

Clinical Research Methodology

David Kim

Virginia University of Oriental Medicine

Doctor of Acupuncture and Oriental Medicine (DAOM) Program

Research 1

Effectiveness of Duhuo Jisheng wan on chronic pain due to osteoarthritis of the knee comparing with Non-Steroidal anti-inflammatory drugs (NSAIDs)

*"Tae Y. Rim, L.Ac.a, David Kim, L.Ac.a, Ockhee Jung, L.Ac.a," **

"a Virginia University of Oriental Medicine, 9401 Mathy Dr. Fairfax, VA 22031, U.S.A."

ARTICLE INFO

Article history:

Submitted: RE700 Assignement

JULY 29, 2017

Keywords:

Duhuo Jisheng Wan, Osteoarthritis,

Knee, Pain, NSAIDs

ABSTRACT

Duhuo Jisheng Wan (DJSW) is a Chinese herbal medicine. The compound seems to activate specific anti-inflammatory cells in the body. The only Randomized Control Trial RCT testing Duhuo Jisheng Wan for **Knee osteoarthritis (KOA)** suggests that it has an effect equal to that of **non-steroidal anti-inflammatory drugs (NSAIDs)**, but more evidence is needed before a conclusion can be reached on effectiveness.

1. Hypothesis and Proposal

2. Participants who received Duhuo Ji Sheng Wan (DJSW) should have significantly lower score for knee pain, ROM of Knee, and side effects from non-steroidal anti-inflammatory drugs (NSAIDs).

3.

4. Aim of the Research

To assess the efficacy and safety of traditional Chinese patent medicine (DJSW) compared with non-steroidal anti-inflammatory drugs (NSAIDs) in patients with chronic pain due to osteoarthritis of the knee.

- a. Patients who received DJSW should have lower knee pain with OA score compare to non-steroidal anti-inflammatory drugs (NSAIDs) administered patients.
- b. Patients who received DJSW will have increased ROM of the knee compare to NSAIDs administered patients.
- c. Patients who received DJSW should have less side effects compare to NSAIDs administered patients during 3months clinical trial.

5. Background

Current literature in WM and TCM

Western Medicine

Epidemiology of Osteoarthritis

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920533/>

Osteoarthritis (OA) is the most common joint disorder in the United States. Among adults 60 years of age or older the prevalence of symptomatic knee OA is approximately 10% in men and 13% in women. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic.

Pain from OA is a key symptom in the decision to seek medical care and is an important antecedent to disability. Because of its high prevalence and the frequent disability that accompanies disease in major joints such as the knee and hip, OA accounts for more difficulty with climbing stairs and walking than any other disease. OA is also the most common reason for total hip and total knee replacement. The rapid increase in the prevalence of this already common disease suggests that OA will have a growing impact on health care and public health systems in the future.

1. Osteoarthritis Fact Sheet
<https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>

What is osteoarthritis (OA)?

Osteoarthritis (OA) is the most common form of arthritis. It is sometimes called degenerative joint disease or “wear and tear” arthritis. It most frequently occurs in the hands, hips, and knees.

With OA, the cartilage and bones within a joint begin to break down. These changes usually develop slowly and get worse over time. OA can cause pain, stiffness, and swelling, and can result in disability.

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How many people get OA?

OA affects over 30 million US adults.

What causes OA?

OA is caused by damage or breakdown of joint cartilage between bones.

What are the risk factors for OA?

- Joint injury or overuse (such as knee bending and repetitive stress on a joint).
- Age—The risk of developing OA increases with age.
- Gender—Women are more likely to develop OA than men, especially after age 50.
- Being obese—Extra weight puts more stress on joints, particularly weight-bearing joints like the hips and knees.
- Genetics—People who have family members with OA are more likely to develop OA. People who have hand OA are more likely to develop knee OA.
- Race— Some Asian populations have lower risk for OA.

How is OA diagnosed?

OA is diagnosed through a physical examination and review of symptoms, X-rays, and lab tests.

OA should be diagnosed by a doctor, particularly a rheumatologist who specializes in arthritis and other related conditions.

How is OA treated?

Doctors usually treat OA with a combination of therapies, which may include the following:

- Physical activity.
- Medications, including prescription drugs and over-the-counter pain relievers.
- Physical therapy with muscle strengthening exercises.
- Weight loss.
- Supportive devices such as crutches or canes.
- Surgery (if other treatment options have not been effective).

In addition to medical treatment, people with OA can gain confidence in managing their condition with self-management strategies proven to reduce pain and disability, so they can pursue the activities important to them. People with OA can relieve pain and improve function of your joints by learning and using five simple and effective [arthritis management strategies](#).

What are the complications of OA?

Osteoarthritis can cause severe joint pain, swelling, and stiffness. In some cases it also causes reduced function and disability; some people are no longer able to do daily tasks and, in some cases, are not able to work. Severe cases may require joint replacement surgery, particularly for knee or hip OA.

2. <https://www.drugs.com/advil.html>

What is Advil?

Advil (ibuprofen) is a nonsteroidal anti-inflammatory drug (NSAID). Ibuprofen works by reducing hormones that cause inflammation and pain in the body.

