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## Moxibustion for Knee Osteoarthritis: A Protocol for a Pilot Randomized Controlled Trial

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### Abstract

**Objectives:** The purpose of this study was to evaluate the feasibility of massive clinical research and to make a basic analysis on the effectiveness and the safety of moxibustion treatment for knee osteoarthritis compared to usual care.

**Methods and Results:** This study was a protocol for a pilot randomized controlled trial. Forty participants were assigned to the moxibustion group (n=20) and the usual care group (n=20). Participants assigned to the moxibustion group received moxibustion treatment on the affected knee(s) at six standard acupuncture points (ST36, ST35, ST34, SP9, Ex-LE04 and SP10) three times per week for four weeks (total of 12 sessions). Participants in the usual care group did not receive moxibustion treatment during the study period and follow-ups were made during the 5th, 9<sup>th</sup> and 13th weeks after random allocation. Both groups were allowed to use any kind of treatment, including surgery, conventional medication, physical treatment, acupuncture, herbal medicine, over-the-counter drugs and other active treatments. Education material that explained knee osteoarthritis and current management options and self-exercise was provided for each group. The pain scale of the Korean Western Ontario and McMaster Universities Questionnaire (K-WOMAC) was the primary outcome measurement used in this study. Other subscales of the K-WOMAC, the Short-Form 36 Health Survey (SF-36), Beck Depression Inventory (BDI), Physical Function Test, Patient Global Assessment, and Pain Numeric Rating Scale (NRS) were used as outcome variables to evaluate the effectiveness of acupuncture. Safety was assessed at every visit.

**Conclusions:** The result of this trial will provide a basis for establishing the effectiveness and the safety of acupuncture treatment for knee osteoarthritis.

**Key Words:** moxibustion; osteoarthritis; pilot trial