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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

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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.

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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.

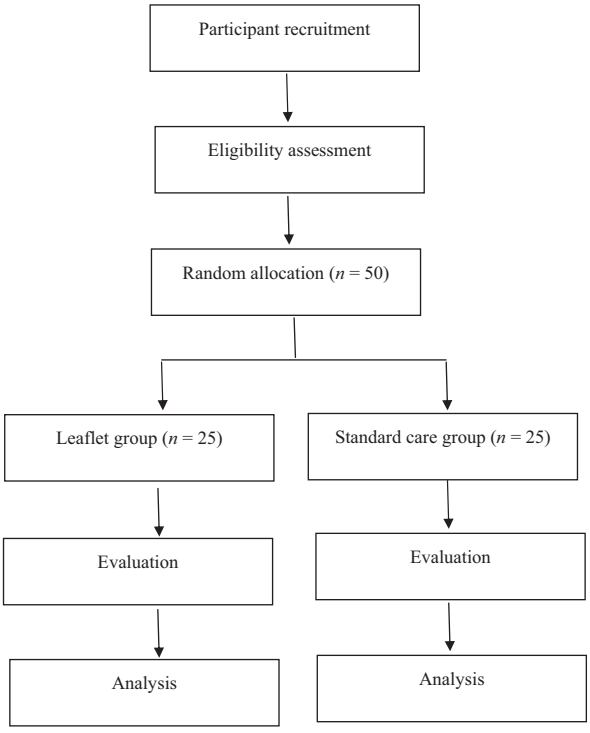

Fig. 1 – A flowchart of the study.

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

Table 1 – Schedule for treatment and outcome measurements.

Period	S	T
Visit	1	1
Day	1	1
Informed consent	—	
Inclusion/exclusion criteria	—	
Random allocation		—
Explanation		—
Satisfaction assessment (patients)		—
Satisfaction assessment (doctors)		—

S, screening period; T, treatment period.

communication between doctors and patients and to provide information to both groups (Supplementary Fig. 1).

Standard explanation of diagnosis and therapy: The patients in this group will receive general information regarding the diagnosis and treatment of HIVD. We will conduct standard operation procedure training for every practitioner to unify the process, which will include the following: (1) general diagnosis and method prognosis and (2) administration of TKM intervention and other treatments following prognosis.

2.5. *Data collection*

The data will be collected to develop a leaflet describing evidence-based CPGs that will be prepared in collaboration with TKM hospitals. Through the analysis of outcome measures, we will review the pattern of medical treatments derived from key recommendations that are based on these evidence-based CPGs. In addition, we will prepare a leaflet describing evidence-based CPGs regarding herniation of the lumbar vertebrae. Thus, we will be able to evaluate the applicability of evidence-based clinical practice guidelines in an actual clinical setting. All data will be collected and analyzed without the inclusion of any identifying information.

The outcome measurements will be verified by an independent assessor for each patient. These data will be entered into the case report form by a certificated clinical research coordinator.

When we receive informed consent from patients, we will inform the patients as follows: "This study seeks to assist in treatment decision-making by utilizing a leaflet, which describes the clinical practice guidelines, as a tool for communication between patients with lumbar disk herniation (HIVD) and the doctor. The basic data collected will be used to help ensure increases in patient satisfaction and treatment."

2.6. *Types of outcome measurements*

Primary outcome measurement: We will use a 5-point Likert scale to evaluate patient satisfaction with the doctor's explanation. A clinician will assess the patients. Each variable will be graded according to the following scale: 1 = bad, 2 = not good, 3 = moderate, 4 = good, 5 = very good (Supplementary Table 1).

Secondary outcomes measurement: We will use a 5-point Likert scale to evaluate doctor satisfaction with the leaflet. We will use a divided questionnaire for doctors who use the leaflet and doctors who do not use the leaflet for patient communication. Each variable will be graded according to the following scale: 1 = bad, 2 = not good, 3 = moderate, 4 = good, 5 = very good (Supplementary Tables 2 and 3).

2.7. *Sample size*

A power calculation was not used to calculate the sample size because this research is a pilot study.

2.8. *Statistical analysis*

The statistical analysis will be performed on an intent-to-treat basis with a 95% confidence interval using multiple inputs. The intent-to-treat analysis will include all randomized patients.

All analyses will be performed with SAS (version 9.1.3; SAS Institute, Inc., Cary, NC, USA) as follows: (1) descriptive statistics will be used to summarize participant characteristics; (2) Chi-square tests will be used to compare categorical data, and paired *t*-tests will be used to compare continuous data if participant characteristics differ among the leaflet group and the typical explanation group; and (3) Chi-square tests and paired *t*-tests will be used to compare the outcomes of the leaflet group and the typical explanation group. The primary outcome will be analyzed with an intention-to-treat analysis. All statistical tests will be performed using a two-sided 5% level of significance.

3. Adverse events

Any expected or unexpected adverse events will be reported by the participants and practitioners at every visit and followed-up to completion.

4. Ethics

This research protocol has been reviewed and approved by the institutional review board of the trial center (Jaseng Korean Medicine Hospital, KMJSIRB2015-39). Written informed consent will be obtained from all study participants prior to enrolment in the study.

5. Application of the protocol

A CPG can be defined as "A statement developed through a systematic procedure to promote the decision-making process between health care practitioners and patients in a specific situation."[8] The previous study was conducted over a 3-year period from January 2013 to December 2015 for the purpose of developing evidence-based CPGs for TKM as initiated by the Korean Institute of Oriental Medicine and to standardize the therapeutic technology of TKM through evidence-based clinical approaches.[9,10] Based on the above rationale, this study followed the protocol described in this report to develop evidence-based CPGs for the treatment of frequently diagnosed diseases in the field of TKM. The study also attempted

to improve the quality of medical service and reduce both the patient risk and cost.

To translate evidence into clinical practice, the clinicians must be aware of the evidence, agree with it, confidently deliver the intervention, and adhere to the evidence in appropriate situations.[11]

This study explored methods to increase the utilization of the existing guidelines in the field and in the provision of quality TKM services. Based on these goals, we prepared a user-oriented leaflet describing preexisting, evidence-based CPGs and also developed expanded guidelines. We then will evaluate the satisfaction of both patients and health care practitioners with the applicability of this CPG leaflet in a clinical setting. In addition, we determined the priority of practices for which evidence-based CPGs are required. Finally, the current study will be conducted with the aim of promoting the value of evidence-based TKM.

Conflicts of interest

The authors declare that they have no competing interests.

Ethics and dissemination

This research protocol has been reviewed and approved by the institutional review board of the trial center (Jaseng Korean Medicine Hospital, KMJSIRB2015-39). The results will be published in a peer-reviewed journal and will be disseminated electronically and in print.

Trial registration number

Clinical Research Information Service: KCT0001762.

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The protocol was drafted and revised by all authors. The final version was approved by all authors. JAL, JC, and TYC designed the research protocol. JAL and MSL wrote the manuscript. IHH and JH created the case report form.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.imr.2016.04.003.

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