




BMJ Open Effectiveness of qigong and tai chi in the quality of life of patients with cancer: protocol for an umbrella review

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ABSTRACT

Introduction Qigong and tai chi (QTC) have been adopted by many patients with cancer as a complementary treatment with their conventional mainstream cancer management. Findings from current systematic reviews are inconsistent. Some research indicated that either qigong or tai chi interventions could enhance quality of life (QoL), and improve cancer-related symptoms such as fatigue, sleep disturbance and anxiety; while others argued that there was a lack of efficacy of QTC on QoL improvement. This umbrella review will analyse and synthesise the findings from published systematic reviews and meta-analyses regarding the effectiveness of QTC in the QoL of patients with cancer. Twenty-five databases will be searched from their respective inception to December 2021.

Methods and analysis We will conduct a search in 21 English and 4 Chinese databases to identify qualified systematic reviews and meta-analyses. Two reviewers will independently screen all the titles and abstracts, and determine whether the article meets the inclusion criteria. After the identified systematic reviews and/or meta-analyses are confirmed, important information from each article will be extracted to the characteristics table by two reviewers independently. Two reviewers will independently analyse the quality of the selected reviews based on the Assessment of Multiple Systematic Reviews guideline. Findings from the systematic reviews and/or meta-analyses will be summarised and reported.

Ethics and dissemination This review does not require ethics approval as the study is based on the published articles. The results drawn from the present review will be submitted to peer-reviewed journals for publication or presented at conferences.

PROSPERO registration number CRD42021253216.

BACKGROUND

Cancer has been recognised as a severe threat to regional, national and global development. The number of new cancer cases in the year 2020 was 19.29 million worldwide. The most common cancer types were breast (11.7%), lung (11.4%), colorectum (10%), prostate (7.3%), stomach (5.6%), liver (4.7%), cervix uteri (3.1%) and oesophagus (3.1%) cancer.¹ Based on patient-reported outcomes, patients with cancer may present with various

Strengths and limitations of this study

- This umbrella review will be based on the evaluation of evidence from the existing systematic reviews and meta-analyses.
- This proposed review will involve 21 English databases and 4 Chinese databases to ensure a comprehensive literature search.
- It will conduct a quality assessment on the included systematic reviews and meta-analyses.
- It will provide a comprehensive assessment, qualitatively and quantitatively, regarding the effectiveness of qigong and tai chi in the quality of life of patients with cancer.
- Only reviews published in English and Chinese will be included.

symptoms such as nausea, vomiting, pain, fatigue, physical dysfunction, sleep disturbance, anxiety and depression.² These symptoms could be caused by cancer itself, and subsequent treatment such as surgery and chemotherapy, which have significantly impeded the quality of life (QoL) of patients with cancer.

Qigong and tai chi (QTC) are the meditative movement and mind-body exercises of eastern medicine, which originated from China more than 4000 years ago.³ Qigong is considered to be able to strengthen or balance the subtle energy (Qi) circulation throughout a person's entire body; achieve the optimal harmonisation of the body, mind and spirit of a person; and thus improve overall health and prevent diseases.⁴ Many randomised controlled trials (RCTs) have been carried out to investigate the clinical effects and safety of qigong on the QoL of patients with cancer, particularly the psychological and physiological aspects including bone density, cardiopulmonary effects, physical function, falls, balance and related risk factors, anxiety, depression, immunity and inflammation-related responses.^{5 6}

Research conducted in the USA regarding the interference of chemotherapy on oncology patient's QoL indicated that 36% of patients suffering from acute chemotherapy-induced nausea and vomiting, and 59% of participants developed delayed chemotherapy-induced nausea and vomiting during the first chemotherapy cycle, which impacted on the patient's QoL significantly at cancer survivorship. Similar results were presented at chemotherapy cycles 2 and 3.⁷

During 2000–2010, a research project was conducted on peripheral neuropathy induced by chemotherapy on 191 Dutch ovarian cancer survivors. Among them, 67.5% reported feeling tingling and numbness in hands/feet or fingers/toes. Results from linear regression analysis showed that the increasing cycles of chemotherapy were associated with higher neuropathy scores, which lowered patients' overall QoL, with increased symptoms including pain, fatigue, insomnia, as well as physical, emotional and financial issues. The study found that the side effects of chemotherapy could persist long term after the treatment, and impact on the patient's QoL even 12 years on treatment.⁸ Therefore, many cancer sufferers are seeking alternative approaches such as QTC to improve their QoL.⁹

Many RCTs have been carried out to investigate the clinical effects and safety of QTC on the QoL of patients with cancer.^{5 6} Published systematic reviews (SRs) reported that QTC may have positive effects on improving the overall QoL of patients with cancer, such as physical functioning, fatigue, sleep quality and psychological symptoms^{10 11}; whereas other SRs did not observe significant differences.¹² Thus, an umbrella review has become necessary.