Advil is used to reduce fever and treat pain or inflammation caused by many conditions such as headache, toothache, back pain, **arthritis**, **menstrual cramps**, or minor injury.

Traditional Chinese Medicine

1. Arthritis Research UK

file:///C:/Users/ICNM/Downloads/CAM%20Report.pdf

2. BMJ – Evidence of Chinese herbal medicine Duhuo Jisheng decoction for knee osteoarthritis: a systematic review of randomised clinical

trials

<http://bmjopen.bmj.com/content/6/1/e008973>

3. Acupuncture Today - Herbal Alternative to Pain Killer <http://www.acupuncturetoday.com/mpacms/at/article.php?id=32437>

6. Significance

Osteoarthritis (OA) is the most common joint disorder in the United States. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic. OA has a multi-factorial etiology and can be considered the product of an interplay between systemic and local factors. Old age, female gender, overweight and obesity, knee injury, repetitive use of joints, bone density, muscle weakness, and joint laxity all play roles in the development of joint osteoarthritis, particularly in the weight-bearing joints. Modifying these factors may reduce the risk of osteoarthritis and prevent subsequent pain and disability.

(REF. Epidemiology of Osteoarthritis - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920533/>)

Du Huo Ji Sheng Wan is a Chinese Medicinal Formula that is utilized when a patient is suffering from lower back pain, joint pain, rheumatoid arthritis, and lower back pain accompanied with numbness, weakness, and/or stiffness. It has been considered especially helpful and is commonly prescribed for elderly people.

7. Rationale

8. Patient with knee osteoarthritis (OA) – whether from an injury or carrying some extra weight on the knee joints or the genetic condition the result is pretty much the same: pain and less ability to live an active life. But there are ways to ease discomfort and delay or avoid knee replacement surgery.

9. Recently published guidelines from several medical organizations offer people with knee osteoarthritis and their doctors a larger toolbox of treatments – and a better breakdown of the risks and benefits.

10. Experiment Design and Methods

11. SUMMARY:

12. **Design:** Randomized, controlled trial

Participants: 100 patients who had had chronic pain for at least 6 months due to osteoarthritis of the knee (American College of Rheumatology [ACR] criteria and Kellgren–Lawrence score of 2 or 3).

Possible Osteoarthritis of the knee - grading

- Ahlbäck classification system
- Kellgren and Lawrence system

The inclusion criteria were signed declaration of consent; age 40 years and older; chronic pain in the knee joint for the last 6 months, according to American College of Rheumatology (ACR) criteria (8); radiologic confirmation of osteoarthritis in 1 or both knees (Kellgren–Lawrence score 2 or 3 [9]); Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (10, 11) score of at least 3 points; and a chronic pain score of at least 1, according to the criteria of von Korff and colleagues (12). Patients with other diseases affecting the knee, neurologic and psychiatric diseases, severe coagulopathy, pregnancy, or previous acupuncture treatment for osteoarthritis of the knee were excluded. A detailed list of eligibility criteria was reported by Streitberger and colleagues (13). The physicians checked the patients' eligibility criteria during a screening examination. A screening telephone interview was done to record baseline WOMAC values, quality of life (12-item Short-Form Health Survey [SF-12]) (14), von Korff scores (15), and use of analgesics. Finally, patients were randomly assigned into 3 treatment groups.

Setting: 2 primary integrated care practices staffed by 3 TCM practitioners with at least 5 years' experience.

In our trial, we want 100 participants with osteoarthritis of the knee were randomly divided given daily doses of following:

1. Duhuo Jisheng Wan Tablets
2. Anti-inflammatory drugs: NSAIDS: Advil (ibuprofen),
3. Placebo tablets identical to the Duhuo Jisheng Wan Tablets.
4. Placebo tablets identical to the Anti-inflammatory drugs: NSAIDS: Advil (ibuprofen)

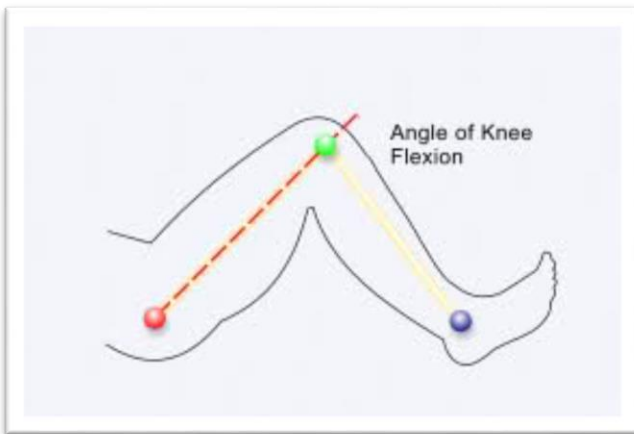
Interventions: 12 weeks self administered dosage DJSW and anti-inflammatory drugs. Follow up functional knee pain assessment every 3 weeks.

Measurements:

PAIN: The WOMAC measures five items for pain (score range 0–20), two for stiffness (score range 0–8), and 17 for functional limitation (score range 0–68).

<https://en.wikipedia.org/wiki/WOMAC>

<http://www.performanceptpc.com/paperwork/womac.pdf>



Range of Motion: ROM is measured by our trained practitioners using a device (Goniometer).