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Effectiveness of cognitive behavioural therapy on quality of life in patients with prostate cancer after androgen deprivation therapy: a protocol for systematic review and meta-analysis

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ABSTRACT

Introduction Prostate cancer (PCa), as a malignant tumour with rapid development in recent years, significantly affects men's health, work, life and economy. Androgen deprivation therapy (ADT) plays an important role in the treatment of PCa and can be used as a complementary therapy in the late stage of castration-resistant prostate cancer. Though ADT targeting PCa shows an effective therapeutic effect, the underlying side effects (cognitive disorder, hot flashes, a decrease in sexuality) cannot be ignored. At present, cognitive behavioural therapy (CBT) has been widely used for patients with PCa after ADT due to its confirmed efficacy, fewer side effects and lower economic burden. However, the effectiveness of CBT for patients with PCa after ADT is still controversial. Therefore, we will conduct a systematic review and meta-analysis of the effectiveness of CBT for patients with PCa after ADT.

Methods and analysis Literatures will be searched from establishment of the database to 31 May 2021 with the language restrictions of English and Chinese in eight online databases (PubMed, Embase, the Web of Science, Cochrane Library, VIP, CNKI, CBM, and WAN FANG). This study will include RCTs that performed CBT as the main method of the experimental group for patients with PCa after ADT. Two or more reviewers will independently conduct the selection of studies, data extraction and data analysis. The risk ratios with 95% CIs will be used to present the data synthesis result of dichotomous data, while weighted mean differences or standardised mean differences with 95% CIs will be used to present the data synthesis result of continuous data. Meanwhile, evidence quality of outcome will be assessed by using the Grading of Recommendations Assessment, Development and Evaluation method. Stata V.13.0 and Review Manager software V.5.3 will be used for analysis and synthesis.

Ethics and dissemination This protocol is a second study based on a completed randomised controlled study. Thus, ethical approval is not required, and no additional data are available.

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Strengths and limitations of this study

- This is a protocol for the first systematic review and meta-analysis of the existing prospective, longitudinal evidence on cognitive behavioural therapy (CBT) for patients with prostate cancer (PCa) after androgen deprivation therapy (ADT).
- This protocol will strictly adhere to the recommendations of the Cochrane handbook for systematic reviews of interventions.
- We predict that the pooled effects may be influenced by high statistical heterogeneity.
- We will use the Grading of Recommendations Assessment, Development and Evaluation system to assess evidence quality of outcomes, which would help clinicians and patients decide whether or not to choose CBT for treating PCa after ADT.
- A potential limitation of this protocol may be the lack of sufficient evidences on the intervention of CBT on the quality of life of patients with PCa after androgen deprivation treatment, and there may be heterogeneity in available studies.

INTRODUCTION

Prostate cancer (PCa) is a malignant tumour occurring in the prostate, and its incidence is gradually increasing. Studies showed that PCa was the second most frequently diagnosed cancer and the fifth leading cause of cancer mortality among men worldwide in 2012.[1] The incidence and mortality of PCa had international variation.[2] Recent studies suggest that the incidence and mortality of PCa are lower in Asia, but the regions with high incidence rates are Australia/New Zealand, northern America, and western and northern Europe.[3] These variations may be caused by the regional differences in the diagnosis of PCa through PSA-based screening, the availability of treatment and lifestyle.[4 5] However, the cause of PCa is not clear until now. The current consensus is that older age, ethnicity

and genetic predisposition are the specific risk factors for PCa.[6] Besides, unhealthy lifestyle is also a risk factor for PCa, such as obesity, diet high in calcium, dairy products.[7–9] The current treatments for PCa include: radical prostatectomy, endocrine therapy, external beam radiotherapy, plesioradiotherapy (both high and low doses), active surveillance and watchful waiting, cryotherapy, high intensity focused ultrasound, and so on.[10–12]

Androgen deprivation therapy (ADT), which is considered as one of endocrine therapies, is widely used in the treatment of patients with PCa, mainly including bilateral orchiectomy and luteinising hormone-releasing hormone (LHRH) agonists or antagonists, and LHRH agonists are the most commonly used at present.[13] ADT can significantly prolong the life of patients with metastatic PCa in the earliest stage.[14] However, with the continuation of ADT, problems such as drug-induced gonadal function decline and adverse reactions of treatment become more obvious.[15] PCa is a great psychological burden for patients. Hormonal changes caused by ADT make the situation worse. Studies have shown that about a third of patients will have severe anxiety and even suicidal tendencies in the first 12 months after diagnosis of metastatic disease.[16] In addition, an RCT showed that half of the patients experienced a decline in cognitive abilities after 6 months of ADT.[16 17] Another study has also confirmed that the cognitive abilities of patients in the ADT group, especially memory, attention and information processing, are significantly lower than that of the non-ADT group and the healthy group.[18] ADT inhibits the growth of cancer cells by reducing the concentration of androgens in the body and inhibiting the conversion of testosterone to dihydrotestosterone. However, with the decrease in androgen level, patients will show symptoms of hypogonadism, such as hot flashes,[19] anxiety,[19] a decrease in sexuality,[20] and even the occurrence of male breast cancer after antiandrogenic treatment.[20] Besides, ADT can also lead to osteoporosis,[21 22] cardiovascular disease,[23 24] metabolic disorders[23 25] and other systemic diseases. The economic burden of other systemic diseases caused by ADT including the direct and indirect costs is substantial and significant.

