European Journal of Integrative Medicine 19 (2018) 1–9

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/locate/eujim

Protocol

Chuna manual therapy combined with acupuncture and cupping for frozen shoulder (adhesive capsulitis): Study protocol for a multicenter, randomized, patient-assessor blind, clinical trial

Hee-Ra Shin[a,1], Jihye Seo[b,1], Eun-Jung Lee[c], Jin-Bong Choi[d], Yeon-Cheol Park[e], Yong-Hyeon Baek[e,*], Seung-Ryong Yeom[a,*]

[a] Department of Korean Medicine Rehabilitation, Gwangju Medical Center, College of Korean Medicine, Wonkwang University, Gwangju 61729, Republic of Korea
[b] Clinical Trial center, Gwangju Medical Center, College of Korean Medicine, Wonkwang University, Gwangju 61729, Republic of Korea
[c] Department of Korean Medicine Rehabilitation, Dunsan Korean Medicine Hospital, College of Korean Medicine, Daejeon University, Daejeon 35235, Republic of Korea
[d] Department of Korean Medicine Rehabilitation, Gwangju Oriental Hospital, College of Korean Medicine, Dongshin University, Gwangju 61619, Republic of Korea
[e] Department of Acupuncture and Moxibustion Medicine, Kyung Hee University Hospital at Gangdong, College of Korean Medicine, Kyung Hee University, Seoul 05278, Republic of Korea

ARTICLE INFO

Keywords:
Frozen shoulder
Adhesive capsulitis
Chuna manual therapy
Manipulation
Randomized controlled trial
Study protocol

ABSTRACT

Introduction: Frozen shoulder, also called adhesive capsulitis is an obstinate disease involving severe shoulder pain and limitation of range of motion. The aim of this study is to establish a protocol to carry out research which evaluates the effectiveness, safety, and economic efficiency of Chuna manual therapy on frozen shoulder by combining treatments with acupuncture, cupping, and self-exercise.

Methods/design: A multicenter, randomized, patient-assessor blind, parallel clinical trial will be carried out. Eligible subjects will be allocated to one of two groups with randomized sampling. The experimental group will receive acupuncture, cupping and real Chuna manual therapy, and control group will receive acupuncture, cupping and sham Chuna manual therapy. During the 8-weeks treatment period, effectiveness and safety evaluations will be carried out and evaluation of satisfaction and economic efficiency will be performed at the end of the trial (20-week). The primary outcome is shoulder pain and disability index. The secondary outcomes are 100 mm pain VAS, passive range of motion of the shoulder, Korean shoulder scoring system score, quality of life score, use of relief medicine, evaluation of patient satisfaction, safety, and economic efficiency.

Discussion/conclusion: This is the first trial evaluating the effectiveness, safety, and economic efficiency of Chuna manual therapy for frozen shoulder. The results of this trial will be used to underpin basis for the use of Chuna manual therapy for pain relief, improvement in range of motion and shoulder joint function for people with frozen shoulder.

Trial registration: Clinical Research Information Service Registration Number is KCT0002300. Registered on 6 April 2017.

Abbreviations: FS, frozen shoulder; ROM, range of motion; NSAIDs, non-steroidal anti-inflammatory drugs; CMT, chuna manual therapy; CONSORT, consolidated standards of reporting trials; SPIRIT, standard protocol items: recommendations for interventional trials; KMD, Korean medicine doctor; VAS, visual analogue scale; ALT, alanine transaminase; AST, aspartate transaminase; BUN, blood urea nitrogen; KMCPG, Korean medicine clinical practice guideline; STRICTA, standards for reporting interventions in clinical trials of acupuncture; SPADI, shoulder pain and disability index; KSS, Korean shoulder scoring system; RC-QOL, rotator cuff quality of life index; EQ-5D, euroQol-5 Dimension; ECG, electrocardiogram; RBC, red blood cell; WBC, white blood cell; ESR, erythrocyte sedimentation rate; GGT, gamma glutamyl transpeptidase; CRP, C-reactive protein; pH, potential of hydrogen; AEs, adverse events; SAEs, serious adverse events; CRF, case report form; IRB, Institutional review board; ITT, intention-to-treat analysis; PP, per-protocol analysis; ANOVA, analysis of variance; ANCOVA, analysis of covariance; ICER, incremental cost-effectiveness ratio; LOCF, last observation carried forward; GCP, clinical trial management standards for drugs; SOP, standard operating procedure; CRO, contract research organization

* Corresponding authors.
E-mail addresses: shin376@wku.ac.kr (H.-R. Shin), jmaal87@wku.ac.kr (J. Seo), jungkahn@dju.kr (E.-J. Lee), jbchoi@dsu.ac.kr (J.-B. Choi), icarus08@khu.ac.kr (Y.-C. Park), byhacu@khu.ac.kr (Y.-H. Baek), yeom2589@wku.ac.kr (S.-R. Yeom).

[1] HRS and JS equally contributed (co-first authors).

https://doi.org/10.1016/j.eujim.2018.02.004
Received 7 December 2017; Received in revised form 14 February 2018; Accepted 14 February 2018

1. Introduction

Frozen shoulder (FS) is also called as adhesive capsulitis or periarthritis. The prevalence of FS is 2% or more in general population, characteristically the average age being people in their fifties, and it affects women more than men [1]. The diagnosis is defined when there is a limitation of active and passive range of motion (ROM) of the shoulder, with no other identified causes [2]. The main symptom of FS is pain at the deep inside or posterior region of the shoulder. It may radiate to the deltoid muscle region and patients can also suffer from night pain. Muscle weakness due to the pain and restriction of ROM may also occur and its functional restriction makes the daily living activities difficult. FS lasts for an average of 30 months (12–42 months), some restriction of ROM may remains in some patients [3].

