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# 측두하악 장애 치료를 위한 수기치료에 대한 체계적 고찰의 프로토콜

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# Manual Therapy in the Treatment of Temporomandibular Disorders: A Protocol for a Systematic Review

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Objectives This systematic review will analyse randomised controlled trials (RCTs) of manual therapy in patients with temporomandibular disorders (TMDs) to evaluate the efficacy of this approach.

Methods RCTs will be identified in the following ten databases based on searches starting with their inception: MEDLINE, EMBASE, CENTRAL, four Korean databases as KoreaMed, DBPIA, NDSL, and RISS and three Chinese databases as CNKI, VIP and Wanfang. The quality of these studies will be analysed using the Cochrane risk of bias. A meta-analysis will be conducted, and subgroup analysis will be considered if comparatively large heterogeneity is detected.

Conclusions We plan to publish this systematic review in a peer-reviewed journal. Findings from this review may contribute to the treatment process in clinical situations. Trial registration number: PROSPERO 2015: CRD42015024090 (J Korean Med Rehab 2015;25(4):41-46)

Key words Temporomandibular disorders, Temporomandibular joint, Manual therapy, Manipulation

# Introduction»»»

#### 1 Description of the condition

Temporomandibular disorders (TMDs) are clinical

conditions characterised by abnormalities of the jaw muscles, temporomandibular joints, and surrounding structures<sup>1)</sup>. Symptoms are usually represented by pain and/or dysfunction in these structures<sup>2)</sup>. Dysfunction includes a limited range of motion and popping or clicking sounds during the closing or opening of the joints. In the United States, the lifetime prevalence of TMDs is  $6 \sim 12\%^3$ , many sufferers are  $20 \sim 40$  years of age, and the condition is observed more frequently in women than in men<sup>1)</sup>.

Two types of treatment can be used for TMD: conservative and operative methods. Conservative, reversible treatments should be the first choice before considering surgery<sup>4)</sup>. Conservative methods include occlusal splint, acupuncture, electrotherapy, manual therapy, and exercise.

## 2. Description of the intervention

Manual therapy (MT), also called musculoskeletal manipulation or manipulative therapy, is the most popular method for treating patients with spinal problems<sup>5)</sup>. Because TMDs are often associated with spinal symptoms and are problems of the jaw joints and surrounding muscles, MT can be used to improve these conditions<sup>6)</sup>. When MT is performed, the practitioner's hands or fingers are placed on the patient's body to assess, diagnose, and treat multiple symptoms<sup>7)</sup>. MT is also called Chuna in Korean medicine (Tuina in traditional Chinese medicine) and, along with acupuncture, moxibustion, and herbal therapy, has roots in both traditions. Chuna occupies a dominant position compared with acupuncture in that it is less invasive,

## 3. How the intervention might work

MT targets intra-oral, jaw, and spinal muscles and structures, as TMDs are thought to be related to musculature in those areas. Structural abnormalities of the oral cavity and the excessive contraction of jaw muscles undoubtedly affect the condition of TMDs. Manual intervention can bring improvement by relaxing contracted muscles and treating the trigger points of the muscles. TMDs can be also caused by long-term cervical dysfunction and vice versa<sup>8,9)</sup>. Thus, manipulation

of the cervical region can ameliorate the symptoms of TMDs. Manipulation of the spinal region brings benefits through a neurophysiological mechanism rather than a biomechanical one<sup>10)</sup>. A hypoalgesic effect<sup>11)</sup> and a reduction in inflammatory cytokines are also possible explanations for its therapeutic action<sup>12)</sup>.

Additionally, placebo mechanisms also contribute to the functional improvement and reduction of pain<sup>13)</sup>. Comparisons between experimental and placebo groups will be assessed in this review.

# 4. Why it is important to conduct this review

As the number of individuals exhibiting TMD symptoms grows, the need for a systematic review (SR) to assess the efficacy of manipulative therapy, a safe and reversible procedure, is becoming increasingly urgent. Two SRs published in 2006 investigated the use of manipulative therapy for TMDs<sup>6,14</sup>; however, several RCTs related to this topic have been published since then. Furthermore, the previous SRs included only English-language studies, and the authors did not perform a meta-analysis. Two SRs of manipulative therapy published in 2015<sup>15,16)</sup> each analysed eight RCTs; however, only four studies were common to both reviews. Different search strategies and inclusion criteria may explain this disparity. Nevertheless, there is an increasing need to conduct a SR that includes all RCTs of MT efficacy for TMDs.

## 5. Objectives

This systematic review will analyse RCTs of MT in TMD patients to evaluate its efficacy.

# Methods»»»

## 1. Data sources

Articles will be extracted from MEDLINE, EMBASE,

and CENTRAL and from four Korean databases: KoreaMed, DBPIA, NDSL, and RISS and from three Chinese databases: CNKI, VIP, and Wanfang. There will be no limitation on the starting date, and the end date will be June 2015. Key words will be retrieved using the following MeSH terms in titles and abstracts: "musculoskeletal manipulation" and "temporomandibular disorder". Articles written in English, Korean and Chinese will be included. In addition to searching these databases, we will screen the reference lists of articles that have been identified to locate additional studies. A Preferred Reporting Items of Systematic reviews and Meta-Analysis (PRISMA) flow chart will be used to show the inclusion and exclusion process (Fig. 1).

