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Role of traditional, complementary and integrative medicine for people with limb amputation: a scoping review

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 February 2024 and was last updated on 05 February 2024.

INTRODUCTION

Review question / Objective This scoping review aims to identify the types of available evidence in a field of traditional, complementary, and integrative medicine for people with limb amputation.

Rationale Traditional, complementary and integrative medicine (TCIM) is widely used for various health problems. The World Health Organisation endorsed the use of TCIM for improving health and well-being. Selected interventions, such as acupuncture and yoga, are based on evidence from randomised trials. Other types of TCIM interventions are also used, but their role on the management of pain and psychological conditions, which are prevalent in amputee population, remains unclear. Risk of amputation

either due to poorly managed underlying pathology such as diabetes or due to traumatic injuries are higher in resource-limited settings than in high-income countries, where TCIM can fill the gap between the unmet needs of long-term postamputation care and insufficient healthcare resources. Given little information on the potential benefit of TCIM for amputees against substantial unmet need for symptom management and functional improvement, a comprehensive scoping review of available evidence of TCIM for amputee is justified.

Condition being studied People with limb amputation faces multiple physical, psychological, socioeconomic challenges in their life. Pain not only on the amputated limb but also on the joints on the unaffected limb or low back pain are common. Prevalence of psychological

comorbidities, including depression, anxiety, and post-traumatic stress disorder, are high in the affected population. Impaired quality of life and long-term disability may persist and compromise social integrity and financial security of the patients. Among the aforementioned problems, chronic pain and mental health issues are known as the major attributable sources to the complexity of care for those with limb amputation. Interventions for patients with limb amputation include analgesics, paraspinal and/or epidural nerve block, mirror therapy and imaginary education. Evidence on the effects of such treatments either as standalone therapy or as combined care remains limited. Patients with chronic pain refractory to the existing treatments and long-term disability often seek TCIM, although their evidence on the role for managing post-amputation symptoms and dysfunctions are not well addressed.

METHODS

Search strategy Search terms include TCIM-related terms including but not limited to acupuncture, moxibustion, cupping, traditional medicine, folk/alternative therapy, complementary therapies, mind-body interventions, herbal medicine and hypnosis (i.e., group 1) as well as amputation-related terms including but not limited to phantom limb pain, residual limb pain, stump pain and amputation (i.e., group 2).

We searched the following databases.

MEDLINE (Pubmed) from the inception to 19th Sep 2023.

Embase from the inception to 19th Sep 2023

Cochrane Central Register of Controlled Trials (CENTRAL) from the inception to 19th Sep 2023

KoreaMed from the inception to 19th Sep 2023.

OASIS from the inception to 19th Sep 2023.

CAJ from the inception to 19th Sep 2023.

PROQUEST from the inception to 19th Sep 2023.

The World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP; apps.who.int/trialsearch) was searched to identify ongoing trials at 19th Sep 2023.

Reference lists of literature reviews will be screened to retrieve potentially relevant reports.

Participant or population Adult patients with limb amputations regardless of underlying etiology (e.g, both traumatic and non-traumatic) will be eligible.

Intervention Traditional, complementary and integrative medicine interventions including but not limited to acupuncture, moxibustion, cupping, traditional medicine, folk/alternative therapy, complementary therapies, mind-body

interventions, herbal medicine and hypnosis for treating symptoms after limb amputation will be eligible. Interventions to prevent limb amputation will not be included.

Comparator All types of comparator interventions will be eligible (if applicable).

Study designs to be included Both uncontrolled observational studies which report changes of conditions after TCIM treatment and controlled trials which compare TCIM with other interventions will be eligible. Types of observational study will include case report, uncontrolled case-series, cohort studies and retrospective chart reviews. Types of controlled trial will include non-randomised controlled trials and randomised controlled trials.

Eligibility criteria Preclinical studies, qualitative studies, studies to prevent limb amputation, study protocols and studies regarding interventions which are not based on TCIM will be excluded.

Information sources A researcher (GHS) will search the electronic databases mentioned above to retrieve potentially relevant reports. Ten percent of the initially retrieved reports will be independently screened based on the title and abstract by two researchers (GHS and YNO). After fulfilling sufficient inter-rater agreement of screening (i.e., kappa value of 0.9 or more), a researcher (GHS) will complete the screening process. Full-text screening will be independently conducted by two researchers (GHS and YNO). A senior researcher (KHK) will arbitrate any disagreement between two researchers during screening process. We will contact the corresponding author of ongoing trials, grey literature via e-mail to request further information if necessary.

Main outcome(s) Describe the outcomes of the review including all relevant details such as timing and effect measures.

This is a scoping review thus we will not quantitatively estimate the effects of TCIM. Instead, we will descriptively summarize all reported clinical outcomes and timing of outcome measure. Expected clinical outcomes include pain associated with limb amputation, pain at non-amputated body parts, sleep disorders, psychological health outcomes, dysfunction and quality of life.

Additional outcome(s) Harms of TCIM interventions will be descriptively illustrated.

Data management We will use Endnote version 19 to manage records during the review process. Bibliographic information and the extracted data will be summarized using the Excel spreadsheet. A pre-defined data extraction sheet per individual studies will be used to aid data extraction sheet. One researcher (GHS) will manage and extract the data under supervision of the principal investigator (KHK).

Quality assessment / Risk of bias analysis This is a scoping review and the formal quality assessment will not be conducted.

Strategy of data synthesis Descriptive characteristics of the included studies, including design, population, intervention, comparator, and outcomes, will be tabulated. Qualitative synthesis of the data based on the types of clinical outcomes will be performed. Other relevant information regarding the research question will also be summarised.

Subgroup analysis No subgroup analysis will be performed.

Sensitivity analysis No sensitivity analysis will be performed.

Language restriction No language restriction will be imposed.

Country(ies) involved South Korea, United Kingdom.

Keywords limb amputation; phantom limb pain; acupuncture; traditional medicine; complementary medicine; integrative medicine; scoping review.

Dissemination plans The protocol and the main results will be presented in academic conferences and be published on the peer-reviewed journals.

Contributions of each author

Author 1 - Kunhyung Kim - Author 1 conceived the study; drafted the protocol; obtained the research grant; is a principal investigator.

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Author 2 - Kahyun Seo - Author 2 drafted the protocol with author 1; developed the search formula; searched the database; screened the hits and will review the full-text, extract data and draft the manuscript.

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Author 3 - Seonhee Kim - Author 3 gave critical comments for the draft version of the protocol; will draft the main manuscript with other authors.

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Author 4 - Yoona Oh - Author 4 drafted the protocol with other authors; screened the 10% random sample of the initial screened hits; will review the full-text and draft the manuscript with other authors.

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