The effectiveness of mindfulness-based stress reduction intervention on alleviating anxiety and depression in postoperative patients with cervical cancer

A protocol for systematic review and meta-analysis

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Abstract
Background: Surgical treatment for cervical cancer, as a stressor, largely leads to strong psychological reactions to stress like anxiety and depression. Whether mindfulness-based stress reduction (MBSR) can alleviate anxiety and depression in patients after cervical cancer surgery is controversial. Therefore, we aim to perform a meta-analysis involving randomized controlled trials analyzing the effect of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery, thus providing evidence-based medical evidences for nonpharmacological interventions.

Methods: Randomized controlled trials analyzing the effect of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery will be searched in online databases, including Cochrane Central Register of Controlled Trials Repositories, PubMed, Embase, Web of Science, Chinese Science Citation Database, China National Knowledge Infrastructure, Chinese Biomedical Literature Database, Chinese Scientific Journal Database, and Wan Fang Data. After screening eligible studies, we will perform a meta-analysis on the effect of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery.

Results: The results of this meta-analysis will be submitted to a peer-reviewed journal for publication.

Conclusion: This study will provide reliable evidence-based evidences for the effects of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery.

Ethics and dissemination: Ethical approval was not required for this study. The systematic review will be published in a peer-reviewed journal, presented at conferences, and shared on social media platforms.

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Abbreviations: $I^2$ = I-square, MBSR = mindfulness-based stress reduction.

Keywords: anxiety, cervical cancer, depression, meta-analysis, mindfulness-based stress reduction, protocol

1. Introduction
Cervical cancer is one of the most common gynecological malignancies. It is reported that about 200,000 women die of cervical cancer each year worldwide, and more than 130,000 new cases of cervical cancer are diagnosed each year in China. Cervical cancer is usually treated by surgery after diagnosis. As a kind of stressor, surgical treatment of cervical cancer will, to a large extent, lead to strong stress psychological reactions like
anxiety and depression. Improper handling of stress response can cause psychological disorders to varying extents.\[^4,5\] Adverse psychological conditions like anxiety, depression and fear can negatively affect psychological and emotional well-being and reduce the quality of survival of patients.\[^6\] Therefore, interventions to alleviate negative emotions in patients after cervical cancer surgery are particularly important.

Mindfulness-based stress reduction (MBSR) is a nonpharmacological intervention based on positive thinking, which enhances the ability to live with stress and improves quality of life by positive thinking sessions involving positive diet, meditation, body scanning, yoga, nonjudgmental attitudes, and management of stressors and emotions.\[^16–19\] It has been successfully applied in foreign countries for emotion management, stress relief and clinical treatment of illnesses.\[^11,12\] At present, MBSR is widely used in the field of psychotherapy at abroad. Moreover, it has been used in the treatment of cervical cancer patients in other countries, which has achieved positive results.\[^13\]

MBSR has become one of the treatment methods for the systematic treatment of cancer patients at home and abroad. MBSR can be used as a nonpharmacological intervention for postoperative psychological intervention in cervical cancer. However, clinical evidences are scant.\[^14,15\] Therefore, in this study, we perform a meta-analysis to assess the effect of MBSR on alleviating anxiety and depression levels in patients after cervical cancer surgery.

2. Methods

2.1. Protocol

Under the guidance of the preferred reporting items for systematic reviews and meta-analysis protocols, this protocol of systematic review and meta-analysis has been drafted.\[^16\] The research framework has been registered on the open science framework (Registration Number: DOI 10.17605/OSF.IO/EXUM3).

2.2. Ethics

Since this is a protocol without patient recruitment and personal information collection, the approval of the ethics committee is not required.

2.3. Eligibility criteria

2.3.1. Types of studies.

i) Randomized controlled trials;

ii) Publication language in Chinese or English;

iii) Outcome indicators will include testing data on depression and anxiety.

2.3.2. Types of participants. Adult patients over 18 years old after cervical cancer surgery.

2.3.3. Types of interventions. Patients in the control group will be given conventional care measures, while those in the experimental group will receive MBSR.

2.3.4. Types of outcome measurements. Any rating scale that describes anxiety and depression.

2.4. Exclusion criteria

1. Studies with incomplete data;

2. Repeatedly published literatures;

3. Review articles, techniques, case reports, letters to the editor, and editorials.

2.5. Searching strategy

We will systematically search relevant randomized controlled trials published before January 2022 in the following databases: Cochrane Central Register of Controlled Trials Repositories, PubMed, Embase, Web of Science, Chinese Science Citation Database, China National Knowledge Infrastructure, Chinese Biomedical Literature Database, Chinese Scientific Journal Database, and Wan Fang. Searching strategy in Pubmed was shown in Table 1, which will be suitable in searching other online databases.

