

STUDY PROTOCOL WITH SAP

TITLE

Therapeutic exercise protocol for the prevention of anterior cruciate ligament injuries in female football players with dynamic knee valgus.

DOCUMENT DATE: 30/07/2023

INTRODUCTION

In recent years there has been an exponential growth of women participating in team sports such as football. Around 29 million footballers worldwide are women. In addition, the numbers are constantly growing with an estimated 51% increase in the number of registered players, as is the interest of the female society in this sport¹. The popularity and visibility of women's football is associated with an increase in the number of lower extremity injuries, especially with a high risk of knee injuries. Of all the knee injuries that can occur, women are particularly susceptible to anterior cruciate ligament (ACL) injuries. The ACL plays an important role in knee kinematics². It stabilizes the joint in full extension, prevents rotational loads and anterior displacement of the tibia³. These injuries are a major current problem^{4,5} accounting for 16% to 32% of all injuries and 43% of the injury burden during the sports season⁶. Regardless of their level of participation, female footballers have between 2 and 8 times⁷ times the risk of suffering ACL injuries compared to their male counterparts⁵ performing similar training^{8,9,10}. Injury incidence rates among female soccer players range from 1.1 to 3.1 injuries per 1000 hours of training and from 12.6 to 23.6 injuries per 1000 hours of play over the past decade¹.

Most ACL injuries among female players occur without contact from another player⁵. Current evidence suggests that the etiology of these lesions is multifactorial and results from the interaction of modifiable and non-modifiable risk factors^{5,11-14}. They can be caused by poor biomechanics on the field during sport-specific movements that female footballers frequently execute; due to anatomical differences in the lower kinematic chain¹⁵ (ACL weakness, generalized tibiofemoral laxity, narrow intercondylar space, hormonal fluctuations, unfavorable alignment of the pelvis, hip, knee and foot or presence of valgus knees)¹¹; and lack of neuromuscular control^{5,13,15}. The two most common mechanisms that can produce these non-contact injuries during dynamic sports activities are plantar and cutting or a sudden slowdown⁵. Neuromuscular control is a modifiable risk factor, therefore non-contact ACL injuries could be prevented if proper prevention protocols are established. In addition, Coves García et al.¹⁶ suggests that the recovery of neuromuscular control is fundamental and essential to reduce the incidence of these injuries^{2,17,18} and to maintain correct joint biomechanics in female athletes. Shams et al.¹⁹ and Sasaki et al.²⁰ support its importance and define it as proper muscle timing and proper force

generation. In addition, Arundale et al.⁷ and others point out that the most common neuromuscular disorders in women, which can contribute to ACL injuries, are the high landing forces and knee movements that occur in the frontal plane in addition to lower hip and knee flexion angles due to muscle weakness during landing, using the quadriceps to stabilize the knee joint. It can lead to compensatory patterns²¹ in muscle co-contraction actions²², greater degrees of ankle eversion, asymmetric landings and poor ability to control the trunk⁷ associated with a high moment of abduction and valgus collapse during jump-landing tasks or posterior displacement of the center of gravity compared to men^{2,14,17}. According to Cannon et al.²³ Inadequate neuromuscular control of proximal motor components (trunk and hip) also negatively influences the control of knee biomechanics during dynamic sports tasks. Zago et al.¹¹ note that the joint biomechanics of ACL injuries during football matches is the same between male and female footballers. In addition, they confirm that 80% of injuries occur among female footballers because the load on valgus, internal rotation and hip abduction is significantly higher than in footballers during sports tasks.

