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Review article

# The effect of traditional Chinese medicine education programs on people's subhealth status: A systematic review of clinical studies



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#### ABSTRACT

*Introduction:* Subhealth status is an intermediate state between health and disease. If relevant risk factors are addressed appropriately, better health can be restored. Traditional Chinese medicine (TCM) health education is helpful for cultivating self-care awareness, ensuring the accumulation of health knowledge and modifying poor habits and behaviors. This review aimed to systematically review the evidence for the effect of TCM health education on subhealth status.

*Methods:* The Cochrane library, PubMed, and four Chinese databases were searched for clinical studies exploring the effect of TCM education on subhealth status. Randomized controlled trials (RCTs), quasi-RCTs, cohort, case-control, and cross-sectional studies were included. The primary outcomes were prevalence of subhealth and subhealth status score. Appropriate tools were used to assess quality (e.g. risk of bias tool for RCTs).

*Results*: Of the 1559 citations, one RCT and four cross-sectional studies were included after 125 full-text reading. The quality of all included studies was generally poor. A meta-analysis of three cross-sectional studies (n = 2802) showed no difference in subhealth prevalence between people accepting TCM education and those not (Risk ratio 0.92; 95% confidence interval (CI) 0.82–1.02). The trial result (n = 80) favored integration therapy of TCM education and general health education versus general education on overall subhealth status (Mean difference -13.90; 95% CI -19.54 to -8.26).

*Conclusions*: The effect of TCM education on subhealth is unclear based on the current evidence, as cross-sectional studies cannot provide a causal link and only one poor quality RCT was available. Better designed RCTs are needed to provide definitive conclusions.

#### 1. Introduction

As the definition of health changes from 'a merely absence of disease or infirmity' to 'a state of complete physical, mental and social well-being', a new concept of a health gap known as a 'grey state', 'subhealth status' or 'latent symptoms state' has been described [1–3]. It refers to an intermediate state between health and diseased states and is characterized by some disturbances in psychological, physical or behavioral states, or disturbances or anomalies in some indices or in a medical examination, but with no typical pathological features, and lasting for at least 3 months [2,4]. Fatigue, sleeping disorders, amnesia, bodily pain, anxiety, depression, and disturbance in social activities are the common problems for many subhealth suffers [5].

In China, subhealth has become a public health challenge as a large number of people suffer this condition [5]. According to a survey of 1473 randomly recruited adults in central region of China, the prevalence of subhealth was 36.6%, almost as high as that of disease which was 43.1% [2]. Moreover, as subhealth is reversible and dynamic, people could restore their health if they modified aspects of their life appropriately and in a timely manner. If not attended to subhealth status will further proceed to diseases or even led to the ultimately death [6,7]. So, to intervene in pre-disease condition, that is subhealth status, is as important as in treating disease.

Subhealth is mostly associated with lifestyle risk factors including excessive pressure, unbalanced diet, and insufficient exercise [4,8]. The recommended management strategy to reduce risk factors is changing unhealthy lifestyle behaviors [9]. The benefit of lifestyle intervention has been demonstrated in a randomized trial showing that an intensive lifestyle modification program can favorably influence risk-factor profiles in high risk individuals of cardiovascular diseases [10].

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Traditional Chinese medicine (TCM) education programs are set to educate people on health prevention knowledge and behaviors, under the 'preventive treatment' theory in TCM (intervene before the disease actually attacks). Patients will be given suggestions based on varied channels to facilitate individuals to adopt healthy lifestyles such as written materials (e.g. booklets), mobile applications, face-to-face counseling [11]. In clinical practice, TCM education is sometimes incorporated with other TCM therapies with the aim of preventing disease [12,13]. Lin and his colleagues found that health education in combination with acupuncture, moxibustion and cupping brought improvements in psychological symptoms, depression, and anxiety domains of patients with subhealth status [13].

Considering the potential effect of TCM education programs for preventing diseases, 'TCM health prevention' is very popular in China attracting people to chase after related TV programs and mobile applications and even medical products [14]. Indeed, the effectiveness of TCM education programs has not yet determined. As far as we know, there is no systematic and explicit study on this topic, as previous studies are more focused on associated risk factors and etiology analysis [15–17]. This review is an initial attempt to explore the effect of TCM education on subhealth status.

#### 2. Methods

The protocol of this review was registered at PROSPERO (NO: CRD42016042079). And we conducted and reported the review according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement [18].

