CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Questions and Objectives

3.1.1 Research Questions

Primary : Can acupuncture therapy combined with physical therapy decrease the patellofemoral pain caused by patellar chondromalacia by 30% or more compared with physical therapy alone in the athletic population?

Secondary: Can acupuncture therapy combined the physical therapy increase the quadriceps muscle activity and motion by 10% compared with physical therapy alone?

3.1.2 Objectives

1.To evaluate the efficacy of the acupuncture therapy combined with physical therapy in the conservative treatment of patellofemoral pain caused by patellar

chondromalacia.

2.To evaluate the efficacy of the acupuncture therapy combined with physical therapy for increasing the quadriceps muscle activity and motion.

3.2 Research Design

This is a double blind randomized controlled clinical trial. The patients with patellofemoral pain which was caused by patellar chondromalacia were randomized into two groups. Control group underwent a standard physical therapy program for patellofemoral pain and placebo acupuncture. The evaluators of this study did not know about the research.

Experimental group underwent the same physical therapy and acupuncture therapy.

3.3 The Sample

3.3.1 Target Population

Athletes who attended the Sports Medicine Clinic aged 15-40 years with pellofemoral pain which was caused by patellar chondromalacia.

3.3.2 Sampled population

Athletes aged 15-40 years with patellofemoral pain caused by patellar chondromalacia who met eligible criteria of this study in the Sports Medicine Clinic of Hei Long-Jiang Athletic Department in China.

3.3.3 Eligibility Criteria

3.3.3.1 Inclusion Criteria

TABLE 3.1 Inclusion Criteria

* Age:15-40 years.
* The duration of symptoms was from 1 month to 2 years.
* Unilateral patellofemoral pain.
* The patients must be diagnosed as patellofemoral pain caused by chondromalacia in the sports medicine clinic of Hei Long-Jiang Athletic Department in China.
* Ability to complete formal physical therapy program.

Inclusion criteria emphasized that patients must be diagnosed as a patellofemoral pain caused by patellar chondromalacia, because it was the most

frequent cause of PF pain in the sports population. There are many kinds of causes of patellofemoral pain, and different causes of pain may be in different situations. So we had to define the cause of patellofemoral pain, so that the selection bias can be minimized and validity inference more strengthened. Exclusion criteria are patients having no history of knee surgery or serious ligamentous injury, since we just want to study about conservative treatment of patellofemoral pain.

3.3.3.2 Exclusion Criteria

TABLE 3.2 Exclusion Criteria

* Age below 15 years or over 40 years.
* Duration of symptoms is less than 1 month or over 2 years.
* Has a history or clinical evidence of patellofemoral dislocation, synovial plicae, or meniscal or ligamentous injury.
* Has a history of knee surgery.

3.3.4 Allocation technique

This study used the randomization strategy to allocate subject into 2 groups, using individual patient as a unit of randomization. One of the investigators was not involved with the care or evaluation of the subject prepared for randomization scheme

using block randomization (block size of 4) for assignment at the central -unit before the trial began. 4 patients formed one group, according to the table of randomization, each patient could get a number, patients who got odd number were assigned to Experimental group, patients who got even number were assigned to Control group.

3.4 Intervention

3.4.1 Acupuncture Therapy

The experimental group patients received acupuncture therapy on their knee area in the clinic for 30 minutes per day.

1. Special points selection:

a. Yang Ling Quan point : 3 "inches" (equal the maximum width of patient's palm) below the edge of patellar, in the middle of the surface of tibiofibular tubercles.

b. Liang Qiu point : 2 "inches" (equal the width of patient's 3 fingers) above the edge of patellar on the lateral side).

2. Disinfecting the knee area by the tincture of iodine and alcohol.

3. Perform acupuncture on the above two points mentioned for 30 minutes each time: The needle should be put inside the body 3 inches deep in italic direction.

Control group patients received placebo acupuncture. That was to insert needles to the other 2 different points which are near the proper points by shallow depth (subcutaneous needling).

3.4.2 Physical Therapy

The two groups of patients received physical therapy and exercise program as follows:

1. Ultrared waves irradiated the knee area with patellofemoral pain for 30 minutes per day.
2. Ultrashort waves irradiated the knee area with patellofemoral pain for 30 minutes per day.

3.4.3 Muscle Strengthening Exercises

A standard quadriceps muscle strengthening exercise program was used in both 2 groups patient for 30 minutes per day. (including quadriceps muscle progressive isometric. isotonic, and isokinetic exercises).

The two groups were instructed by the doctors to receive physical therapy in the clinic. For a standard quadriceps muscle strengthening exercise program, the two groups were instructed and monitored by their coaches to use the same instrument. Since our clinic is the only professional Sports Medicine Clinic in the province, and the athletes

are all in patients, therefore, the contamination should be avoided.

