

Official title:
**Effects of UC-II, Glucosamine and Curcumin
Supplementation on Knee Pain and
Inflammation: A Randomized, Single-blind,
Placebo-controlled Parallel-group Trial**

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Study protocol

I. Study design

Study type: Interventional

Primary purpose: Treatment

Interventional study model: Parallel assignment

Number of Arms: 2

Allocation: Randomized

Enrollment: 32

II. Arms and interventions

Arms	Assigned interventions
<ul style="list-style-type: none">● Placebo Comparator: Control group● Control group use 42 mg UCII.	<ul style="list-style-type: none">● Dietary Supplement: Placebo● Placebo capsules twice daily.
<ul style="list-style-type: none">● Experimental: Test group (UCII, glucosamine, and curcumin)● Test group use 42 mg UCII, 460 mg glucosamine and 380 mg curcumin	<ul style="list-style-type: none">● Dietary Supplement: UCII, glucosamine and curcumin● Compound capsules twice daily.

III. Outcome measures

1. Points Change of Pain Evaluation Scale

Self-assess pain using a visual analog scale (VAS), which is a straight line 10 cm in length, with 0 cm on the left representing no pain and 10 cm on the right representing extreme pain. Explain to the subjects that the pain intensity increases from left to right. Ask the subjects to mark the point on the line that corresponds to their pain level, and then record the distance in centimeters from the 0 cm mark. Record the points that the subjects wrote.

2. Time Change of Up-and-go Test

Timed up-and-go test (TUG) was a professional physical therapist marked a distance of 3 meters on the ground and placed an armless chair at one end. The subject sat on the chair with a straight back, and the time was measured from when the subject stood up and walked to the 3-meter mark at their usual speed, turned around, walked back, and sat down again. Shorter time spent indicates better knee function. Record the time that the subjects spent.

3. Angle Change of Range of Motion (ROM)

A professional physical therapist tested the active flexion and extension of the knee joint (range of motion, ROM) as the subjects attempted to achieve maximum active flexion and extension. Record the angle that the physical therapist measured.

AROM: active range of motion; PROM: passive range of motion.

4. Points Change of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a widely used questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints. The higher score meant worse knee joint function. Record the points that the subjects got.

5. The Concentration of Serum Inflammatory Factors

Using commercial kits to test the concentration of interleukin-6 (IL-6), interleukin-1 beta (IL-1 β), and tumor necrosis factor alpha (TNF- α) in serum.

Statistical analysis plan

Values were displayed as mean \pm SD. Statistical Product and Service Solutions software (v.18) was used for data analysis. The paired t test was used to compare the basic data during the same period. Repeated measured ANOVA was used to compare the statistical differences between the other groups (UCII structural group and turmeric compound product) * (weeks 0, 6, and 12).