OBJECTIVES

This study aims to synthesise the findings of the SRs and meta-analyses regarding the effectiveness of QTC in the QoL of patients with cancer in an umbrella review. It will address the following research questions: (1) Is QTC effective in improving the QoL of patients with cancer, such as strengthening physical fitness, reducing fatigue, improving sleep quality and enhancing their emotional well-being? (2) If there are any effects, are the results related to a specific type of cancer, type of QTC, QoL instrument or other variables?

METHODS

This study is designed as an umbrella review of the published SRs and meta-analyses. This protocol is presented based on the statement of Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols (online supplemental file 1). The protocol has been registered with the Prospective Register of Systematic Reviews (PROSPERO) (CRD42021253216).

Selection criteria

Types of studies

Papers that were published in English or Chinese language and classified as SRs and/or meta-analyses will be considered for inclusion.

Types of participants

This study will focus on adult patients (≥ 18 years old) who have been diagnosed with any types of cancer and any stages of cancer, and have been practising any type of QTC.

Types of interventions

Any type of QTC will be considered for inclusion if it was used as the intervention and its effects were investigated in the review. QTC may consist of moving meditation or gentle relaxation exercises such as Guolin Qigong, rather than practice focused on meditation and spiritual enlightenment.

Comparator(s)/control

The intervention in the control group can be active or inactive. Active control may include, but not limited to, sham qigong, routine care, other physical exercises or psychosocial support therapy; whereas inactive control may be described as waitlist, no treatment or blank control. The standard healthcare or routine care is allowed to be used in both groups.

Types of main outcome measures

The main outcome measures will be the QoL of patients with cancer, including both cancer-specific QoL and general QoL. Cancer-specific QoL measured by validated instruments will be included for meta-analyses, such as Functional Assessment of Cancer Therapy-General, Functional Assessment of Cancer Therapy-Breast, and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire. General QoL will be analysed if it was assessed by a validated tool such as Short-Form Health Survey, WHO Quality of Life Brief Questionnaire or other scales.

Types of additional outcome measures

Additional outcome measures will include patient-reported physical-specific symptoms, such as fatigue and sleep. Data will be synthesised if fatigue was measured by such instruments as Brief Fatigue Inventory, Multidimensional Fatigue Symptom Inventory-Short Form, Fatigue Symptom Inventory, Functional Assessment of Chronic Illness Therapy-Fatigue, Piper Fatigue Scale and Multidimensional Fatigue Inventory; and sleep quality was assessed by Pittsburgh Sleep Quality Index, General Sleep Disturbance Scale or other scales. Patients' psychological-specific symptoms will be analysed if they were assessed by Depression Anxiety Stress Scale-21, Beck Depression Inventory, Center for Epidemiologic Studies Depression, Profile of Mood State or other scales. Safety data (ie, adverse events) of the QTC intervention will be descriptively reported.

Search strategy

To identify the SRs and meta-analyses of QTC on the QoL of patients with cancer, we will search the following databases through university's library: AcuBriefs, Allied and Complementary Medicine, Cumulative Index of Nursing and Allied Health Literature, Cochrane Database of Systematic Reviews, Elton B Stephens Co Host, Excerpta Medica Database, Electronic Management Research Library Database, Education Resources Information Center, Indian Medical, Informit, Ingenta, Korean Medical, Latin American and Caribbean Health Sciences, metaRegister of Controlled Trials, ProQuest, Psychological Information Database, PubMed, Science Direct, Scopus, Wiley Online Library and the PROSPERO register. Considering that QTC originated from China, and is widely adopted in China, we will search four Chinese databases including China National Knowledge Infrastructure, Chinese BioMedical Literature Database, Wanfang Data and VIP Database for Chinese Technical Periodicals. The combination of the following terms and their synonyms will be used to search the above-mentioned databases: Qigong, Qi gong, Tai Chi, Taichi; quality of life; cancer, tumor, oncology; systematic review and meta-analysis. Both Medical Subject Headings (MeSH) terms and free text will be used for literature retrieval. The corresponding Chinese characters will be used to search Chinese databases.

Screening and selection

After a thorough search of the selected biomedical journal databases, all the hits from each database will be imported to EndNote. Two reviewers (JX and HL) will then independently go through all the titles and abstracts, and determine whether the article is meeting the inclusion criteria. If a decision cannot be made, the full text of the selected articles will be downloaded. Then the two reviewers will further independently analyse and evaluate each of the full-text articles based on the inclusion criteria. If there is any disagreement, they will discuss or consult a third senior reviewer (AWHY) to reach a consensus.

Data extraction

After the SRs and/or meta-analyses are identified, data from each included SR will be extracted to the characteristics table by the two reviewers (JX and HL) independently. For each included SR and/or meta-analysis, the data to be extracted will include characteristics of the article (article title, authors, published year, published language), participants (sample size and type and stage of cancer), intervention (type of QTC, duration, frequency, and session length of QTC for both treatment and control groups), outcome measure (eg, QoL instrument), original authors' conclusions, setting (hospital, community clinic or private clinic), country/region and funding sources. When there are missing data or the information is unclear, the corresponding authors of the included articles will be contacted in an attempt to retrieve the critical information.