In China, the athletes are strictly controlled by their coaches, including training and daily living, so it was important to cooperate with the patients'coaches to get good compliance.

3.5 Measurements

3.5.1 Outcome Variables To Be Measured

There were many factors affecting the severity of patellofemoral pain in sports population, such as age, weight, height, sports training courses, intensity of training, degree of knee trauma, quadriceps muscle activity, etc.

Considering the necessity, the time and facility limitation and availability of instruments, the following variables were selected as outcome variables to be measured:

TABLE 3.3 Outcome Variables

*.Severity of patellofemoral pain.
*.Quadriceps muscle activity.
*.Isokinetic muscle testing.

In this study, the primary outcome variable was the severity of patellofemoral pain. It could answer primary research question. We used "Descriptive Pain Scale" (DPS) to measure the subjective knee pain.

The descriptive pain scale was based on a rank ordered 8-point scales, the range is from 1-8.

The quadriceps muscle activity and Isokinetic muscle testing were secondary outcomes, they could answer the secondary research question. They were measured by dynamometers in the Hei Long-Jiang Athletic Department in China.

3.5.2 Outcome Measurement

3.5.2.1 Severity of patellofemoral pain

Descriptive Pain Scale (DPS)

A Descriptive Pain Scale was used to assess subjective pain. The patients were asked to characterize their knee pain. Answers were based on a 8-point scale.

The pain was classified from no pain to very serious pain. The scale was focused on whether the severity of pain interfere patients activity.

TABLE 3.4 Descriptive Pain Scale

Please choose a number according to the scales as follow:

1.No knee pain.

2.Knee pain at present, but can easily be ignored.

3.Knee pain at present, can not be ignored.

4.Knee pain at present, can not be ignored, does not interfere with everyday activity.

5.Knee pain at present, can not be ignored, interfere concentration.

6.Knee pain at present, can not be ignored, interfere some activities, except taking care of basic needs such as eating and toileting.

7.Knee pain at present, can not be ignored, interfere some activities, but rest or bed rest required.

8.Knee pain at present, can not be ignored, interfere basic needs, such as bed rest and eating.

Therefore, each patient could get knee pain's score range from 1-8, and the cutting point of this score is 5. If the score was less than 5, that means the marked reduction of knee pain, and athletes could go back to practice.

Because the sports population is a special population, they usually go on practising even though they have slight pain or trauma. In cases of serious pain they stop

to practice and go to a clinic.

Many previous studies showed that the measurement of sports diseases always focused on whether patients can return to sports. So in this study, the cutting point was used to define the patients who can return to sports or not. This was the important point of the measurement in this study.

3.5.2.2 Quadriceps Muscle Activity

The activity and strength of the quadriceps muscle was assessed by using dynamometer in the Hei long-jiang Athletic Department in China.

3.5.2.3 Isokinetic Muscle Testing

The Cybex II isokinetic dynamometer was used to assess peak torque strength in patients at the start and at the completion of the therapy program. The range of motion at angular velocities is from 60 deg/sec and 180 deg/sec.

3.5.3 Test of Validity of the Measurement

Content validity:

It has been consulted by 3 experts to evaluate the Descriptive Pain Scale. They are all physical therapists or famous sports coaches in Athletic Department of Hei Long

Jiang Province in China. In their opinions the questions in the scale were suitable in the sports population. The important content (severity of knee pain) had been covered into all questions in the scales.

3.5.4 Test of Reliability of the Measurement

Test of Stability of measurement:

The interobserver consistency method has been used to assess the stability of measurement. There were two observers performed the measurement of the outcome variables for 20 patients in this study at the same time. The agreement between two observers has been assessed by calculating the Intraclass Correlation Coefficient by ANOVA in SPSS program. The intraclass correlation coefficient of Descriptive Pain Scale was 0.65, which was acceptable to this study ($R > 0.5$). It was reported that this scale used to measure the knee pain in previous study, the intraclass correlation coefficient was 0.69. The intraclass correlation coefficient of Quadriceps muscle activity and Isokonetic muscle testing were 0.93 and 0.96.

The intraclass correlation between the two observers in measuring the outcome variables all got the standard of acceptable reliability. (Stability > 0.5). But the agreement of Descriptive Pain Scale was not very high. That might be because of the subjectivity of the knee pain. The intraclass correlation coefficient should be an appropriate tools for the test of reliability in this study. Since the main outcome variable

was subjective pain. More instruments should be used to increase the objectivity and the validity and reliability of measurement in the future study.

Because of time and facility limitations, intraobserver reliability was not determined in this study, but this should also be taken in consideration in the future study.

3.6 Consideration of Some Confounding Factors

3.6.1 Selection Bias

Since all patients in this study were athletes from the Provincial Athletic Department where our internal clinic is, the selection bias have been reduced because the sample population were from the same group (athletes).

