Individualized acupuncture randomized trials in patients with osteoarthritis of the knee: -Design and protocols-

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Over the last thirty years, a variety of clinical trials have been conducted to define the effectiveness of acupuncture. Unfortunately, these outcomes are far from the real outcomes of practice where many patients and doctors actually experience the effectiveness of acupuncture. Researchers evaluating acupuncture have little guidance in selecting appropriate interventions for their studies because treatments in actual practice are individualized to the needs of patients. Acupuncture studies should be planned on theoretical basis of Oriental Medical systems and designed to allow divergent approaches as in clinical practice and to compare these systems with treatment using fixed acupuncture points.

In order to develop protocols for the individualized acupuncture, some obstacles such as the pattern identification, selection of acupuncture points, period of time to retain needles, number of needles practiced, elicitation of de qi, depth of insertion, types of needle manipulation must be overcome in rigorous way. In order to make a consensus concerning acupuncture prescription, we conducted e-mail and telephone survey questionnaires, and followed up with face-to-face interviews with acupuncture practitioner. Similar survey will be conducted in Japanese acupuncturists.

We, Koran-Japan EBM working group, will investigate whether individualized acupuncture provides greater pain relief and more improvement of quality of life among patients with osteoarthritis of the knee in Korea and Japan than standardized acupuncture. This randomized clinical trial will recruit 126 participants with osteoarthritis of the knee. This study consists of a screening visit, baseline assessment visit, a treatment period, and a three-month follow-up visit. Following screening, eligible participants will be randomized to one of two groups: individualized and standardized acupuncture. For individualized acupuncture, acupuncture points will be tailored to each participant. For standardized acupuncture we will use a pre-specified set of acupuncture points. Acupuncture treatment will be delivered twice a week for 6 weeks. Each patient will participate in this study for maximum of 5 months. The primary outcome measure is the difference between baseline and the end of the 6-week treatment period in the pain intensity as measured by a visual analogue scale (VAS; 0-100 mm). The secondary outcome measures are as follows: Western Ontario and McMaster University (WOMAC) osteoarthritis score, quality of life (QOL) and Lequensne Functional Index Score. All main analyses will be made by intention to treat (ITT). Some modifications of the protocol will be made, and preliminary results of the individualized acupuncture trials will be presented for the discussion.