INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

Effects of cognitive behavioral therapy on quality of life, depression and anxiety in informal cancer caregivers: A systematic review and meta-analysisEffects of cognitive behavioral therapy on quality of life and negative emotions in informal caregivers of patients with cancer: A systematic review and meta-analysis

Ren, H[1]; Zhou, S[2].

Review question / Objective: This study aimed to systematically review the effect of cognitive behavioral therapy (CBT) in terms of improving the quality of life (QOL), depression, and anxiety of informal cancer caregivers. The search strategy followed the PICO model: Population: family caregivers of patients with cancer; Intervention: cognitive behavioral therapy; Comparison: routine nursing/health education, or blank control; Outcome: QOL, depression, or anxiety.

Condition being studied: A literature search focused only on studies published in peer-reviewed journals to enhance the rigor of the methodology examined. In addition, manual retrieval of existing references was carried out to select targeted studies that met the inclusion criteria. Both computer and manual retrieval processes are carried out independently by two researchers, and any differences of opinion will be negotiated by a third principal researcher.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 March 2022 and was last updated on 23 March 2022 (registration number INPLASY202230120).

INTRODUCTION

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METHODS

Search strategy: Publications from establishment of the database to October 2021 were systematically selected. A literature search was conducted in the following digital databases: PubMed, the Cochrane Library, EMBASE, Web of Science, MEDLINE, China National Knowledge Infrastructure (CNKI) and China Biology Medicine DISC (CBMdisc). Keywords related to oncology (cancer OR neoplasm OR oncology OR palliative care OR palliative medicine OR malignancy) were combined with keywords related to the population (caregiver OR carer OR caregiving OR spouse OR relative OR partner OR family) and the intervention (CBT OR iCBT OR cognitive therapy OR behavioral intervention OR cognitive intervention OR coping skills OR psychosocial OR problem-solving OR cognitive restructuring OR exposure OR mindfulness OR meditation OR relaxation training OR cognitive behavior therapy OR cognitive behavioral therapy OR psychotherapy). In addition, a backward search (snowballing) of reference lists of identified studies was conducted, and earlier systematic reviews together with a forward search (citation tracking) until no additional relevant studies were found.

Participant or population: Informal cancer caregivers: usually refers to the patient's family, spouse, neighbors, or friends.

Intervention: The intervention content of the article shall conform to the CBT content standard, and the intervention content shall include at least one of the following components; and be considered as CBT: Cognitive recombination, imaginary or in-body exposure, coping skills training, problem solving, behavioral activation, structured work, reception-based cognitive intervention, managing stress through relaxation or mindfulness.

Comparator: Health education for informal caregivers of cancer patients, including nursing, medication, emotional counseling, etc.

Study designs to be included: Randomized controlled trial will be included.

Eligibility criteria: Our literature search was designed to identify existing studies that evaluated interventions for informal caregivers of cancer patients; and eligible studies were selected using the following three criteria: a. Interventions must include informal caregivers, alone or with cancer patients. b. The intervention content of the article shall conform to the CBT content standard; c. Participants were randomly assigned to either the intervention group or the control group of the study. In addition, because of the nature of the parent-child relationship, studies involving children with cancer were excluded, as were studies involving drug interventions.

Information sources: Information comes from electronic databases contact with authors.

Main outcome(s): Considering that psychosocial interventions for caregivers in recent years have not been limited to a single outcome variable, for example, some studies may involve a number of measures of caregiver quality of life, depression, anxiety, sleep, or self-efficacy, and a large number of randomized controls no longer

used blank controls without intervention, all of these factors make systematic review difficult. Therefore, this study only selected quality of life, depression and anxiety scores reported in most randomized controlled trials as outcome indicators, and selected the control group as routine mental health education or related studies without intervention for meta-analysis.

Quality assessment / Risk of bias analysis:
This study adopted the Cochrane Reviewer Handbook 5.1.018 as the risk-of-bias (ROB) assessment tool to evaluate the overall quality of the study: random allocation method, allocation concealment, blinding (investigator-blinded and/or participant-blinded), integrity of result data, selective reporting of research results, and other sources of bias. All studies were scored as possessing (a) low risk of bias, (b) unclear, or (c) high risk of bias.

Strategy of data synthesis:
Using Stata 14.0 software for meta-analysis, we adopted the random-effects model because different measuring tools were used to measure the same outcome. For continuous data, the standardized mean difference (SMD) was selected as the effect scale index for statistics. The magnitude of effect indicated the degree of influence of CBT on informal cancer caregivers. The effect values were all expressed in a 95% confidence interval (CI). Heterogeneity was explored using Q and I2 statistics. Q-tests were related to the probability that the results reflected systematic between-study differences. A P value ≤0.10 was used to determine significant heterogeneity because of the generally low statistical power of heterogeneity tests. The I2 statistic was an estimate of the degree of observed heterogeneity unexplained by sampling error and was unaffected by the number of studies. I2 values of 0%, 25%, 50%, and 75% were considered negligible, low, moderate, and high, respectively. Subgroup analysis, meta-regression and sensitivity analysis were conducted to explore the source of heterogeneity. Funnel plots and Egger's test were used to assess the presence of any publication biases.

Subgroup analysis:
Subgroup analysis was further conducted according to measurement tools, and studies with the same measurement tools were included in the same subgroup.

Sensitivity analysis:
Sensitivity analysis was further conducted for the results with high heterogeneity, and the studies with great influence on heterogeneity were excluded.

Language: English.

Country(ies) involved: China - Author country.

Keywords: Cognitive behavioral therapy; informal cancer caregivers; Quality of life; Depression; Anxiety.

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