#### 2.1. Eligibility criteria

Clinical studies with control group, including randomized controlled trials (RCT), non-randomized controlled trials, cohort, casecontrol, and cross-sectional studies in which the data on subhealth status of participants could be compared between groups were eligible (we thought case-control studies should also be eligible for our objectives, so we added this type to the protocol). We included studies if it provided both data on TCM education and subhealth status for us to compare and analyze. Subhealth status were defined according to definitive diagnostic criteria or by clinicians or researchers. Gender, age, and nationality were not limited. TCM education for health prevention with no limitation on the method of delivery was explored as the intervention or exposure factor, compared with no treatment or any other active intervention such as other types of education. Co-intervention was allowed for both groups but only if the co-intervention was administered equally. The primary outcome was incidence/ prevalence of subhealth, symptom changes as assessed by valid tools (e.g. CorneU Medical Index, Symptom Evaluation Form-90) or self-rating scales. Acquirement and maintenance of health knowledge and behavior were assessed as secondary outcomes.

#### 2.2. Search strategy

A systematic approach was used to search the literature for relevant articles. The following databases were searched: China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database, Wanfang database, Chinese Biomedical database (Sinomed), PubMed, and Cochrane Library from their inception till 2017 September. The search terms were: ("Traditional Chinese Medicine" OR "health prevention" OR "rehabilitation") AND ("education" OR "public dissemination" OR "counseling" OR "knowledge" OR "advice") AND ("subhealth status") when searching the databases. The specific search strategy of PubMed is shown as follows:

#1 Search (((Traditional Chinese medicine [Title/Abstract]) OR Health prevention [Title/Abstract]) OR rehabilitation [Title/Abstract]) #2 Search (((education [Title/Abstract]) OR Public dissemination [Title/Abstract]) OR Counseling [Title/ Abstract]) OR knowledge [Title/ Abstract]) OR advice [Title/ Abstract])

#3 Search subhealth status

#1 and #2 and #3

Reference lists of included studies were searched, and authors were contacted for additional articles.

#### 2.3. Study selection and data extraction

Two authors (NL and XF) screened the titles and abstracts and identified the studies according to the eligibility criteria. Any disagreements were resolved by discussion with a third author (HJC). Two authors (NL and XF) in duplicate extracted the data and assessed the methodological quality. For each included study, we extracted the following information: title, first author, publication year, type of studies, participants, methodological items, interventions and controls, outcomes and results, and author's conclusions, and entered into the predesigned extraction table through Excel software.

#### 2.4. Quality assessment

For randomized controlled trials and non-randomized controlled trials, we planned to use Cochrane Collaboration's Tool for Assessing Risk of Bias to assess the quality of studies [19]. Briefly, the reviewers considered the following points: selection bias (random sequence generation and allocation concealment), performance bias (blinding of study personnel), detection bias (blinding of outcome assessors), attribution bias (incomplete outcome data), reporting bias and other biases were judged as low, high, or unclear risk of bias.

For cross-sectional studies, it was planned to use an 11-item checklist which was recommended by Agency for Healthcare Research and Quality (AHRQ). Each item was judged as "yes", "no", or "unclear" [20].

We planned to assess the methodological quality of cohort studies or case-control studies according to Newcastle Ottawa Scale [21], but we did not find such studies.

#### 2.5. Data analysis

Revman 5.3 software was applied for data analysis. We provided summaries of effects for each study by calculating (standardized) mean differences (for continuous data), odds ratio (for dichotomous data within case control studies) or risk ratios (for dichotomous data within other type studies) with 95% confidence interval. If the studies were clinically different from each other, we planned to use a random-effects model to conduct the meta-analysis. We used the I-squared statistic to measure the percentage of the variability in effect sizes between studies that is due to heterogeneity rather than to sampling error. If there was substantial statistic heterogeneity (i.e.  $I^2 > 50\%$ ), we would try to explore and discuss possible reasons for heterogeneity. If the I-squared statistic was more than 75% or clinical or methodological heterogeneity exists, we used a narrative approach to data analysis rather than data synthesis through meta-analysis. Sensitivity analysis was intended to be conducted to explore the stability of the pooling results with small variation in the data or methods. The variation may include different choice of effect models for pooling analysis, inclusion/exclusion of trials with high risk of bias or with dubious data. Subgroup analysis would be done for different study types or different type of TCM education delivery way if available. A funnel plot was planned to be generated to explore publication bias if data from more than 10 studies was included in one meta-analysis.

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