Cognitive behavioural therapy (CBT, including psychological interventions) has been proven to be effective in reducing negative effects and improving the quality of life of patients with cancer. Studies have shown that cancer survivors have anxiety, depression and poor quality of life,[26] and the severity of symptoms is associated with prolonged treatment cycles and increased use of medical resources.[27] CBT can relieve anxiety and depression in patients with cancer to a great extent,[28] and it can also effectively treat persistent fatigue and insomnia caused by cancer.[29 30] In addition, a randomised controlled trial (RCT) showed that the quality of life in patients with PCa (Most of them non-Hispanic whites) was improved significantly after 10 weeks of cognitive behavioural stress management (awareness of disease, change of mood, communication with medical staffs, etc).[31] Other studies have shown that psychoeducational interventions can improve the coping skills of patients with PCa and improve their sexual function to a some extent.[32]

Therefore, it is necessary to assess the issue and design this systematic review and meta-analysis to determine the effectiveness of CBT for patients with PCa after ADT based on the latest evidence.

METHODS

We will formulate this protocol based on the standard of 'Preferred Reporting Items for Systematic Review and Meta-analysis Protocols (PRISMA-P)'.[33–35] And this study will be carried out on 1 June 2021.

Patient and public involvement

No patient and public were involved.

Inclusion criteria

Types of studies

Our research will include RCTs which access the effectiveness of CBT for patients with PCa after ADT.

Types of patients

Our objective population will be patients with PCa owing to the decrease in quality of life after ADT. The diagnostic criteria will be based on the prostate cancer-related quality of life (PCa-QoL) Scale.[36]

Types of intervention

CBT, including mindfulness-based cognitive therapy,[37] psychological guidance, stress management and cognitive couple therapy, and so on, is defined as the treatment group. No treatment can be provided for the control groups.

Types of outcome measures

Primary outcomes

The primary outcome is the PCa-QoL scales.[37] The PCa-QoL Scale has two main components which including 11 subindex scales. Seven were generically relevant to patients with PCa: urinary control, sexual intimacy, sexual confidence, marital affection, masculine self-esteem, health worry and PSA concern. Four scales were specific to the treatment experience: perceived cancer control, quality of treatment decision making, regret of treatment choice and cancer-related outlook.

Secondary outcomes

The secondary outcomes mainly include the following aspects: the Hospital Anxiety and Depression Scale,[38] Cancer Worry Scale,[39] IIEF-5,[40 41] recurrence rate.

Exclusion criteria

1. Grey literature such as animal experiments, mechanism of disease, case reports, systematic review, meta-analysis and meeting abstracts will be excluded.

Box 1 The search strategy of the Cochrane Library

- #1 MeSH descriptor: ((Prostatic Neoplasms)) explode all trees
- #2 ('Prostatic Neoplasms'):ti,ab,kw OR ('Prostate Neoplasm*'):ti,ab,kw OR ('Prostatic Neoplasm*'):ti,ab,kw
- #3 ('Prostate Cancer*') :ti,ab,kw OR ('Prostatic Cancer*'):ti,ab,kw OR ('Cancer of the Prostate'):ti,ab,kw OR ('PCa'):ti,ab,kw
- #4 #1 OR #2 OR #3
- #5 MeSH descriptor: ((Cognitive Behavior Therapycognitive–behavioral therapy)) explode all trees
- #6 ('Cognitive BehaviorBehaviour Therap*'):ti,ab,kw OR ('Therapy, Cognitive BehaviorBehaviour*'):ti,ab,kw OR ('BehavioralBehavioural Therapies, Cognitive'):ti,ab,kw OR ('CBT'):ti,ab,kw OR ('bCBT'):ti,ab,kw
- #7 ('Therapies, Cognitive Behavio*'):ti,ab,kw OR ('Cognition Therap*'):ti,ab,kw OR ('Cognitive Psychotherapy'):ti,ab,kw
- #8 ('Mind Body Medicine'):ti,ab,kw OR ('Mind-Body Therapies'):ti,ab,kw OR ('Mindful cognitive therapy'):ti,ab,kw OR ('MBCT'):ti,ab,kw OR ('mindfulness-based interventions'):ti,ab,kw
- #9 ('Couples therapy'):ti,ab,kw OR ('Cognitive Couple Therapy'):ti,ab,kw OR ('stress management '):ti,ab,kw
- #10 #5 OR #6 OR #7 OR #8 OR #9
- #11 MeSH descriptor: ((Randomised controlled trial)) explode all trees
- #12 ('RandomizedRandomised controlled trial'):ti,ab,kw OR ('RandomizedRandomised'):ti,ab,kw OR ('controlled'):ti,ab,kw
- #13 #11 OR #12
- #14 #4 AND #10 AND #13