2.6. Data screening and extraction

The literature selection process was listed in Figure 1. Two investigators will independently review all abstracts and full-texts according to inclusion and exclusion criteria. Any disagreement will be resolved through a discussion with a third investigator.

| Table 1 |
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| PubMed search strategy. |
| Number | Search terms |
| #1 | Uterine cervical neoplasms[MeSH] |
| #2 | Cancer of cervix[Title/Abstract] |
| #3 | Cancer of the cervix[Title/Abstract] |
| #4 | Cancer of the uterine Cervix[Title/Abstract] |
| #5 | Cervical cancer[Title/Abstract] |
| #6 | Cervical neoplasms[Title/Abstract] |
| #7 | Cervix cancer[Title/Abstract] |
| #8 | Cervix neoplasms[Title/Abstract] |
| #9 | Neoplasms, cervical[Title/Abstract] |
| #10 | Neoplasms, cervix[Title/Abstract] |
| #11 | Uterine cervical cancer[Title/Abstract] |
| #12 | Cancer, cervix[Title/Abstract] |
| #13 | Cancer, uterine cervical[Title/Abstract] |
| #14 | Cancers, cervix[Title/Abstract] |
| #15 | Cancers, uterine cervical[Title/Abstract] |
| #16 | Cervical cancer, uterine[Title/Abstract] |
| #17 | Cervical cancers, uterine[Title/Abstract] |
| #18 | Cervical neoplasm[Title/Abstract] |
| #19 | Cervical neoplasm, uterine[Title/Abstract] |
| #20 | Cervical neoplasms, cervix[Title/Abstract] |
| #21 | Cervix neoplasm[Title/Abstract] |
| #22 | Neoplasms, cervical[Title/Abstract] |
| #23 | Neoplasms, cervix[Title/Abstract] |
| #24 | Neoplasms, uterine cervical[Title/Abstract] |
| #25 | Neoplasms, uterine cervix[Title/Abstract] |
| #26 | Uterine cervical cancers[Title/Abstract] |
| #27 | Uterine cervical neoplasms[Title/Abstract] |
| #28 | OR1–27 |
| #29 | Mindfulness-based stress reduction[Title/Abstract] |
| #30 | MBSR[Title/Abstract] |
| #31 | OR29–30 |
| #32 | Randomized controlled trials as topic[MeSH] |
| #33 | Clinical trials, randomized[Title/Abstract] |
| #34 | Controlled clinical trials, randomized[Title/Abstract] |
| #35 | Trials, randomized clinical[Title/Abstract] |
| #36 | Random n[Title/Abstract] |
| #37 | OR32–36 |
| #38 | #28 and #31 and #37 |
Two investigators will extract data from eligible studies using a predesigned information sheet and cross-check them. Any uncertainty will be solved by discussing with the third investigator. The following data will be extracted: first, author, year of publication, study population, study type, interventions, time of measurement, and relevant outcome indicators.

2.7. Quality evaluation
Two authors will independently assess the risk of bias of included studies using Cochrane Collaboration risk of bias assessment tool, and all disagreements will be resolved by discussing with a third investigator.

2.8. Statistical analysis
Rev-Man 5.3 software will be applied for the meta-analysis. The pooled effects will be estimated by using the standardized mean differences and its 95% confidence interval. Heterogeneity between studies will be assessed by I-square ($I^2$) and Q-statistic ($P < .10$), and $I^2 > 50\%$ will be recognized as heterogeneity. [17] If $P \geq .1$ and $I^2 \leq 50\%$, a fixed-effect model (Mantel–Haenszel method) will be adopted for analysis; otherwise, a random-effect model will be used.

2.8.1. Dealing with missing data. Insufficient or missing data in the literature will be obtained by e-mailing the authors. If data are still not available, only the current available data will be analyzed and the potential impacts will be discussed.

2.8.2. Subgroup analysis. Subgroup analysis will be carried out according to the duration of intervention.

2.8.3. Sensitivity analysis. We will conduct sensitivity analysis by analyzing the remaining studies after removing one study at each time.

2.8.4. Publication bias. If the number of included studies is no less than 10, a funnel chart will be used to assess publication bias. [18,19]

3. Discussion
Recently, various nonpharmacological interventions on alleviating negative emotions after cancer surgery have emerged and increasingly applied. [20–22] There is growing evidence that MBSR can alleviate anxious and depressive symptoms, and promote healthy outcomes in patients after cervical cancer surgery. MBSR is a cognitive therapy based on mindfulness meditation aiming to cultivate positive thinking. It helps people to develop the ability to cope with the present experience in a nonjudgmental or open-hearted way. [23,24] MBSR has been widely used clinically, commonly in breast cancer patients to reduce psychological symptoms and enhance positive psychological constructs, which has obtained a significant success. [25–27] However, the specific
effects of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery may differ from the subject, timing, frequency, method, and duration of the intervention. Based on the principles and methods of evidence-based medicine, the present study aims to further clarify the effects of MBSR on alleviating anxiety and depression in patients after cervical cancer surgery, and to provide a basis for clinical application.

Author contributions

Conceptualization: Hongcheng Zhu, Xiaoju Yang.
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