measures are not used, researchers cannot be confident that intended outcomes were measured.

It is therefore crucial that the quality of trials of psychological treatments is known if policymakers and clinicians are to make informed decisions about the implementation of, and referral to, psychological treatments in clinical services. Assessing the methodological quality of RCTs has been fundamental to advancing the scientific credibility and reporting standards of psychotherapy outcome trials in mental health settings [21,27–29]. For example, it appears that as the quality of psychotherapy trials for depression have improved, the magnitude of treatment effects have diminished [23,30].

In BCa, there have been two Cochrane reviews that assessed the risk of bias (RoB) of individual trials [10,11] using the Cochrane RoB tool [31] (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, complete outcome data, and selective outcome reporting) and both found that, in most trials, the RoB was unknown. In addition, two meta-analyses [13,14] assessed the risk of bias using the Jadad scale [32] (random sequence generation, blinding of participants and personnel, and complete outcome data). One reported that 87% of trials were of high quality [13] while the other reported that only 29% were of high quality [14]. A further meta-analysis [12] assessed two RoB elements (random sequence generation and complete outcome data) and two other design features (adequacy of sample size and control for patient demoralisation) essential to high quality RCTs and reported that 44% of trials were of high methodological quality. However, all five failed to assess many other generic design features that are equally essential to high quality RCTs (including clarity of sample description, representativeness of the sample, specificity of outcome measures, reliability and validity of outcome measures, nature of control conditions, length of follow-up, control of concomitant treatments, statistical methods, and reporting of clinical significance). Available meta-analyses therefore provide only a partial assessment of trial quality in BCa.

Moreover, meta-analyses have largely disregarded design elements that are important specifically for psychotherapy trials. Conclusions drawn from RCTs that inadequately specify the nature of the intervention being evaluated are of limited value and also negate replication [33]. Therefore, treatment manuals are crucial to standardising psychological treatment and to discriminating between alternative treatments. Furthermore, to be confident that treatment was carried out as designed, it should be delivered by certified therapists trained in the treatment being investigated [34,35], and treatment must be monitored for therapist adherence (faithfulness to the prescribed treatment) and competence (skilfulness with which the treatment is delivered) [36,37]. Ideally, treatment should be delivered by more than one therapist and therapists should be included as a random design factor in analysis to avoid confounding between therapist and treatment [28]. Lastly, the conclusions that can be drawn from a psychotherapy trial depend on whether the duration and intensity of treatment conditions was matched. Only two meta-analyses in BCa reported on psychotherapy-specific design elements, and in a limited manner [11,12]: Naaman et al. [12] assessed treatment fidelity and manualisation, and Mustafa et al. [11] provided information on therapist training.

Available meta-analyses have therefore inadequately assessed the methodological quality of RCTs in BCa. To overcome the limitations of previous assessments of trial quality, we used the Psychotherapy Outcome Study Methodology Rating Form (POMRF), which was explicitly designed to assess both generic design elements and those specific to psychotherapy trials [38]. The POMRF has been used to assess the quality of psychological treatment trials for mental health populations in four reviews. The first examined the quality of cognitive behavioural therapy (CBT) trials for depression in children [39], the second examined the quality of CBT trials for obsessive compulsive disorder in adults [28], and the third examined the quality of acceptance and commitment therapy trials across a range of mental and physical health conditions [40]. The final review, also across a range of mental and physical health conditions, compared the quality of CBT trials to those using third wave CBT approaches and found that the quality of CBT trials were more methodologically rigorous [38].

Considering the recent evolution of methodological standards in psychological treatment trials generally, our study had five aims: (1) evaluate the overall quality of RCTs of psychological treatments for emotional distress in BCa, considering both generic design elements and those specific to psychotherapy trials; (2) evaluate specific design elements that have previously been inadequately evaluated in meta-analyses or are poorly implemented in clinical trials; (3) assess the quality of RCTs in this population against the benchmark of RCTs in mental health populations; (4) assess whether the quality of RCTs differ depending on the type of treatment being tested; and (5) determine whether methodological quality has improved over time.

2. Method

This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [41]. All analyses used SPSS version 22.0.0.1.

2.1. Eligibility criteria

Eligibility criteria are detailed according to the PICOS framework [41].

2.1.1. Participants

The participants of the studies included in the present review were exclusively adults aged 18 years or older with a histologically confirmed diagnosis of BCa. Participants across all stages of the BCa disease trajectory (i.e. shortly after diagnosis, during medical treatment, and survivorship) were included.

2.1.2. Interventions

As the term “psychological treatment” is poorly defined in the literature [10], we used a generic definition: treatments using psychological or behavioural techniques not based solely on impersonal media (i.e. written or visual material distributed on-line or by electronic or printed media).

2.1.3. Controls

Either no treatment (usual care) or active (attention placebo) control conditions. Trials comparing two or more specific psychological treatments without the use of a control condition were also included.

2.1.4. Outcomes

The primary and/or secondary outcome was emotional distress, defined as anxiety, depression, general mood, or global emotional distress. This definition was chosen to be as inclusive as possible as it matches the inclusion criteria used in previous meta-analyses [10–13,15].