

INPLASY PROTOCOL

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The authors declare that they have no competing interests.

Effects of high-quality nursing care on psychological outcomes and quality of life in patients with hepatocellular carcinoma: A protocol of systematic review and meta-analysis

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Review question / Objective: Is high-quality nursing care (HQNC) effective on psychological disorders and quality of life (QoL) in patients with HCC?

Condition being studied: High quality nursing care, psychological disorder, quality of life and hepatocellular carcinoma.

Information sources: Electronic databases including Google Scholar, Medline, Excerpt Medica Database (Embase), PubMed, Web of Science (WOS), Cochrane Library, China Scientific Journal Database (CSJD), China National Knowledge Infrastructure (CNKI), Chinese BioMedical Database (CBM) and Wanfang Database, will be systematically searched for eligible studies from January 2000 to July 2020. 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 21 July 2020 and was last updated on 21 July 2020 (registration number INPLASY202070096).

INTRODUCTION

Review question / Objective: Is high-quality nursing care (HQNC) effective on psychological disorders and quality of life (QoL) in patients with HCC?

Rationale: HQNC has been reported to effectively prevent psychological disorders

and improve the QoL in patients with HCC. However, the exact effect of HQNC remains controversial. Therefore, in this study, we will systematically evaluate the effect of HQNC on psychological disorders and QoL in patient with HCC through the meta-analysis, in order to provide scientific reference for the design of future clinical trials.

Condition being studied: High quality nursing care, psychological disorder, quality of life and hepatocellular carcinoma.

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: “liver cancer” or “hepatocellular cancer” or “LC” or “HC” or “HCC” and “depression” or “anxiety” or “psychological disorder” or “quality of life” or “adverse events” and “nursing care” or “advanced nursing care” or “high quality nursing care” or “psychological 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: All patients with HCC are 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 HQNC for the psychological disorders or for improving the QoL.

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

Study designs to be included: All available comparative clinical trials that assessed the effectiveness of HQNC on psychological outcomes and QoL in HCC patients will be included.

Eligibility criteria: This study will include randomized controlled trials (RCTs) or quasi-RCTs, and high-quality prospective cohort studies that assessed the effectiveness of HQNC on psychological outcomes and QoL in patients with HCC. Articles without sufficient available data, non-comparative studies, non-peer reviewed articles, literature reviews, meta-analysis, commentaries, case reports and series, meeting abstracts, letter to the

editor, editorials, and other unrelated studies will be all excluded from analysis.

Information sources: Electronic databases including Google Scholar, Medline, Excerpt Medica Database (Embase), PubMed, Web of Science (WOS), Cochrane Library, China Scientific Journal Database (CSJD), China National Knowledge Infrastructure (CNKI), Chinese BioMedical Database (CBM) and Wanfang Database, will be systematically searched for eligible studies from January 2000 to July 2020. Language is limited with English and Chinese.

Main outcome(s): The primary outcomes will include: I) Depression, which is measured by the Hamilton Depression Rating Scale or any relevant scales. II) Anxiety, which is measured by the Hamilton Anxiety Rating Scale or other tools. III) QoL which is assessed by 36-Item Short Form Health Survey or any other associated scales or scores.

Additional outcome(s): The secondary outcomes comprise of pain intensity and adverse events. I) Pain intensity can be assessed by visual analog scale or other scales. II) Any expected or unexpected adverse events, which are measured according to World Health Organization (WHO) standards, will be also measured.

Data management: Two investigators (Zhang L and Zhang X) 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.), periods of data collection and follow-up duration, et al. II) Participant characteristics: tumor stage (staging of the tumor according to the AJCC TNM classification for esophageal cancer), age, gender, ethnicity, pathology diagnosis, pathologic tumor size, inclusion and exclusion criteria, et al. III) Interventions: intervention methods and duration of intervention, et al.

Quality assessment / Risk of bias analysis:

Two experienced authors (Zhang L and Zhang X) 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. EPHCC guidelines will be used to assess the risks of non-RCTs. Any disagreements will be resolved via discussion with a third researcher (Zhou LJ).

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. Cochrane's Q test and I² statistics were used to assess heterogeneity among the included clinical trials. If $P > 0.1$ or $I^2 < 50\%$, a fixed effects model was used for the meta-analysis; otherwise, a random effects model was used.

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 age, gender, tumor stage, intervention types, study quality, location and treatment duration.

Sensibility analysis: Sensitivity analysis will be carried out to assess the reliability and robustness of the aggregation results via eliminating trials with low quality or high bias risk. 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: We will detect publication biases and poor methodological quality of small studies using funnel plots if 10 or more studies are included in the meta-analysis. Begg's and Egger regression test will be utilized to detect the funnel plot asymmetry. If reporting bias is suspected, we will consult the study author to get more information. If publication bias existed, a trim-and-fill method should be applied to coordinate the estimates from unpublished studies, and the adjusted results were compared with the original pooled RR. II) Evidence evaluation: The evidence grade 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: High quality nursing care, psychological disorder, quality of life, hepatocellular carcinoma, meta-analysis.

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 - Lei Zhang - Investigation; Methodology; Project administration; Supervision; Writing-original draft; Writing-review & editing.

Author 2 - Xuan Zhang - Investigation; Methodology; Writing-original draft.

Author 3 - Zhaokun Cui - Investigation; Methodology; Writing-original draft.

Author 4 - Lijuan Zhou - Investigation; Methodology; Writing-original draft.

Author 5 - Kai Qu - Funding acquisition; Writing-review & editing.

Author 6 - Nannan Wang - Conceptualization; Project administration; Supervision; Writing-review & editing.