INPLASY PROTOCOL

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The authors declare that they have no competing interests.

Effectiveness of advanced nursing care (ANC) on bone cancer pain, psychological disorders and quality of life in patients with primary bone cancers: protocol for a PRISMA-compliant meta-analysis

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Review question / Objective: **Whether advanced nursing care (ANC) is effective or not on bone cancer pain, psychological disorders and quality of life (QoL) in patients with primary bone cancers (PBC)?**
Condition being studied: **Advanced nursing care, primary bone cancers, bone cancer pain, psychological disorder and quality of life.**
Information sources: **Electronic databases including Excerpt Medica Database (Embase), PubMed, Google Scholar, Medline, Cochrane Library, Web of Science (WOS), China National Knowledge Infrastructure (CNKI), Chinese BioMedical Database (CBM), China Scientific Journal Database (CSJD) and Wanfang Database, will be systematically searched for eligible studies from January 2000 to September 2020. In addition, we will also identify conference proceedings, reference lists of included studies, and websites of clinical trials registry. Language is limited with English and Chinese.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 September 2020 and was last updated on 09 September 2020 (registration number INPLASY202090037).

INTRODUCTION

Review question / Objective: **Whether advanced nursing care (ANC) is effective or not on bone cancer pain, psychological disorders and quality of life (QoL) in patients with primary bone cancers (PBC)?**

Rationale: **Advanced nursing care (ANC) has been reported to effectively relieve bone cancer pain, prevent psychological disorders and improve the quality of life (QoL) in patients with primary bone cancers (PBC) during the treatment.**

However, the exact effect of ANC remains controversial. This systematic review will aimed to assess the effectiveness of ANC on bone cancer pain, psychological disorders and QoL in patients with PBC.

Condition being studied: Advanced nursing care, primary bone cancers, bone cancer pain, psychological disorder and quality of life.

METHODS

Search strategy: To perform a comprehensive and focused search, experienced systematic review researchers will be invited to develop a search strategy. The plan searched terms are as follows: "bone cancer" or "primary bone cancers" or "cancer in the bones" or "osteosarcoma" or "Ewing sarcoma" or "chondrosarcoma" or "BC" or "OS" or "ES" or "CS" and "pain" or "cancer pain" or "bone cancer pain" or "quality of life" or "QoL" or "psychological disorder" or "adverse events" and "nursing care" or "advanced nursing care" et al. The detailed sample of search strategy for PubMed database is shown in Table 1. Similar search strategies will be modified and used for the other databases.

Participant or population: Osteosarcoma (OS), Ewing sarcoma (ES), and chondrosarcoma (CS) patients who had severe bone cancer pain, or clinically diagnosed depression disorder or poor QoL will be included in this study, without restrictions of country, race, gender, etc.

Intervention: In the experimental group, all patients must receive ANC for bone cancer pain, psychological disorders or for improving the QoL.

Comparator: The control intervention can be any therapies, except ANC.

Study designs to be included: All available comparative clinical trials that assessed the efficacy of ANC on bone cancer pain, psychological disorders and QoL in patients with PBC will be included.

Eligibility criteria: This study will include randomized controlled trials (RCTs) or quasi-RCTs, and high-quality prospective cohort studies that investigated the efficacy of ANC on bone cancer pain, psychological disorders and QoL in patients with PBC. Articles without sufficient available data, non-comparative studies, case reports and series, literature reviews, meta-analysis, letter to the editor, and other unrelated studies will be all excluded from analysis.

Information sources: Electronic databases including Excerpt Medica Database (Embase), PubMed, Google Scholar, Medline, Cochrane Library, Web of Science (WOS), China National Knowledge Infrastructure (CNKI), Chinese BioMedical Database (CBM), China Scientific Journal Database (CSJD) and Wanfang Database, will be systematically searched for eligible studies from January 2000 to September 2020. In addition, we will also identify conference proceedings, reference lists of included studies, and websites of clinical trials registry. Language is limited with English and Chinese.

