Available online at www.sciencedirect.com

Integrative Medicine Research

journal homepage: www.imr-journal.com

Study Protocol

Evaluation of the clinical application of a leaflet for clinical practice guidelines in patients with herniated intervertebral discs: a study protocol for a randomized controlled trial

Ju Ah Lee[a], *Jiae Choi*[b], *Tae-Young Choi*[b], *Ji Hee Jun*[b], *In-Hyuk Ha*[c], *Myeong Soo Lee*[b,*]

[a] *KM Fundamental Research Division, Korea Institute of Oriental Medicine, Daejeon, Korea*
[b] *Clinical Research Division, Korea Institute of Oriental Medicine, Daejeon, Korea*
[c] *Jaseng Spine and Joint Research Institute, Jaseng Medical Foundation, Seoul, Korea*

ARTICLE INFO

Article history:
Received 5 February 2016
Received in revised form
22 March 2016
Accepted 5 April 2016
Available online 13 April 2016

Keywords:
clinical practice guideline
efficacy
herniated lumbar disk
leaflet
protocol
traditional Korean medicine

ABSTRACT

Introduction: This study aims to demonstrate the effectiveness of using clinical practice guideline (CPG) leaflets as a communication tool between doctors and patients. We will collect basic data on whether using leaflets based on traditional Korean medicine (TKM) CPGs accomplishes the goal of improving clinical decision-making for diagnosis and treatment by TKM doctors. We will also evaluate the leaflets as a communication tool in the treatment of lumbar herniated intervertebral discs (HIVDs) in terms of patient and physician satisfaction and ease of treatment.

Methods and analysis: We will evaluate efficacy through a comparison of satisfaction and clinical outcomes in randomly allocated groups of HIVD lumbar patients visiting the Jaseng Hospital of Korean Medicine who do or do not receive CPG-based treatment. Following the evaluation, we will make recommendations on whether to implement CPG interventions for patients selecting TKM treatment after HIVD diagnosis and the method of clinical treatment. Finally, we will evaluate the perception of and satisfaction with CPGs among TKM doctors and patients.

* *Corresponding author*. Medical Research Division, Korea Institute of Oriental Medicine, Yuseongdaero 1672, Daejeon 34054, Korea.
E-mail address: drmslee@gmail.com (M.S. Lee).

http://dx.doi.org/10.1016/j.imr.2016.04.003

1. Introduction

Lumbar disk herniation occurs most commonly at approximately 60 years of age and a large number of patients are admitted to Korean hospitals for this condition.[1] In recent years, nonsurgical therapy for conservative treatment along with an increasing use of alternative treatments has been used for various ailments, including back pain.[2,3] In Korea, traditional Korean medicine (TKM), which includes acupuncture, herbal medicine, pharmacopuncture, *chuna*, and cupping, is widely used to treat herniated intervertebral discs (HIVDs).[4]

However, until recently, TKM clinical practice guidelines (CPGs) for HIVD were inadequate, and additional development was needed. A project to develop TKM CPGs for HIVD began in 2013 and was reported in 2014. While CPGs have been developed, the more important process of implementation still remains. The application of recent, evidence-based research to clinical practice improves the safety and quality of real health care.

Although several studies have explored methods that address the implementation of evidence-based CPGs,[5–7] CPG implementation studies and detailed implementation methods are currently lacking in literature.

This study focuses on CPGs that were developed to assist in the diagnosis and treatment of HIVD patients and uses leaflets as a tool for communication between clinicians and patients to help ensure excellent care and patient satisfaction. Through this study, we are attempting to create a novel, evidence-based implementation process. Finally, we aim to demonstrate the effectiveness of using CPG leaflets as a tool for communication between doctors and patients.

2. Methods and design

2.1. Study design

This paper describes a study protocol for a randomized controlled trial with two parallel arms and an assessor-blinded design. The trial will be performed at the Jaseng Korean Medicine Hospital in Korea in accordance with the Declaration of Helsinki and the Guidelines for Good Clinical Practice. The protocol of this study has been registered with the Clinical Research Information Service, which is the Korean registry of the World health Organization Registry Network. Eligible participants will be randomly divided into either the leaflet group or the standard care group with a 1:1 allocation ratio (Fig. 1). The evaluation of participants and the analysis of the results will be performed by professionals blinded to the group allocation.

2.2. Study participants

Inclusion criteria: A total of 50 patients will be recruited through local advertising and from the outpatient department at the Jaseng Korean Medicine Hospital. The inclusion criteria are patients of both sex between the ages of 18 years and 65 years who have been diagnosed with HIVD using computer tomography or magnetic resonance imaging. All patients will provide informed written consent to participate and agree to comply with the study regulations.

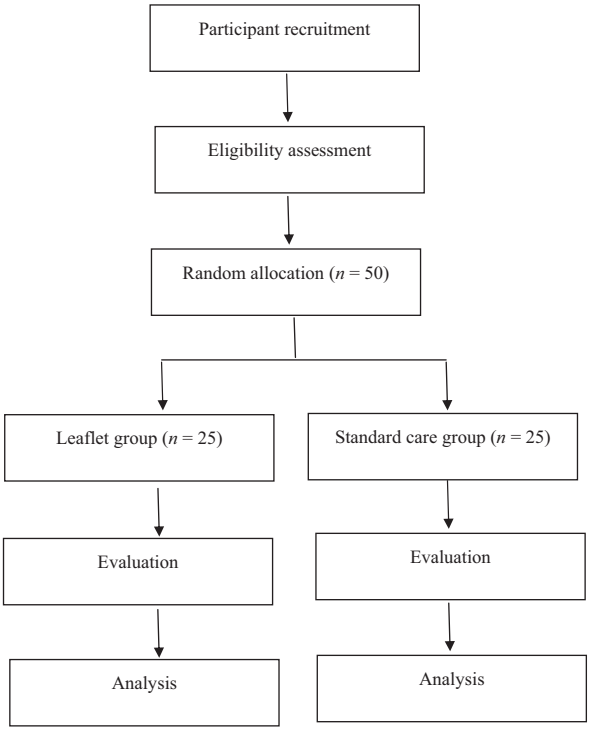

Fig. 1 – A flowchart of the study.

The exclusion criteria include heart disease, liver disease, kidney disease, any psychiatric condition, the inability to communicate, critical illness, pregnancy, or any condition that could influence the study assessment.

2.3. Randomization

The study participants who meet the eligibility criteria will be randomly assigned to one of two groups (the leaflet group or the standard care group) at the first visit using a central randomization system with a 1:1 ratio. Randomization will be conducted with a computer-generated random allocation sequence using the stratified block randomization method of the SAS package (version 9.1.3; SAS Institute, Inc., Cary, NC, USA) and will be performed by a statistician with no clinical involvement in this trial. The size of the block will be two. The allocation concealment will be ensured because the randomization code will only be released after the participants are recruited to the trial and all baseline measurements are taken. The patients and practitioners will be aware of the allocation given the routine care setting. However, the outcome assessors and the statistician performing the data analyses will be masked to the treatment allocation (Table 1).

2.4. Interventions

Leaflets based on CPG: The leaflet group will receive an explanation of the overall treatment and diagnosis of HIVD based on a leaflet that includes recommendations and evidence based on TKM CPGs. This leaflet was created to improve the