# 2. Eligibility criteria

#### 1) Population

Patients who have TMDs will be included. The most common standards for the diagnosis of TMDs are provided by the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)<sup>17)</sup>. The American Association of Orofacial Pain (AAOP) guideline 18 is also considered when diagnosing TMDs. Articles that use these criteria will be included in this review.

#### 2) Interventions

MT is a treatment in which the practitioner uses his/her hands to relax muscles or correct the alignment of bones and joints. The target lesion could be orofacial muscles or spinal structures. Studies that examined complex therapies that involved other treatments

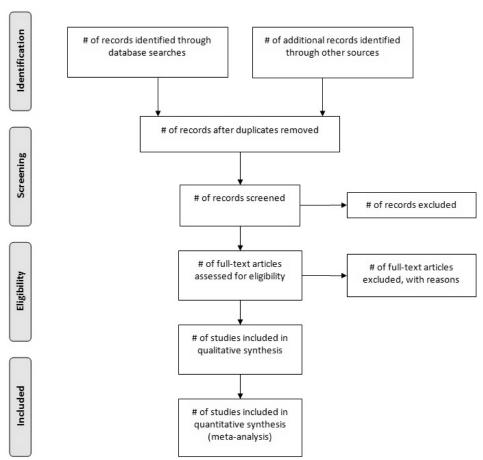


Fig. 1. Flow diagram of selection procedure.

(e.g., acupuncture, exercise, orally administered drugs, etc.) will be included if they only investigated the use of manipulative therapy.

Control groups will consist of individuals who received orally administered drugs, placebo, no treatment, acupuncture, an active exercise intervention, or another intervention,

#### 3) Outcome measures

## (1) Primary outcomes

- 1. Range of motion in mouth opening: possible maximum range/pain-free range, evaluated with a ruler or callipers to reveal the degree of functioning
- 2. Pain: visual analogue scale (VAS)/numeric rating scale (NRS)/pressure pain threshold/facial pain score scale (FPSS).

#### (2) Secondary outcomes

- 1. Frequency of clicking or popping sounds during masticatory movements.
  - 2. Quality of life.
  - 3. Adverse events.

#### 4) Study design

Only RCTs will be analysed. Case reports, observational studies, and uncontrolled trials will be excluded.

## 3. Data collection and analysis

## 1) Data extraction

Articles will be assessed by two independent reviewers (OO, OO). If disagreements occur between the two authors, OO will make the decision or e-mail the article to clarify the details and make a decision.

#### 2) Risk of bias assessment

All articles will be evaluated using the 'risk-of-bias' tool from the Cochrane Handbook for Systematic Reviews of Interventions<sup>19)</sup>. Factors include random sequence generation, allocation concealment, masking of

participants, masking of healthcare providers, masking of data collectors, masking of outcome assessment, masking of data analysis, incomplete outcome data, selective reporting, and other biases. This assessment yields ratings of low, unclear, or high risk of bias, according to the quality of the article.

### 3) Data synthesis

We will use the Review Manager software (RevMan; ver. 5.3 for Windows, the Nordic Cochrane Centre, Copenhagen, Denmark) to conduct the meta-analysis. The difference in efficacy between the experimental group and the control group will be evaluated. Count data will be expressed as risk ratios (RRs), and continuous data will be expressed as mean differences (MDs). If a different scale is applied to the same outcome, a standardised MD will be used. In the case of heterogeneity, a random-effect model will be applied; 95% confidence intervals (CIs) will be determined. If we cannot find the needed details in the article, we will contact to the authors to request additional information,

# Subgroup analysis and investigation of heterogeneity

If the data reflect comparatively large heterogeneity, we will conduct a subgroup analysis as follows:

- 1. Target region of MT (intra-oral and masseteric/neck and spinal muscles).
  - 2. Type of TMD (joint/muscle/disc).
  - 3. Type of control group.

# 5) Sensitivity analysis

To assess the robustness of the results of the meta-analysis, a sensitivity analysis will be conducted as follows:

Methodological qualities.

Size of sample.

Analysis issues.

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# Discussion»»»

Our SR was designed to evaluate the effectiveness of MT for patients with TMD. Two SRs conducted in 2006 were broadly focused on conservative measures, such as MT, acupuncture, and electrotherapy, rather than on MT alone<sup>6,14)</sup>. A review article published in 2007 included three RCTs of MT for patients with TMDs; however, it was not systematic<sup>20)</sup>. Moreover, the previous SRs are out of date because several RCTs of MT have been published since 2007. An SR of RCTs conducted in 2013 was limited because the review was restricted to the treatment of the mandibular region 21). Of the two most recent SRs of MT, one performed a meta-analysis according to outcome 16) and the other did not perform a meta-analysis because of extreme heterogeneity<sup>15)</sup>. Notably, only half of the RCTs analysed were common to both SRs, possibly because of different search strategies.

This SR will screen all English-, Korean- and Chinese-language RCTs assessing the efficacy of MT for TMDs. A data synthesis and meta-analysis will also be performed. This research will inform practitioners and patients about whether manipulative therapy is effective and safe for TMDs.

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