Main outcome(s): The primary outcomes will include total pain relief rate and QoL. I) Total pain relief rate. The reduction in pain intensity was measured using a visual analogue scale (VAS), verbal rating scale, or numerical rating scale (NRS). The intensity of pain was evaluated by the World Health Organization (WHO) standards with NRS, and expressed as numerical numbers ranging from 0 (for no pain) to 10 (for extreme pain). II) QoL which is assessed using Karnofsky performance score (KPS) or any other associated scales or scores.

Additional outcome(s): The secondary outcomes comprise of psychological outcomes and adverse events. I) Psychological outcomes. Depression will be measured by using the Hamilton Depression Rating Scale or any relevant scales; Anxiety will be measured by using the Hamilton Anxiety Rating Scale or other tools. II) Adverse events. Any expected or

unexpected adverse events are measured according to WHO standards.

Data management: Two investigators (Lekun Li and Yujie Liu) will be responsible for the data extraction independently. The following data will be extracted from eligible literatures: I) Study characteristics: first author's name, year of publication, country of study, sample size, study methods (such as randomization, blinding, etc.) and follow-up duration, et al. II) Participant characteristics: age, gender, ethnicity, KPS score, pain score, severity of psychological disorder, inclusion and exclusion criteria, et al. III) Interventions: intervention methods and duration of intervention, et al. Dealing with missing data: When any data are missing or insufficient, we will contact original authors by using email. If those relevant data are not acquired, we will only analyze the available data, and discuss its impact as a limitation.

Quality assessment / Risk of bias analysis: Two experienced authors (Lekun Li and Yujie Liu) will assess the risk of bias for each eligible trial according to the guidance of the Cochrane Handbook for Systematic Review of Interventions independently. This tool comprises of 7 items including selection, selection, performance, detection, attrition, reporting and other bias, and each item is further divided as 3 different levels: high, unclear, or low risk of bias. EPPBC guidelines will be used to assess the risks of non-RCTs. Any disagreements will be resolved via discussion with a third researcher (Xiaofeng Ren).

Strategy of data synthesis: Stata 14.0 (Stata Corp., College Station, TX, USA) and Review Manager 5.3 (Nordic Cochran Centre, Copenhagen, Denmark) statistical software were used for statistical analyses. Continuous data will be presented as standardized mean difference (SMD) with their 95% confidence intervals (CIs), and dichotomous data will be recorded as risk ratio (RR) with 95% their CIs. A two-tailed P < 0.05 was considered statistically significant. Cochran's Q and Higgins I2 statistic were used to assess heterogeneity among the included clinical trials. P < 0.1 for the Chi2 statistic or an I2 > 50% will be considered as showing considerable heterogeneity. A fixed effect model will be used to calculate the outcomes when statistical heterogeneity is absent; otherwise, the random effects model will be used for analysis.

Subgroup analysis: If the data are available and sufficient, subgroup and meta-regression analysis will be conducted to explore the source of heterogeneity with respect to location, study quality, intervention types, and treatment duration.

Sensibility analysis: Sensitivity analysis will be carried out to assess the reliability and robustness of the aggregation results by eliminating low quality or high bias risk trials. A summary table will report the results of the sensitivity analyses.

Language: Language is limited with English and Chinese.

Country(ies) involved: China.

Other relevant information: I) Publication bias analysis. If the included studies are sufficient (≥10 trials), we will detect publication biases of included trials using funnel plots, Begg's and Egger regression test. If publication bias existed, a trim-and-fill method should be used to coordinate the estimates from unpublished studies, and the adjusted results were compared with the original pooled RR. II) Evidence evaluation. The quality of evidence and the strength of the main result recommendations will be determined by using the guidelines of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE). The quality of all evidence will be evaluated as high, moderate, low, and very low levels respectively.

Keywords: advanced nursing care; primary bone cancers; bone cancer pain; psychological disorder; quality of life.

Dissemination plans: We will disseminate the results of this systematic review by publishing the manuscript in a peer-reviewed journal.

Contributions of each author:

Author 1 - Lekun Li - Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing-original draft, Writing-original draft.

Author 2 - Yujie Liu - Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing-original draft.

Author 3 - Xiaofeng Ren - Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing-original draft.

Author 4 - Kai Qu - Funding acquisition, Methodology, Validation, Writing-review & editing.

Author 5 - Xiaona Liu - Conceptualization, Project administration, Resources, Software, Supervision, Validation, Writing-review & editing.