For the treatment of pain, medication such as non-steroidal anti-inflammatory drugs (NSAIDs), local anesthetic and steroid injection, nerve block, exercise, physiotherapy are available [4–6]. If patients do not respond to conservative treatments, capsular distension, manual therapy under anesthesia and surgical treatment can be considered [7,8]. But it is rather a symptomatic treatment, and the disease period is very long and it also has a great influence on the quality of life. Therefore, developments of efficient treatment models are needed to reduce indiscriminate use of analgesics or anesthetics, and to prevent habitual addiction. Korean medicine treatments have been found to be effective in managing shoulder pain, and there is interest in treating FS with Korean medicine treatments. Acupuncture treatment is effective for chronic pain such as low back pain, neck pain, knee pain, shoulder pain [9] and its therapeutic effect for the pain relief, improvement of ROM and function of shoulder joints can last up to 6 months [10,11]. The combined treatment of acupuncture and cuppinghas been shown to be effective in improving shoulder joint function [12] and is effective as the treatment of shoulder pain.

Previous studies on FS have been about the effectiveness of the pain relief and improvement of shoulder joint function. When treating acupuncture for shoulder pain, the method of taking local acupoints and distal acupoints at the same time was effective [13]. Combined treatment of acupuncture and self-exercise also had a significant effect even after 20 weeks [14]. In studies of Chuna manual therapy (CMT) for FS, CMT was more effective for the pain relief compared to exercise therapy [15]. CMT was more effective for the improvement of range of shoulder joint motion compared to physiotherapy [16]. Combined treatment of CMT and cupping therapy had a significant effect for improvement of shoulder joint ROM [17]. More studies on CMT are needed to demonstrate improvements in shoulder function and shoulder ROM and to verify the effectiveness of combined treatment of CMT and other Korean medicine therapies.

The frequency of shoulder pain and its socioeconomic costs are increasing due to aging and increased sports activities. According to the data from Korean health insurance review & assessment service from 2010 to 2016, The medical expenditure of FS is steadily increasing and it is thought to be due to its characteristics that FS is obstinate and has a long duration. Treatments that can improve shoulder joint function and ROM are needed to maximize patient's satisfaction and to achieve the ultimate therapeutic effect. Through the verification of its objective effectiveness and mechanisms, we have to enhance the therapeutic effect by establishing the optimal treatments and find good-quality medical care in response to patient's expectation and improve their treatment satisfaction.

We designed clinical trial study about the acupuncture and cupping therapy which are widely used for the purpose of pain relief in FS patients. In addition to this, we combined CMT which is expected to improve the shoulder joint function and ROM. We expect that the combined treatment of acupuncture, cupping and CMT will show a significant effect in pain relief, improvement in shoulder joint function and ROM. The aim of this study is to establish a protocol to carry out research which evaluates the effectiveness, safety, and economic efficiency of CMT on the frozen shoulder through the combining treatment with acupuncture, cupping, and self-exercise.

2. Methods/design

2.1. Study design

This study is a protocol for a multicenter, randomized, patient-assessor blind, parallel clinical trial for the patient diagnosed as frozen shoulder (adhesive capsulitis). Subjects will be recruited from Wonkwang University Gwangju Medical Center, Daejeon University Dunsan Korean Medicine Hospital and Dongsin University Gwangju Oriental Hospital in Korea from May 2017 to December 2018.

Subjects who voluntarily signed the consent form will be evaluated the eligibility by the screening test. Eligible subjects will be allocated to one of two parallel groups in accordance with randomized sampling. According to the prescribed manner, experimental group ($n = 33$) will receive acupuncture, cupping and real CMT, and control group ($n = 33$) will receive acupuncture, cupping and sham CMT. Self-exercise therapy will be provided to both groups by educating both groups of subjects in the same way. From the point of randomization, effectiveness and safety will be evaluated in the outpatient department by setting the baseline (V2), 2 week (V5), 4 week (V9) and 8 week (V17) as the primary endpoint. After 12 week (V18) and 20 week (V19), as a follow-up period, we will evaluate the effectiveness, safety, and economic efficiency.

The flow of the study protocol is described in Fig. 1, and the additional file 1 presents the Consolidated Standards of Reporting Trials (CONSORT) checklist. [See Additional file 1.] Additional file 2 presents the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. [See additional file 2.]

All the procedures of the clinical trial will follow the prescribed clinical trial progress table (Table 1). However, if it is not possible for subjects to visit on the day of predetermined visit by unavoidable circumstances, the reason will be recorded and the effectiveness and safety evaluated.

2.2. Recruitment

Hospital websites, advertisements in local newspapers and posters in each hospital will be used for recruitment. Among the participants complaining shoulder pain and limitation of ROM, subjects who voluntarily signed the consent form will be evaluated the eligibility by the screening test. Eligible subjects who are diagnosed as FS by history taking, physical examinations, and shoulder X-ray will be enrolled in this study. The screening test and enrollment of subject will be conducted by the researcher (Korean Medicine Doctor (KMD)). Obtaining consent will be carried out by the KMD with the principle of informed consent. And the subjects have the right to withdraw the consent at any time during the trial.

2.3. Criteria

2.3.1. Inclusion criteria

Subjects who meet the following criteria will be considered for enrollment

1) Males and females aged 25 to 65 years old, one side-shoulder pain for 6 weeks to 12 months, with a significant pain of visual analogue scale (VAS) between 50 mm to 100 mm, with more than 25% limitation of ROM in two or more movements compared to the contralateral side, who can be diagnosed as frozen shoulder (adhesive capsulitis) by excluding simple fracture, dislocation, degenerative arthropathy, and calcific tendinitis in plain radiography.
2) Those who are able to communicate sufficiently with the researcher and complete the questionnaire.