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Effects of non-pharmacological interventions on symptom clusters in breast cancer survivors: A systematic review of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380028

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 August 2023 and was last updated on 08 August 2023.

INTRODUCTION

Review question / Objective (1) What is the effectiveness of non-pharmacological interventions in relieving symptom clusters and improving quality of life (QoL) among breast cancer survivors? (2) What is the safety of non-pharmacological interventions for symptom clusters in breast cancer survivors?

Rationale Lengthy cancer experience and relevant side effects of adjuvant therapies make breast cancer (BC) survivors suffer from various physical and emotional symptoms. These symptoms were potentially related to each other and co-occur in BC survivors, thereby forming a symptom cluster, leading to a drastic reduction in BC survivors' function status and QoL. Currently, nonpharmacological interventions have been suggested as an alternative approach, such as physical exercises, and mindfulness-based interventions may have positive effectiveness in managing cancer-related symptoms and symptom clusters. Numerous systematic reviews have ostensibly incorporated studies under the premise of system clusters. Nevertheless, upon rigorous scrutiny, it becomes apparent that these so-called clusters are essentially individual symptoms rather than authentic and distinct symptom clusters. Evidence specifically on what effectiveness of nonpharmacological interventions on symptom clusters in BC survivors is lacking.

Condition being studied A symptom cluster is defined as two or more concurrent symptoms related to one another, frequently reported in BC survivors. For managing these symptom clusters in BC survivors, nonpharmacological interventions have been recommended as potential alternatives.

METHODS

Search strategy The Mesh terms, keywords, and entry terms both in English and Chinese will be used as search terms to identify possible studies: breast neoplasms, breast cancer, breast carcinoma,乳腺癌, and 乳腺肿瘤, etc.; syndrome,

symptom cluster, and 症状群etc.; 随机, 对照, and randomized controlled trials, etc.

Participant or population Diagnosed BC aged over 18 years regardless of stages of cancer and types of treatment; (2) BC survivors who experiencing symptom clusters, and a symptom cluster is defined as two or more concurrent symptoms that are related to one another, such as fatigue-sleep disturbance symptom cluster, fatigue -sleep disturbance-depression symptom cluster, insomnia-depression-anxiety symptom cluster.

Intervention The nonpharmacological intervention will be defined as those interventions that did not involve any drug or medicine, such as cognitive behavioral therapy, physical exercises, yoga, acupressure, massage in managing symptom clusters or along with usual/standard care. Moreover, intervention frequency/intensity/duration and other intervention components should be clearly described in the intervention protocols.

Comparator Comparisons will include usual care and or standard medication, other nonpharmacological intervention and or pharmacological intervention) or no intervention, waitlist control.

Study designs to be included Randomised control trials (RCTs).

Eligibility criteria (1)Published in English peer-review and Chinese core journals. (2)Given the concept of "symptom cluster" was first introduced in 2001. Therefore it is reasonable to limit studies to be included since 2001 for inclusion. (3) RCTs with full text.

Information sources Two reviewers will independently search for published RCTs in the following databases: PubMed, Web of Science, Ovid Medline, Excerpta Medica database (EMBase), Cochrane Library, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Chinese Biomedical Literature Database, China National Knowledge Infrastructure, and Wan Fang Data.
Grey literature, including unpublished dissertations, and conference abstracts will be searched through the library. The metaRegister of Controlled Trials (mRCT), WHO international clinical trial registry, and ClinicalTrials.gov will be searched for ongoing trials. Manual searches will include reviewing reference lists of included studies.

Main outcome(s) The primary outcomes will include symptom clusters with referring to the term "cluster" or its synonyms and their interactions. The symptoms within clusters can be measured individually (such as the Pittsburgh Sleep Quality Index for sleep disturbance and Brief Fatigue Inventory for cancer-related fatigue) or in a constellation in terms of presence and severity, such as Numerical Rating Scales (NRS).
Secondary outcomes will include QoL (such as Functional Assessment of Cancer Therapy-Breast), and adverse events associated with the intervention.

Data management Literature management will be facilitated using Endnote.

Quality assessment / Risk of bias analysis Two reviewers will independently evaluate the methodological quality and risk of bias for all included RCTs utilizing the Joanna Briggs Institute(JBI) critical appraisal tool.

Strategy of data synthesis Once the data is extracted, it will be assessed for the possibility of meta-analysis. This will be based on the included studies measuring the same outcome and showing satisfactory homogeneity regarding the intervention modality and duration. Cochrane RevMan 5. Will be used for meta-analysis The standardized mean differences (SMD) or mean differences (MD) with 95% confidence intervals (CIs) will be used for the continuous outcomes, while the risk ratio (RR) will be considered for the dichotomous outcomes. Heterogeneity will be assessed by the chi-squared test and the I2 statistic. Statistical heterogeneity will be analysed by calculating the I2. A fixed effects model will be employed if I2< 50% and no significant clinical and methodological heterogeneity are identified. Otherwise, a random effect model will be selected.
Furthermore, a narrative synthesis approach will be performed, if meta-analysis is not applicable.

Subgroup analysis Subgroup analysis will be considered on the premise of the types of symptom clusters (the same or similar symptom clusters), and the same or similar individual symptoms. Within the same pharmacological intervention for the same or similar symptom clusters or individual symptoms, further subgroup analysis will be conducted based on the duration of the intervention (e.g., short-term, mid-term, and long-term). In addition, analysis of subgroups will also be considered based on different modalities of the same approaches (e.g., somatic acupuncture and somatic acupressure).

Sensitivity analysis NA.

Language restriction English, Chinese.

Country(ies) involved Austraila.

Keywords Symptom cluster; Breast cancer; Nonpharmacological intervention; Quality of life; Safety.

Dissemination plans The systematic review will be for publication in a peer-reviewed journal or conference.

Contributions of each author

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