Among all the most commonly cited biomechanical risk factors for this injury, dynamic valgus knee (DKV) has been documented as the highest risk factor²⁴ for non-contact ACL injury^{17,23,25} in female soccer players. This movement pattern is the result of combining three main components: internal rotation and hip adduction and knee abduction, in addition to distal joint modifications such as anterior translation and tibial external rotation and ankle eversion. It can also transmit harmful loads to the internal collateral ligament, internal meniscus and ACL.^{14,24,26-29}

The rehabilitation period after suffering an ACL injury is long and demanding. In addition, it is estimated that the average time to return to play in women's football is about 8.5 months or more⁶, which can mean the premature end of the player due to a decrease in her sports performance². These injuries can cause significant morbidities in the short and long term, highlighting chronic knee instability, persistent knee pain³⁰, meniscal and cartilaginous lesions or premature osteoarthritis of the knee^{6,11}.

Justification for the study

Current training methods include preventive strategies focused on modifying neuromuscular and biomechanical risk factors^{31,32} using non-football-specific tasks such as eccentric exercises or verbal or visual *feedback* combined with plyometric, *core*, balance, resistance or trunk strengthening exercises. These could be the most effective to positively modify the screening, identification and correction of dangerous movement patterns^{1,26} such as DKV during jump-landing tasks^{14,21,31,33,34}. However, no uniform criteria have been established to design a precise intervention protocol, with specific tasks linked to women's football, nor has it been proposed to optimize current programs despite having a high number of injuries associated with DKV^{33,34}. On the other hand, there is no consensus or unification on the establishment of defined parameters regarding the effective dosage of a specific training program, since there is great heterogeneity in terms of the doses and times of the scheduled exercises. These preventive programs are effective in the short term, but it is not equally confirmed whether they produce positive effects in the long term³¹. Current evidence reports that the implementation of specific preventive programs according to the sport practiced is imperative to reduce the incidence of ACL injuries. In addition, in terms of exercise effectiveness, it suggests a 51% reduction in these injuries^{2,20,35,36}.

Based on the review recently published in the journal *Fisioterapia*¹⁶, we proceed to propose, as a continuation of the current research process, an exercise protocol, as well as its dosage in female footballers with DKV, in order to reduce the risk of ACL injuries.

OBJECTIVES AND HYPOTHESES

Main objective

To assess the efficacy of a comprehensive and specific training protocol focused on female players with DKV in preventing ACL injuries.

Specific objectives

1. To investigate the effects of a specific protocol as a preventive method of ACL injuries on the physical performance of female football players.
2. To analyze the injury incidence of ACL among players with DKV in both groups.
3. Check the changes in the neuromuscular control of the knee measured with the "*drop vertical jump test*" (DVJ) in both groups after the corresponding training proposal.
4. To evaluate the biomechanics of landing with jump landing measured with the landing error scoring system (LESS) in participants in both groups.
5. To analyze the perceived satisfaction rates of the athletes, using the SF-12 questionnaire after the intervention.
6. Know the effective dosage of a specific protocol for the prevention of ACL injuries.

PICO Question

In soccer players with DKV... Does a specific training protocol reduce the risk of ACL injuries compared to the conventional program?

Study hypothesis

A comprehensive and specific 12-week training protocol for the 2023-2024 season will significantly reduce the risk of ACL injuries compared to conventional training for female soccer players with DKV.

METHODOLOGY

Ethical documents and prior registration

This study has the Authorization of the Ethics Committee of the Responsible Research Office of the Miguel Hernández University of Elche for the 2022/2023 academic year and will be registered as a clinical trial in the clinicalTrials platform.

Studio Design

The study is designed as a randomized and controlled, double-blind, unicentric and parallel group clinical trial protocol that will be carried out with the female players of Elche CF and Intercity CF in the province of Alicante. The recommendations of the SPIRIT guide³⁶ have been followed for the realization of this study. Annex I.

Before starting the study, they will be provided with a written informed consent that they must sign to record their intention to participate in it, being able to revoke it at any time and accepting the conditions that will appear in the document (Annex II). They will be randomly assigned to a conventional fitness training program or a specific training protocol for 12 weeks. This study will consist of 3 time measurement points, the first prior to the intervention, the second at the end of the 6-week period of intervention and the last at 4 weeks after its completion. The study schedule and flowchart are in Annex III and IV, respectively.

