INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effect of vitamins on temporomandibular disorders: a protocol of systematic review and meta-analysis

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Review question / Objective: **The purpose of this systematic review is to find out if vitamin supplementation had different effects than a placebo intervention, no treatment, or other types of interventions in temporomandibular disorder.**
Condition being studied: **Temporomandibular disorder (TMD), also known as temporomandibular joint (TMJ) syndrome, is a common disease of the oral and maxillofacial regions. TMD is a major cause of non-dental pain in the orofacial region. Epidemiological studies worldwide have confirmed a very high prevalence of TMJ dysfunction. Recently, a systematic review and meta-analysis of the prevalence of TMD, which included 21 articles and a total of 11,535 subjects, reported that the overall prevalence of TMD was approximately 31% for adults and the elderly, and 11% for children and adolescents.The etiology of TMD is multifactorial, as evidenced by the combination of psychological, physiological, structural, traumatic, mechanical, and genetic factors. Several factors, either individually or in combination, are responsible for TMD. Because the multifactorial etiology and mechanism of this condition are poorly understood, the management of TMD could be challenging. Indeed, TMD is poorly managed in dental practice. To date, effective therapies for TMD are still controversial and are urgently needed in clinical practice.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 November 2021 and was last updated on 23 November 2021 (registration number INPLASY2021110084).

INTRODUCTION

Review question / Objective: **The purpose of this systematic review is to find out if vitamin supplementation had different effects than a placebo intervention, no treatment, or other types of interventions in temporomandibular disorder.**

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METHODS

Participant or population: Patients who diagnosed with temporomandibular disorder according to Diagnostic Criteria for TMD (DC/TMD), regardless of gender, age.

Intervention: Vitamins are organic compounds that support health, growth, and reproduction, which are needed in small amounts to prevent clinical deficiencies and decline in health. Some studies indicate that vitamins are important in the etiology of TMD. Several systematic reviews have indicated that vitamin D supplementation could have a role in the management of chronic pain, and vitamin B and D supplementation could benefit TMD patients.

Comparator: A placebo intervention, no treatment, or other types of interventions will be included in control groups.

Study designs to be included: Randomized controlled trials or controlled clinical trials, regardless of language or publication state.

Eligibility criteria: (1) Population: patients who diagnosed with temporomandibular disorder according to Diagnostic Criteria for TMD (DC/TMD), regardless of gender, age; (2) Intervention: vitamins (not limited to particular types); (3) Control: a placebo intervention, no treatment, or other types of interventions.

Information sources: Multiple sources, including PubMed, EMBASE, Cochrane Library database, Web of Science, SCOPUS, China National Knowledge Infrastructure, Chinese Biomedical Literature, Wanfang databases, Weipu databases, ClinicalTrials.gov, and the World Health Organization (WHO) trial registry will be searched. The reference lists of all retrieved studies and relevant reviews will be searched manually to identify additional trials missed by the electronic literature search. When necessary, we will attempt to identify unpublished/ongoing randomized controlled trials or controlled clinical trials.

Main outcome(s): (1) Pain intensity, as expressed by the visual analog scale (VAS) score; (2) The change in VAS score in the vitamin and control groups.

Additional outcome(s): (1) The changes in TMJ function, which was assessed in terms of maximum active vertical opening (MAVO), maximum passive vertical opening (MPVO), lateral excursion (LE), and protrusive excursion (PE), expressed in millimeters; (2) Oral function (masticatory performance); (3) Electromyographic activity; (4) Pressure pain threshold; (5) Joint noises; (6) Tinnitus; (7) Adverse effects; (8) Quality of life; (9) Psychological satisfaction.

Data management: Endnote software will be used to manage all of the searched records. Two review authors will independently scan the titles and abstracts (when available) of all identified records. For each trial, we will enter the following information on a standard data collection

form that contained general information (authors, publication year, country of origin). Details of the participants included demographic characteristics, criteria for inclusion and exclusion, and sample size by study group. Details on the interventions included appliance type, treatment-related information, and details of the outcomes reported, including method of assessment and time intervals.

Quality assessment / Risk of bias analysis: Two review authors independently will assess random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and "other issues" for each study, using the "Risk of bias" tool recommended by the Cochrane Review. Any disagreements will be resolved by discussion, and whenever this approach failed, a third party (DYC) would be consulted.

Strategy of data synthesis: Relative risks will be calculated for dichotomous outcomes and mean differences will be calculated for continuous data; both were presented with 95% confidence intervals. Pooled effect sizes will based on the results of pain intensity (assessed by VAS) as well as MAVO, MPVO, LE, and PE values in millimeters. A qualitative analysis will be performed when the studies fail to provide data to be pooled for analysis. Publication bias will be assessed by examining funnel plots for the primary outcomes. Review Manager 5.4 (The Cochrane Collaboration) will be used to process the results.

Subgroup analysis: Heterogeneity will be examined according to the I2 statistic alongside the chi-squared test; when I2 is greater than 50%, the random-effects model will be applied. If the results of the study are heterogeneous, we will conduct a subgroup analysis for different reasons. Heterogeneity is manifested in the following several aspects, such as race, age, gender, vitamin types, doses, treatment course, and follow-up duration.

Sensitivity analysis: Sensitivity analysis will be conducted by sequential elimination of each study and excluding low quality studies to determine whether these excluded studies affect the conclusions.

Language: No language restrictions were imposed.

Country(ies) involved: China.

Keywords: Temporomandibular joint disorders; Temporomandibular joint; Temporomandibular disorders; Vitamins; Clinical trial; Systematic review; Analgesia.

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