Selection bias could have been occurred from the various causes of patellofemoral pain, therefore, in order to minimize the selection bias, patellar chondromalacia was defined as the cause of patellofemoral pain in this study. First, patellar chondromalacia occur very frequently in athletic population; Secondly, patellar chondromalacia is from repetitive and competitive sports training, it can occur in any types of sports training courses. The patients' sports training courses do not need to be defined.

3.6.2 Assessment Bias

To avoid the potential bias from the subjective assessment of the severity of patellofemoral pain, the interobserver consistency method was used to test the reliability of measurement. Content validity of Descriptive Pain Scale was also tested.

3.6.3 Contamination

The acupuncture therapy for relieving the patellofemoral pain -- the experimental therapy of this study, which could only be prescribed by the investigators, had been only used in experimental group patients.

The research setting, an internal clinic for athletes, is the only professional sports medicine clinic in the province, and all patients in this study were in-patients of the clinic, so contamination could be avoided.

3.6.4 Co-intervention

In order to avoid co-intervention, we adopted placebo acupuncture therapy in control group to blind patients. Placebo acupuncture therapy means to choose 2 other different points which are near from the proper points to insert the needles by shallow depth (subcutaneous needling), which only cause a very little pain and no side-effects to patients. These points have no effect to relieve patellofemoral pain. Also the shallow

depth of the inserted needles was too shallow to have any effects of acupuncture. Since the position of these points are very close to the proper points, and most patients had very little knowledge on acupuncture, so it was quite difficult for them to distinguish the difference.

3.6.5 Compliance

Since the research setting, an internal clinic for athletes, is the only professional sports medicine clinic of the province, most athletes respected the medical technique of this clinic.

The researchers also had a good cooperation with the patients' coaches, who could strictly direct the athletes both in sports training and daily living.

3.7 Data Collection

3.7.1 Demographic and Medical History Data

Demographic and medical history data were obtained from patients' medical files in the clinic. The clinic keeps all athletes' medical files since they joined the Hei Long Jiang athletic Department.

3.7.2 Outcome Variables Data

All the variables have been measured and tested by the staff in the sports medicine clinic. As there were some subjective outcome variables, we also co-ordinated with the patients' coaches in the course of treatment and measurement.

All the outcome variables have been measured 2 times (before and after the treatment). Since patients were in different situations, the duration of treatment might not be the same, so we had to fix the duration of treatment to 30 days.

3.8 Data Analysis

3.8.1 Demographic Data

TABLE 3.5 Demographic Data Analysis

Variables	Statistical Test	Purpose of test
Age	unpaired t-test	the difference in age between 2 groups
Sex	chi-square	the difference in sex between 2 groups
Weight	unpaired t-test	the difference in weight between 2 groups

3.8.2 Outcome variables data

TABLE 3.6 Outcome Variables Data

Outcome variables	Type of data	Statistical test
Severity of pain	nominal	Chi-square test or Fisher's exact test
Quadriceps muscle activity	numerical	paired and unpaired t-test
Isokinetic muscle testing	numerical	paired and unpaired t-test

3.9 Sample Size Justification

By using the sample size formula for proportion[62]. Power=0.8, α=0.05, β=0.2. Assuming: reduction rate of Patellofemoral pain in experimental group p_T= 60%[23], reduction rate of patellofemoral pain in controlled group p_C= 30%[41], p=45%

$$2n = \frac{2\{Z\alpha[2p(1-p)]^{1/2} + Z\beta[p_T(1-p_T) + p_C(1-p_C)]^{1/2}\}^2}{2(p_C - p_T)^2}$$

n=48

Sample size totally were 96.

3.10 Ethical Consideration

Even though all athletes are in-patients, free informed consent was still obtained before the study.

Since the placebo acupuncture therapy was used in control group to blind patients, concerning the ethical consideration, we chose different points which were near from the proper points to insert the needles by shallow depth (subcutaneous needling). These points have no effect to relieve knee pain, just caused little pain and no side-effects to patients. This study has also been approved by the Ethical Consideration Committee of our Province.

3.11 Limitation

Subjective assessment of the severity of patellofemoral pain could be a potential source of bias in this study.

Sometimes the treatment might be influenced by patient's practice or competition.

In this case, we have sent some team physicians to follow them up for continuing the treatment.

3.12 Time Schedule

TABLE 3.7 Time Schedule

Month	1997												1998			
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4
Preparation	****															
Intervention					**********											
Analysis																**********

3.13 Budget

1.Personnel	Budget (Dollars)
1.1 Faculty Cost	

1.1.1 Physicians	800
1.1.2 Research staff	600
2.Equipment	
2.1 Irradiating Machine	200
2.2 Needles	100
3.Communication	
3.1 Fax and Telephone	100
4.Supplies	200
Total:	2000