Participants

The recruited population will be formed by the 44 elite players (22 per team) with a federative record belonging to the first senior team of Elche CF and Intercity CF of the province of Alicante of the national women's football league during the 2023-2024 season, where three weekly training sessions of one hour each are carried out. Prior to the collection of data, permission will be requested from the Club and the coach of both teams to carry out the study at the Martínez Valero Stadium in Elche. In the same way,

the recruitment will be carried out through a direct contact, as an interview, with the coach, the physiotherapist and the physical trainer of the participating teams.

Inclusion and exclusion criteria

The inclusion criteria will be:

- Football players registered and federated in the corresponding team.
- With an age range between 18 and 35 years.
- Minimum experience of one year playing football.
- With the presence of DKV.

The exclusion criteria will be:

- Previously injured subjects of ACL or other knee ligament injury.
- Subjects with a history of lower extremity injuries that have resulted in surgery during the six months prior to the study.
- Players with chronic illnesses that may affect test results.
- Subjects who practice other sports in the professional field.

Study variables and measurements

To record the number of injuries produced among the players of both groups at the end of the study and the frequency of weekly training, an Excel table will be used. The kinetics and kinematics of the lower extremities will also be analyzed with a motion capture system, surface EMG markers and a force platform. The LESS scoring system (Annex V) and the DVJ task will be used to identify the risk of injury during the jump-landing task and the presence of DKV among the players, respectively. In addition, we will measure their pre- and post-intervention satisfaction rates using the SF-12 questionnaire³⁸. Annex VI.

Sample size

An analysis was performed with Epidat 4.2 software to calculate the sample size required in the present study. A comparison of independent means will be performed and a standardized mean difference of 1, a significance level of 0.05, a 95% CI and a power of 90% will be considered, which determines a total sample size of 44 subjects, 22 in each group. It is necessary to consider an abandonment rate, so we will increase the sample by 10%. Therefore, the total sample size will be 48 women, 24 in each study group. Annex VII.

Randomization and blinding

Teams will be randomly assigned to one of the two groups in a simple manner and will be performed once subject selection has been completed. This assignment will be hidden and will be carried out by a person independent of the study. The randomization method will consist of the toss of a coin assigning "heads" to the intervention group and "tails" to the control group.

The study will have two physiotherapist evaluators, with at least five years of clinical experience. They will be responsible for the collection and analysis of data, assessments and evaluation of the final results. There will also be two sports physiotherapists, with at least five years of experience in the sports field, who will be responsible for the explanation and supervision of the exercises, in addition to being knowledgeable about the execution of specific training protocols.

A double-blind masking will be carried out, in which the evaluating physiotherapists and the players themselves will be blinded. Sports physiotherapists will be the only professionals who will not be. In addition, interventions and measurements will be performed in separate rooms, which will facilitate the blinding of subjects and evaluators.

Intervention

First, an invitation will be made to all the players who are part of the teams mentioned above during the 2023-2024 preseason with the aim of starting the intervention during that same season. All respondents will receive a Google survey via WhatsApp. This questionnaire will include questions about the inclusion and exclusion criteria to select the study sample of interest as well as questions about their sports background (position, dominant limb and sports experience); anthropometric measurements (age, height, BMI and weight), which will be provided by the coaches of the selected teams; and aspects related to training (frequency of weekly training and rest period). After completing the survey, three weeks prior to the start of the clinical trial, all players who agree to participate must undergo a final screening to be included in the study. This screening will consist of undergoing a qualitative analysis of the DVJ (Annex VIII), so that, through a simple visual examination, the inclusion of those players who do not present DKV can be ruled out and only those who test positive for DKV can be registered. After selecting the final number of players, a joint talk will be given to both teams to expose the dynamics of the study and the confidentiality of the data. Subsequently, pre-intervention measurements will be carried out by the evaluating physiotherapists to record the initial state of the players. These measures will be: the quantitative analysis of the DVJ, the LESS score, the initial score in the SF-12 scale, the biomechanics of the lower extremities, the muscular activation of the lumbo-pelvic complex and the lower extremity.