2. The exclusion criteria for this study will be persons receiving treatment other than ADT and suffering from severe cognitive or psychiatric problems.
3. The patients in the control group were treated with any form of CBT.
4. Considering the longer treatment period of CBT, studies with treatment time less than 4 weeks will be excluded.
5. Studies from which raw data cannot be extracted and studies of which the authors cannot be contacted will be excluded.

Search methods for identification of studies

Electronic searches

English and Chinese databases will be searched from inception to 31 May 2021, including PubMed, Embase, Web of Science, Cochrane Library, VIP, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM) and Wan Fang Data Knowledge Service Platform (WAN FANG). The key search terms of the study include 'Prostatic Neoplasms', 'PCa', 'Prostatic Cancer', 'Cancer of the Prostate', 'cognitive–behavioral therapy', 'Therapy, Cognitive Behaviour', 'Therapy, Cognitive Behaviour', 'Mind-Body Therapies', 'mindfulness-based intervention', 'Cognitive Couple Therapy', 'CBT', 'bCBT' and 'Randomised controlled trial'. The search strategy of the Cochrane Library is presented in box 1.

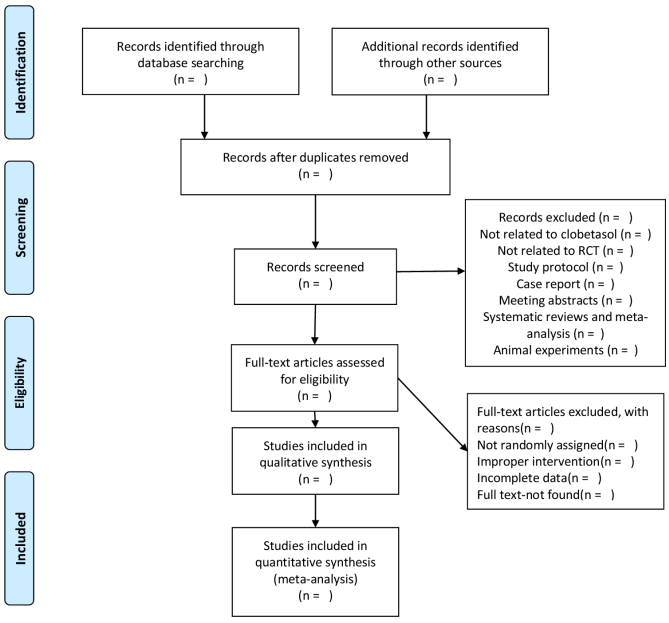

Figure 1 Process of study screening (adapted from Moher *et al* [51]). RCT, randomised controlled trial.

Searching other resources

We will search the National Institutes of Health clinical registry Clinical Trials, International Clinical Trials Registry Platform, Australian New Zealand Clinical Trials Registry and Chinese clinical registry to find the unpublished or ongoing trial data. Additionally, Interlibrary Loan and Baidu academic will be used to assist in the acquisition of full-text documents.

Selection and management of studies

All relevant references were selected, downloaded and uploaded in EndNote software. First, duplicates will be automatically deleted by EndNote(X8) software. Second, two researchers will filter out ineligible articles by title and abstracts based on the criterion of inclusion and exclusion. Moreover, they will read full texts if the studies cannot be screened only though the title and abstracts. Lastly, two reviewers cross-check after screening. If an inconsistent opinion exists, they will resolve it through discussion. Otherwise, a third researcher will make the judgement. The process and results of the studies' selection will be presented in a flow chart (figure 1).

Data extraction

Two reviewers independently extract data from the included studies based on the Cochrane Handbook 5.2.0 guidelines after literature screening.[35] Data will include the following information:

1. Study information: author, country, journal, publication date.
2. Characteristics of patients: average age, numbers of patients, race, region, scores of outcomes at baseline and follow-up.
3. Intervening measure: type, duration and frequency of CBT.

4. Methodological Information: information was extracted from six aspects including: random sequence generation, allocation concealment, blind method, result data integrity, selective reporting and other biases. The quality of the information will be assessed with standards of the Cochrane Handbook 5.2.0 which be graded into 'low risk', 'medium risk' and 'high risk' levels.