Quality assessment

Two reviewers (JX and HL) will independently assess the methodological quality of included reviews based on the Assessment of Multiple Systematic Reviews (AMSTAR) guideline.¹³ The AMSTAR 2 tool will be adopted, including 16 items to evaluate the following: (1) population, intervention, comparator group, outcome; (2) protocol; (3) selection of the study designs; (4) search strategy; (5) study selection in duplicate; (6) data extraction in duplicate; (7) list of excluded studies; (8) included studies in detail; (9) satisfactory technique for risk of bias (RoB); (10) sources of funding of included studies; (11) appropriate methods for meta-analyses; (12) the potential impact of RoB; (13) RoB in individual studies when discussing the results; (14) heterogeneity; (15) publication bias and (16) conflict of interest.¹⁴

Strategy for data synthesis

A combination of narrative and quantitative methods will be used for data synthesis. The information related to the type of QTC, number of RCTs, type of cancer, number of participants, QoL instruments, adverse events and AMSTAR results will be descriptively summarised and reported. For QoL measures (eg, fatigue and sleep), data will be synthesised when data from the same outcome are available from three or more included studies. Mean difference (MD) will be applied when the same scale was used to measure the outcomes, whereas standardised MD will be used when the outcomes were measured by different scales. All the results will be presented with a 95% CI. The random-effects model will be used to minimise the potential heterogeneity when the I^2 value is over 50%.

Analysis of subgroups or subsets

Subgroup analysis will be conducted regarding the method of QTC intervention, QoL physical and psychological factors, comparisons, cancer types and QoL instruments, when applicable.

Patient and public involvement

No patient involved.

DISCUSSION

In recent years, the cancer survivor rate has been increasing, and the 5-year prevalence was 50.55 million worldwide in 2020.¹⁵ Thus, it is critical to improve the QoL of patients with cancer and reduce the cancer-related symptoms caused by the diseases and conventional treatment physically and psychologically.

QTC have been a popular practice by patients with cancer for self-management.¹⁶ SRs and meta-analyses conducted regarding the effectiveness of QTC in the QoL of patients with cancer may improve precision and increase power from individual RCTs. Contradictory results from the published reviews have urged us to perform an umbrella review.

This proposed review will include 21 English and 4 Chinese databases from multiple regions to enable a comprehensive literature search. Due to the language barrier, our search strategy will only be limited to English and Chinese languages. SRs and meta-analyses published in other languages will be missed out inevitably.

This umbrella review will be conducted strictly following the methodology specified in the Cochrane Handbook for Systematic Reviews of Interventions.¹⁷ Data analyses will be challenging as it is expected to include reviews with different quality RCTs, variety of interventions (types of QTC, duration, frequency) and various cancer types. The heterogeneity of the included studies will trigger the difficulty in interpreting the data. Subgroup analyses will be performed as per cancer types and cancer stages as well as comparisons of interventions to address this potential high heterogeneity if the number of included studies is sufficient. These analyses will assist the interpretation of implications for clinical practice.

It is also worth noting that the selection of an appropriate instrument for evaluating the QoL of patients with cancer is critical as there are diverse QoL assessment tools developed for a wide range of clinical conditions.¹⁸ This umbrella review will summarise all the QoL instruments used in the included reviews and identify the most frequently used tools for investigating QTC's effects on the QoL of patients with cancer.

In the research domain of QTC for QoL in patients with cancer, this is the first umbrella review of SRs and meta-analyses to increase the understanding of QTC and its relationship to QoL. At present, clinical guidelines for cancer management do not include QTC. The findings from this present review may support the evidence-based practice of QTC for cancer care. In addition, this research may generate evidence for insurance companies and health funds to consider rebates for QTC training.

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Contributors Conceptualisation—JX, HL, DM-yS, VWSC and AWHY. Methodology—JX, HL and AWHY. Software—JX, HL and AWHY. Validation—JX, HL, DM-yS, VWSC and AWHY. Data analysis—JX, HL and AWHY. Writing (original draft preparation)—JX. Writing (review and editing)—JX, HL, DM-yS, VWSC and AWHY. Supervision—DM-yS, VWSC and AWHY.

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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.

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review. *Int J Nurs Stud* 2013;50:688–707.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO registration number: CRD42021253216
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Contributors section
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Acknowledgements and funding statement sections
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Background section
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Objectives section
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Selection criteria section
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Search strategy section

Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Search strategy section
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Methods section
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Screening and selection section
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Data extraction section
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Data extraction section
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Types of main outcome measures and types of additional outcome measures sections
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Quality assessment section
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Strategy for data synthesis section
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	Strategy for data synthesis section
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Analysis of subgroups or subsets section
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Quality assessment section
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Discussion section

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.