During the 12 weeks that the intervention will last, periodic measurements will be made. The last one will take place one month after the end of it. In addition, the players will be asked to refrain from consuming performance stimulants, tobacco or alcohol, non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics 24 hours before each session, as well as strenuous exercise. As a reminder, a WhatsApp will be sent to each athlete the day before each session, indicating the time at which they will be scheduled for training the next day. The appearance of pain during the sessions will not be allowed and, if at any time it appears, the training of the player in question will be stopped immediately and recorded for further analysis.

The intervention will consist of performing 3 weekly training sessions for 12 weeks to reach a total of 36 sessions of 30-60 minutes each. The days that will be set for training will be Mondays, Wednesdays and Fridays, leaving a rest day between sessions to ensure adequate recovery and quality training. The physical trainers will have to agree so that the training load in both groups is very similar.

Next, we will proceed to detail the intervention that will be carried out in each of the two groups of this clinical trial:

Conventional fitness training group

The players who belong to this group will maintain the usual practice of football training, so no new intervention will be applied.

Training group with a specific ACL injury prevention protocol

This protocol is based on prevention programs that use a multifaceted approach, effective in reducing the risk of ACL injuries compared to those who used only one type of exercise^{14,21,34}. A wide variety of studies defend the importance of working the muscles of the trunk, hip and knee to prevent DKV^{23,28,30}. Therefore, lumbo-pelvic stabilization training (*core* stability) that includes motor stability and strengthening of the gluteal muscles, in addition to strengthening the lower limb itself, will lead to a significant improvement in neuromuscular control of the lower extremities and trunk in addition to producing a significant decrease in DKV and valgus moments^{10,18,20,24,29,30,32}.

The proposed exercise protocol will be designed taking into account the inclusion of three main components. Annex IX:

- Lumbo-pelvic stabilization exercises.
- Lower limb strengthening exercises.
- Integration exercises (plyometrics and balance).

The exercises integrated into the programme will be organised into three phases of implementation:

- **Phase 1** (adaptation - 1st month): Its objective is that the players learn and integrate new patterns while they train.
- **Phase 2** (Proficiency - 2nd month): Aims for players to master new patterns in a controlled environment.
- **Phase 3** (performance - 3rd month): Its objective is to perform exercises in situations as specific as possible and close to the demand and explosiveness of movements typical of the pitch.

During the execution of all the exercises, verbal and visual inputs will be received, such as the presence of a full-body mirror so that they can correct positions and verbal indications focused on lumbo-pelvic stability and the biomechanics of the lower limb to improve the concentration and motivation of the players during the execution of the scheduled exercises^{9, 12,17,21,33}.

The progression of the exercises will be established by increasing the speed of execution of the same, increasing the complexity of the task to be performed and by promoting neurocognitive implications (for example, counting backwards from 10 to 0 during the execution of the exercises). In addition, compliance with the proposed protocol will be verified through weekly self-reported questionnaires that will be sent via WhatsApp and will be part of the records to be analyzed later by the evaluators.

Expected results

The results we expect to obtain from the intervention group are directly related to the modification of risk factors such as DKV and the decrease in the injury incidence of ACL. It is expected to improve proprioception, body balance and motor control, not only of the lower extremities, but of the entire lumbo-pelvic complex. In addition, it is expected to improve sports performance and ball control on the pitch.

