INPLASY PROTOCOL

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Corresponding author: Yong Chai

458170613@qq.com

Author Affiliation:

The Second People's Hospital of Yibin.

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The Effects of case management for breast cancer patients: A Systematic Review and Meta-analysis of Randomized Controlled Trials

Yong, C1;Li, L2; Tao, W3; Yun-Lian, W4.

Review question / Objective: The aim of this study is to explore the difference between the impact of case management on breast cancer patients and the impact of other models of care by selecting the RCT trial.

Condition being studied: The Effects of case management for breast cancer patients. The research team includes three masters in nursing, two chief nursing officers and one chief physician with extensive expertise in breast cancer-related issues. Research members are well versed in literature searching and skilled in tools such as Endnote and RevMan. Information sources: The search includes PubMed, Embase, Cochrane Library, Scopus, CINAHL and Chinese repositories such as China National Knowledge, Infrastructure Database (CNKI), Wan fang Database, China, Biology Medicine Database (CBM). Biology Medicine Database (CBM). We will also search for unpublished literature at ClinicalTrials.gov. The search strategy will be adapted to the various databases.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 January 2022 and was last updated on 11 January 2022 (registration number INPLASY202210055).

INTRODUCTION

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METHODS

Search strategy: Order Search strategy #1 ((((("Breast Neoplasms"[Mesh]) OR (breast carcinoma*[Title/Abstract])) OR (breast tumour*[Title/Abstract])) OR (breast tumor*[Title/Abstract])) OR (breast cancer[Title/Abstract])) OR (breast disease[Title/Abstract]) #2 (((((("Case Management"[Mesh]) OR ("Patient Care Management"[Mesh])) OR ("Patient Care Planning"[Mesh])) OR ("Comprehensive Health Care [Mesh])) OR ("Critical Pathways"[Mesh])) OR (Disease Management[Title/Abstract])) OR ("Patient Navigation"[Mesh])) OR (patient navigator[Title/Abstract]) #3 (randomized controlled trial[Publication Type]) OR ((((randomized[Title/Abstract]) OR (randomised[Title/Abstract])) AND (controlled[Title/Abstract])) AND (trial[Title/ Abstract])) #4 #1 AND #2 AND #3.

Participant or population: Female breast cancer patients.

Intervention: Case Management.

Comparator: Other care models.

Study designs to be included: Randomised controlled trials.

Eligibility criteria: All RCTs which compared case care with other forms of care for breast cancer, RCTs conducted in female adults (participants aged >18 years) without regional and language restrictions.

Information sources: The search includes PubMed, Embase, Cochrane Library, Scopus, CINAHL and Chinese repositories such as China National Knowledge, Infrastructure Database (CNKI), Wan fang Database, China, Biology Medicine Database (CBM). Biology Medicine Database (CBM). We will also search for unpublished literature at ClinicalTrials.gov.

The search strategy will be adapted to the various databases.

Main outcome(s): The primary outcome will be the patient Satisfaction.

Additional outcome(s): The Additional outcome(s)secondary outcomes will be quality of life, pain, depressive disorder, anxiety.

Data management: All data included in the trial were extracted independently by two investigators, recorded on a data extraction form and analyzed for: general information (author information, year of publication, country of publication, funding); trial-type; participant characteristics; interventions; trial outcomes. In a disagreement between two researchers, a third researcher will arbitrate, and incomplete data will be provided by contacting the original author.

Quality assessment / Risk of bias analysis:

We will use the Cochrane risk assessment tool to assess the quality of the RCT trial literature, which consists of seven items: random sequence generation, allocation concealment, implementation bias, measurement bias, follow-up bias, reporting bias, and other biases. Each risk bias was judged on the following criteria: low risk of bias, high risk of bias, unclear.

Strategy of data synthesis: Data will be analyzed and quantitative data synthesized using RevMan V.5.4. Dichotomous variables will be expressed as risk ratios (RR), and continuous variables will be expressed as mean differences (MD) or standards mean differences (SMD). Evidence-based final effect size estimates and 95% confidence intervals (95% CI) will be given.

Subgroup analysis: Subgroup analysis will be performed if there is sufficient literature included or a high degree of heterogeneity, depending on the Type of patient outcome.

Sensitivity analysis: A sensitivity analysis will be performed using Revman 5.4 software to evaluate the reliability of the Meta-analysis. If heterogeneity is high, we

will verify the heterogeneity of all included literature one by one, exclude low-quality studies as needed, and then re-run the meta-analysis, comparing the results with the previous meta-analysis. If the results are generally stable, they will be considered reliable.

Country(ies) involved: China.

Keywords: Case Management, Breast cancer, protocol, systematic review.

Contributions of each author:

Author 1 - Yong Chai.

Author 2 - Li Li.

Author 3 - Tao Wang.

Author 4 - Yun-Lian Wu.