Data analysis

RevMan V.5.3 and Stata V.13.0 software will be used to analyse all data. Continuous variables such as the scale of PCa-QoL and dichotomous variables such as the recurrence rate will be represented as weighted mean difference and relative risk with 95% CI separately. The results of data analysis were considered statistically significant at a value of $p<0.05$.

Heterogeneity test and subgroup analysis

The application of Q and I^2 statistics can detect both the existence and degree of heterogeneity. Q test is obviously affected by the number of included studies, while I^2 statistics will not change with the number of studies, and its results of heterogeneity test are more stable. When the value of $I^2=0$, it indicates that the variation between studies is only caused by sampling error; when $0.25 < I^2 <0.5$, it is considered that there is moderate heterogeneity; when $I^2 >0.5$, high heterogeneity is identified. Meanwhile, the treatment method of heterogeneity is based on the values of I^2 and χ^2 statistics (expressed by p value). When $I^2 <50\%$ and $p>0.10$, a fixed-effect model was used; when $I^2 \geq 50\%$ or $p<0.10$, a random-effect model was used. It is necessary to find sources of heterogeneity through meta-regression, subgroup meta-analyses and sensitivity analysis. We will consider $I^2 \geq 50\%$ or $p<0.1$ as substantial heterogeneity, which will be further studied by subgroup analyses. Subgroup analyses will be carried out for the different interventions (eg, mindfulness-based intervention, cognitive couple therapy), length of treatment, and duration and frequency at baseline. Moreover, we will conduct subgroup analysis according to the participants' characteristics such as age and phase (advanced or not), to explore which group benefited the most.

Sensitivity analysis

Sensitivity analysis is mainly used to evaluate the reliability of the meta-analysis results. We will determine the stability of meta-analysis results by means of excluding studies with small sample sizes or low evidence. The results of meta-analysis can be accepted if the outcomes have no change after sensitivity analysis. Otherwise, we will be cautious with the results.

Assessment of publication bias

It is necessary to use an inverted funnel plot to evaluate publication bias when more than 10 studies are included. Publication bias depends on whether the funnel plot is symmetrical. If the number of studies is less than 10, Egger's linear regression method would be used to analyse the risk of bias. We can prevent publication bias though establishing a trial registration system, changing the editing and reviewing strategy, and so on.

Grading the quality of evidence

The development of clinical practice guidelines depend on the acquisition of scientific evidence. So, the quality of evidence will be classified into high, moderate, low or very low based on the Grading of Recommendations Assessment, Development and Evaluation guidelines system.[42]

ETHICS AND DISSEMINATION

Ethical approval is not required since this study is a secondary analysis of existing literature. Also, we hope to publish our study in a peer-reviewed journal or present at relevant conferences for clinical doctors and patients.

DISCUSSION

The quality of life of patients with PCa after ADT may be reduced due to maladjustment of androgen levels or fear of cancer recurrence (FCR). CBT, which is a non-drug therapy psychological intervention, can improve patients' confidence in the treatment of diseases by correcting patients' cognitive bias, enhancing patients' beliefs and changing attitudes towards their own problems from irrational knowledge to rational knowledge.[43] In addition, CBT effectively improves the quality of life in patients with cancer, with anxiety, depression,[44] fatigue,[45] insomnia,[30 46] hot flashes,[47] sexual dysfunction,[48] and so on. In an RCT of blended cognitive behavioural therapy (bCBT) to reduce the severity of FCR in cancer survivors, FCR scores were significantly lower in the bCBT group than in the care as usual group.[49] Another study has found that parents of children with cancer often experienced mental pressure, but post-traumatic stress symptoms, depression and anxiety were significantly improved by providing CBT training to parents.[50] Therefore, we plan to study the effectiveness of CBT in patients with PCa after ADT. If the results of the study prove that CBT is an effective treatment for patients with PCa after ADT, it will improve the quality of life in patients with PCa after ADT and save on medical expenses.

This systematic review has the following limitations: (1) In order to ensure the quality of research, we have formulated strict standards for admission, which can lead to a limited number of studies. Therefore, it is recommended to increase the corresponding RCTs. (2) Because of language limitations, this study only included literature in Chinese and English, and does not include any literature in other languages. We should consider including literature in other languages. (3) The quality of original trials will affect the quality of the pooled effects. In order to demonstrate these effects on our assessment and promote the use of evidence in practice, we will assess the quality of evidence for the primary outcomes.

Contributors FY and YY contributed to the design of the research and concept of the review. FY and BZ developed the search strategy. MJ and BZ will search,

select and identify the studies included, and extract data independently. DC will be the third reviewer for study selection and data extraction. FY and MJ drafted the manuscript. All authors have approved the publication of this protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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