All changes that occur between the players in the intervention group will be measured and recorded. Changes in the neuromuscular control of the knee and the mechanical behavior of the joints proximal and distal to it^{23,28} will be analyzed with a jump-landing test (DVJ)^{19,27,28,32}. Taking advantage of the

previous test, the biomechanics of the jump landing will be evaluated and the risk of non-contact injuries will be identified using the LESS scoring system. In addition, during the execution of the DVJ, the data obtained from the activation of the different pre- and post-intervention muscle groups will be collected and processed with an EMG system^{19,27,29,30}. All these positive changes would imply a lower incidence of injury for the players in the intervention group, as well as higher levels of satisfaction compared to the control group.

Statistical analysis

First, qualitative variables will be described with frequencies and percentages. For these variables, hypothesis tests will be performed using the Chi-squared test. On the other hand, quantitative variables will be expressed with median and interquartile range (IQR) or with mean, standard deviation and confidence interval (95% CI). It should be verified that the data follow a normal distribution with the Shapiro Wilk test to test this hypothesis. If it were not met, a nonparametric test such as the Mann-Whitney test would be performed. If, on the other hand, it follows a normal distribution, an ANOVA test will be carried out to contrast the mean difference and assess whether or not the results of the clinical trial have been significant. A level of bilateral statistical significance (limit for judging a result as statistically significant) of $\alpha = 0.05$ shall be established for all hypothesis contrasts. The data will be analyzed with the statistical program SPSS.

Budget estimate

The budget available for this study is limited to material costs, since we have the collaboration of the team of physiotherapists from several clinics in the province of Alicante. Therefore, we will select, from among those who are willing to collaborate, both the evaluating and sports physiotherapists for the study. In addition, they will provide much of the materials needed to conduct the study. If, on the other hand, the collaborating clinics did not have all the necessary material, the cost of more specific devices

such as the mDurance surface EMG (€ 5,500 approx.) and the BMS force platform (€ 3,000 approx.) should be included in the budget.

FUTURE EXPECTATIONS OF THE STUDY

This clinical trial protocol seeks to encourage coaches of women's soccer teams to follow this type of program because of its potential benefits in preventing ACL injuries. Annex X. Almost all the studies reviewed confirm that there are varied prevention programs (plyometrics, balance, strength, among others) that provide a significant improvement in DKV and, therefore, in the prevention of ACL injuries, but none of them has been based on a standard dosage or applied specifically to female footballers in this age range who have the highest injury rate^{5,14,19,21,34}. On the other hand, studies such as Willadsen et al.³¹ report short-term benefits and intervention programs that do not exceed 6-8 weeks of training¹⁴. The purpose of this study is to implement a standardized protocol for a period of 12 weeks (longer intervention time) in players of senior women's teams with the aim of achieving long-term benefits.

Limitations

- The study will be carried out only with female footballers of a specific age range, so that, when extrapolating the results, data such as the prevalence of ACL injuries could not be generalized to the entire population, so it would reduce external validity.
- We would not have all the control over the execution of the exercises described in the protocol, since the physiotherapists in charge of giving instructions would not be constantly controlling how each player performs the exercises, only at the beginning of the program or when introducing new exercises.

- To properly quantify the load, it might be more appropriate to do so with an accelerometer. It would serve to better control the exercise since, when the speed decreased, it would be indicative of stopping the exercise.
- As in almost any study, there is a risk of abandonment of the subjects, which increases with the duration of the study. Being a 12-week intervention, dropout rates could be higher.
- The relationship of the menstrual cycle in female footballers could be considered throughout the protocol, since there could be alterations in the performance and execution of the exercises¹¹.

Strengths

- Observer bias will be mitigated because measurements will be performed by two different physiotherapists. Both will not know the results of the other measurements made to prevent their expectations from influencing the result.
- This type of protocol is focused on the specific needs of players with DKV, which should be promoted among women's football coaches because it helps reduce the incidence of ACL injuries.
- Few published studies have developed multifaceted and specific intervention protocols for this group like the present one, despite the benefits that scientific evidence suggests for this type of program^{14,21,34}.
- Nowadays, women's football is becoming increasingly important, a fact that leads to an increase in the incidence of ACL injuries and, therefore, increases economic and research investment.

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